UWHealth | School of Medicine and Public Health
UNIVERSITY OF WISCONSIN-MADISON

Contact: Connie Schulze
Director, Government Affairs
749 University Row, Suite 240
Madison, WI 53705
608/422-8063 office
608/516-2552 mobile
cschulze@uwhealth.org

Assembly Committee on Constitution and Ethics
Testimony provided by Theresa Dulski, MD MPH
March 3, 2020
RE: Support for Clearinghouse Rule 19-079

Chairman Wichgers and members of the committee:

My name is Dr. Dulski and I appear before you today as a representative of UW Health, the UW School of Medicine and Public Health, and the Wisconsin Chapter of the American Academy of Pediatrics to express support for the new immunization regulations proposed by the Wisconsin Department of Health Services as outlined in Clearinghouse Rule 19-079. Thank you for your time and attention and this opportunity to share my expertise.

As a primary care pediatrician in Madison, I spend every day working to ensure optimal health and well-being for the children I treat and their families. Immunizations play a significant role in the care I provide. Immunizations help children avoid preventable illnesses that adversely impact their health and the health of others with whom they come into contact with in their communities, including babies who are too young to be immunized and people with medically-indicated contraindications to vaccines at risk. I have personally taken care of children with immunization-preventable diseases, including the ones being discussed today, and unfortunately have witnessed firsthand the devastating effects that they can have.

The rule before you seeks to bring student immunization regulations in DHS Chapter 144 into alignment with current recommendations put forth by the CDC, the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and current evidence-based practices.

The rule includes adding the 2-dose meningococcal vaccine series to the list of vaccines required for students. Meningococcus causes meningitis, an infection of the lining of brain and spinal cord that can progress so rapidly that an otherwise healthy child can be in a coma within a matter of hours. While the majority of children already receive this immunization, some are still susceptible to the severe effects of this illness. What I see in clinic is that some of these children are not immunized because they are brought in only to get the immunizations that are required for school. Adding the meningococcal vaccine to this required list would help provide protection for all children in Wisconsin, similar to the many states that already include this vaccine as a requirement for school. Children in Wisconsin deserve an equal opportunity to be protected from this devastating disease.

The department is also proposing to move the current recommendation for Tdap from 6th grade to 7th grade—or 11 years, which is also when the first meningococcus immunization is given. This would help make sure that children meet the minimum age requirement for the Tdap vaccine and will ease the burden on families, providers, and schools by ensuring that both meningococcal and Tdap vaccines are administered at the same well child visit.

In addition, the rule proposes to remove parent or self-report of varicella, or chickenpox, as an acceptable exception to varicella vaccination. Recent studies have shown that there is a high incidence of unvaccinated children who report a positive history of varicella that are not immune. I have personally seen many children in clinic with chief complaint of possible chickenpox, the vast majority of which did not have chickenpox but rather unrelated skin conditions. Due to the success of the varicella immunization, chickenpox is now less common and can be difficult for people to discern from other seemingly similar appearing rashes.

We applaud these proposed updates and the others included in the rule that are the result of many months of work on the part of staff and leaders at the Wisconsin Department of Health Services. They have done an excellent job outlining a plan to protect the public's health based on prevailing recommendations from the scientific community.

I know that everyone in this room has children's best interest at heart. Immunizations are a safe, evidence-based, life-saving way to prevent the spread of disease and keep children healthy as they grow. All children in Wisconsin deserve an equal opportunity to be protected from immunization-preventable diseases.

Please join us in supporting Clearinghouse Rule 19-079 as written. Thank you for your consideration.

Wisconsin United for Freedom
P.O. Box 894
Cedarburg, WI 53012
info@wisconsinunitedforfreedom.org

TO: Members of the Assembly Committee on Constitution and Ethics

FROM: Jamie Bernander, *Wisconsin United For Freedom*

DATE: March 3, 2020

RE: DHS 144 or CR19-079, concerning Immunization of Students

Good morning, Representatives. Thank you very much for holding a hearing and for being here. We greatly appreciate your service to our state, and for your consideration of all that you have heard today.

My name is Jamie Bernander. I am from Wisconsin Dells, where I am a wife and mother of three. I also represent Wisconsin United For Freedom, a non-profit committed to protecting health freedom in our state. We have a particular focus on the preservation of parental rights concerning vaccination.

I attended the public hearing held by the Wisconsin Department of Health Services on July 26, 2019. And while DHS may have followed procedure, as they have emphasized, our question is, **is *this* good government**? Could our health agency have *done better* and included parents during the development of these rule changes, in order to achieve greater transparency?

Concerned moms and dads throughout our state mobilized quickly in the short notice given for the hearing. Parents drove 3, 4 hours to attend. They drove, to speak in opposition to rule changes that would *impact their families.* When they arrived, they sat through 20 minutes of unproductive anticipation – as DHS officials scrambled to troubleshoot technological issues that hadn't been dealt with prior to the hearing's start.

And so, not everyone was afforded the opportunity to speak, as DHS strictly stuck to its one hour requirement. No consideration was given to the fact that technological issues cut into valuable hearing time. No, 40 minutes, in strict 2 minute allotments, devoted to public comment. DHS further expressed its *disdain* for mothers and for *parental inclusion* in immunization rule-making by their behavior during public comment. Mothers had the microphone ripped from their very hands at 2 minutes.

Was this within the scope of agency requirements? **So we have been told**. Evidently, agency requirements *do not extend to moral conduct*. Given the severity of the proposed changes, is it unreasonable to expect that a Wisconsin governmental agency would be flexible in their rigid rule-following behavior and perhaps extend the hearing?

DHS also failed to include moms and dads in the development of these rule changes. The advisory committee consisted of representatives of mainstream education and medical

establishments. I think we all can agree that biases within these organizations are unavoidable, therefore warranting the need for alternative points-of-view. And the fact that neighboring states have implemented some of these rules is simply *not a good enough reason* for Wisconsin DHS to follow suit.

What ***is*** apparent is that *DHS really wanted to work on these rule changes behind closed doors*. They made sure to stack their advisory board with people that would agree with their agenda. No one with a differing perspective was given a voice. Again I ask, *is this fair government?*

Furthermore, when concerned parent organizations requested both a second hearing and/or a private meeting to give a voice to those who were robbed the chance to speak, our requests were denied. Given these circumstances, it is unsurprising that DHS did not make a single edit to ANY of the proposed rules despite enormous written public comment expressing concern.

While apparently this is indicative of the DHS following requirements, I have to ask, *is creating an environment of distrust and exclusion going to improve the case for public health in Wisconsin*? There is a growing chasm of distrust between the Wisconsin Department of Health Services and the parents, the families, the individuals in this room. And we represent thousands of other Wisconsin residents. DHS ought to place greater focus on fostering transparency within its agency, rather than, for instance, further discriminating against children not vaccinated against mumps and chickenpox during outbreaks, despite the fact that DHS data displays that these particular illnesses are *most often contracted by vaccinated individuals*![1]

Representatives, I implore you to reflect on this question: *are these changes really necessary?* If the MenACWY vaccine were to be added to the required list, would the incidence of the targeted strains of meningitis decrease from the mere ***4*** cases that the *United States* experienced in 2018 within the targeted age group?[2] Not to mention, this vaccine *is readily available* to any family desiring it.

Wisconsin United For Freedom supports a family's right-to-choose vaccinations for their children. We respect that many may desire this vaccine. We understand that although rare, meningococcal disease can be severe, and I have great compassion for the parents that have experienced the death of their child. Unfortunately, there have also been reported deaths and injury from the meningococcal vaccine,[3] [4]and in Wisconsin, at least 3 teenagers developed

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[1] Wisconsin Department of Health Services (DHS) Vaccine-Preventable Diseases Surveillance Summary Wisconsin Oct. 21, 2019

[2] https://www.cdc.gov/meningococcal/downloads/NCIRD-EMS-Report-2018.pdf

[3] https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX[]=MNC&VAX[]=MNQ&VAX_YEAR_HIGH=2019&VAX_MONTH_HIGH=12

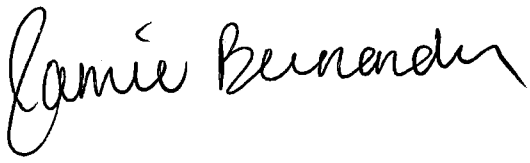
[4] https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX[]=MNC&VAX[]=MNQ&STATE[]=WI&VAX_YEAR_HIGH=2019&VAX_MONTH_HIGH=12

meningococcal disease and died despite being vaccinated.[5] It's not a perfect system. But, the vaccine **is** readily available and we had only 4 cases of the targeted serogroups within the targeted age group in 2018. In the WHOLE COUNTRY. Why, then, is this even an item of public health discussion in Wisconsin?

We would like to see the Wisconsin Department of Health Services focus on *rebuilding trust with **parents and families.*** Where is the data that suggests that parents are being deceitful in reporting their child's history of chicken pox? Why does the WI DHS not trust parents? Allowing this chasm of distrust to continue growing between us does not help anyone's cause, particularly public health. We request to be included in discussions, in immunization rule-making consultation, and we would like to simply be afforded respect. *Is the bare minimum acceptable in government?* I'd like to think not, in a state as respectable as Wisconsin. *We can do better.*

I ask you today, on behalf of Wisconsin United For Freedom and the vast majority of the individuals in this room, to please strike out proposed rule changes 1, 2, 4, and 5 from within Chapter DHS 144. Please remove these 4 rule changes and send the proposal back to DHS. Until we are offered proper inclusion, proper consultation, and proper courtesy as the moms and dads of the children affected by these proposed rule changes, the Wisconsin Department of Health Services should not be given free agency to passively move significant policy through our legislature.

Thank you for your time.



Jamie Bernander

Wisconsin Dells, WI

Jamie.bernander@wisconsinunitedforfreedom.org

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5 https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX[]=MEN&VAX[]=MENB&VAX[]=MENHIB&VAX[]=MNC&VAX[]=MNQ&VAX[]=MNQHIB&VAXTYPES[]=Meningitis&DIED=Yes&STATE[]=WI&VAX_YEAR_HIGH=2019&VAX_MONTH_HIGH=11

Good morning. Thank you for your time and thank you for having this hearing. My name is Melanie Metz. I am a lifelong resident of Wisconsin and I currently live in Delafield with my husband and three children. I am here this morning to state my opposition to Rules 1, 2, 4 & 5 in Clearing house rule 19-079. Many others have spoken and will speak about those specifically and why they are opposed to them, and I have my specific reasons about each one too. However, to keep this brief, and allow everyone else a chance of speak, I want to state how disappointed I was in the way many parents were treated during the first hearing for these rule changes. I have been paying close attention to things in my state for the last 5 years, after my second son was injured by vaccines. I would have attended the hearing last July, however, we were given a week's notice, making it hard to rearrange work and childcare schedules. Many parents drove hours to this hearing. With only 60 minutes set aside for the entire meeting, there wasn't nearly enough time for every voice to be heard. Having people leave that day, who did not even get to speak, is not acceptable. I had emailed DHS to express my opposition and then later emailed to express my disappointment in how the hearing was handled. I never heard a word back from anyone. However, my biggest issue is one that effects every single parent in this state. The advisory board, the ones who weighed in and wrote these rule changes, did not include anyone who was just simply a parent. Are we not the largest group effected by rules that will impact medical decisions for our children? Why weren't any parents part of this discussion? The advisory board consisted of mostly medical organizations, many of which have a vested financial interest in most of this. When you are making rule changes that effect ALL children in this state, you need to consider all groups...Parents who are for vaccines, and also parents who have concerns about vaccines, especially when their child was injured by that particular pharmaceutical product. We need conventional providers as part of the discussion, and we also need alternative providers in the conversations too. As I stated, my son was injured by vaccines as an infant. In the time since then, I have continually seen the way those who have concerns about vaccines are treated. It has happened to me. I have witnessed it happen to others. The way DHS has gone about this entire process (from gathering their one-sided advisory board to drafting the rule changes to the way they conducted the first hearing) is, yet, another example of inappropriate treatment of a group of people who are raising valid concerns about vaccines. This should not be considered an acceptable way to treat anyone, especially the main stakeholders for this issue. I appreciate you all taking the time to be here and thank you for listening.

Hello I am Kara Paske, a concerned parent on rule changes 1, 2, 4 and 5; here on behalf of my family as well as many many others. Those paper letters of opposition you have been receiving for weeks.....many of those my two young children have been collecting in preparation of today.

Although I oppose all of the rule changes I have a few questions regarding rules one and five.

Close to my hometown on December 12th 2019 Rusk County announced a chicken pox outbreak in Ladysmith. In this outbreak a total of 13 children were infected to the knowledge of the county public health officer.

ONE of these children was not vaccinated; this child was not the first to exhibit symptoms.

At the time of 11 breakthrough cases and 1 full blown case the county health department contacted families using the waiver offering options of completing the doses or quarantine. I do not have the details of how many this affected in the small community.

After these options were offered only one more case was reported of breakthrough.

This means that an outbreak of 13 children was started by a vaccinated child as far back as they can trace and only one of the affected children was not vaccinated for this viral infection.

It would be a financial burden to many families to be excluded from school for weeks - especially for a mild childhood illness that most people in this room had as children, and were no worse for it.

1. If this rule would have already been in effect when this outbreak occurred, how would the families of children who had previously had the chickenpox but not been into the doctor for a diagnosis been handled? Would they have also been required to get the vaccine in order to continue attending school or would they have been excluded from school even though they already possessed natural immunity?

2. What is the definition of substantial outbreak? I would like clarification of exact number of how many it would take to determine a "substantial outbreak." Why is this information absent from rule 1 of this rule change proposal?

3. What steps are in place to ensure that children who are receiving the live-virus chicken pox vaccine known to shed and cause others to develop vaccine strain chickenpox are not contributing to outbreaks? According to the vaccine package insert, persons vaccinated with the chickenpox vaccine can shed the virus for up to 42 days. Shouldn't they be excluded from school during this time to ensure that they do not cause an outbreak - especially since DHS's data reports that vaccinated children can still come down with chickenpox as this recent outbreak proves.

Thank you.

Kara Paske
W9892 Ziehmke Rd
Portage, WI 53901
608-697-4360
mattkarapaske@gmail.com

Hello, and thank you for the opportunity to speak today. My name is Justin Brusveen, and I am a concerned father and husband who opposes points 1,2,4 and 5 of this clearinghouse rule for most of the same reasons that have already been mentioned.

I know that you don't see many men visiting your offices on this topic or showing up in equal numbers at public hearings, but know that we are here. Know that we support our wives and all the mothers advocating on behalf of our children. Many mothers here today, including my wife, have dedicated a tremendous amount of time to educating themselves on this clearinghouse rule and its consequences for Wisconsin families.

They have sacrificed time away from their own families. Some have used vacation days or taken unpaid days off from their work. They have nothing to gain financially from this. They do it because they care about what is in the best interest of their children. I hope you will take them seriously as you make your decision regarding this clearinghouse rule. Thank you.

Wisconsin United for Freedom
P.O. Box 894
Cedarburg, WI 53012
info@wisconsinunitedforfreedom.org

My name is Kimberly Smith and I'm with Wisconsin United For Freedom. Thank you all for your time today. While I oppose rules 1,2,4,5, today I'm speaking specifically on rules 2 and 5.

My concerns with rule change 2 proposed by DHS is that they are choosing to use what the CDC considers an outbreak of mumps to exclude only unvaccinated individuals from school. Statues states that, if an emergency arises, consisting of a "substantial outbreak" as determined by the department, the department may order the school to exclude students who are not immunized until the outbreak subsides. DHS proposes this rule change despite the fact that their own data has determined that unvaccinated persons are not developing mumps. Vaccine failure related to an ineffective vaccine is responsible for more than half of reported mumps cases in Wisconsin in recent years.[1]

Vaccine failure and mumps outbreaks are not unique to Wisconsin. Numerous studies examining mumps outbreaks that have occurred in highly vaccinated populations, have experts admitting that both the waning of vaccine-acquired immunity and an ineffective vaccine are to blame. These outbreaks continue to occur worldwide, including populations with adequate immunization schedules and coverage. Why, when the CDC and even DHS acknowledge that mumps outbreaks are occurring in highly vaccinated populations, are only unvaccinated children going to be excluded? [2][3][4]

The MMR vaccine cannot give us what natural immunity gives us, which is life long immunity. A lawsuit filed by two former Merck scientists in 2010 accuses Merck of knowingly falsifying its mumps vaccine test data and issuing a vaccine that it knew was not as effective against the disease as they claimed. Chatom Primary Care filed a suit against Merck that alleges the company, among other things, falsified and misrepresented the true efficacy of its vaccine. They state that Merck fraudulently represented and continues to falsely represent in its labeling that its mumps vaccine has an efficacy rate of 95 percent or higher. The scientists also claim Merck used animal antibodies to artificially inflate results, destroyed evidence of falsified data, and lied to the FDA. Merck's actions have allowed the disease to spread and is responsible for outbreaks, not the unvaccinated population. [5][6]

With rule change 5 the concern I have is that a DHS report states there is no fiscal impact on specific businesses, local governments, or the state's economy, and that "There are no implementation or compliance costs expected to be incurred from this rule change." But what about my family? DHS failed to include the expenses that moms and dads will incur, because people like myself were excluded from the advisory board. My monthly premium is $396 and I get no tax credit, our individual deductible is $2,500. A visit to our doctor on average costs us $200 individually, not including testing. With two children this rule change could potentially cost my family more than $400 of out of pocket expenses. And that is a low estimate.[7]

Thank you

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[1] https://www.dhs.wisconsin.gov/publications/p02321-18.pdf
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Good morning,

Thank you Rep. Wichgers and committee members for holding this hearing. I attended the hearing in July and was very disappointed with the lack of transparency by the WI DHS employees. It is natural for citizens to want their government to be transparent and honest with them. I appreciate the opportunity to address you today in support of medical freedom and bodily autonomy. I am here to oppose rule changes 1, 2, 4 and 5. More specifically I am going to expand on my concerns with rule change 2 and 5.

Rule change 5, the Varicella vaccination. I am a Chicken Pox survivor and so are my children. This was a mild illness that did not require an expensive doctor visit. I called my doctor to get permission to bring my child into officially diagnose so it could be on record that my child did have this mild childhood illness. The Nurse asked a series of questions to make sure my child wasn't in need of emergency care. The nurse told me not to come into the clinic because my child would expose the whole office to Chicken Pox. This rule change does not make logical sense. My child doesn't need a vaccine for an illness they have immunity for. Please take this rule change off all together.

Rule change #2:

1. **Change in the *'substantial outbreak'* definition of mumps from *"an incidence of the disease exceeding 2% of the unvaccinated population"* to define *'substantial outbreak'* as *"three or more cases linked by time and place."* –** *(In recent years, mumps outbreaks have occurred in highly-vaccinated populations and in high transmission settings, including elementary, middle, and high schools, colleges, and camps. A substantial outbreak of mumps is currently defined as an incidence of the disease exceeding 2% of the unvaccinated population. In 2012, the CDC revised the Manual for the Surveillance of Vaccine-Preventable Diseases, to define a substantial outbreak of mumps as three or more cases linked by time and place. The department proposes to amend the definition of a "substantial outbreak" of mumps to be consistent with the CDC Manual for the Surveillance of Vaccine Preventable Diseases.)*

    1. In 2012, the CDC defined a mumps outbreak as three or more cases linked by time and place. This is not referred to in the CDC Manual for the Surveillance of Vaccine Preventable Diseases as the definition of "substantial outbreak".[1] The CDC does not use the term "substantial outbreak" – that term is unique to Wisconsin DHS.

    2. If the CDC's definition of an outbreak is to be used by DHS to define "substantial outbreak" per Wisconsin DHS 144.02 (12) than DHS needs to revise their definitions of what is considered a substantial outbreak for the following diseases

        - Measles – The CDC defines an outbreak of measles as >3 cases (with at least one laboratory confirmed case) clustered in space and time.[2] Wisconsin DHS, however, defines a "substantial outbreak" of measles as 1 case.[3]

- Rubella – The CDC defines an outbreak of rubella as 3 or more cases (with at least one laboratory confirmed case) clustered in space and time[4] Wisconsin DHS, however, defines a "substantial outbreak" of rubella as 1 case.[5]
- Pertussis – The CDC generally considers an outbreak of pertussis to be "two or more cases occurring in separate households within a community" but reports that some states "require a minimum of 3 cases before declaring an outbreak."[6] Wisconsin DHS, however, uses their own definition and defines a "substantial outbreak" of pertussis as 2 cases in a 30-day period.[7]

Rule changes 1, 2, 4 and 5 affect my family in many ways. I ask that you remove them all from these proposed rule changes. Thank you for your time.

Sincerely,
Alesha Cowen

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[1] https://www.cdc.gov/vaccines/pubs/surv-manual/chpt09-mumps.html#outbreak

[2] https://www.cdc.gov/vaccines/pubs/surv-manual/appx/appendix08-1-mea-wrsht-in.pdf

[3] https://www.dhs.wisconsin.gov/publications/p4/p44329.pdf - page 19

[4] https://www.cdc.gov/vaccines/pubs/surv-manual/appx/appendix16-1-rubella-inst.pdf

[5] https://www.dhs.wisconsin.gov/publications/p4/p44329.pdf - page 19

[6] https://www.cdc.gov/vaccines/pubs/surv-manual/appx/appendix11-1-pertussis-instruc.pdf

[7] https://www.dhs.wisconsin.gov/publications/p4/p44329.pdf - page 19

(No subject)

Joel Kirchberg <kirchberg25@hotmail.com>

Tue 3/3/2020 6:32 AM

To: clinic email <riverviewchiropractic@hotmail.com>

Good morning, thank you for taking the time to be here today to listen to what we have to say. My name is Joel Kirchberg. I am from Lake Mills Wisconsin and I strongly oppose clearinghouse rule 19-079.

By changing the definition of substantial outbreak of mumps for an incidence of the disease exceeding 2% of the unvaccinated population to define a substantial outbreak as 3 or more cases linked by time and place is absolutely egregious.

Changing this definition will prohibit children from their taxed funded public education, even considering that the data shows that unvaccinated children are not developing the mumps.

Through the years mumps outbreaks have occurred in very highly vaccinated populations. The ACIP has acknowledged this occurrence and this has lead to an additional dose of the MMR vaccine to be administered. However, despite the increased administration of MMR mumps infections continued in highly vaccinated populations.

In 2010 former Merck employees filed a lawsuit claiming that that the outbreaks in the vaccinated population occurred due to the falsified data regarding the efficacy of the vaccine itself.

As a result as of 2017 outbreaks continued and the ACIP recommended a 3ird dose of a mumps vaccine be administered in the event of an outbreak.

Clearly the mumps vaccine failure was obvious.

In addition, to its failure, the mumps vaccine can, has, and does cause harm.

As of January 2, 2019, there has been 1,o91 claims against the mumps containing vaccination including 63 deaths.

This data firmly does not support any rule changes in Wisconsin regarding clearinghouse rule 19-079.

Thank you for you time.

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Wisconsin United for Freedom
P.O. Box 894
Cedarburg, WI 53012
info@wisconsinunitedforfreedom.org

Hello, I'm Abby Englert and I'm representing Wisconsin United For Freedom.

I've been very disheartened by the secrecy and lack of transparency DHS has shown with the introduction of these rule changes. Hearing of the disrespect that was shown to Moms, Dads, grandparents, and other concerned citizens during the hearing is very concerning to me. As a mom, I am the one who will be most affected by these changes, and yet people like me, were never considered in the drafting. I hope in the future that this government agency will be more transparent with and considerate to the residents of Wisconsin.

Although there are multiple rules that raise alarm to me, I wanted to address a specific issue in regards to Rule 4. Rule 4 proposes to mandate the Meningococcal vaccine for strains A, C, W, & Y. The two largely used vaccines for these strains are Sanofi Pasteur's Menactra and GlaxoSmithKline's Menveo. Both of these vaccines can come with mild to severe side effects, and even death.

As of December 31st, 2019, there have been 23,257 adverse events with 1,596 listed as SERIOUS adverse events reported to the Vaccine Adverse Events Reporting System or VAERS (1). *There have also been 71 deaths reported to VAERS specific to these 2 available vaccines. While a report to VAERS does not mean that the vaccine was responsible for the death, it also doesn't rule out an association. Several of these death reports listed on VAERS, included vaccinated persons, for whom the vaccine failed to protect.*

To bring the numbers closer to home; In Wisconsin, as of December 31, 2019, there have been 395 reports of adverse reactions associated with Menactra and Menveo (2). 15 of these reports were defined as serious. And of these serious reports, 7 were life threatening; 9 required hospitalization, 1 of which was a prolonged hospitalization; 3 reported permanent disability; and 3 reported deaths. The reported deaths were reported to be related to meningococcal disease from strains covered within the vaccine received (3).

From the vaccine product insert for Menactra, comes this partial list of reported adverse events: anorexia; anaphylaxis; upper airway swelling; Guillain-Barre syndrome; convulsions; transverse myelitis; and acute disseminated encephalomyelitis (4).

During the pre-licensing clinical trials of Menveo, adverse events included: changes in eating habits; headache; joint and muscle pain; Kawasaki's Disease; acute disseminated encephalomyelitis; and Suicidal depression and suicide attempts.

After the licensing of the Menveo vaccine, the adverse events reported on the package insert included, but are not limited to: anaphylaxis; vaccination site cellulitis; hearing impairment; vestibular disorder; vertigo; tonic convulsions; and Bell's Palsy. (5)

Interestingly enough, the Journal of the American Academy of Pediatrics concluded in a study that they found a significant increased risk of having Bell's palsy with the administration of a MenACWY vaccine and another at the same time. Which means that if the Meningococcal vaccine is given at the same time as Tdap, or HPV, or Influenza, that child's risk of developing Bell's Palsy is much greater. (6)

A 2017 published study on the adverse events reported on VAERS between 2010-2015, by researchers, noted the Menveo vaccine included the following medical reactions: Guillain-Barre syndrome; seizures; acute disseminated encephalomyelitis; chronic inflammatory demyelinating polyradiculopathy (CIDP); viral meningitis; Steven Johnson Syndrome; juvenile idiopathic arthritis; psychiatric disorders; Kawasaki's disease; and idiopathic thrombocytopenic purpura (ITP). (7)

Based on this extensive list of potential side effects from meningococcal vaccines, and the fact that adverse events are horribly under reported – 1-10% at best (8,9,10), should we be mandating this vaccine for all 7th graders? The option is available to anyone who feels the benefits outweigh the risks. But the age group most likely to be affected by meningococcal strains A, C, W, and Y, are the older highschool and college aged students.

Harvard Pilgrim Health Care was given a grant by CDC to evaluate the effectiveness of the passive VAERS database. After temporarily changing VAERS to an Electronic System using Electronic Medical Records, they found that "fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health." After these results were shared with the CDC, Harvard Pilgrim shared that their contacts at CDC never responded to their many attempts to put this new system into effect. The study was done in 2010. Now, a decade later, we are still only left with the passive Vaccine Adverse Event Reporting System. Knowing this, we must ask, what are the true measures and numbers of vaccine injuries caused by MenACWY vaccines? We don't know. However, we do know that the true number of adverse events reported, is realistically much higher than the 23,257 currently documented.

The Institute of Medicine (IOM) has also acknowledged that there is individual susceptibility to vaccine reactions for genetic, biological and environmental reasons, but that vaccine providers cannot accurately predict prior to a vaccine's administration who will suffer complications, injury or death from vaccination. (9)

It is pertinent that moms and dads be provided true informed consent on the risks, benefits, and possible failures of the meningococcal vaccine. Considering that meningococcal disease is rare, and that the vaccine does not offer "herd immunity", it should not be mandated for Wisconsin children.

Please note, that in the copies I've handed you, I include more information I left out due to time. Thank you.

(1) https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX%5b%5d=MNC&VAX%5b%5d=MNQ&VAX_YEAR_HIGH=2019&VAX_MONTH_HIGH=12

(2) https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX%5b%5d=MNC&VAX%5b%5d=MNQ&STATE%5b%5d=WI&VAX_YEAR_HIGH=2019&VAX_MONTH_HIGH=12

(3) https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX%5b%5d=MNC&VAX%5b%5d=MNQ&SERIOUS=ON&STATE%5b%5d=WI&VAX_YEAR_HIGH=2019&VAX_MONTH_HIGH=12

(4) https://www.fda.gov/vaccines-blood-biologics/vaccines/menactra

(5) https://www.fda.gov/vaccines-blood-biologics/vaccines/menveo

(6) Safety of Quadrivalent Meningococcal Conjugate Vaccine in 11- to 21-year-olds https://pediatrics.aappublications.org/content/139/1/e20162084.long

(7) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5444082/
(8) https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf
(9) https://ajph.aphapublications.org/doi/abs/10.2105/AJPH.85.12.1706?view=long&pmid=7503351
(10)https://jamanetwork.com/journals/jama/article-abstract/406452
(11)https://www.nap.edu/read/13164/chapter/5#82
(12)https://www.nap.edu/read/13164/chapter/13

(1)

National Vaccine
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MedAlerts Home

Search Results

Found 23,257 cases where Vaccine is MNC or MNQ and Vaccination Date on/before '2019-12-31'

Table

Age	Count	Percent
< 3 Years	465	2%
3-6 Years	108	0.46%
6-9 Years	79	0.34%
9-12 Years	6097	26.22%
12-17 Years	8305	35.71%
17-44 Years	5985	25.73%
44-65 Years	500	2.15%
65-75 Years	64	0.28%
75+ Years	24	0.1%
Unknown	1630	7.01%
TOTAL	23257	100%

Case Details

This is page 1 out of 2,326

Result pages: 1 2 3 4 5 6 7 8 9 10 **next**

(2)

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Search Results

Found 395 cases where Location is Wisconsin and Vaccine is MNC or MNQ and Vaccination Date on/before '2019-12-31'

Table

Age	Count	Percent
< 3 Years	3	0.76%
6-9 Years	2	0.51%
9-12 Years	113	28.61%
12-17 Years	151	38.23%
17-44 Years	113	28.61%
44-65 Years	6	1.52%
75+ Years	1	0.25%
Unknown	6	1.52%
TOTAL	395	100%

Case Details

This is page 1 out of 40

Result pages: 1 2 3 4 5 6 7 8 9 10 **next**

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(3)

Search Results

Found 15 cases where Location is Wisconsin and Vaccine is MNC or MNQ and Serious and Vaccination Date on/before '2019-12-31'

Table

Age	Count	Percent
9-12 Years	4	26.67%
12-17 Years	6	40%
17-44 Years	5	33.33%
TOTAL	15	100%

Case Details

This is page 1 out of 2

Result pages: 1 2 **next**

VAERS ID:	266888 (history)	**Vaccinated:**	2006-08-14
Form:	Version 1.0	**Onset:**	2006-08-16
Age:	18.0	**Days after vaccination:**	2
Sex:	Female	**Submitted:**	2006-11-10
Location:	Wisconsin	**Days after onset:**	86
		Entered:	2006-11-16
		Days after submission:	6

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Menactra® safely and effectively. See full prescribing information for Menactra vaccine.

Menactra®, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine
Solution for Intramuscular Injection

Initial U.S. Approval: 2005

----------RECENT MAJOR CHANGES ----------
Warnings and Precautions, Altered Immunocompetence (5.3) 4/2018

----------INDICATIONS AND USAGE----------
Menactra is indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135. Menactra is approved for use in individuals 9 months through 55 years of age. Menactra does not prevent *N meningitidis* serogroup B disease. (1)

----------DOSAGE AND ADMINISTRATION----------
A 0.5 mL dose for intramuscular injection. (2)

Primary Vaccination:
- Children 9 through 23 months of age: Two doses, three months apart.
- Individuals 2 through 55 years of age: A single dose.

Booster Vaccination:
- A single booster dose may be given to individuals 15 through 55 years of age at continued risk for meningococcal disease, if at least 4 years have elapsed since the prior dose.

----------DOSAGE FORMS AND STRENGTHS----------
Solution supplied in 0.5 mL single-dose vials (3)

----------CONTRAINDICATIONS----------
- Severe allergic reaction (eg, anaphylaxis) after a previous dose of a meningococcal capsular polysaccharide-, diphtheria toxoid- or CRM_{197}-containing vaccine, or to any component of Menactra. (4)

----------WARNINGS AND PRECAUTIONS----------
- Persons previously diagnosed with Guillain-Barré syndrome (GBS) may be at increased risk of GBS following receipt of Menactra. The decision to give Menactra should take into account the potential benefits and risks. (5.1)

----------ADVERSE REACTIONS----------
- Common (≥10%) solicited adverse events in infants and toddlers 9 and 12 months of age were injection site tenderness, erythema, and swelling; irritability, abnormal crying, drowsiness, appetite loss, vomiting, and fever. (6)
- Common (≥10%) solicited adverse events in individuals 2 through 55 years of age who received a single dose were injection site pain, redness, induration, and swelling; anorexia and diarrhea. Other common solicited adverse events were irritability and drowsiness (2-10 years of age), headache, fatigue, malaise, and arthralgia (11-55 years of age). (6)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Pasteur Inc. at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 or http://vaers.hhs.gov.

----------DRUG INTERACTIONS----------
- When Menactra and DAPTACEL® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) are to be administered to children 4 through 6 years of age, preference should be given to simultaneous administration of the 2 vaccines or administration of Menactra prior to DAPTACEL. Administraton of Menactra one month after DAPTACEL has been shown to reduce meningococcal antibody responses to Menactra. (7.1)
- Pneumococcal antibody responses to some serotypes in Prevnar (PCV7) were decreased following co-administration of Menactra and PCV7. (7.1)

----------USE IN SPECIFIC POPULATIONS----------
- Safety and effectiveness of Menactra have not been established in children younger than 9 months of age, pregnant women, nursing mothers, and adults older than 55 years of age. (8.1, 8.2, 8.4, 8 5)
- A pregnancy registry is available. Contact Sanofi Pasteur Inc. at 1-800-822-2463. (8.1)

See **17 PATIENT_COUNSELING_INFORMATION.**
Revised: April 2018

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION:

1 INDICATIONS AND USAGE

Menactra®, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine, is indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135. Menactra is approved for use in individuals 9 months through 55 years of age. Menactra does not prevent *N meningitidis* serogroup B disease.

2 DOSAGE AND ADMINISTRATION

2.1 Preparation for Administration

Menactra is a clear to slightly turbid solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If any of these conditions exist, the vaccine should not be administered.

Withdraw the 0.5 mL dose of vaccine from the single-dose vial using a sterile needle and syringe.

2.2 Dose and Schedule

Menactra is administered as a 0.5 mL dose by intramuscular injection. Do not administer this product intravenously or subcutaneously.

Primary Vaccination:

- In children 9 through 23 months of age, Menactra is given as a 2-dose series three months apart.

(5)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MENVEO safely and effectively. See full prescribing information for MENVEO.

MENVEO [Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM_{197} Conjugate Vaccine]
for injection, for intramuscular use
Initial U.S. Approval: 2010

RECENT MAJOR CHANGES

Dosage and Administration (2.1, 2.2)	09/2019
Dosage and Administration, Dosing Schedule (2.3)	12/2019

INDICATIONS AND USAGE

MENVEO is a vaccine indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135. MENVEO is approved for use in persons aged 2 months through 55 years. MENVEO does not prevent *N. meningitidis* serogroup B infections. (1)

DOSAGE AND ADMINISTRATION

- For intramuscular injection only (0.5 mL). (2)
- MENVEO is supplied in 2 vials that must be combined prior to administration: reconstitute the MenA lyophilized conjugate vaccine component with the MenCYW-135 liquid conjugate vaccine component immediately before administration. (2.1)

Primary Vaccination

- In children initiating vaccination at 2 months of age, MENVEO is to be administered as a 4-dose series at 2, 4, 6, and 12 months of age. (2.3)
- In children initiating vaccination at 7 months through 23 months of age, MENVEO is to be administered as a 2-dose series with the second dose administered in the second year of life and at least 3 months after the first dose. (2.3)
- In individuals aged 2 through 55 years MENVEO is to be administered as a single dose. (2.3)

Booster Vaccination

- A single booster dose of MENVEO may be administered to individuals aged 15 through 55 years who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of a meningococcal (serogroups A, C, Y, W-135) conjugate vaccine. (2.3)

DOSAGE FORMS AND STRENGTHS

Solution for intramuscular injection supplied as a lyophilized MenA conjugate vaccine component to be reconstituted with the accompanying MenCYW-135 liquid conjugate vaccine component. A single dose after reconstitution is 0.5 mL. (3)

CONTRAINDICATIONS

Severe allergic reaction (e.g., anaphylaxis) after a previous dose of MENVEO, any component of this vaccine, or any other CRM_{197}-, diphtheria toxoid-, or meningococcal-containing vaccine is a contraindication to administration of MENVEO. (4)

WARNINGS AND PRECAUTIONS

- Appropriate medical treatment must be available should an acute allergic reaction, including an anaphylactic reaction, occur following administration of MENVEO. (5.1)
- Syncope, sometimes resulting in falling injury, has been reported following vaccination with MENVEO. Vaccinees should be observed for at least 15 minutes after vaccine administration. (5.2)
- Apnea following intramuscular vaccination has been observed in some infants born prematurely. The decision about when to administer an intramuscular vaccine, including MENVEO, to an infant born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination. (5.5)

ADVERSE REACTIONS

- Common solicited adverse reactions (≥10%) among children initiating vaccination at 2 months of age and receiving the 4-dose series were tenderness (24% to 41%) and erythema at injection site (11% to 15%), irritability (42% to 57%), sleepiness (29% to 50%), persistent crying (21% to 41%), change in eating habits (17% to 23%), vomiting (5% to 11%), and diarrhea (8% to 16%). (6.1)
- Common solicited adverse reactions (≥10%) among children initiating vaccination at 7 months through 23 months of age and receiving the 2-dose series were tenderness (10% to 16%) and erythema at injection site (12% to 15%), irritability (27% to 40%), sleepiness (17% to 29%), persistent crying (12-21%), change in eating habits (12% to 20%), and diarrhea (10% to 16%). (6.1)
- Common solicited adverse reactions (≥10%) among children aged 2 through 10 years who received MENVEO were injection site pain (31%), erythema (23%), irritability (18%), induration (16%), sleepiness (14%), malaise (12%), and headache (11%). (6.1)
- Common solicited adverse reactions (≥10%) among adolescents and adults who received a single dose of MENVEO were pain at the injection site (41%), headache (30%), myalgia (18%), malaise (16%), and nausea (10%). Similar rates of solicited adverse reactions were observed following a single booster dose. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

DRUG INTERACTIONS

Do not mix MENVEO or any of its components with any other vaccine or diluent in the same syringe or vial. (7.1)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 01/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

6

PEDIATRICS

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Article

Safety of Quadrivalent Meningococcal Conjugate Vaccine in 11 to 21-Year-Olds

Hung-Fu Tseng, Lina S. Sy, Bradley K. Ackerson, Rulin C. Hechter, Sara Y. Tartof, Mendel Haag, Jeffrey M. Slezak, Yi Luo, Christine A. Fischetti, Harp S. Takhar, Yan Miao, Marianne Cunnington, Zendi Sol and Steven J. Jacobsen

Pediatrics January 2017, 139 (1) e20162084; DOI: https://doi.org/10.1542/peds.2016-2084

Abstract

BACKGROUND: Meningococcal conjugate vaccination is recommended in the United States. This study evaluates the safety of quadrivalent

METHODS: This cohort study with self-controlled case-series analysis was conducted at Kaiser Permanente Southern California. Individuals receiving MenACWY-CRM, a quadrivalent meningococcal conjugate vaccine, during September 30, 2011 to June 30, 2013, were included. Twenty-six prespecified events of interest (EOIs), including neurologic, rheumatologic, hematologic, endocrine, renal, pediatric, and pediatric infectious disease EOIs, were identified through electronic health records 1 year after vaccination. Of these, 16 were reviewed by case review committees. Specific risk and comparison windows after vaccination were predefined for each EOI. The relative incidence (RI) and 95% confidence intervals (CIs) were estimated through conditional Poisson regression models, adjusted for seasonality.

RESULTS: This study included 48 899 vaccinated individuals. No cases were observed in the risk window for 14 of 26 EOIs. The RI for Bell's palsy, a case review committee-reviewed EOI, was statistically significant (adjusted RI: 2.9, 95% CI: 1.1–7.5). Stratified analyses demonstrated an increased risk for Bell's palsy in subjects receiving concomitant vaccines (RI = 5.0, 95% CI = 1.4–17.8), and no increased risk for those without concomitant vaccine (RI = 1.1, 95% CI = 0.2–5.5).

CONCLUSIONS: We observed a temporal association between occurrence of Bell's palsy and receipt of MenACWY-CRM concomitantly with other vaccines.

In this issue

Pediatrics

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Table of Contents
Index by author

View this article with ***LENS***

Previous Next

Email Article Share
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Article Alerts Download PDF
Citation Tools Insight Alerts

Table of Contents

Jump to section

- Article
  - Abstract
  - Methods
  - Results
  - Discussion
  - Conclusions
  - Acknowledgments
  - Footnotes
  - References
- Figures & Data
- Supplemental

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PMID: 282

Adverse Events Following Quadrivalent Meningococcal CRM-Conju Vaccine (Menveo®) Reported to the Vaccine Adverse Event Report System (VAERS), 2010–2015

Tanya R. Myers, PhD MSc,[a,b,*] Michael M. McNeil, MD MPH,[a] Carmen S. Ng, MSPH,[a] Rongxia Li, PhD Paige W. Lewis, MSPH,[a] and Maria V. Cano, MD MPH[a]

[a]Immunization Safety Office, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Atlanta, GA 30333, USA
[b]Rollins School of Public Health, Emory University, 1518 Clifton Road, Atlanta, GA 30322, USA
[*]Correspondence: Tanya R. Myers, PhD MSc, Division of Healthcare Quality Promotion, Centers for Dis Control and Prevention, 1600 Clifton Rd NE, MS D-26, Atlanta, GA 30333, USA (vje9@cdc.gov)

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Abstract

Background

Limited data are available describing the post-licensure safety of meningococcal vaccines, inclu Menveo®. We reviewed reports of adverse events (AEs) to the Vaccine Adverse Event Reportin System (VAERS) to assess safety in all age groups.

Methods

VAERS is a national spontaneous vaccine safety surveillance system co-administered by the Ce for Disease Control and Prevention and the US Food and Drug Administration. We searched the VAERS database for US reports of adverse events in persons who received Menveo from 1 Janu 2010 through 31 December 2015. We clinically reviewed reports and available medical records serious AEs, selected pre-specified outcomes, and vaccination during pregnancy. We used empi Bayesian data mining to identify AEs that were disproportionately reported after receipt of Men

Results

During the study period, VAERS received 2614 US reports after receipt of Menveo. Of these, 6' classified as serious, including 1 report of death. Adolescents (aged 11–18 years) accounted for reports. Most of the reported AEs were non-serious and described AEs consistent with data fron licensure studies. Anaphylaxis and syncope were the two most common events in the serious re] We did not identify any new safety concerns after review of AEs that exceeded the data mining threshold, although we did observe disproportionate reporting for terms that were not associatec an adverse event (e.g., "incorrect drug dosage form administered", "wrong technique in drug us: process"). Although reports were limited, we did not find any evidence for concern regarding th of Menveo during pregnancy.

Conclusions

In our review of VAERS reports, findings of AEs were consistent with the data from pre-licensu studies. Vaccine providers should continue to emphasize and adhere to proper administration of vaccine.

Keywords: meningococcal disease, meningitis vaccine, vaccines, vaccine safety, epidemiology, Vaccine Adverse Event Reporting System (VAERS)

INTRODUCTION

To protect against invasive meningococcal disease caused by *Neisseria meningitidis* groups A, (W-135, and Y, the Advisory Committee on Immunization Practices (ACIP) currently recommen adolescents receive quadrivalent meningococcal conjugate vaccine (MCV4) at 11–12 years foll(by a booster dose at 16 years and that persons at increased risk receive a dose series and recomn vaccine product depending upon age and condition [1]. Coverage in the adolescent population i: nearing 80% for at least one dose [2], indicating that a substantial proportion of this population electing to receive MCV4 vaccine, of which two brands are currently available in the United St: (US). The most recently licensed MCV4 vaccine, Menveo®, was approved in 2010 for use amo persons aged 11–55 years [3] with subsequent approvals for use in children and infants as youn; months [4–5].

Pre-licensure studies of Menveo found adverse events (AEs) that were mainly mild and quickly resolved. In infants and children between 2 and 23 months of age, the most frequently reported were tenderness, erythema, induration, irritability, and sleepiness [6–9]. In children aged 2–10 y the most frequently reported AEs were injection site pain, erythema, irritability, induration and sleepiness [9–11]. The most frequently reported AEs from adolescents and adults were injection pain, headache, erythema and myalgia [9,12]. Reports of post-licensure data in the US are limit recent review of reports to VAERS following improperly prepared doses of Menveo found AEs to those reported in preclinical studies [13]. Although the Menveo label includes events that hav reported voluntarily since licensure, frequency of occurrence and causal relationships have not l determined [9]. To provide additional information on post-licensure safety, we reviewed reports

8

Grant Final Report

Grant ID: R18 HS 017045

Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS)

Inclusive dates: 12/01/07 - 09/30/10

Principal Investigator:
Lazarus, Ross, MBBS, MPH, MMed, GDCompSci

Team members:
Michael Klompas, MD, MPH

Performing Organization:
Harvard Pilgrim Health Care, Inc.

Project Officer:
Steve Bernstein

Submitted to:
The Agency for Healthcare Research and Quality (AHRQ)
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Abstract

Purpose: To develop and disseminate HIT evidence and evidence-based tools to improve healthcare decision making through the use of integrated data and knowledge management.

Scope: To create a generalizable system to facilitate detection and clinician reporting of vaccine adverse events, in order to improve the safety of national vaccination programs.

Methods: Electronic medical records available from all ambulatory care encounters in a large multi-specialty practice were used. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions were evaluated for values suggestive of an adverse event.

Results: Restructuring at CDC and consequent delays in terms of decision making have made it challenging despite best efforts to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial and comparison of ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. However, Preliminary data were collected and analyzed and this initiative has been presented at a number of national symposia.

Key Words: electronic health records, vaccinations, adverse event reporting

The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services of a particular drug, device, test, treatment, or other clinical service.

Final Report

Purpose

This research project was funded to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS), via the following aims:

Aim 1. Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration.

Aim 2. Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS).

Aim 3. Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.

Aim 4. Distribute documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems.

Scope

Public and professional confidence in vaccination depends on reliable postmarketing surveillance systems to ensure that rare and unexpected adverse effects are rapidly identified. The goal of this project is to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS). This project is serving as an extension of the Electronic Support for Public Health (ESP) project, an automated system using electronic health record (EHR) data to detect and securely report cases of certain diseases to a local public health authority. ESP provides a ready-made platform for automatically converting clinical, laboratory, prescription, and demographic data from almost any EHR system into database tables on a completely independent server, physically located and secured by the same logical and physical security as the EHR data itself. The ESP:VAERS project developed criteria and algorithms to identify important adverse events related to vaccinations in ambulatory care EHR data, and made attempts at formatting and securely sending electronic VAERS reports directly to the Centers for Disease Control and Prevention (CDC).

Patient data were available from Epic System's Certification Commission for Health Information Technology-certified EpicCare system at all ambulatory care encounters within Atrius Health, a large multispecialty group practice with over 35 facilities. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions are evaluated for values

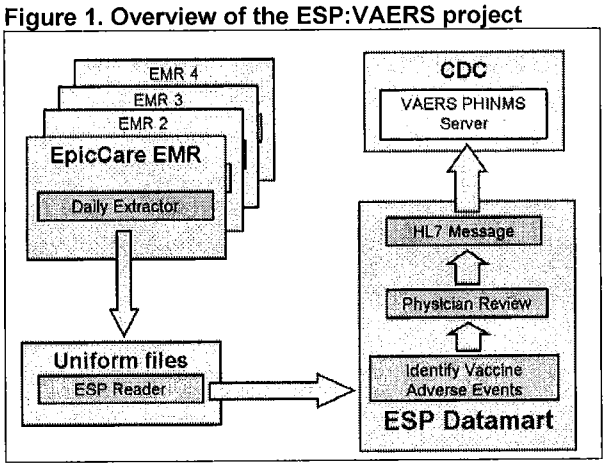
suggestive of an adverse vaccine event. When a possible adverse event was detected, it was recorded, and the appropriate clinician was to be notified electronically.

Clinicians in-basket messaging was designed to provide a preview a pre-populated report with information from the EHR about the patient, including vaccine type, lot number, and possible adverse effect, to inform their clinical judgment regarding whether they wish to send a report to VAERS. Clinicians would then have the option of adding free-text comments to pre-populated VAERS reports or to document their decision not to send a report. The CDC's Public Health Information Network Messaging System (PHIN-MS) software was installed within the facilities so that the approved reports could be securely transferred to VAERS as electronic messages in an interoperable health data exchange format using Health Level 7 (HL7).

Methods

The goal of Aim 1: *Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration,* and Aim 2: *Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS)*, was to construct the below flow of data in order to support the first two Aims:

Figure 1. Overview of the ESP:VAERS project



Existing and functioning ESP components are shown on the left, and Aims 1 and 2 on the right. ESP:VAERS flags every vaccinated patient, and prospectively accumulate that patient's diagnostic codes, laboratory tests, allergy lists, vital signs, and medication prescriptions. A main component of Aim 1 was to *Develop AE criteria to assess these parameters for new or abnormal values that might be suggestive of an adverse effect.* A reporting protocol & corresponding algorithms were developed to detect potential adverse event cases using diagnostic codes, and methods were tested to identify prescriptions or abnormal laboratory values that might be suggestive of an adverse effect. These algorithms were designed to seek both expected and unexpected adverse effects.

This reporting protocol was approved by both internal & external partners. We initially prepared a draft document describing the elements, algorithms, interval of interest after vaccination, and actions for broad classes of post-vaccination events, including those to be reported immediately without delay (such as acute anaphylactic reaction following vaccination), those never to be reported (such as routine check-ups following vaccination) and those to be reported at the discretion and with additional information from the attending physician through a feedback mechanism. The draft was then widely circulated as an initial / working draft for comment by relevant staff in the CDC and among our clinical colleagues at Atrius. In addition to review by the internal CDC Brighton Collaboration liaison, this protocol has also received review & comment via the CDC's Clinical Immunization Safety Assessment (CISA) Network.

The goal of Aim 2 was the *Development of HL7 messages code for ESP:VAERS to ensure secure transmission to CDC via PHIN-MS.* The HL7 specification describing the elements for an electronic message to be submitted to Constella, the consultants engaged by CDC for this project was implemented. Synthetic and real test data was been generated and transmitted between Harvard and Constella. However, real data transmissions of non-physician approved reports to the CDC was unable to commence, as by the end of this project, the CDC had yet to respond to multiple requests to partner for this activity.

The goal of Aim 3 was to *Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.*

We had initially planned to evaluate the system by comparing adverse event findings to those in the Vaccine Safety Datalink project—a collaborative effort between CDC's Immunization Safety Office and eight large managed care organizations. Through a randomized trial, we would also test the hypothesis that the combination of secure, computer-assisted, clinician-approved, adverse event detection, and automated electronic reporting will substantially increase the number, completeness, validity, and timeliness of physician-approved case reports to VAERS compared to the existing spontaneous reporting system; however, due to restructuring at CDC and consequent delays in terms of decision making, it became impossible to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial, and compare ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. Therefore, the components under this particular Aim were not achieved.

Aim 4 *Distribution of documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems* has been successfully completed. Functioning source code is available to share under an approved open source license. ESP:VAERS source code is available as part of the ESP source code distribution. It is licensed under the LGPL, an open source license compatible with commercial use. We have added the ESP:VAERS code, HL7 and other specifications and documentation to the existing ESP web documentation and distribution resource center http://esphealth.org, specifically, the Subversion repository available at:
http://esphealth.org/trac/ESP/wiki/ESPVAERS.

Results

Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6 percent of vaccinations) were identified. This is an average of 890 possible events, an average of 1.3 events per clinician, per month. These data were presented at the 2009 AMIA conference.

In addition, ESP:VAERS investigators participated on a panel to explore the perspective of clinicians, electronic health record (EHR) vendors, the pharmaceutical industry, and the FDA towards systems that use proactive, automated adverse event reporting.

Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.

Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.

Inclusion of AHRQ Priority Populations

The focus of our project was the Atrius Health (formerly HealthOne) provider & patient community. This community serves several AHRQ inclusion populations, specifically low-income and minority populations in primarily urban settings.

Atruis currently employs approximately 700 physicians to serve 500,000 patients at more than 18 office sites spread throughout the greater Metropolitan Boston area. The majority of Atruis physicians are primary care internal medicine physicians or pediatricians but the network also includes physicians from every major specialty.

The entire adult and pediatric population served by Atruis was included in our adverse event surveillance system (ESP:VAERS). Atruis serves a full spectrum of patients that reflects the broad diversity of Eastern Massachusetts. A recent analysis suggests that the population served by Atruis is 56% female, 16.6% African American, 4% Hispanic. The prevalence of type 2 diabetes in the adult population is 5.7%. About a quarter of the Atruis population is under age 18.

List of Publications and Products

ESP:VAERS [source code available as part of the ESP source code distribution]. Licensed under the GNU Lesser General Public License (LGPL), an open source license compatible with commercial use. Freely available under an approved open source license at: http://esphealth.org.

Lazarus, R, Klompas M, Hou X, Campion FX, Dunn J, Platt R. Automated Electronic Detection & Reporting of Adverse Events Following Vaccination: ESP:VAERS. The CDC Vaccine Safety Datalink (VSD) Annual Meeting. Atlanta, GA; April, 2008.

Lazarus R, Klompas M Automated vaccine adverse event detection and reporting from electronic medical records. CDC Public Health Informatics Network (PHIN) Conference August 27, 2008.

Klompas M, Lazarus R ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 17th.

Lazarus R, Klompas M, Kruskal B, Platt R Temporal patterns of fever following immunization in ambulatory care data identified by ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Linder J, Klompas M, Cass B, et al. Spontaneous Electronic Adverse Event Reporting: Perspectives from Clinicians, EHR Vendors, Biopharma, and the FDA. Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

9

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The reporting sensitivities of two passive surveillance systems for vaccine adverse events.

S Rosenthal, and **R Chen**

Published Online: October 07, 2011

Abstract PDF PDF Plus

To evaluate reporting sensitivities for vaccine adverse events, reporting rates were estimated by dividing the number of events reported to the Monitoring System for Adverse Events Following Immunization and the Vaccine Adverse Event Reporting System in a given period by the number of doses administered or distributed during the same period. Reporting sensitivity was calculated as the ratio of the rates at which events were reported to each passive surveillance system (numerator) and occurred in controlled studies (denominator). Reporting sensitivities were generally better in the public sector than in the private sector. The significant underreporting of known outcomes, together with the nonspecific nature of most adverse event reports, highlights the limitations of passive surveillance systems in assessing the incidence of vaccine adverse events.

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S Rosenthal, and R ChenNational Immunization Program, Centers for Disease Control and Prevention, Atlanta, Ga 30333, USA. "The reporting sensitivities of two passive surveillance systems for vaccine adverse events.", *American Journal of Public Health* 85, no. 12 (December 1, 1995): pp. 1706-1709.

https://doi.org/10.2105/AJPH.85.12.1706

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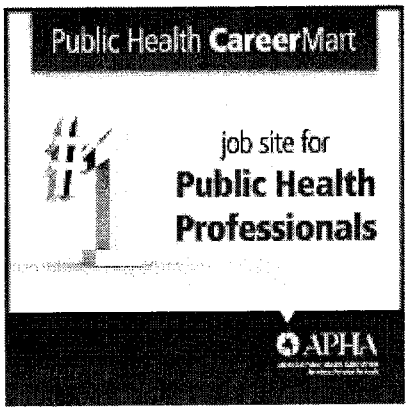

We recommend

Retrospective Validation of a Surveillance System for Unexplained Illness and Death: New Haven County, Connecticut

Michael D. Kluger et al., Am J Public Health, 2011

What Should an Ideal Vaccine Postlicensure Safety System Be?
Marie R. Griffin et al., Am J Public Health, 2011

Surveillance for Guillain–Barré Syndrome After Influenza Vaccination Among the Medicare Population, 2009–2010
Dale R. Burwen et al., Am J Public Health, 2012

Active and passive surveillance for communicable diseases in child care facilities, Seattle-King County, Washington.
J K MacDonald et al., Am J Public Health, 2011

CDC: HCPs should heed short shelf life of LAIV
Healio

Benefits of rotavirus vaccine outweigh potential risks
Healio

Adverse Events Following MMR Vaccination in Adults
PracticeUpdate, 2015

Safety Surveillance Data of DTaP Vaccines
PracticeUpdate, 2018

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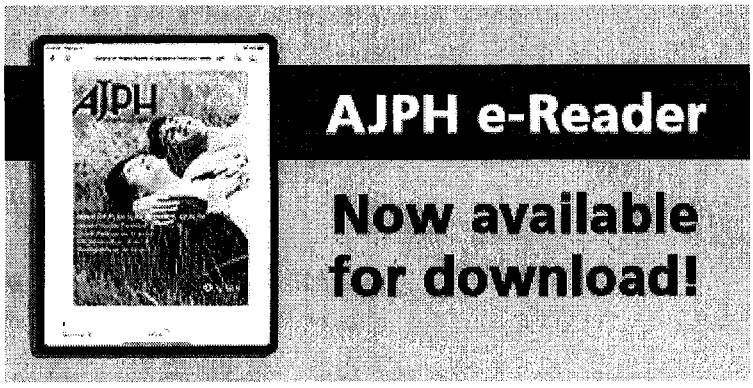

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proteinases 1 and 3, which are elements of plaque destabilization (Shantsila and Lip, 2009). Monocytes can activate coagulation factor X, which is responsible for the generation of thrombin (Shantsila and Lip, 2009).

A few proteins facilitate regulation of the coagulation cascade. Protein C, which circulates in the plasma, is activated by the serine protease thrombin and its cofactor thrombin-thrombomodulin (Rezaie, 2010). Activated protein C functions as an anticoagulant by proteolytically degrading procoagulant cofactors essential for the generation of thrombin (Rezaie, 2010). The cofactor protein S enchances effects of activated protein C (Anderson and Weitz, 2010). In addition, the serine protease inhibitor antithrombin regulates the coagulation cascade by inactivating thrombin as well as other enzymes in the cascade (Rodgers, 2009).

In individuals with inherited (e.g., antithrombin deficiency, Factor V Leiden) or acquired (e.g., obesity, pregnancy) hypercoagulable states, the function of the enzymes involved in the aforementioned coagulation cascade and its regulation are altered or deficient, leading to excessive coagulability (Anderson and Weitz, 2010). Excessive coagulation can contribute to the development of thrombosis, myocardial infarction, and stroke (Anderson and Weitz, 2010).

INCREASED SUSCEPTIBILITY

Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a preexisting susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness, or developmental stage, to name just a few—all of which can interact as suggested graphically in Figure 3-1.

Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine; others, at least with current technology and practice, are not. Moreover, the occurrence of the adverse event is often the first sign of the underlying condition that confers sus-

ceptibility.

The best-understood vaccine-associated adverse effect is the occurrence of invasive disease (such as meningoencephalitis and arthritis) caused by the vaccine virus itself in individuals with an acquired or genetic immunodeficiency who receive live vaccines such as VZV, MMR, and oral polio vaccine. Although the incidence of such infections may decrease with the introduction of newborn screening for severe combined immunodeficiency, the occurrence of vaccine-related disease can be the trigger that leads to the recognition of immunodeficiency (Galea et al., 2008; Ghaffar et al., 2000; Kramer et al., 2001; Levy et al., 2003). Invasive disease may also occur by viral reactivation in individuals who previously received these vaccines while healthy, but who subsequently become immunocompromised, for example, as a result of chemotherapy should they later develop cancer or leukemia (Chan et al., 2007; Levin et al., 2003). Not all individuals who suffer invasive disease have demonstrated recognized immune deficien-cies, even when vaccine virus is recovered from the patient (Iyer et al.,

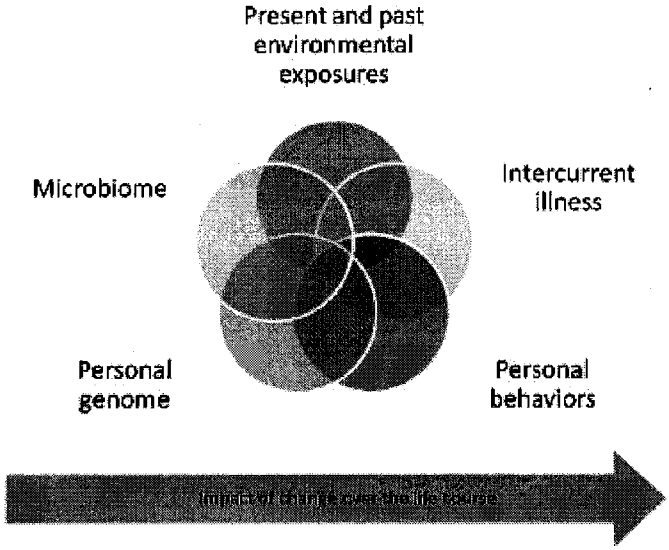


FIGURE 3-1 Present and past environmental exposures.

2009; Levin et al., 2008). This leads to two hypotheses: either immunocom-

Wisconsin United for Freedom
P.O. Box 894
Cedarburg, WI 53012
info@wisconsinunitedforfreedom.org

Good morning,

Thank you so much for sitting in for today's session with regards to Clearinghouse Rule 19-079, pertaining the Immunization of Students.

While I come here today with staunch resistance of Clearinghouse Rules 1, 2, 4 and 5; I stand in vehement opposition to Clearinghouse Rule 4, which pertains to adding the Meningococcal vaccine to the already overzealous and aggressive CDC Vaccine Schedule for our children.

With Senate Bill 262 and Assembly Bill 248, regarding the removal of our State's Personal Belief Exemptions from vaccination, currently circulating county by county in our state, adding yet another Mandated vaccine at the behest of Wisconsin DHS is setting a perilous precedent for what may be coming down the pipeline in the future with regards to mandated vaccines for all Wisconsin Children.

Clearinghouse Rule #4 expressly wishes to Mandate the Meningococcal Vaccine against Bacterial Meningitis strains A, C, W & Y – for all 7th graders with the requirement of an additional booster for all 12th graders. This increases the doses of childhood vaccines for all Wisconsin children to 71 by the time they graduate high school – this excludes the currently optional annual flu vaccine and the three-dose HPV Vaccines…but, for how long do these remain optional? Current Events elude to even more vaccines being mandated, if Wisconsin DHS has their way and thusly projecting Wisconsin into a dismal kinship with the states of California, New York, New Jersey and Connecticut, and other threatened with similar legislature.

When most of us hear the word "Meningitis", we think instant death, no hope and no treatment. And sadly, for some, this can be true; however, this is not anything close to being the norm. Bacterial Meningitis is highly treatable with prompt medical care and proper diagnosis along with antibiotic treatments.

In fact, the Wisconsin Bureau of Communicable Diseases stated in their report from 2016 and I quote, "Most people who come into contact with meningitis do not get sick. However, some people become seriously ill, which may be related to societal factors such as overcrowding or smoke exposure, or physical factors such as a weakened immune system that make more likely to get sick:"

Similarly, n the CDC website, I came across a page last update on July 26, 2019 that stated the following: I quote

"As part of the licensure process, MenACWY and MenB vaccines showed that they produce an immune response. This immune response suggests the vaccines provide protection, but data are limited on how well they work."

Wisconsin DHS wants to mandate a vaccine for a product that isn't even proven to work, as stated by the CDC? They want to mandate a vaccine for an illness that reported only 327 cases NATIONALLY in 2018? They want to mandate a vaccine for a bacterial infection that has an amazing opportunity for full recovery with sound medical recognition of symptoms and proper treatment? I further quote from the same CDC page:

"Since meningococcal disease is uncommon, many people need to get these vaccines in order to measure their effectiveness."

Does anyone else truly hear how absurd this sounds? This disease is very uncommon, we don't know how well the vaccine works or for how long, but, the answer to this is vaccinate everyone for an illness they almost surely never come into contact with or acquire? This is the science that you want us, as parents to blindly follow as "settled"?

The very same page further exclaims:

"Today, meningococcal disease is at a historic low in the United States. Rates of meningococcal disease have been declining in the United States since the 1990s. Much of the decline occurred before the routine use of meningitis vaccines".

The disease was already on its way out, per the CDC, prior to the vaccine. There have been no widespread outbreaks of meningitis, ever, in the history of our recorded statistics. In fact, the CDCs shares that from 2005 to 2017, there have been a total of 2,889 cases. There are zero fatalities recorded on this report, however, there unfortunately are sure to have been some. Lastly, almost every single adult in this room has never had a Meningococcal vaccine, and Wisconsin has never, seen an outbreak – thus proving the fallacy of herd immunity.

When reviewing the state and national statistics of Meningitis, anyone with Critical Thought and a discerning eye is wondering with great suspicion as to why DHS is proposing this Meningitis Vaccine mandate. Wisconsin currently has a high voluntary vaccine uptake of 83.8%, per Wisconsin DHS data for the MenACWY vaccines, which cover bacterial meningitis strains A, C, W and Y. The Wisconsin Bureau of Communicable Diseases also states that the bacterial strains of meningitis are not spread by casual contact or by simply breathing the air where a person with meningococcal disease has been and once an infected person has been treated with antibiotics for 24 hours they are no longer contagious.

So, I ask: why is DHS pushing the mandate of this vaccine when their own data, coupled with CDC data and that of the National Meningitis Association express that this is not a public health threat or concern. This vaccine is readily available for those who wish and there is no scientific data supporting any need whatsoever for a mandate!

Wisconsin Representatives: we are better than this! We have to stop and ask what is the true vested interest here and why is this being pushed so heavily when there is no threat? This is your opportunity to see where we, the parents of the

potentially affected children recognize the government overreach and the violation of our civil rights! This is why we asked you to hear us today; and thank you all so much; for being here.

All I know is, as a Mother, I never entered into parenthood thinking that I would be speaking in front a group of my elected officials, Wisconsin DHS, health professionals, and my peers - battling in a proverbial war for children's fundamental rights to bodily autonomy. Fighting a war that has nothing to do with public health but, but one perpetuated on the bases of greed, control and force. I never thought we'd all be "here". All I can say is that at the end of the day, I know with every fiber of my being, that I am standing on the right side of history. I'm asking you to stand alongside me. Alongside us. No to every Clearinghouse Rule.

Thank you,

A.Ohlsen

Fitchburg, Wisconsin

Sources

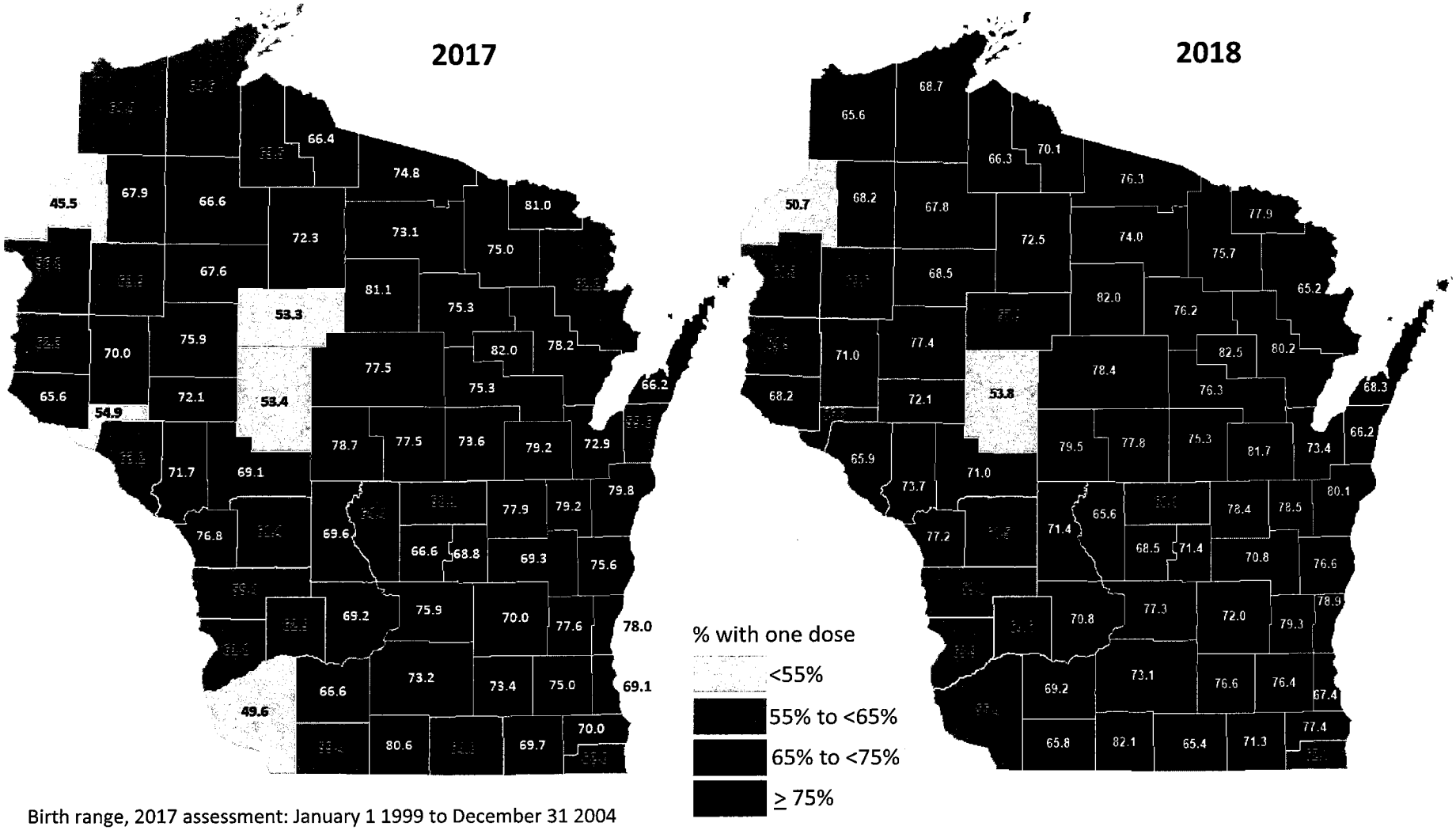
CDC: Meningococcal Vaccination: What everyone should know
https://www.cdc.gov/vaccines/vpd/mening/public/index.html#types

Meningococcal Disease – National Meningitis Association
https://www.nmaus.org/meningococcal-disease/#resources

Meningococcal Disease – Bureau of Communicable Diseases – Wisconsin DHS
https://www.dhs.wisconsin.gov/publications/p4/p42072.pdf

Wisconsin Communicable Disease Report
https://www.dhs.wisconsin.gov/publications/p02194.pdf

Percent of adolescents aged 13-18 who have received one dose of meningococcal (MenACWY) vaccine, 2017 and 2018



Birth range, 2017 assessment: January 1 1999 to December 31 2004
Birth range, 2018 assessment: January 1 2000 to December 31 2005

Prepared by the Wisconsin Immunization Program, Division of Public Health, April 2019

Data source: Wisconsin Immunization Registry

P-02279B (4/2019)

WISCONSIN DEPARTMENT *of* HEALTH SERVICES

MENINGOCOCCAL DISEASE
(Meningococcal meningitis, Meningococcemia)

Meningococcal disease includes meningitis (swelling of the tissues that cover the brain and spinal cord) and sepsis (blood infection). Someone with meningococcal disease can have meningitis, sepsis, or both at the same time. Anyone can get meningococcal disease, but it is most common in children under 5 years of age and young adults ages 16 through 23 years.

What causes it?

- Meningococcal disease is caused by *Neisseria meningitidis* bacteria. *N. meningitidis* bacteria are often found in the nose and throat without causing illness. Most people who come into contact with *N. meningitidis* do not get sick. Only some people become seriously ill, which may be related to societal factors such as overcrowding or smoke exposure, or physical factors such as a weakened immune system that make them more likely to get sick.
- Meningococcal disease is spread from person to person. *N. meningitidis* bacteria are spread by exchanging respiratory and throat secretions (saliva or spit) during close or lengthy contact (e.g., sharing utensils or kissing), especially if living in the same household.
  - The bacteria are not as contagious as germs that cause the common cold or the flu. They are not spread by casual contact or by simply breathing the air where a person with meningococcal disease has been.
  - Someone with meningococcal disease can spread *N. meningitidis* bacteria for several days before they have symptoms. Once people are treated with antibiotics for 24 hours, they are not contagious.
- There are five serogroups ("strains") of *N. meningitidis*: A, B, C, W, and Y that cause most disease worldwide. Three of these serogroups (B, C, and Y) cause most of the illness seen in the United States.

What are the signs and symptoms?

Common Symptoms

- High fever
- Headache
- Vomiting
- Stiff neck
- Purple or pinpoint red rash
- Sensitivity to light
- Sleepiness
- Confusion

Symptoms in Infants

- Sluggishness
- Irritability
- Vomiting
- Poor feeding

**Symptoms usually appear three to four days after being exposed, but can start anytime between two and 10 days after exposure. Symptoms may start suddenly and the disease can become severe very quickly. Prompt medical attention is important.*

BUREAU OF COMMUNICABLE DISEASES
https://www.dhs.wisconsin.gov/dph/bcd.htm | DHSDPHBCD@dhs.wi.gov
Wisconsin Department of Health Services | Division of Public Health
P-42072 (03/2017)

What are the treatment options?

- Antibiotics are used to treat meningococcal disease. It is important that treatment with antibiotics begin as soon as possible.
  - Even with antibiotic treatment, 10-15% of people infected with meningococcal disease will die. Approximately 11-19% of survivors will have long-term disabilities, such as loss of limb(s), deafness, nervous system problems, or brain damage.
- People who had close, direct contact with someone who had meningococcal disease may need to take antibiotics to reduce their chances of becoming sick.
  - Close contacts include household members, intimate contacts, day care center contacts, and those who are directly exposed to the oral or nasal secretions of someone who is infected.
  - Kissing as well as sharing eating utensils, smoking materials, or beverage containers can be classified as direct contact.

How can it be prevented?

- Keeping up-to-date with recommended immunizations is the best defense against meningococcal disease. There are several vaccines that protect against the different types of *N. meningitidis* bacteria.
  - Three vaccines (Menomune®, Menactra®, and Menveo®) protect against four of the five types of *N. meningitidis* bacteria (**serogroups A, C, Y, and W-135**). The Advisory Committee on Immunization Practices (ACIP) recommends children get their first dose of meningococcal vaccine (Menactra® or Menveo®) when they are between 11 and 12 years and get a booster dose when they are 16 years of age.
  - Two vaccines (Trumenba® and Bexsero®) protect against the fifth type of *N. meningitidis* bacteria, **serogroup B**. These were recently licensed for use in the United States. The ACIP recommends the vaccine be given to people aged 16-23 years. The ideal age to vaccinate is between 16 and 18 years, to provide protection when individuals are at greatest risk of getting meningococcal disease.
- The meningococcal vaccine should also be given to those who are traveling to areas of the world with high rates of meningococcal disease (e.g., areas of Africa) as well as locations having an outbreak of meningitis.
- Avoid kissing or sharing cups, plates, forks, etc. with someone who is sick.

For more information about the vaccine that protects against *N. meningitidis* bacteria, please visit these websites:

http://www.immunize.org/vis/meningococcal_b.pdf

http://www.immunize.org/vis/meningococcal_mcv_mpsv.pdf

Reported Cases and Deaths from Vaccine Preventable Diseases, United States

	Diphtheria		Tetanus		Pertussis		Polio (paralytic)		Measles		Mumps		Rubella		CRS
Year	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases
1950	5,796	410	486	336	120,718	1,118	33,300†	1,904	319,124	468	NR		NR		NR
1951	3,983	302	506	394	68,687	951	28,386†	1,551	530,118	683	NR		NR		NR
1952	2,960	217	484	360	45,030	402	57,879†	3,145	683,077	618	NR		NR		NR
1953	2,355	156	506	337	37,129	270	35,592†	1,450	449,146	462	NR		NR		NR
1954	2,041	145	524	332	60,886	373	18,308	1,368	682,720	518	NR		NR		NR
1955	1,984	150	462	265	62,786	467	13,850	1043	555,156	345	NR		NR		NR
1956	1,568	103	468	246	31,732	266	7,911	566	611,936	530	NR		NR		NR
1957	1,211	81	447	279	28,295	183	2,499	221	486,799	389	NR		NR		NR
1958	918	74	445	303	32,148	177	3,697	255	763,094	552	NR		NR		NR
1959	934	72	445	283	40,005	269	6,289	454	406,162	385	NR		NR		NR
1960	918	69	368	231	14,809	118	2,525	230	441,703	380	NR	42	NR	12	NR
1961	617	68	379	242	11,468	76	988	90	423,919	434	NR	53	NR	14	NR
1962	444	41	322	215	17,749	83	762	60	481,530	408	NR	43	NR	8	NR
1963	314	45	325	210	17,135	115	396	41	385,156	364	NR	48	NR	16	NR
1964	293	42	289	179	13,005	93	106	17	458,083	421	NR	50	NR	53	NR
1965	164	18	300	181	6,799	55	61	16	261,904	276	NR	31	NR	16	NR
1966	209	20	235	158	7,717	49	106	9	204,136	261	NR	43	46,975	12	NR
1967	219	32	263	144	9,718	37	40	16	62,705	81	NR	37	46,888	16	NR
1968	260	30	178	66	4,810	36	53	24	22,231	24	152,209	25	49,371	24	NR
1969	241	25	192	89	3,285	13	18	13	25,826	41	90,918	22	57,686	29	62
1970	435	30	148	79	4,249	12	31	7	47,351	89	104,953	16	56,552	31	67
1971	215	13	116	64	3036	18	17	18	75,290	90	124,939	22	45,086	20	44
1972	152	10	128	58	3,287	6	29	2	32,275	24	74,215	16	25,507	14	32
1973	228	10	101	40	1,759	5	7	10	26,690	23	69,612	12	27,804	16	30
1974	272	5	101	44	2,402	14	7	3	22,094	20	59,128	6	11,917	15	22
1975	307	5	102	45	1,738	8	13	9	24,374	20	59,647	8	16,652	21	32
1976	128	7	75	32	1,010	7	10	16	41,126	12	38,492	8	12,491	12	22
1977	84	5	87	24	2,177	10	19	16	57,345	15	21,436	5	20,395	17	29
1978	76	4	86	32	2,063	6	8	13	26,871	11	16,817	3	18,269	10	30
1979	59	1	81	30	1,623	6	22	1	13,597	6	14,255	2	11,795	1	57
1980	3	1	95	28	1,730	11	9	2	13,506	11	8,576	2	3,904	1	14
1981	5	0	72	31	1,248	6	10	0	3,124	2	4,941	1	2,077	5	10
1982	2	1	88	22	1,895	4	12	0	1,714	2	5,270	2	2,325	4	13
1983	5	0	91	22	2,463	5	13	0	1,497	4	3,355	2	970	3	7
1984	1	0	74	20	2,276	7	9	0	2,587	1	3,021	1	752	1	2
1985	3	0	83	23	3,589	4	8	0	2,822	4	2,982	0	630	1	2
1986	0	0	64	22	4,195	6	10	0	6,282	2	7,790	0	55	1	13
1987	3	1	48	16	2,823	1	9	0	3,655	2	12,848	2	306	0	3
1988	2	0	53	17	3,450	4	9	0	3,396	3	4,866	2	225	1	2
1989	3	0	53	9	4,157	12	11	0	18,193	32	5,712	3	396	4	2
1990	4	1	64	11	4,570	12	6	0	27,786	64	5,292	1	1,125	8	32
1991	5	0	57	11	2,719	0	10	1	9,643	27	4,264	1	1,401	1	34
1992	4	1	45	9	4,083	5	6	0	2,237	4	2,572	0	160	1	11

†Total reported cases (i.e., including non-paralytic)

	Diphtheria		Tetanus		Pertussis		Polio (paralytic)		Measles		Mumps		Rubella		CRS
Year	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases
1993	0	0	48	11	6,586	1	4	0	312	0	1,692	0	192	0	4
1994	2	0	51	9	4,617	8	8	0	963	0	1,537	0	227	0	7
1995	0	1	41	5	5,137	6	7	1	309	2	906	0	128	1	3
1996	2	0	36	1	7,796	4	7	0	508	1	751	1	238	0	2
1997	4	0	50	4	6,564	6	6	0	138	2	683	0	181	0	9
1998	1	1	34	7	6,279	5	3	0	100	0	666	1	364	0	9
1999	1	1	40	7	7,288	7	2	0	100	2	387	1	267	0	6
2000	1	0	35	5	7,867	12	0	0	86	1	338	2	176	0	8
2001	2	0	37	5	7,580	17	0	0	116	1	266	0	23	2	3
2002	1	0	25	5	9,771	18	0	0	44	0	270	1	18	0	1
2003	1	1	20	4	11,647	11	0	0	56	1	231	0	7	0	4
2004	0	0	34	4	25,827	16	0	0	37	0	258	0	10	1	0
2005	0	0	27	1	25,616	31	1§	0	66	NA	314	0	11	0	1
2006	0	0	41	4	15,632	9	0	0	55	0	6,584	1	11	0	1
2007	0	0	28	5	10,454	9	0	0	43	0	800	0	11	1	0
2008	0	0	19	3	13,278	6	0	0	140	0	454	2	16	0	0
2009	0	0	18	6	16,858	1	1§	0	71	2	1991	2	3	2	2
2010	0	0	26	3	27,550	5	0	0	63	2	2,612	1	5	2	0
2011	0	0	36	6	18,719	1	0	0	220	0	404	0	4	1	0
2012	1	0	37	4	48,277	4	0	0	55	2	229	0	9	0	3
2013	0	0	26	3	28,639	2	1§	0	187	0	584	1	9	0	1
2014	1	0	25	1	32,971	7	0	0	667	0	1,223	0	6	0	1
2015	0	NA	29	NA	20,762	NA	0	NA	188	NA	1,329	NA	5	NA	1
2016	0	NA	34	NA	17,972	NA	0	NA	85	NA	6,369	NA	1	NA	2
2017	0	NA	33	NA	18,975	NA	0	NA	120	NA	6,109	NA	7	NA	5

§ Vaccine-associated/derived paralytic polio.

	Hepatitis A		Hepatitis B		Haemophilus		Varicella	
Year	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths
1966	32,859	NA	1,497	NA	NR	NR	NR	NA
1967	38,909	NA	2,458	NA	NR	NR	NR	NA
1968	45,893	NA	4,829	NA	NR	NR	NR	NA
1969	48,416	NA	5,909	NA	NR	NR	NR	NA
1970	56,797	NA	8,310	NA	NR	NR	NR	NA
1971	59,606	NA	9,556	NA	NR	NR	NR	NA
1972	54,074	NA	9,402	NA	NR	NR	164,114	122
1973	50,749	NA	8,451	NA	NR	NR	182,927	138
1974	40,358	NA	10,631	NA	NR	NR	141,495	106
1975	35,855	NA	13,121	NA	NR	NR	154,248	83
1976	33,288	NA	14,973	NA	NR	NR	183,990	106
1977	31,153	NA	16,831	NA	NR	NR	188,396	89
1978	29,500	NA	15,016	NA	NR	NR	154,089	91
1979	30,407	129	15,452	260	NR	NR	199,081	103
1980	29,087	112	19,015	294	NR	NR	190,894	78
1981	25,802	93	21,152	394	NR	NR	200,766	84
1982	23,403	83	22,177	375	NR	NR	167,423	61
1983	21,532	82	24,318	438	NR	NR	177,462	57
1984	22,040	77	26,115	465	NR	NR	221,983	53
1985	23,210	80	26,611	490	NR	NR	178,162	68
1986	23,430	65	26,107	557	NR	NR	183,243	47
1987	25,280	77	25,916	595	NR	NR	213,196	89
1988	28,507	70	23,177	621	NR	NR	192,857	83
1989	35,821	88	23,419	711	NR	NR	185,441	89
1990	31,441	76	21,102	816	NR	NR	173,099	120
1991	24,378	71	18,003	912	2,764	17	147,076	81
1992	23,112	82	16,126	903	1,412	16	158,364	100
1993	24,238	95	13,361	1041	1,419	7	134,722	100
1994	26,796	97	12,517	1120	1,174	5	151,219	124
1995	31,582	142	10,805	1027	1,180	12	120,624	115
1996	31,032	121	10,637	1082	1,170	7	83,511	81
1997	30,021	127	10,416	1,030	1,162	7	98,727	99
1998	23,229	114	10,258	1,052	1,194	11	82,455	81
1999	17,047	134	7,694	832	1,309	6	46,016	48
2000	13,397	106	8,036	886	1,398	6	27,382	44
2001	10,609	83	7,843	769	1,597	11	22,536	26
2002	8,795	76	7,996	762	1,743	7	22,841	32
2003	7,653	54	7,526	685	2,013	5	20,948	16
2004	5,970	58	6,741	643	2,085	11	26,659	19

	Hepatitis A		Hepatitis B		Haemophilus		Varicella		Meningococcal ACWY*		Meningococcal B*	
Year	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths	Cases	Deaths
2005	4,488	43	5,119	642	2,304	4	32,242	13	297	NA	156	NA
2006	3,579	34	4,713	700	2,436	4	48,445	18	318	NA	193	NA
2007	2,979	34	4,519	719	2,541	10	40,146	6	325	NA	167	NA
2008	2,585	37	4,033	671	2,886	3	30,386	18	330	NA	188	NA
2009	1,987	26	3,405	597	3,022	7	20,480	22	301	NA	174	NA
2010	1,670	29	3,374	588	3,151	4	15,427	15	280	NA	135	NA
2011	1,398	25	2,903	614	3,539	NA	14,513	14	257	NA	159	NA
2012	1,562	23	2,895	581	3,418	NA	13,447	16	161	NA	110	NA
2013	1,781	24	3.050	573	3,792	NA	11,359	8	142	NA	99	NA
2014	1,239	26	2,791	535	3,541	NA	10,172	4	123	NA	89	NA
2015	1,390	NA	3,370	NA	4,138	NA	9,789	NA	120	NA	111	NA
2016	2,007	NA	3,218	NA	4,895	NA	8,953	NA	126	NA	86	NA
2017	3,365	NA	3,409	NA	5,548	NA	8,775	2	109	NA	90	NA

*Meningococcal cases were not separated by serogroup prior to 2005.

Notes

NA - Not Available
NR - Not nationally reportable
CRS: Congenital Rubella Syndrome

Prior to 1966, hepatitis A and B were not separated from other types of hepatitis. Prior to 1978, deaths from hepatitis A and B were not separated from deaths from other types of hepatitis.

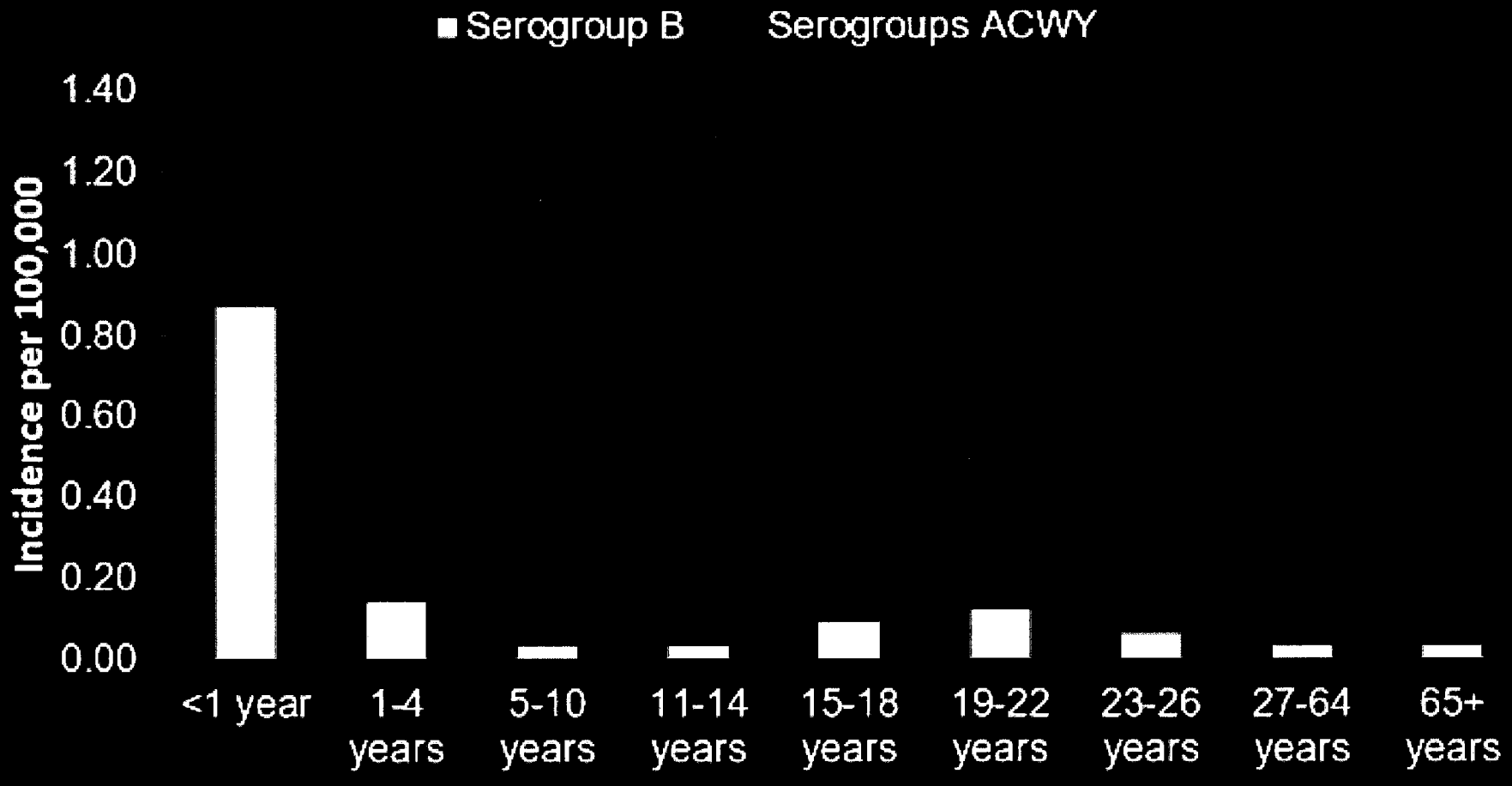
Haemophilus (Hi) reporting includes all serotypes and all ages. In 2017, 33 cases of invasive Hi type b disease were reported among children younger than 5 years of age.

Varicella was removed from the nationally notifiable disease list in 1991. In 2015, varicella cases were reported from 47 states, the District of Columbia, New York City, Guam, Puerto Rico, the Northern Mariana Islands and the U.S. Virgin Islands.

Sources:
Final totals for nationally reportable infectious diseases are reported in *Morbidity and Mortality Weekly Report* (*MMWR*). Tables are published for the previous year in August or September of the following year. Final totals for 2016 were published by the National Notifiable Diseases Surveillance System (NNDSS), accessible through *MMWR* 2017;66(38). CDC also publishes a more comprehensive surveillance document, the annual *Summary of Notifiable Diseases*. The most current annual summary was published on August 11, 2017 for calendar year 2015. This document and annual summaries for previous years are available on the MMWR website at http://www.cdc.gov/mmwr/. Beginning with data year 2016, links to annual data from the National Notifiable Diseases Surveillance System (NNDSS) are available on the NNDSS Data and Statistics web page at https://wwwn.cdc.gov/nndss/data-and-statistics.html.

May 2019

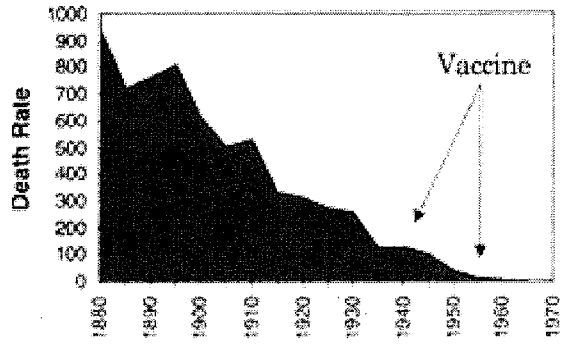
Meningococcal Incidence by Serogroup* and Age-Group, 2009-2018



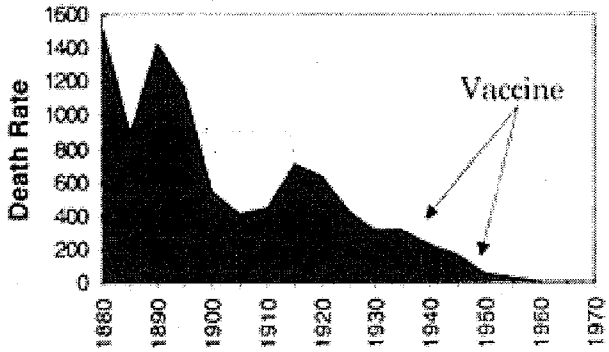
SOURCE: CDC; National Notifiable Diseases Surveillance System with additional serogroup data from Active Bacterial Core surveillance and state health departments.

Unknown serogroup (16%) and other serogroups (6%) excluded

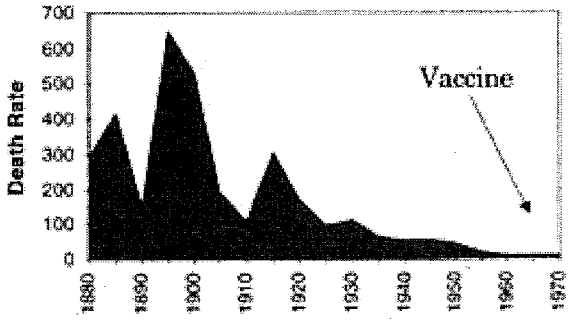
Whooping Cough



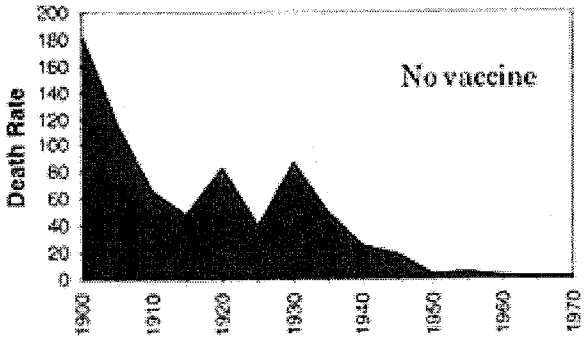
Diphtheria



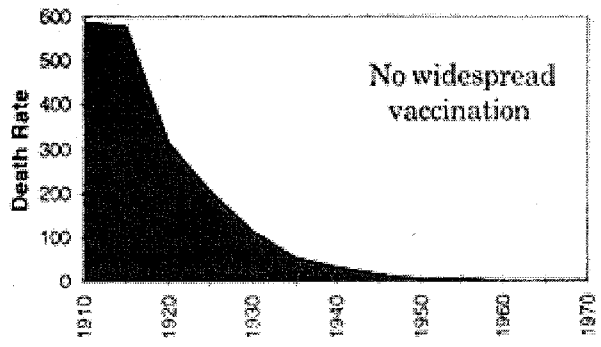
Measles



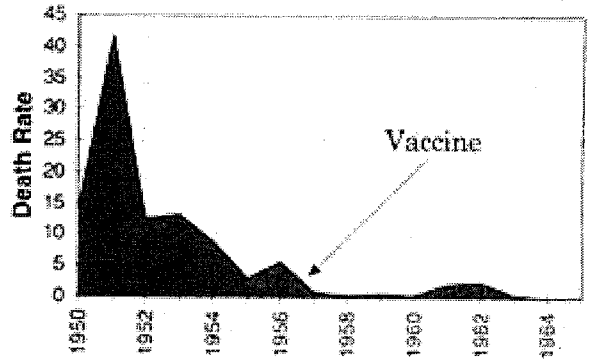
Scarlet Fever



Typhoid Fever



Polio



The above graphs, based on the official death numbers as recorded in the Official Year Books of the Commonwealth of Australia, are taken from Greg Beattie's excellent book *"Vaccination A Parent's Dilemma"* and represent the decline in death rates from infectious disease in Australia. They clearly show that vaccines had nothing to do with the decline in death rates. (Note: Graphical evidence on the decline in death rates from infectious disease for USA, England, New Zealand and many other countries shows the exact same scenario as above).

http://www.neuroprocare.com/vaccination/vaccination

Vaccine Excipient Summary

Excipients Included in U.S. Vaccines, by Vaccine

In addition to weakened or killed disease antigens (viruses or bacteria), vaccines contain very small amounts of other ingredients – excipients.

Some excipients are added to a vaccine for a specific purpose. These include:
Preservatives, to prevent contamination. For example, thimerosal.
Adjuvants, to help stimulate a stronger immune response. For example, aluminum salts.
Stabilizers, to keep the vaccine potent during transportation and storage. For example, sugars or gelatin.

Others are residual trace amounts of materials that were used during the manufacturing process and removed. These can include:
Cell culture materials, used to grow the vaccine antigens. For example, egg protein, various culture media.
Inactivating ingredients, used to kill viruses or inactivate toxins. For example, formaldehyde.
Antibiotics, used to prevent contamination by bacteria. For example, neomycin.

The following table lists substances, other than active ingredients (i.e., antigens), shown in the manufacturers' package insert (PI) as being contained in the final formulation of each vaccine. **Note: Substances used in the manufacture of a vaccine but not listed as contained in the final product (e.g., culture media) can be found in each PI, but are not shown on this table.** Each PI, which can be found on the FDA's website (see below) contains a description of that vaccine's manufacturing process, including the amount and purpose of each substance. In most PIs, this information is found in Section 11: "Description."

All information was extracted from manufacturers' package inserts.
If in doubt about whether a PI has been updated since this table was prepared, check the FDA's website at:
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

Vaccine	Contains
Adenovirus	monosodium glutamate, sucrose, D-mannose, D-fructose, dextrose, human serum albumin, potassium phosphate, plasdone C, anhydrous lactose, microcrystalline cellulose, polacrilin potassium, magnesium stearate, cellulose acetate phthalate, alcohol, acetone, castor oil, FD&C Yellow #6 aluminum lake dye
Anthrax (Biothrax)	aluminum hydroxide, sodium chloride, benzethonium chloride, formaldehyde
BCG (Tice)	glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, iron ammonium citrate, lactose
Cholera (Vaxchora)	ascorbic acid, hydrolyzed casein, sodium chloride, sucrose, dried lactose, sodium bicarbonate, sodium carbonate
DT (Sanofi)	aluminum phosphate, isotonic sodium chloride, formaldehyde
DTaP (Daptacel)	aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol
DTaP (Infanrix)	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80)
DTaP-IPV (Kinrix)	Formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B
DTaP-IPV (Quadracel)	formaldehyde, aluminum phosphate, 2-phenoxyethanol, polysorbate 80, glutaraldehyde, neomycin, polymyxin B sulfate, bovine serum albumin
DTaP-HepB-IPV (Pediarix)	formaldehyde, aluminum hydroxide, aluminum phosphate, sodium chloride, polysorbate 80 (Tween 80), neomycin sulfate, polymyxin B, yeast protein
DTaP-IPV/Hib (Pentacel)	aluminum phosphate, polysorbate 80, sucrose, formaldehyde, glutaraldehyde, bovine serum albumin, 2-phenoxyethanol, neomycin, polymyxin B sulfate
Hib (ActHIB)	sodium chloride, formaldehyde, sucrose
Hib (Hiberix)	formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB)	amorphous aluminum hydroxyphosphate sulfate, sodium chloride
Hep A (Havrix)	MRC-5 cellular proteins, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic
Hep A (Vaqta)	amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride, other process chemical residuals
Hep B (Engerix-B)	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
Hep B (Recombivax)	formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein

Vaccine	Contains
Hep B (Heplisav-B)	yeast protein, yeast DNA, deoxycholate, phosphorothioate linked oligodeoxynucleotide, sodium phosphate, dibasic dodecahydrate, sodium chloride, monobasic dehydrate, polysorbate 80
Hep A/Hep B (Twinrix)	MRC-5 human diploid cells, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein, water
Human Papillomavirus (HPV) (Gardasil 9)	amorphous aluminum hydroxyphosphate sulfate, sodium chloride, L-histidine, polysorbate 80, sodium borate, yeast protein
Influenza (Afluria) Trivalent & Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multi-dose vials)
Influenza (Fluad)	squalene, polysorbate 80, sorbitan trioleate, sodium citrate dehydrate, citric acid monohydrate, neomycin, kanamycin, barium, hydrocortisone, egg proteins, cetyltrimethylammonium bromide (CTAB), formaldehyde
Influenza (Fluarix) Quadrivalent	octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Influenza (Flublok) Quadrivalent	sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and *Spodoptera frugiperda* cell proteins, baculovirus and cellular DNA, Triton X-100
Influenza (Flucelvax) Quadrivalent	Madin Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethlyammonium bromide, and β-propiolactone, Thimerosal (multi-dose vials)
Influenza (Flulaval) Quadrivalent	ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials), phosphate-buffered saline solution
Influenza (Fluzone) Quadrivalent	formaldehyde, egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials)
Influenza (Fluzone) High Dose	egg protein, octylphenol ethoxylate (Triton X-100), sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde
Influenza (FluMist) Quadrivalent	monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA)
Japanese Encephalitis (Ixiaro)	aluminum hydroxide, protamine sulfate, formaldehyde, bovine serum albumin, Vero cell DNA, sodium metabisulphite, Vero cell protein
Meningococcal (MenACWY-Menactra)	sodium phosphate-buffered isotonic sodium chloride solution, formaldehyde, diphtheria toxoid
Meningococcal (MenACWY-Menveo)	formaldehyde, CRM_{197} protein
Meningococcal (MenB – Bexsero)	aluminum hydroxide, sodium chloride, histidine, sucrose, kanamycin
Meningococcal (MenB – Trumenba)	polysorbate 80, aluminum phosphate, histidine buffered saline
MMR (MMR-II)	vitamins, amino acids, fetal bovine serum, sucrose, glutamate, recombinant human albumin, neomycin, sorbitol, hydrolyzed gelatin, sodium phosphate, sodium chloride
MMRV (ProQuad) (Frozen: Recombinant Albumin)	MRC-5 cells including DNA and protein, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, recombinant human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride; potassium phosphate dibasic, neomycin, bovine calf serum
MMRV (ProQuad) (Frozen: Human Serum Albumin)	MRC-5 cells including DNA and protein, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride; potassium phosphate dibasic, neomycin, bovine calf serum
MMRV (ProQuad) (Refrigerator Stable)	MRC-5 cells including DNA and protein, sucrose, hydrolyzed gelatin, urea, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate, recombinant human albumin, sodium bicarbonate, potassium phosphate, potassium chloride, neomycin, bovine serum albumin

Vaccine	Contains
Pneumococcal (PCV13 – Prevnar 13)	CRM_{197} carrier protein, polysorbate 80, succinate buffer, aluminum phosphate
Pneumococcal (PPSV-23 – Pneumovax)	phenol
Polio (IPV – Ipol)	calf bovine serum albumin, 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B, M-199 medium
Rabies (Imovax)	human albumin, neomycin sulfate, phenol red, beta-propriolactone
Rabies (RabAvert)	chicken protein, polygeline (processed bovine gelatin), human serum albumin, potassium glutamate, sodium EDTA, ovalbumin, neomycin, chlortetracycline, amphotericin B
Rotavirus (RotaTeq)	sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum *[DNA from porcine circoviruses (PCV) 1 and 2 has been detected in RotaTeq. PCV-1 and PCV-2 are not known to cause disease in humans.]*
Rotavirus (Rotarix)	Dextran, Dulbecco's Modified Eagle Medium (sodium chloride, potassium chloride, magnesium sulfate, ferric (III) nitrate, sodium phosphate, sodium pyruvate, D-glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids, L-glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red), sorbitol, sucrose, calcium carbonate, sterile water, xanthan *[Porcine circovirus type 1 (PCV-1) is present in Rotarix. PCV-1 is not known to cause disease in humans.]*
Smallpox (Vaccinia) (ACAM2000)	HEPES, 2% human serum albumin, 0.5 - 0.7% sodium chloride USP, 5% Mannitol USP, neomycin, polymyxin B, 50% Glycerin USP, 0.25% phenol USP
Td (Tenivac)	aluminum phosphate, formaldehyde, ammonium sulfate, sodium chloride, water
Td (Mass Biologics)	aluminum phosphate, formaldehyde, thimerosal
Tdap (Adacel)	aluminum phosphate, formaldehyde, 2-phenoxyethanol, glutaraldehyde
Tdap (Boostrix)	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80
Typhoid (Typhim Vi)	formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, sodium chloride, sterile water
Typhoid (Vivotif Ty21a)	sucrose, ascorbic acid, amino acids, lactose, magnesium stearate. gelatin
Varicella (Varivax) *Frozen*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, sodium phosphate monobasic, potassium phosphate monobasic, potassium chloride, EDTA, neomycin, fetal bovine serum
Varicella (Varivax) *Refrigerator Stable*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, urea, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
Yellow Fever (YF-Vax)	sorbitol, gelatin, sodium chloride, egg protein
Zoster (Shingles) (Zostavax) *Frozen*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed porcine gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride; neomycin, bovine calf serum
Zoster (Shingles) (Zostavax) *Refrigerator Stable*	MRC-5 human diploid cells, including DNA & protein, sucrose, hydrolyzed porcine gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, neomycin, bovine calf serum
Zoster (Shingles) (Shingrix)	sucrose, sodium chloride, dioleoyl phosphatidylcholine (DOPC), 3-*O*-desacl-4'monophosphoryl lipid A (MPL), QS-21 (a saponin purified from plant extract *Quillaja saponaria* Molina), potassium dihydrogen phosphate, cholesterol, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, dipotassium phosphate, polysorbate 80, host cell protein and DNA

A table listing vaccine excipients and media *by excipient* is published by the Institute for Vaccine Safety at Johns Hopkins University, and can be found at http://www.vaccinesafety.edu/components-Excipients.htm.

January 2019

My name is Jennifer Nordin and I am here because I oppose rules 1, 2, 4, and 5 of CR 19-079.

I would like to address my opposition to Rule 1- change in the 'substantial outbreak' classification to include chickenpox.

Chickenpox, also known as varicella, is a mild childhood illness. Most parents can identify and treat chickenpox from their homes meaning very little exposure to the public. Chickenpox very rarely requires medical intervention and thus does not warrant the classification of "substantial outbreak".

Furthermore this change would punish unvaccinated children by excluding them from school even though data collected by the DHS has shown failure of the vaccine to provide protection. I'd like to add that numerous peer review studies conclude the live virus chickenpox vaccine can cause vaccine strain chicken pox and potentially infect others via shedding.

How is it logical to keep a child home that is not ill yet a child who has received the chickenpox vaccine and could potentially shed the virus infecting others is allowed to attend without restrictions?

This rule change would impact many families in WI and many of them here today. I urge you to be open to the comments, concerns and education that you receive from the mothers, fathers and concerned WI residents. I do not feel our wants and needs were considered when these rules changes were drafted. You cannot do right by a child when their only advocate is excluded from the decision making process.

Thank you,

Jennifer Nordin

Wisconsin United for Freedom
P.O. Box 894
Cedarburg, WI 53012
info@wisconsinunitedforfreedom.org

March 3, 2020

Mr. Chairman and Committee, I thank you for the opportunity to testify today.

My name is Erin Runk. I am here to state my opposition to CR 19-079 rules 1, 2, 4, and 5, sharing the same concerns and sediment as you have heard this morning and will continue to hear this afternoon. I implore you to listen to the voices of the citizens of our state.

I sit before you as a co-founder of a rapidly growing 501c4 nonprofit organization, Wisconsin United for Freedom. A community of over 2500 moms, dads, grandparents – citizens of our great state. A community that shares the same goal of protecting our fundamental rights.

I am not here today to speak directly to the specific rule changes. I am here to discuss a bigger picture concerning government transparency.

On July 26th, 2017, a statement of scope for rule changes to DHS 144 was approved by our Governor. Within the text of this scope, section 6 lists those entities that will be affected. Contained in that affected list, are the children and parents of Wisconsin. This information is critical because in the process of changing the rules before you, the stakeholders – the parents were not included in the advisory. Moms and dads did not have a seat at the table and government policy was changed behind closed doors.

So, I must ask, what makes good government? Is it acceptable to exclude stakeholders in changes that directly impact them? Is it acceptable to exclude stakeholders that might not share an exact view, but may be able to offer substantial input to changes being proposed?

As documented on the bottom of page 2 of the Rule Making Report to Legislature, F-02113, '*The department* [DHS] *began accepting public comments on the proposed rule …on July 15, 2019. …Public comments on the proposed rule were accepted until July 26, 2019.*'

July 15 to July 26. That is 12 days.

What this means is that moms and dads, the directly affected stakeholders were given 12 days to have a seat at the table.

In those 12 day, moms and dads voiced their concerns. DHS states on page 5, *"Overall, 460 individuals or entities provided comments"* and they go on to say, *"Many comments had more than one issue or concern…"*

When you hear that and pair it with those concerns being expressed in a short, 12-day window – it is alarming to know that DHS did not make a single change to their proposed rule changes even when they agreed with the lack of content within their changes.

As part of the rule making process, DHS was required to hold a public hearing. They did so on July 26th, 2019, with little notice to the public. Parents, the primary stakeholders, drove up to 4 and 5 hours from across the state to ensure their voices would be heard. DHS wasted 20 minutes of the strict 1 hour hearing time on the technical difficulties that they experienced, thus restricting the public comment to a mere 40 minutes. Of those afforded the opportunity to speak (myself included), nearly all in opposition, were treated disrespectfully. I stood in shock as microphones were aggressively removed from speakers' hands at exactly 2 minutes. DHS denied parents, the primary stakeholder, the right to be heard. After public comment and over 460 submissions, DHS failed to address concerns from the hundreds of dissenting voices, and again, not a single change was made to the proposed rule changes. WUFF contacted DHS following the public hearing to request either a new hearing or private meetings with concerned parents. DHS declined, stating they followed the statute.

It is clear that DHS is only interested in meeting the minimum requirements of the rule making process, and they are not interested in addressing the concerns of parents across Wisconsin.

We have agencies in place, and I fully respect the work that they do – but when the outcry is overwhelming in opposition to some (not all) of the points - when moms and dads are not offered a seat at the table, when the agency has complete disregard to any and ALL concerns, the question is, was the scope of the agency actually fulfilled? Even if the boxes were checked, is this good government? Is this government transparency? Many of you, being stakeholders yourself, is this what we as citizens should expect of an agency? Is government best executed behind closed doors?

Chairman, I genuinely thank you for holding this hearing – I appreciate you allowing the citizens, the stakeholders, to be heard.

Erin Runk
erin.runk@wisconsinunitedforfreedom.org

STATEMENT OF SCOPE

DEPARTMENT OF HEALTH SERVICES

Rule: DHS 144

Relating to: Immunization of Students

Type of Statement of Scope: Original

1. Finding/nature of emergency (Emergency Rule only):
Not Applicable.

2. Detailed description of the objective of the proposed rule:
The department proposes to update ch. DHS 144 to ensure consistency with definitions from the Centers for Disease Control and Prevention (CDC) and to update statewide immunization program requirements to reduce the incidence of vaccine-preventable disease and outbreaks.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:
The department is required to carry out a statewide immunization program to eliminate mumps, measles, rubella (German measles), diphtheria, pertussis (whooping cough), poliomyelitis and other diseases that the department specifies by rule, and to protect against tetanus. Minimum immunization requirements for entry into Wisconsin schools and day care centers are established in ch. DHS 144. The department proposes to make the following revisions to the rule chapter:

1. Varicella (chicken pox) and meningococcal disease are identified by the department as vaccine-preventable diseases. However, a substantial outbreak of these diseases is not currently defined in ch. DHS 144. The department proposes to amend the definition of a "substantial outbreak" to include Varicella (chicken pox) and meningococcal disease, and to ensure consistency with CDC recommendations.

2. In recent years, mumps outbreaks have occurred in highly-vaccinated populations and in high-transmission settings, including elementary, middle, and high schools, colleges, and camps. A substantial outbreak of mumps is currently defined as an incidence of the disease exceeding 2% of the unvaccinated population. In 2012, the CDC revised the *Manual for the Surveillance of Vaccine-Preventable Diseases*, to define a substantial outbreak of mumps as three or more cases linked by time and place. The department proposes to amend the definition of a "substantial outbreak" of mumps to be consistent with the CDC *Manual for the Surveillance of Vaccine-Preventable Diseases*.

3. The department is proposing to move the current recommendation for Tdap from 6th grade to 7th grade to ensure that children are old enough to meet this age minimum (some children are 10 years old when starting 6th grade). This will reduce the number of children who enter 6th grade and are not vaccinated with Tdap, as some clinicians choose to wait until they are 11 years of age to vaccinate.

4. *Neisseria meningitidis* is a vaccine-preventable disease and a leading cause of bacterial meningitis and sepsis in the United States. The meningococcal vaccine is recommended by the Wisconsin Chapter of the American Academy of Pediatrics and the Wisconsin Academy of Family Physicians to reduce the incidence of bacterial meningitis and sepsis. Since 2005, the CDC Advisory Committee on Immunization Practices has recommended that the vaccine be administered at the 11-12 year old health care visit, along with other routine vaccinations such as Tdap. The department proposes to add the meningococcal vaccine to the list of vaccines required for students entering the 7th grade. This provision will ease the burden on

families, providers, and schools by ensuring that both meningococcal and Tdap vaccines are administered at the same visit and the same grade level.

5. Under the current rule, a parent or adult student may report a history of varicella disease as an acceptable exception to varicella vaccination. Recent studies have demonstrated that there is a high incidence of unvaccinated children who report a positive history of varicella that are not immune. The department proposes to allow the exception only when a history of varicella disease has been reported by a health care provider.

6. Chapter DHS 144 currently includes provisions relating to the 2008-2009 phase-in of Tdap and Varicella Vaccine coverage. The department proposes to eliminate these provisions because phase-ins are completed.

7. Curently, schools must only report compliance with program requirements and key indicators of vaccine-preventable disease and outbreaks to local health departments. The department proposes to add the state as a recipient of these reports which would be congruent with the current day care reporting requirements. This will improve the availability and of important information and improve the department's reporting to the legislature, under s. 252.04 (11), Stats..

8. Chapter DHS 144 has not been substantially revised since 1981. The department proposes to update, correct, or clarify any outdated provisions in order to reflect current definitions, standards, and best practices.

There are no reasonable alternative to the proposed rulemaking. The department is required by s. 252.04 (1), Stats., to maintain a statewide immunization program.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):
DHS Chapter 144 is promulgated under the authority of ss. 252.04 (1) and (10), and 227.11 (2) (a), Stats..

Section 252.04 (1), Stats., reads: The department shall carry out a statewide immunization program to eliminate mumps, measles, rubella (German measles), diphtheria, pertussis (whooping cough), poliomyelitis and other diseases that the department specifies by rule, and to protect against tetanus. Any person who immunizes an individual under this section shall maintain records identifying the manufacturer and lot number of the vaccine used, the date of immunization and the name and title of the person who immunized the individual. These records shall be available to the individual or, if the individual is a minor, to his or her parent, guardian or legal custodian upon request.

Section 252.04 (10), Stats., reads: The department shall, by rule, prescribe the mechanisms for implementing and monitoring compliance with this section. The department shall prescribe, by rule, the form that any person immunizing a student shall provide to the student under sub. (1).

Section 227.11 (2) (a), Stats., reads: Rule-making authority is expressly conferred on an agency as follows:
(a) Each agency may promulgate rules interpreting the provisions of any statute enforced or administered by the agency, if the agency considers it necessary to effectuate the purpose of the statute, but a rule is not valid if the rule exceeds the bounds of correct interpretation. All of the following apply to the promulgation of a rule interpreting the provisions of a statute enforced or administered by an agency:

1. A statutory or nonstatutory provision containing a statement or declaration of legislative intent, purpose, findings, or policy does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.

2. A statutory provision describing the agency's general powers or duties does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.

3. A statutory provision containing a specific standard, requirement, or threshold does not confer on the agency the authority to promulgate, enforce, or administer a rule that contains a standard, requirement, or threshold that is more restrictive than the standard, requirement, or threshold contained in the statutory provision.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:
The department estimates that it will take approximately 1,040 hours to develop the proposed rule changes. This includes the time required for research and analysis, coordinating an advisory committee, rule drafting, preparing any related documents, holding a public hearing and communicating with affect persons and groups.

6. List with description of all entities that may be affected by the proposed rule:
Schools, school-aged children and parents, school boards, and public and private health care providers.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:
There are no existing or proposed federal regulations that address the activities to be regulated by the rules.

8. Anticipated economic impact of implementing the rule:
The proposed rule is anticipated to have little to no economic impact if promulgated.

Contact Person:
Stephanie Schauer
(608) 264-9884
Stephanie.Schauer@dhs.wisconsin.gov

RULEMAKING REPORT TO LEGISLATURE

CLEARINGHOUSE RULE 19-079

Ch. DHS 144

Basis and Purpose of Proposed Rule

The department is required to carry out a statewide immunization program to eliminate mumps, measles, rubella (German measles), diphtheria, pertussis (whooping cough), poliomyelitis and other diseases that the department specifies by rule, and to protect against tetanus. Minimum immunization requirements for entry into Wisconsin schools and child care centers are established in ch. DHS 144. The department proposes to make the following revisions to the rule chapter:

1. Varicella (chicken pox) and meningococcal disease are identified by the department as vaccine-preventable diseases. However, a substantial outbreak of these diseases is not currently defined in ch. DHS 144. The department proposes to amend the definition of a "substantial outbreak" to include Varicella (chicken pox) and meningococcal disease, and to ensure consistency with CDC recommendations.

2. In recent years, mumps outbreaks have occurred in highly-vaccinated populations and in high-transmission settings, including elementary, middle, and high schools, colleges, and camps. A substantial outbreak of mumps is currently defined as an incidence of the disease exceeding 2% of the unvaccinated population. In 2012, the CDC revised the Manual for the Surveillance of Vaccine-Preventable Diseases, to define a substantial outbreak of mumps as three or more cases linked by time and place. The department proposes to amend the definition of a "substantial outbreak" of mumps to be consistent with the CDC Manual for the Surveillance of Vaccine-Preventable Diseases.

3. The department is proposing to move the current recommendation for Tdap from 6th grade to 7th grade to ensure that children are old enough to meet this age minimum (some children are 10 years old when starting 6th grade). This will reduce the number of children who enter 6th grade and are not vaccinated for Tdap, as some clinicians choose to wait until they are 11 years of age to vaccinate.

4. Neisseria meningitidis is a vaccine-preventable disease and a leading cause of bacterial meningitis and sepsis in the United States. The meningococcal vaccine is recommended by the Wisconsin Chapter of the American Academy of Pediatrics and the Wisconsin Academy of Family Physicians to reduce the incidence of bacterial meningitis and sepsis. Since 2005, the CDC Advisory Committee on Immunization Practices has recommended that the vaccine be administered at the 11-12 year old health care visit, along with other routine vaccinations such as Tdap. The department proposes to add the meningococcal vaccine to the list of vaccines required for students entering the 7th grade. This provision will ease the burden on families, providers, and schools by ensuring that both meningococcal and Tdap vaccines are receivedat the same visit and the same grade level. The department also proposes a booster dose for students entering 12th grade which is in accordance with ACIP recommendations. This will help to ensure students are fully vaccinated prior to leaving school.

5. Under the current rule, a parent or adult student may report a history of varicella disease as an acceptable exception to varicella vaccination. Recent studies have demonstrated that there is a high incidence of unvaccinated children who report a positive history of varicella that are not immune. The department proposes to allow the exception only when a history of varicella disease has been reported by a health care provider.

6. Chapter DHS 144 currently includes provisions relating to the 2008-2009 phase-in of Tdap and Varicella Vaccine coverage. The department proposes to eliminate these provisions because phase-ins are completed.

7. Curently, schools must only report compliance with program requirements and key indicators of vaccine-preventable disease and outbreaks to local health departments. The department proposes to add the state as a recipient of these reports which would be congruent with the current day care reporting requirements. This will improve the availability of important information and improve the department's reporting to the legislature, under s. 252.04 (11), Stats..

8. Chapter DHS 144 has not been substantially revised since 1981. The department proposes to update, correct, or clarify any outdated provisions in order to reflect current definitions, standards, and best practices.

Department Response to Legislative Council Rules Clearinghouse Recommendations

All recommendations were accepted.

Final Regulatory Flexibility Analysis

The issues raised by each small business during the public hearing(s).

N/A

Any changes in the rule as a result of an alternative suggested by a small business and the reasons for rejecting any of those alternatives.

N/A

The nature of any reports and estimated cost of their preparation by small businesses that must comply with the rule.

N/A

The nature and estimated costs of other measures and investments that will be required by small businesses in complying with the rule.

N/A

The reason for including or not including in the proposed rule any of the following methods for reducing the rule's impact on small businesses, including additional cost, if any, to the department for administering or enforcing a rule which includes methods for reducing the rule's impact on small businesses and the impact on public health, safety and welfare, if any, caused by including methods in rules

N/A

Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis

Analysis

N/A

Fiscal Estimate/Economic Impact Analysis

N/A

Public Hearing Summary

The department began accepting public comments on the proposed rule via the Wisconsin Legislature Administrative Rules website, and through the Department's Administrative Rules Website on July 15, 2019. A public hearing was held on July 26, 2019, in Madison, Wisconsin. Public comments on the proposed rule were accepted until July 26, 2019.

List of the persons who appeared or registered for or against the Proposed Rule at the Public Hearing.

Registrant	Position Taken (Support or Opposed)
Kevin Tuttle- Sun Prairie, WI	Opposed
Kari Pagel- Oconto, WI	Opposed
Donna Knutter	Supported
Erika Shaff-Bow	Opposed
Sarah Hardison	Opposed
Marty Young	Supported
Tara	Opposed
Jamie Bernander	Opposed
Denise Brusveen	Opposed
HJ Waukan with the WI Medical Society	Supported
Ann Lewandowski	Supported
Sarah Biskobing	Opposed
Justin Ziacore	Opposed
Andrea Wahhab	Opposed
Alesha Cowen	Opposed
Amber Psket	Opposed
Steve Puckette	Opposed
Judith Jolly- Pardiville, WI 53954	Opposed
Amy Heffernan	Opposed
Nathan Jackson	Opposed
Erin Runk	Opposed
Wade Anunson	Opposed
Dilson Bucl	Opposed
Lona Cook	Neither
Robin Baker	Neither
Lisa J. Barnett	Opposed
Shelby Lemke	Neither
Sarah Hillman	Neither
Arlis Fadt	Neither
Carl Landsness	Neither
Malanie Strauch	Opposed
Janel Retzlaft- Combined Locks, WI	Neither
Ruth Mueller	Supported
Colleen Marie Morhen	Neither

Elizabeth McLean	Opposed
Louise Wilson	Neither
Kelsey Anderson- University Health Services	Neither
Rebecca Lenz- University Health Service	Neither
Melanie Fritz	Opposed
Sarah Hughes	Supported
Steven Conway	Opposed
Amanda Haines	Opposed
Derek Ellerman- Office of State Rep. Shae Sortwell	Opposed

Summary of Public Comments to the Proposed Rule and the Agency's response to those comments, and an explanation of any modification made in the proposed rule as a result of public comments or testimony received at the Public Hearing.

Rule Provision	Public Comment	Department Response
	Overall, 460 individuals or entities provided comments. Many comments had more than one issue or concern, and for the purposes of the Department response, each concern was counted in the appropriate category below. Therefore, the number of comments do not add up to the total number of individuals /entities who provided a comment.	
144.01 (1)	DHS received 12 comments stating the proposed changes would benefit/protect the health and well-being of all our school-age children. These changes are essential for prevention. Generally speaking, these changes are good.	This is in alignment with the proposed rule changes.
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 11 comments stating that adding Meningococcal vaccines to the list of school requirements will help reduce/eliminate meningitis and its symptoms such as: hearing loss, amputations, kidney damage, and memory loss and death.	This is in alignment with the proposed rule change.
144.03 (20) (b) 144.03-A	DHS received 8 comments stating that moving Tdap requirements to the 7th grade will help families of children who don't become 11 until 5th or 6th grade. Also, this change will reduce confusion and conflict between families, schools, and providers on when to administer Tdap.	Because some students entering 6th grade are not yet age 11, some schools and students have had difficulty meeting this requirement and have had to be vaccinated at age 10 or sign a waiver. This results in additional work for the school, student, and parents. To ensure that children are 11 years old to meet this age minimum, we are proposing changing the requirement to 7th grade. This will ease the burden on the schools, students and parents and will be consistent with the Meningococcal vaccination requirement at grade 7.
144.03	DHS received 1 comment stating that currently, families receive non-compliance letters from schools when the provider won't vaccinate based on the CDC recommendations. Updating the polio rule in accordance with CDC recommendations will reduce frustration and confusion among families.	The proposed changes align with current CDC recommendations and should reduce the confusion about the requirement.
144.02 (21) (h) 144.03 (20) (g)	DHS received 2 comments stating that client's varicella histories being recorded by a medical provider will help with medical record accuracy and consistency	This is in alignment with our proposed change as well as with ACIP recommendations for evidence of immunity to varicella.

144.04 144.05	DHS received 6 comments stating that immunizations should be mandatory except for medical exemptions. Doing so protects the public and immunocompromised individuals. Other exemptions are not supported by science and should not be allowed.	The proposed changes do not include changes to the types of waivers currently allowed.
general	DHS received 2 comments stating that school immunization requirements are known to improve immunization rates.	Per CDC, state and local vaccination requirements for daycare and school entry are important tools for maintaining high vaccination coverage rates, and in turn, lower rates of vaccine-preventable diseases (VPDs).
general	DHS received 5 comments expressing appreciation of updates to the rule's language and definitions. These changes better reflect current public health practices and national guidelines. One respondent recommended DHS review and modernize these rules every 5 years, at least.	Even with the proposed changes, Wisconsin's school requirements are less than the vaccination requirements by ACIP, for example, HPV vaccine. The proposed changes will improve alignments with ACIP recommendations.
general	DHS received 4 comments stating the proposed rule changes would help attenuate the reemergence of vaccine preventable diseases. Sources of vaccine misinformation have reduced vaccination rates, contributing to a reduction in herd immunity and a rise in vaccine preventable diseases.	CDC states there is evidence to suggest that vaccine requirements have broad reach and they may help promote higher rates of vaccination coverage.
general	DHS received 4 comments stating meningococcal vaccination is recommended because of the severity of meningitis, not the rate of meningitis.	According to the CDC, "meningococcal disease can be devastating and often—and unexpectedly—strikes otherwise healthy people. Although meningococcal disease is uncommon, teens and young adults 16 through 23 years old are at increased risk. Meningococcal bacteria can cause severe, even deadly, infections like Meningitis (an infection of the lining of the brain and spinal cord), Bacteremia, or septicemia (bloodstream infections). About 1 in 5 people who survive their meningococcal infection have permanent disabilities. Reference Meningococcal Vaccination for Preteens and Teens: Information for Parents | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/vpd/mening/public/adolescent-vaccine.html
general	DHS received 1 comment stating these rule changes are appreciated because they will help prevent against expensive vaccine preventable diseases. Taxpayers do not want to pay for the healthcare costs associated with these diseases.	The *Journal of Market Access & Health Policy* published seven articles discussing how vaccines are economically beneficial. These articles show the overall benefits of vaccination on economic growth, sustainability, and efficiency of healthcare systems.

		Reference Pasteur, S. (2015). The Economic Value of Vaccination: Why Prevention is Wealth. *Journal of Market Access & Health Policy, 3*(0). doi: 10.3402/jmahp.v3.29414
general	DHS received 1 comment stating politicians should support these rule changes because if a Wisconsin resident dies from a vaccine preventable disease, it will look bad for politicians who did not pass these rule changes.	The Department acknowledges this comment.
144.02 (2)	DHS received 1 comment stating that changing the word daycare to childcare is appreciated.	Early childhood professionals agree the term childcare is important, as not all parents work during the day and the term childcare is more inclusive than daycare. Childcare as a term better reflects the values and mission of the field, as supported by the National Association for the Education of Young Children. Reference Childcare vs. Daycare: What's the Difference? (And Why It Matters). (n.d.). Retrieved from https://www.rasmussen.edu/degrees/education/blog/childcare-vs-daycare/
general	DHS received 1 comment expressing support for surveillance of diseases for epidemiological purposes.	This is in alignment with the Division of Public Health, Bureau of Communicable Diseases responsibilities.
N/A	DHS received 1 comment stating vaccine requirements cannot prohibit accessing public education because education is a public right that is critical to health. If access to education is contingent on vaccinations, vaccines must be affordable and accessible.	The rule outlines the requirements for compliance with the school entry laws. As long as a child is compliant, they may attend school. Compliance entails one of the following: 1- being fully immunized, 2- has received the first dose of each series and is in the process of receiving subsequent doses or 3-has a valid waiver on file. The Affordable Care Act requires new health plans to cover preventative services, such as routinely recommended vaccines, and eliminates cost sharing (such as co-pays and deductibles). Therefore children with private insurance should have access to vaccines without significant cost barriers. For children who do not have health insurance, or are part of a select number of older and more limited plans not covered by the ACA, other mechanisms are in place to ensure access. For example, the Vaccines For Children (VFC) program. VFC is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay.

		The State of Wisconsin's VFC program has approximately 730 health care providers, including local health departments and tribal clinics that are registered in the program throughout the state.
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 202 comments stating the meningococcal vaccination requirement update is unwarranted because there is no urgent public health crisis (i.e., meningitis is rare and/or not very contagious).	The proposed rule aligns with national recommendations. CDC's Advisory Committee on Immunization (ACIP) recommends meningococcal vaccination for all preteens and teens in the prevention of meningococcal disease. The first dose is recommended at 11-12 years of age and the booster at age 16 years. *Neisseria meningitidis* is a vaccine-preventable disease and a leading cause of bacterial meningitis and sepsis in the United States. The disease strikes quickly and can have serious complications, including death. Among survivors, as many as one in five will have permanent disabilities. Complications include hearing loss, brain damage, kidney damage, and limb amputations. Since 2005, the CDC Advisory Committee on Immunization Practices has recommended that the vaccine be routinely administered to all preteens at the 11-12 year old health care visit, along with other routine vaccinations such as Tdap. The meningococcal vaccine is also recommended by the American Academy of Pediatrics and American Academy of Family Physicians to reduce the incidence of bacterial meningitis. Rates of meningococcal disease have been declining in the United States since the late 1990s. In 2017, there were about 350 total cases of meningococcal disease reported. Anyone can get meningococcal disease, but rates of disease are highest in children younger than 1 year old, followed by a second peak in adolescence. Among adolescents and young adults, those 16 through 23 years old have the highest rates of meningococcal disease. Meningococcal disease spreads from person-to-person by coughing or coming into close or lengthy contact with someone who carries the bacteria. Up to one in 10 people carry meningococcal bacteria in their nose or throat without getting sick. Per AAP's Red Book, meningococcal disease remains as an important cause of septicemia in children 11 through 17 years of age. Household contacts of cases have 500 to 800 times the rate of disease for the general population. Per CDC data, Serogroups C, Y, or W, which are covered by meningococcal conjugate

		vaccines, included in the proposed changes, caused approximately two in three cases of meningococcal disease among persons 11 years old or older from 2007 to 2017. However, in 2017, serogroups C, Y, or W caused approximately 1 in 2 cases of meningococcal disease among persons 11 years old or older in the United States. Despite declines in the incidence of meningococcal disease in the United States, outbreaks continue to occur. An article published in Clinical Infectious Diseases in June 2018 found that outbreak-associated cases account for approximately 5% of all meningococcal disease cases in the United States and serogroup C is the primary cause of community-based outbreaks. References Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). (2013). *Prevention and Control of Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP).*, 1–22. Mbaeyi, S. A., Blain, A., Whaley, M. J., Wang, X., Cohn, A. C., & Macneil, J. R. (2018). Epidemiology of Meningococcal Disease Outbreaks in the United States, 2009–2013. *Clinical Infectious Diseases, 68*(4), 580–585. doi: 10.1093/cid/ciy548 Kimberlin D.W., Brady M.T., Jackson M. A., Long S. SI, eds. *Red Book:2018 Report of the Committee on Infectious Diseases.* 31st ed. Itasca, IL: American Academy of Pediatrics, 2018: Meningococcal 550-561.
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 183 comments stating the meningococcal vaccination requirement update is unwarranted because meningococcal vaccine is dangerous (e.g., contains neurotoxins; causes side effects, adverse events, and deaths). Meningococcal vaccine taken in combination with other vaccines is unsafe.	Evidence shows that meningococcal vaccines are safe and as with any vaccine, side effects can occur. The most common side effects include redness and swelling at the injection site. There have been no documented deaths that have a direct correlation after meningococcal vaccination. The FDA has licensed two meningococcal vaccines for use in the United States, MenACWY-D (Menactra, Sanofi Pasteur), and MenACWY-CRM (Menveo, Novartis Vaccines). CDC's Pink Book lists the ingredients for every vaccine. Aside from the antigens, ingredient components of a vaccine include adjuvants, added to enhance the immune system

		response; antibiotics, to prevent contamination during the manufacturing process; and preservatives and stabilizers. Per the FDA, prior to approval, vaccines undergo a rigorous and extensive development program in the laboratory, as well as in animal studies and human clinical trials to determine their safety and effectiveness. Highly trained FDA scientists and clinicians carefully evaluate all of the information in a marketing application and make a determination whether to license (approve) a vaccine before it can be used in the United States. Prior to licensure, as part of FDA's evaluation, FDA takes all of the ingredients of a vaccine into account, including the active ingredients as well as other substances. The benefit-risk profile of each vaccine is assessed constantly during the entire duration of its use. After licensure, adverse events are submitted to the Vaccine Adverse Events Reporting System (VAERS) by parents, healthcare providers, and regulatory authorities. VAERS is maintained jointly by CDC and FDA. Per an article in *Seminars in Pediatric Infectious Diseases*, allegations that administration of multiple vaccines can impair the immune system have been found not to be supported by scientific evidence. Per the Immunization Action Coalition, CDC experts state, "All vaccines can be administered at the same visit. There is no upper limit for the number of vaccines that can be administered during one visit. ACIP and AAP consistently recommend that all needed vaccines be administered during an office visit. Vaccination should not be deferred because multiple vaccines are needed." References Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C. Public Health Foundation, 2015. Kimberlin D.W., Brady M.T., Jackson M. A., Long S. SI, eds. *Red Book:2018 Report of the Committee on Infectious Diseases*. 31st ed. Itasca, IL: American Academy of Pediatrics, 2018: Meningococcal 550-561. Halsey, N. A. (2002). The science of evaluation of adverse events associated with vaccination.

		Seminars in Pediatric Infectious Diseases, *13*(3), 205–214. doi: 10.1053/spid.2002.125864 Ask the Experts. (n.d.). Retrieved from https://www.immunize.org/askexperts/administering-vaccines.asp
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 24 comments stating the meningococcal vaccination requirement update is unwarranted because meningococcal vaccine is expensive.	Under the Affordable Care Act (ACA), all commercial payers programs are to provide coverage of ACIP-routinely recommended vaccines and this includes meningococcal vaccine. Additionally, children who are not insured are eligible to receive the vaccine free of charge through the Vaccines for Children program (see above for a complete description of the program). References Office of Adolescent Health. (2019, August 6). Where and How to Get Vaccines. Retrieved from https://www.hhs.gov/ash/oah/adolescent-development/physical-health-and-nutrition/vaccines/where-and-how-to-get-vaccines/index.html Sanchez, I. R. O., Meltzer, M. I., Shepard, C., Zell, E., Messonnier, M. L., Bilukha, O., Messonnier, N. E. (2008). Economics of an Adolescent Meningococcal Conjugate Vaccination Catch-up Campaign in the United States. *Clinical Infectious Diseases*, *46*(1), 1–13. doi: 10.1086/524041
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 40 comments stating the meningococcal vaccination requirement update is unwarranted because meningococcal vaccine is available to anyone who wants it.	Under Wisconsin Statute Chapter 252.04 (1), "**The department shall carry out a statewide** immunization program to eliminate mumps, measles, rubella (German measles), diphtheria, pertussis (whooping cough), poliomyelitis and other diseases that the department specifies by rule, **and to protect against tetanus.**" School requirements have been shown to be an effective way of increasing immunization rates, and thereby protection of individuals from vaccine-preventable diseases. Per CDC, state school requirements help to promote higher rates of vaccination which equates to lower rates of vaccine preventable disease. The percent of Wisconsin adolescents aged 13-18 years who have received one dose of meningococcal vaccine in 2018 was 72.03% and the percent of adolescents who were up-to-date was 46.02%. Wisconsin is below the Healthy People 2020 goal of 80.0% for adolescents who have received one dose of meningococcal vaccine.

		References State Vaccination Requirements | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html Immunization and Infectious Diseases. (n.d.). Retrieved from https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 146 comments stating the meningococcal vaccination requirement update is unwarranted because the meningococcal vaccine is ineffective.	Per CDC, since 2005 when the recommendation was made from ACIP for adolescents to receive a meningococcal vaccine, the incidence of meningococcal disease in adolescents has decreased by over 90%. Per an article in *Pediatrics*, meningococcal vaccines were 79% effective in the initial year postvaccination, 69% at 1 to less than 3 years, and 61% at 3 to less than 8 years. The overall effectiveness rate estimate for 0 to 8 years postvaccination was 69%. The vaccine effectiveness estimates data informed ACIP in its decision to add a booster dose at 16 years of age. References Meningococcal Vaccination | What You Should Know | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/vpd/mening/public/index.html#how-well-they-work Cohn, A. C., Macneil, J. R., Harrison, L. H., Lynfield, R., Reingold, A., Schaffner, W., ... Messonnier, N. E. (2017). Effectiveness and Duration of Protection of One Dose of a Meningococcal Conjugate Vaccine. *Pediatrics*, *139*(2). doi: 10.1542/peds.2016-2193
144.02 (21) (h) 144.03 (20) (g)	DHS received 32 comments stating the varicella vaccination requirement update is unwarranted because there is no provision for titer confirmation.	While not stated implicitly in the proposed Administrative Rule, a titer could be ordered by a health care provider and if positive, would provide evidence of immunity, allowing the health care provider to indicate on the form that the individual had a history of disease and was immune.
144.02 (21) (h) 144.03 (20) (g)	DHS received 74 comments stating clinicians should not be required to diagnose patients with suspected varicella infections because of the risk varicella-infected individuals would pose to others at a health care facility.	Per CDC, immunity against from varicella would include any of the following criteria: • Documentation of age-appropriate chickenpox vaccination • Laboratory evidence of immunity or laboratory confirmation of disease • Birth in the United States before 1980 • Diagnosis or verification of a history of varicella by a healthcare provider

		The administrative rule change proposal does not dictate that a student be seen by a health care provider while ill with varicella. The health care provider may verify the disease with a history of symptoms or laboratory confirmation.
144.02 (21) (h) 144.03 (20) (g)	DHS received 22 comments stating the varicella vaccination requirement update is unwarranted because it would force patients and their families into an unwanted relationship with unknown health care providers.	The proposed wording does not specify which health care providers a family must use. Families are free to choose their health care provider based on their own preferences, insurance coverage, etc.
144.02 (21) (h) 144.03 (20) (g)	DHS received 54 comments stating the varicella vaccination requirement and provider verification is unwarranted because it is expensive to the parents. Costs include co-pays, laboratory fees, time off work, & transportation.	The administrative rule change proposal does not dictate that a student be seen by a health care provider while ill with varicella. The health care provider may verify the disease with a history of symptoms. In the past, the predictive value of a self-reported positive disease victory for varicella was extremely high in adults in the pre-vaccine era for their children. As disease incidence decreases and the proportion of vaccinated persons with varicella having mild cases increases, varicella will be less readily recognized clinically. A recent study demonstrated that only 75% of unvaccinated children aged 12 months through 4 years who reported a positive history of varicella were in fact immune (confirmed by serological testing), compared with 89% of children aged 5 through 9 and 10 through 14 years. To limit the number of false-positive reports and ensure immunity, ACIP recommends that evidence of immunity should be either a diagnosis of varicella by a health care provider or a health care provider verification of a history of disease rather than parental or self-reporting. Another study published in *Pediatrics,* found that after the introduction of childhood varicella immunization there was a significant reduction in varicella-related hospitalizations and thus a corresponding reduction in hospital charges. *The Journal of Infectious* Diseases reported a substantial societal cost savings with a varicella vaccination program and reduction in morbidity, hospitalization, and mortality due to varicella. References Perella, D., Fiks, A. G., Jumaan, A., Robinson, D., Gargiullo, P., Pletcher, J., ... Spain, C. V. (2009). Validity of Reported Varicella History as a Marker for Varicella Zoster Virus Immunity Among Unvaccinated Children, Adolescents, and Young Adults in the Post-Vaccine Licensure Era. *Pediatrics*, *123*(5). doi: 10.1542/peds.2008-3310

		Davis, M. M. (2004). Decline in Varicella-Related Hospitalizations and Expenditures for Children and Adults After Introduction of Varicella Vaccine in the United States. *Pediatrics*, *114*(3), 786–792. doi: 10.1542/peds.2004-0012 Zhou, F., Ortega-Sanchez, I. R., Guris, D., Shefer, A., Lieu, T., & Seward, J. F. (2008). An Economic Analysis of the Universal Varicella Vaccination Program in the United States. *The Journal of Infectious Diseases*, *197*(s2). doi: 10.1086/522135

144.02 (21) (h)
144.03 (20) (g)
	DHS received 25 comments stating the varicella vaccination requirement update is unwarranted because it will create distrust between parents and school staff for reporting.	Per CDC, evidence of immunity to varicella includes any of the following:
		
		• Documentation of age-appropriate varicella vaccination
		  o Preschool-age children (i.e., age 12 months through 3 years): 1 dose
		  o School-age children, adolescents, and adults: 2 doses
		• Laboratory evidence of immunity or laboratory confirmation of disease*
		• Birth in the United States before 1980 (should not be considered evidence of immunity for healthcare personnel, pregnant women, and immunocompromised people)
		• Diagnosis or verification of a history of varicella or herpes zoster by a healthcare provider
		
		In the past, the predictive value of a self-reported positive disease victory for varicella was extremely high in adults in the pre-vaccine era for their children. As disease incidence decreases and the proportion of vaccinated persons with varicella having mild cases increases, varicella will be less readily recognized clinically.
		
		To limit the number of false-positive reports and ensure immunity, ACIP recommends that evidence of immunity should be either a diagnosis of varicella by a health care provider or a health care provider verification of a history of disease rather than parental or self-reporting.
		
		This will result in more accurate status of immunity for children within the school.
		
		References
		Chickenpox | For Healthcare Professionals | Varicella | CDC. (n.d.). Retrieved from

		https://www.cdc.gov/chickenpox/hcp/index.html#assessing-immunity Perella, D., Fiks, A. G., Jumaan, A., Robinson, D., Gargiullo, P., Pletcher, J., ... Spain, C. V. (2009). Validity of Reported Varicella History as a Marker for Varicella Zoster Virus Immunity Among Unvaccinated Children, Adolescents, and Young Adults in the Post-Vaccine Licensure Era. *Pediatrics*, *123*(5). doi: 10.1542/peds.2008-3310
General	DHS received 23 comments that broadly stated (i.e., generalized to all vaccines), the Department's claim that these rule changes will have "little to no economic impact" is wrong. These changes would have a negative economic impact on families.	The Economic Impact Assessment conducted by the Department in accordance with the Department of Administration, using form DO-2049, requires assessment of the impact on the State's economy, local government units, specific businesses/sectors, public utility rate payers and small businesses. The analyses found that there would be "little to no economic impact" on all groups. The impact to families was a consideration of the Department outside this assessment. The vaccines being proposed are all routinely recommended by the Advisory Committee on Immunization Practices at the proposed ages and therefore are covered by insurance policies that provide coverage for immunizations, which is nearly all plans. Additionally, for families without insurance, or whose insurance does not cover these vaccines, they are eligible for the Vaccines for Children program, which provides vaccines to children who are uninsured, underinsured, on Medicaid, Alaskan Native or American Indian, regardless of the ability to pay through a network of approximately 730 health care providers, local public health and tribal clinics.
144.07 (4) (b)	DHS received 5 comments that broadly stated (i.e., generalized to all vaccines), DHS should modify the timeline schools use for reporting vaccination compliance to the state. For example, one respondent stated, "Schools are currently reporting vaccine compliance rates to the health department by day 40 of the school year and no follow up data is required or even submitted to the health dept. Records obtained by the schools on day 40 are not necessarily indicative of records received by Day 90, when those children considered in progress must submit updated records. If the health department would like the state to receive the reports then we would suggest that schools be required to submit the data by Day 40 and again at 120. The second submission requirement by	While requiring more than one "snapshot" of student vaccination compliance per school year would result in a more accurate assessment, it would create a significant burden on school staff to do the reporting twice in a given school year. Therefore, Wisconsin only requires information is reported once. Students whose compliance status changes will be recorded in the next school year. All states generate an annual immunization status report based on one report and this information is available on state websites and on CDC's website. References SchoolVaxView | School Vaccination Requirements and Exemptions | CDC. (n.d.).

	the state would reflect a more accurate assessment of vaccine rates within schools."	Retrieved from https://www.cdc.gov/vaccines/imz-managers/coverage/schoolvaxview/requirements/index.html
144.02 (21)	DHS received 48 comments stating the substantial outbreak classification change for mumps is unwarranted because the mumps vaccine is ineffective.	In 2012, CDCs Manual for the Surveillance of Vaccine Preventable Disease was updated. In this revision, a mumps outbreak is now defined as three or more cases linked by time and place. In recent years, mumps outbreaks have occurred in highly vaccinated populations in high transmission settings, including elementary, middle, and high schools, colleges, and camps. Especially in these setting, rapid detection and investigation of cases, and implementation of control measures may reduce the magnitude of outbreaks. The proposed changes are in alignment with the current, national guidance. Evidence shows that the MMR vaccine is very safe and effective. The mumps component of the MMR vaccine is about 88% effective when a person gets two doses and 78% effective when a person gets one dose. References Schaffzin, J. K., Pollock, L., Schulte, C., Henry, K., Dayan, G., Blog, D., & Smith, P. (2007). Effectiveness of Previous Mumps Vaccination During a Summer Camp Outbreak. *Pediatrics*, *120*(4). doi: 10.1542/peds.2006-3451 Mumps Vaccination | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/vpd/mumps/index.html Kimberlin D.W., Brady M.T., Jackson M. A., Long S. SI, eds. *Red Book:2018 Report of the Committee on Infectious Diseases.* 31st ed. Itasca, IL: American Academy of Pediatrics, 2018: Mumps 567-573.
144.02 (21) (h) 144.03 (20) (g)	DHS received 79 comments stating the varicella vaccination requirement update is unwarranted because varicella infection is a mild infection and treatable at home.	Varicella can be serious, even life-threatening. Severe bacterial complication of primary varicella in children, such as skin infections, thrombocytopenia, bacteremia, prolonged fever and prolonged hospitalization are risks of contracting varicella. Moreover, other serious complications of the disease include encephalitis (estimated 1.8 per 10,000 cases) which may lead to seizures and coma, and death in 1 out of 60,000 cases. ACIP recommends that healthy people who do not have evidence of immunity to varicella be vaccinated.

		References Aebi, C., Ahmed, A., & Ramilo, O. (1996). Bacterial Complications of Primary Varicella in Children. *Clinical Infectious Diseases*, *23*(4), 698–705. doi: 10.1093/clinids/23.4.698 Ziebold, C., Kries, R. von, Lang, R., Weigl, J., & Schmitt, H. J. (2001, November 1). Severe Complications of Varicella in Previously Healthy Children in Germany: A 1-Year Survey. Retrieved from https://pediatrics.aappublications.org/content/108/5/e79.short Fleisher, G. (1981). Life-Threatening Complications of Varicella. *Archives of Pediatrics & Adolescent Medicine*, *135*(10), 896. doi: 10.1001/archpedi.1981.02130340008004 Jackson, M. A., Burry, V. F., & Olson, L. C. (1992). Complications of varicella requiring hospitalization in previously healthy children. *The Pediatric Infectious Disease Journal*, *11*(6), 441–444. doi: 10.1097/00006454-199206000-00004 Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C. Public Health Foundation, 2015.
general	DHS received 38 comments stating the DHS' public notification of these proposed rules was insufficient—that parents of school-aged children were not well notified.	The Department of Health Services followed all rule promulgation processes and requirements, including public notification. The Statement of Scope was published and available for comment for nearly two years, beginning on July 31, 2017, and was open through the close of business on July 26, 2019, the day of the public hearing. Additionally public notices for the three advisory committee meetings were done in accordance with state rules and each meeting had time in the agenda set aside specifically to receive public comment. An administrative "rule" is defined in s. 227.01 (13), Stats. The authority to create new rules, or to revise and repeal existing rules (promulgation), is delegated to the Department of Health Services (DHS) by the Wisconsin State Legislature. Rules must be promulgated according to a process established by the Legislature in ch. 227, Stats., by the Governor in various Executive Orders (link is external), and by the Courts in various precedents. DHS must obtain approval from the Governor to begin any

		project to create new rules, or to revise or repeal current administrative rules. DHS must also submit final proposed rules to the Wisconsin State Legislature for review prior to enactment. Reference Administrative Rules. (2018, November 29). Retrieved from https://www.dhs.wisconsin.gov/rules/index.htm
general	DHS received 34 comments stating that changing vaccine requirements via the rule change process bypasses legislators' role in the legal process. Legislators need to be allowed to vote on this, as they are accountable to their voting constituents.	Rules must be promulgated according to a process established by the Legislature in ch. 227, Stats. The Department of Health Services followed the outlined process. Reference Wisconsin State Legislature ch. 227, Stats. https://docs.legis.wisconsin.gov/statutes/statutes/227/I/01
general	DHS received 203 comments that broadly stated (i.e., generalized to all vaccines), these changes would infringe on parent's autonomy over care decisions for their children and general personal freedoms.	The Department is proposing adding vaccines to an already established list of required vaccines. The authority to do so is based on Wisconsin Statute section 252.04, which was created in 1975 and which has been amended many times in response to changing public health needs. Therefore, the proposed actions are not setting new precedence but rather amending long-standing requirements implemented to protect the safety and health of Wisconsin's children. Wisconsin allows for medical, religious, and personal conviction waivers and changes to waivers are not included in the proposed changes.
general	DHS received 17 comments with personal anecdotes about the adverse effects of vaccinations.	Per CDC, any vaccine can cause side effects. For the most part these are minor (for example, a sore arm or low-grade fever) and go away within a few days. Additional information regarding each vaccine is available on the CDC's Vaccine Information Statements (VISs). Vaccines are continually monitored for safety, and like any medication, vaccines can cause side effects. However, a decision not to immunize a child also involves risk and could put the child and others who come into contact with him or her at risk of contracting a potentially deadly disease. Reference Vaccine Information Statement | Home | VIS | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/hcp/vis/index.html

144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 79 comments stating the meningococcal vaccination requirement update is unwarranted because mandating the meningococcal vaccine is not supported by valid research or data.	Wisconsin follows the recommendations of the national Advisory Committee on Immunization Practices (ACIP), which reviews relevant safety and efficacy data and provides evidence-based recommendations regarding vaccines. Per the Immunization Action Coalition, the majority of states already have meningococcal ACWY state mandates. In June 2007, ACIP recommended vaccination of all adolescents with meningococcal vaccine beginning at age 11. The ACIP meningococcal vaccine workgroup reviewed data on the epidemiology of meningococcal disease, safety, and the cost-effectiveness of meningococcal vaccine. On the basis of that data, expert opinion of the workgroup members, and feedback from partner organizations, this recommendation was approved. In January 2011, ACIP recommended that all adolescents receive a booster dose at 16 years of age. After licensure, additional data on bactericidal antibody persistence, trends in meningococcal disease epidemiology in the United States, and vaccine effectiveness have indicated many adolescents might not be protected for more than 5 years. Therefore, persons immunized at age 11 or 12 years might have decreased protective immunity by ages 16 through 21 years, when their risk for disease is greatest. References ACIP home page: https://www.cdc.gov/vaccines/acip/index.html State Information. (n.d.). Retrieved from https://www.immunize.org/laws/menin_sec.asp Revised Recommendations of the Advisory Committee on Immunization Practices to Vaccinate All Persons Aged 11-18 Years with Meningococcal Conjugate Vaccine. (2007). *PsycEXTRA Dataset*. doi: 10.1037/e669332007-003 Updated Recommendations for Use of Meningococcal Conjugate Vaccines --- Advisory Committee on Immunization Practices (ACIP), 2010. (2011, January 28). Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 32 comments stating the meningococcal vaccination requirement update is unwarranted because the purposed age group	ACIP's Meningococcal Vaccines Work Group initially recommended a single dose of vaccine to be given at the ages of 11 to 12 years as

	(11 and 12 year olds) misses the target age group for which demographic group is at risk.	more adolescents in this age group have preventive care visits, it would be given in tangent with Tdap and HPV vaccines, and it was expected the vaccine would provide protection through the entire period of risk. After licensure, additional data indicated that after 5 years, waning of protection from disease occurs. The Work Group considered 2 options from this data, 1) moving the dose at age 11 or 12 years to age 14 or 15 years, or 2) vaccinating at age 11 or 12 years and providing a booster dose a age 16 years. Although a single dose at age 14 or 15 years likely would protect most adolescents through the higher risk period at ages 16 through 21 years, the opportunities to administer vaccine at age 14 or 15 years might be more limited. Data indicate that as adolescents grow older, they are less likely to visit a health-care provider for preventive care. Adding a booster dose to the recommended schedule would provide more opportunities to increase vaccination coverage, while persons aged 11 through 13 years would continue to be protected. An economic analysis comparing the three adolescent vaccination strategies concluded that administering a booster dose has a cost per quality-adjusted life year similar to that of a single dose at age 11 years or age 15 years but is estimated to prevent twice the number of cases and deaths per CDC data. These recommendations are in accordance with the national guidelines put forth by the Advisory Committee on Immunization Practices. Reference Updated Recommendations for Use of Meningococcal Conjugate Vaccines --- Advisory Committee on Immunization Practices (ACIP), 2010. (2011, January 28). Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 17 comments stating the meningococcal vaccination requirement update is unwarranted because meningitis is treatable.	Vaccination with the meningococcal vaccine is the best way to prevent very serious infections caused by the bacterium *Neisseria meningitidis*. Per CDC and AAP, meningococcal meningitis and bloodstream infections can be very serious, even deadly. The infections progress quickly. The case-fatality ratio of meningococcal disease is 10% to 15%, even with appropriate antibiotic therapy. The case-fatality ratio of meningococcemia is up to 40%. As many as 20% of survivors have permanent sequelae, such as hearing loss, neurologic damage, or loss of a limb.

		References Hamborsky, J., Kroger, A., & Wolfe, C. (S. (2015). *Epidemiology and prevention of vaccine-preventable diseases*. United States: U.S. Dept. of Health & Human Services, Centers for Disease Control and Prevention. Meningococcal Disease Chapter. Kimberlin D.W., Brady M.T., Jackson M. A., Long S. SI, eds. *Red Book:2018 Report of the Committee on Infectious Diseases*. 31st ed. Itasca, IL: American Academy of Pediatrics, 2018: Meningococcal 550-561.
general	DHS received 26 comments that broadly stated (i.e., generalized to all vaccines), that mandating vaccines is intended to benefit (e.g., financially) Industry/Government.	Vaccines are intended to benefit children and adults by preventing disease. They are credited with saving millions of lives. The CDC estimates that by vaccinating children between 1994-2018, 419 million illnesses, 26.8 million hospitalizations, and 936,000 early deaths will be prevented. Per the U.S. Department of Health & Human Services, immunizations can save a family time and money. A child with a vaccine-preventable disease can be denied attendance at schools or child care facilities. Some vaccine-preventable diseases can result in prolonged disabilities and can take a financial toll because of lost time at work, medical bills or long-term disability care. In contrast, getting vaccinated against these diseases is a good investment and usually covered by insurance. Reference Five Important Reasons to Vaccinate Your Child. (n.d.). Retrieved from https://www.vaccines.gov/getting/for_parents/five_reasons
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 8 comments stating the meningococcal vaccination requirement update is unwarranted because meningococcal vaccine does not provide herd immunity.	It is important for individuals to be vaccinated for protection against disease. CDC first recommended preteens and teens get a MenACWY vaccine in 2005. Since then, rates of meningococcal disease in teens caused by serogroups C, Y, and W has decreased by over 90%. This is a larger percent decline than seen in other groups for which CDC does not recommend routine MenACWY vaccination. These data suggest MenACWY vaccines provide protection to those vaccinated, but probably not to the larger, unvaccinated community (herd immunity). Reference

		Meningococcal Vaccination | What You Should Know | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/vpd/mening/public/index.html
144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 27 comments stating the meningococcal vaccination requirement update is unwarranted because Meningococcal vaccine has never been tested against a placebo.	The meningococcal vaccine, like all licensed vaccines, has undergone rigorous testing prior to licensure, with studies done to evaluate both safety and effectiveness. Moreover, vaccines continue to be monitored post-licensure and are routinely re-assessed to ensure they meet standards set forth in each of these areas. Per CDC, effectiveness of the three meningococcal conjugate vaccines was inferred by comparing serum bactericidal antibody assay (SBA) measurements of the new vaccine with corresponding antibody responses of the U.S.-licensed meningococcal vaccine representing the standard of care at the time (among persons aged 2 through 55 years) or by achieving a seroresponse at or above a predefined bactericidal antibody titer (among children aged 2 through 23 months). A study that was published in *The Lancet*, compared meningococcal vaccine (MenACWY) to meningococcal serogroup B. This study randomly assigned university students ages 18 through 24 years to one of three groups. One group received Japanese Encephalitis vaccine (controls), meningococcal serogroup B vaccine, or meningococcal vaccine (MenACWY). References Hamborsky, J., Kroger, A., & Wolfe, C. (S. (2015). *Epidemiology and prevention of vaccine-preventable diseases*. United States: U.S. Dept. of Health & Human Services, Centers for Disease Control and Prevention. Meningococcal Disease Chapter. Read, R. C., Baxter, D., Chadwick, D. R., Faust, S. N., Finn, A., Gordon, S. B., Borrow, R. (2014). Effect of a quadrivalent meningococcal ACWY glycoconjugate or a serogroup B meningococcal vaccine on meningococcal carriage: an observer-blind, phase 3 randomised clinical trial. *The Lancet*, *384*(9960), 2123–2131. doi: 10.1016/s0140-6736(14)60842-4
144.02 (21) (h) 144.03 (20) (g)	DHS received 15 comments stating the varicella vaccination requirement update is unwarranted because varicella vaccine is ineffective	The varicella vaccine has been demonstrated to be effective. Per CDC and AAP, the effectiveness of 1 dose of varicella vaccine is about 82% against any

		clinical varicella and 98% against severe disease. Two doses of vaccine demonstrated 92% effectiveness against any clinical varicella. Immunity appears to be long-lasting. Breakthrough infection (after vaccination), is significantly milder than infection among unvaccinated persons, with fewer lesions, generally fewer than 50 and without a fever present. References Hamborsky, J., Kroger, A., & Wolfe, C. (S. (2015). *Epidemiology and prevention of vaccine-preventable diseases.* United States: U.S. Dept. of Health & Human Services, Centers for Disease Control and Prevention. Varicella Chapter. Kimberlin D.W., Brady M.T., Jackson M. A., Long S. SI, eds. *Red Book:2018 Report of the Committee on Infectious Diseases.* 31st ed. Itasca, IL: American Academy of Pediatrics, 2018: Varicella 869-893.
general	DHS received 107 comments that broadly stated injecting foreign materials (e.g., chemicals, preservatives, vaccinations) into the body is wrong/dangerous/ineffective/expensive/not trustworthy.	There is solid medical and scientific evidence that the benefits of vaccines far outweigh the risks. Vaccines go through extensive, rigorous testing to ensure safety and efficacy prior to licensure. Monitoring for side effects continues post-licensure through a number of different systems, including the Vaccine Adverse Event Reporting system (VAERS), the Vaccine Safety Datalink, the Post-Licensure Rapid Immunization Safety Monitoring, and the Clinical Immunization Safety Assessment. Additionally, an article published in *Seminars in Pediatric Infectious Diseases,* discusses that since vaccines are administered to children, they are held to a higher safety standard than medications given to treat people who are ill. References Vaccines: Vac-Gen/Side Effects. (n.d.). Retrieved from https://www.cdc.gov/vaccines/vac-gen/side-effects.htm Ensuring the Safety of Vaccines in the United States. Retrieved from https://www.cdc.gov/vaccines/hcp/patient-

		ed/conversations/downloads/vacsafe-ensuring-bw-office.pdf Halsey, N. A. (2002). The science of evaluation of adverse events associated with vaccination. *Seminars in Pediatric Infectious Diseases*, *13*(3), 205–214. doi: 10.1053/spid.2002.125864
general	DHS received 28 comments expressing general opposition to the rule changes (i.e., no specific rationales were provided).	Per the Wisconsin Legislative Council, state agencies promulgate administrative rules to implement or interpret provisions of the statutes enforced or administered by the agency or to establish agency procedures for administering programs. Administrative rules have the force and effect of law. Administrative Rule 144 has not been updated since 2009 and is not current with ACIP recommendations (meningococcal vaccination), it contains outdated language when Tdap and varicella were included as recommendations, it allows for parenteral report of varicella disease, and other minor changes are being proposed. Reference Administrative Rules. (n.d.). Retrieved from https://lc.legis.wisconsin.gov/administrative-rules/
144.03 (20) (g)	DHS received 13 comments stating varicella infection does not need to be diagnosed by providers, it can be diagnosed by parents.	To limit the number of false-positive reports and ensure immunity, the national Advisory Committee on Immunization Practices (ACIP) recommends that evidence of immunity should be either a diagnosis of varicella by a health care provider or a health care provider verification of a history of disease rather than parental or self-reporting. In the past, the predictive value of a self-reported positive disease victory for varicella was extremely high in adults in the pre-vaccine era for their children. As disease incidence decreases and the proportion of vaccinated persons with varicella having mild cases increases, varicella will be less readily recognized clinically. A recent study demonstrated that only 75% of unvaccinated children aged 12 months through 4 years who reported a positive history of varicella were in fact immune (confirmed by serological testing), compared with 89% of children aged 5 through 9 and 10 through 14 years. References Perella, D., Fiks, A. G., Jumaan, A., Robinson, D., Gargiullo, P., Pletcher, J., ... Spain, C. V. (2009). Validity of Reported Varicella History as

		a Marker for Varicella Zoster Virus Immunity Among Unvaccinated Children, Adolescents, and Young Adults in the Post-Vaccine Licensure Era. *Pediatrics*, *123*(5). doi: 10.1542/peds.2008-3310 Davis, M. M. (2004). Decline in Varicella-Related Hospitalizations and Expenditures for Children and Adults After Introduction of Varicella Vaccine in the United States. *Pediatrics*, *114*(3), 786–792. doi: 10.1542/peds.2004-0012
general	DHS received 1 comment stating the vaccine mandates proposed do not follow international trends.	Per the World Health Organization (WHO), immunization has proven the test of time as one of public health's most cost-effective interventions. In 2017, the number of children immunized – 116.2 million – was the highest ever reported. Since 2010, 113 countries have introduced new vaccines, and more than 20 million additional children have been vaccinated. A journal article published in 2018 reported that all 31 European countries recommended vaccines and 11 have compulsory immunization policies. Ten leading medical organizations, including American Academy of Pediatrics to the American Nurses Association to the Infectious Diseases Society of American all endorse strong school and childcare vaccination requirements as a primary way to ensure high vaccination rate. https://www.immunize.org/catg.d/p2071.pdf Mandatory vaccinations in European countries, undocumented information, false news and the impact on vaccination uptake: the position of the Italian pediatric society Elena Bozzola, Giulia Spina, Rocco Russo, Mauro Bozzola, Giovanni Corsello, Alberto Villani. Ital J Pediatr. 2018; 44: 67 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6001041/
144.03 (10) (a)	DHS received 4 comments stating vaccine reporting infringes on health privacy. For example, providers should not share children's' vaccination information with schools, daycares, and other providers without written or verbal permission from an adult. One respondent suggested, "the language be changed to require signed written consent from a student, age 18 or older, or a parent in order for this information to be released to a school or daycare center, or among vaccine providers."	Wisconsin Statute, Chapter 252.04 (2) states that "Any student admitted to any elementary, middle, junior, or senior high school or into any child care center or nursery school shall, within 30 school days after the date on which the student is admitted, present written evidence to the school, child care center, or nursery school of having completed the first immunization for each vaccine requirement for the student's grade and being on schedule for the remainder of the basic and recall (booster) immunization series for mumps, measles, rubella (German

		measles), diphtheria, pertussis (whooping cough), poliomyelitis, tetanus and other diseases that the department specifies by rule or shall present a written waiver under sub. (3)." Chapter 252.04 (4) states "The student, if an adult, or the student's parent, guardian, or legal custodian shall keep the school, child care center, or nursery school informed of the s student's compliance with the immunization schedule." The proposed changes do not affect Wisconsin Statute, Chapter 252. Reference Wisconsin State Legislature ch. 118.125, Stats. http://docs.legis.wisconsin.gov/statutes/statutes/118/125
general	DHS received 2 comments stating vaccinated individuals should tolerate others' decisions not to get vaccinated because they are protected. There is no risk to those not vaccinated.	While vaccines significantly reduce the possibility of contracting a disease, there are rare instances where vaccinated individuals may still become ill (but the illness is likely not to be as severe). However, the greater risk is to those individuals in the community who cannot be vaccinated due to medical reasons (e.g. undergoing chemotherapy). Therefore, those who choose not be vaccinated place these vulnerable at higher risk by decreasing herd immunity, and increasing likelihood of a disease circulating. This results in a greater chance that the vulnerable individual will be exposed and contract the disease.
144.02 (21) (h) 144.03 (20) (g)	DHS received 2 comments stating the recommended change about varicella outbreaks is against the 14th amendment because it segregates/discriminates students' based on their medical history.	Under Wisconsin Statute Chapter 252.04 (1), "The department shall carry out a statewide immunization program to eliminate mumps, measles, rubella (German measles), diphtheria, pertussis (whooping cough), poliomyelitis and other diseases that the department specifies by rule, and to protect against tetanus." Vaccination is the primary mechanism recommended by national and international boards to reduce or eliminate the spread of diseases for which a vaccine is licensed and available. According to the report "Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies" from the Health and Medicine Division of the National Academies of Science, Engineering and Medicine (formerly the Institutes of Medicine),", released in 2013, it states that "Vaccines are among the most safe and effective public health interventions to prevent serious disease and death.".

		As overall disease incidence declines, the risk for exposure to varicella-zoster virus (VZV) decreases, leading to susceptible (unvaccinated and vaccinated) children aging into adolescence and adulthood. Although the total number of varicella cases is declining, a shift of the remaining varicella disease burden to middle school years is being observed. In 1995, the median age of varicella infection ranged from 3-5 years in vaccinated persons and from 5-6 years in unvaccinated persons. By 2005, the median age increased to 6–8 years in vaccinated persons and 13–19 years in unvaccinated persons. Investigations of varicella outbreaks in schools and other settings in the vaccine era will improve our knowledge of the epidemiology of varicella, assess virus transmission patterns, describe disease burden and risk factors for severe varicella, provide estimates of varicella vaccine effectiveness for two versus one dose of vaccine, and identify risk factors for vaccine failure. In addition, monitoring the number and size of varicella outbreaks will help to assess impact of the second-dose recommendation. These data will facilitate the development and refinement of appropriate public health interventions to control and prevent future varicella outbreaks and further reduce varicella morbidity and mortality. References Guris, D., Jumaan, A. O., Mascola, L., Watson, B. M., Zhang, J. X., Chaves, S. S., Seward, J. F. (2008). Changing Varicella Epidemiology in Active Surveillance Sites—United States, 1995–2005. *The Journal of Infectious Diseases*, *197*(s2). doi: 10.1086/522156 Institute of Medicine. 2013. *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies*. Washington, DC: The National Academies Press.https://doi.org/10.17226/13563.
general	DHS received 1 comment stating the advisory Committee on Immunization Practices (ACIP) has conflicts of interest/bias.	Per CDC, vaccine recommendations are developed using an explicit evidence-based method on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. Key factors considered in development of recommendations include balance of benefits and harms, type or quality of

		evidence, values and preferences of the people affected, and health economic analyses. An article in *Pediatrics,* describes fully how ACIP assures avoidance of conflicts of interest and bias with stringent measures in place and rigorous screening of committee members. References About ACIP Evidence-Based Recommendation Method (GRADE) | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html Smith, J. C. (2010). The structure, role, and procedures of the U.S. Advisory Committee on Immunization Practices (ACIP). *Vaccine, 28.* doi: 10.1016/j.vaccine.2010.02.037
general	DHS received 1 comment stating the use of the word "outbreak" in the proposed rules is a "fear mongering" tactic.	This is common terminology for epidemiologic events. Per CDC, epidemic refers to an increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area. Outbreak carries the same definition of epidemic, but is often used for a more limited geographic area. Cluster refers to an aggregation of cases grouped in place and time that are suspected to be greater than the number expected, even though the expected number may not be known. Pandemic refers to an epidemic that has spread over several countries or continents, usually affecting a large number of people. Reference Principles of Epidemiology | Lesson 1 - Section 11. (n.d.). Retrieved from https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section11.html
144.02 (21) (h) 144.03 (20) (g)	DHS received 2 comments stating the varicella vaccination requirement update is unwarranted because there is insufficient supporting research.	The proposed changes do not include any changes to the varicella vaccination requirement. The proposed change is for a health care provider to document varicella disease and remove parental or adult student report of varicella disease as an acceptable exception.
	DHS received 1 comment stating the measles, mumps, and rubella (MMR) vaccine is dangerous.	The measles-mumps-rubella (MMR) vaccine that is in current use today was licensed in 1968 and has a long record of vaccine safety and is used in many parts of the world. Vaccines are rigorously monitored pre and post-licensure, including MMR, and include systems such as the Vaccine Adverse Event Reporting system

		and the Vaccine Safety Datalink to identify safety issues after licensure. The national Advisory Committee on Immunization Practices periodically reviews safety and efficacy data and continue to include the MMR vaccine as part of the routinely recommended vaccines for both children and susceptible adults. Reference Understanding MMR Vaccine Safety retrieved from CDC. https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-mmr-color-office.pdf Ensuring the Safety of Vaccines in the United States . Accessed at: https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-ensuring-bw-office.pdf
144.02 (21) (h) 144.03 (20) (g)	DHS received 2 comments stating the varicella vaccination requirement update is unwarranted because the varicella vaccine is dangerous.	Varicella vaccine, like all vaccines has undergone significant study before and after licensure and has been shown to be safe and well tolerated, with the most common side effects after vaccination being soreness or swelling where the shot was given, fever and a mild rash. The proposed changes do not alter the requirement for varicella vaccination, but rather update the reporting options for those who have had the disease. Reference Chickenpox (Varicella) Vaccine Safety, CDC. Accessed at: https://www.cdc.gov/vaccinesafety/vaccines/varicella-vaccine.html Perella, D., Fiks, A. G., Jumaan, A., Robinson, D., Gargiullo, P., Pletcher, J., ... Spain, C. V. (2009). Validity of Reported Varicella History as a Marker for Varicella Zoster Virus Immunity Among Unvaccinated Children, Adolescents, and Young Adults in the Post-Vaccine Licensure Era. *Pediatrics*, *123*(5). doi: 10.1542/peds.2008-3310

Summary of Items Submitted with this Report to the Legislature

Below is a checklist of the items that are attached to or included in this report to the legislature under s. 227.19 (3), Stats.

Documents/Information	Included in Report	Attached	Not Applicable
Final proposed rule -- Rule Summary and Rule Text		X	
Department response to Rules Clearinghouse recommendations	X		
Final Regulatory Flexibility Analysis			X
Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis			X
Public Hearing Summary	X		
List of Public Hearing Attendees and Commenters	X		
Summary of Public Comments and Department Responses	X		
Fiscal Estimate/Economic Impact Analysis		X	
Revised Fiscal Estimate/Economic Impact Analysis			X
Small Business Regulatory Review Board (SBRRB) statement, suggested changes, or other material, and reports made under s. 227.14 (2g), Stats. and Department's response			X
Department of Administration (DOA) report under s. 227.115 (2), Stats., on rules affecting housing			X
DOA report under s. 227.137 (6), Stats., on rules with economic impact of $20 MM or more			X
Public Safety Commission (PSC) energy impact report under s. 227.117 (2), Stats. and the Department's response, including a description of changes made to the rule			X

From: Amber Psket [mailto:amber.smith@wisconsinunitedforfreedom.org]
Sent: Tuesday, July 30, 2019 12:36 PM
To: DHS Secretary Andrea Palm
Cc: Smiley, Stephanie L - DHS (DPH); Uttech, Susan M - DHS; Erin Runk; judithjolly1@verizon.net; tara.czachor@gmail.com; Rep.Wichgers - LEGIS; Rep.Sortwell - LEGIS; Rep.Ballweg@legis.wi.gov; Sen.Nass - LEGIS; Sen.Jacque - LEGIS
Subject: DHS 144 Inquiry

My name is Amber Psket, cofounder of Wisconsin United For Freedom – a nonprofit here in the State. First off, I wanted to thank you for the opportunity to speak on Friday and express my concerns regarding the proposed rule changes to DHS 144. I would however like to express my objection to the process, as there are several points I'd like to address.

- Public comment was ended before the list of speakers was completed. Many people drove hours to attend this meeting and were not given the chance to speak.

- There was an extensive amount of time spent on technical difficulties which could have been allotted to those speaking in person. Also, phone attendees were given precedence over those in physical attendance.

- The 2 minute time limit was insufficient and the manner in which the microphone was physically removed at the mark was seen as overly aggressive by several who attended the hearing.

- The hearing being set for only one hour was unacceptable as the department was made aware of ample public interest prior to the public hearing and should have been more prepared. More adequate plans should have been made with regard to the amount of people expected to attend and publicly comment at the hearing.

Due to the lack of completion of public comments, I'd like to request another public hearing as we were not given adequate time and that needs to be rectified.

- While written comment was accepted, we received several complaints from members about issues they experienced whilst doing so including technical difficulties when submitting to the legislative website, as well as a lack of requested response from DHS regarding submitted emails. Many members are concerned their written email was not officially accepted.

- The phone number for call in was not updated on the Wisconsin Public Meetings notice webpage.

- I'd like to address the Advisory Committee and the fact that it consists of all medical establishments/entities and not one parent represented as an individual. Parents are the largest stakeholders that would be affected by these proposed rule changes yet none were consulted.

For this reason, I would also like to request a formal meeting with DHS and a panel of parents to discuss our concerns formally before this process proceeds any further.

I thank you for your time and will be awaiting a response.

Amber Psket
Co-Founder
Wisconsin United For Freedom
www.wisconsinunitedforfreedom.org

Wisconsin United for Freedom
P.O. Box 894
Cedarburg, WI 53012
info@wisconsinunitedforfreedom.org

My name is Rachel McCardle, and I represent Wisconsin United for Freedom. I am here today because I oppose rules 1, 2, 4, and 5 from CR 19-079.

I'd like to specifically address rule 5. This new rule change would unnecessarily expose others to the chickenpox. If like me, you've had the Chickenpox yourself, you are aware that Chickenpox is typically a mild childhood illness that does not require medical intervention. I remember having the chicken pox at the same time as my younger brother. My mother was able to diagnose and treat us at home without exposing anyone else. Why is this a radical idea? Why do I not deserve the same right?

Not only does this rule change infringe on parental rights it also takes no consideration of the financial burden of the WI families that this will impact. When speaking with members of my community I found that families are paying anywhere from $150-$250 for an illness visit at the clinic. You might not think $200 is a lot of money. Lets imagine you are a low or middle-income family with 4 children. If each child is required to go in for a formal diagnosis we could be looking at close to $800 or more. An unexpected medical bill of that size would be detrimental to many WI families.

No one knows a child better than their parent. We can pick up on the slightest changes in them and act accordingly. The Chickenpox illness is usually mild and parents can easily identify and treat it from home without an unnecessary trip to the doctor. Parents who are unable to identify the illness will consult a healthcare provider for a formal diagnosis.

I'd like to thank you for letting me speak today. Having my voice heard is very important and I believe strongly in communication between people and their government. I was unable to travel and attend the previous hearing held on July 26, 2019 but I do know many people who did take time away from their personal and professional lives to attend this hearing in the hopes to do what I am doing right now.

Unfortunately, many WI residents that were trying to actively participate and petition their government were turned away because public comment was cut off after just 60 minutes with 20 of those minutes being delegated to technical difficulties. Where is the respect? Where is the communication?

I had to travel four hours to be here today. We are real people with busy lives and we take on these personal, professional and financial burdens to be here not because it is fun but because we care and want to be a part of the conversation.

It is my hopes that as you hear us today that you truly listen to the requests of the public however with the past history I do not know that I fully trust that our concerns will be represented if the rule changes were to be revised.

Communication is a major part of trust. So let us be open to communication so that we can come together to do right by Wisconsin. Thank you.

Rachel McCardle
420 Orange Street
Hudson WI 54016

knowledge changing life

Pharmacy Society of Wisconsin

Thank you, Chairperson and members of the Assembly Committee on Constitution and Ethics, for the opportunity to provide testimony in support of proposed updates to student immunization regulations by the Wisconsin Department of Health Services (DHS). My name is Karen MacKinnon and I am the Director of Outreach and an Assistant Professor at the Medical College of Wisconsin's (MCW) School of Pharmacy, a registered pharmacist in Wisconsin as well as in other states, and an active member of the Pharmacy Society of Wisconsin.

MCW's School of Pharmacy welcomed its first class of Doctor of Pharmacy (PharmD) students in the fall of 2017, whose graduation we will be celebrating this coming May. The School is preparing the next generation of pharmacists to practice at the top of their licenses, fully prepared for the new demands and opportunities of a rapidly-evolving healthcare system. Our three-year PharmD program is providing students with extensive exposure to a variety of clinical settings. It also is teaching students how to provide better quality healthcare as part of an inter-professional team, with the aim of improving care for patients that have chronic diseases or need acute care.

In the state of Wisconsin, pharmacists and pharmacy interns are able to administer any Center for Disease Control and Prevention (CDC) U.S. Advisory Committee on Immunization Practices (ACIP) approved vaccinations. One of the keys for successful implementation of the CDC guidelines for immunizations is increased access to healthcare providers that can administer them. Many pharmacies are open late and on weekends and often do not require appointments for immunizations. All of these factors increase access for patients to be treated. Eliminating cases of vaccine-preventable diseases can lower long-term costs to the healthcare system by preventing treatment costs of disease. Other costs to society, such as lost wages, will also be lowered. It is clear that pharmacists and pharmacies improve access to patients desiring immunizations across the state, from rural to urban areas.

Outlined in Healthiest Wisconsin 2020, the State of Wisconsin aims to protect residents across the life span from vaccine-preventable diseases by expanding access to and administration of Center for Disease Control and Prevention (CDC) U.S. Advisory Committee on Immunization Practices (ACIP) recommended vaccines. As demonstrated by America's Health Rankings, Wisconsin has room to improve: Wisconsin ranks 41st in the number of cases of pertussis, a vaccine-preventable disease.[1] In 2016, all 72 Wisconsin counties fell below Healthy People 2020's influenza vaccination rate goal of 70% for children and adolescents.

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[1] America's Health Rankings. Wisconsin. America's Health Rankings. https://www.americashealthrankings.org/learn/reports/2017-annual-report/state-summaries-wisconsin. Published 2018. Accessed May 17, 2018.

knowledge changing life

Pharmacy Society of Wisconsin

I am speaking today on behalf of the Medical College of Wisconsin and the Pharmacy Society of Wisconsin, which both support the Wisconsin Department of Health Services' (DHS) proposed updates to student immunization regulations. These proposed changes align DHS requirements with current recommendations put forward by the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP).

Immunizations provide proven public health benefits and are an important tool for combatting many life-threatening illnesses. We believe that these provisions would create additional access points throughout the state for patients to receive recommended immunizations, thereby increasing Wisconsin's immunization rates and decreasing its incidence of vaccine-preventable disease. As such, the Medical College of Wisconsin and the Pharmacy Society of Wisconsin support the proposed changes to DHS 144. Thank you again for the opportunity to speak today.

Good Morning,

My name is Danielle Krbecek. I'm the Coordinator of Health Services for the Middleton-Cross Plains Area School District. I'm here to support all proposed changes to DHS Rule 144.

All of the proposed changes reflect current CDC recommendations. The CDC is defined as "the nation's health protection agency...the CDC saves lives and protects people from health, safety, and security threats."

I had to ask myself 'why would anyone want to oppose health care recommendations from arguably the most knowledgeable health institute in the nation'? After much thought, I realized it's not so much about disagreeing with the recommendations, but more about fear. The fear of losing the right as a parent to make personal **choices** for their child.

That word...**Choice.** That word is why I'm here and exactly why I think these proposed changes should be approved.

Parents who do not want to vaccinate their children, that is their **choice**. They get to make that **choice**.

However, for parents who have children that are immunocompromised, that was NOT their **choice**. They didn't get to make a **choice** in that.

There are two types of immunodeficiency disorders, congenital (primary) and acquired (secondary).

A congenital or primary immunodeficiency disorder is one you were born with. There are more than 100 congenital disorders.

An acquired or secondary immunodeficiency disorder can be caused by either:

- having a systemic disorder (some examples include having diabetes, malnutrition, or HIV)
- someone going through immunosuppressive treatments (such as chemotherapy, bone marrow transplants, or radiation treatments)
- or another prolonged serious illness that leaves the body's immune system weak (such as kidney diseases, burn victims, gastrointestinal disorders, or organ transplant patients).

I promise you, everyone in this room would be saddened if they knew just how many students *and staff* within a school district fell under these categories. Cancer patients, diabetics, organ transplant patients, individuals with congenital disorders you've probably never heard of...the list goes on...

These individuals did not get to make a **choice** in their health.

Being in a public setting, they are quite literally relying on other individual's health to keep them safe. As a school nurse, part of my job is to make sure we are doing everything we can to keep ALL students and staff safe, especially those that didn't get to make a **choice** in their health status.

Please understand that the proposed changes to DHS Rule 144 DO still give parents the **choice** to not immunize their children. They still have the **choice** to provide immunization waivers if they choose to not immunize their child. This is not about taking away parental rights.

Rather, these changes that align with CDC recommendations are about updating health and safety guidelines that will keep *many* immunocompromised students and staff safe.

I am here as a voice for those that didn't get to make a **choice** when it came to their health. They didn't get to choose whether or not they got cancer or were born with a health disadvantage. When making a decision, consider them and everything they are already going through.

Again, the proposed changes still allow parents to make personal immunization **choices**. The proposed changes are about keeping the *thousands* of individuals who didn't get to make a **choice** when it came to their health, safe. By approving DHS rule 144, you're merely updating health guidelines for those that DO choose to immunize their children, which ultimately helps protect public communities and especially individuals who didn't get a **choice** when it came to their health.

Thank you.

Danielle Krbecek, BSN/RN
Coordinator of Health Services for the Middleton-Cross Plains Area School District
dkrbecek@mcpasd.k12.wi.us
608-829-9056

Wisconsin United for Freedom
P.O. Box 894
Cedarburg, WI 53012
info@wisconsinunitedforfreedom.org

Hello, my name is Sarah Walker. My husband and I live in Milwaukee with our three children. I am here today to speak on behalf of my family, and as a member of Wisconsin United for Freedom, in opposition to the changes proposed by the Wisconsin Department of Health Services in Clearinghouse Rule 19-079. I respectfully ask that you vote against proposed Rules 1, 2, 4, and 5 for the following reasons.

Through CR 19-079, the Wisconsin Department of Health Services proposes to make substantial changes to the immunization requirements for Wisconsin school children. Yet, when composing an Advisory Panel on the proposed changes, DHS failed to include moms and dads, instead including only groups of bureaucrats who were likely to agree with DHS. When DHS proposes changes which affect all Wisconsin school children, it is imperative that moms and dads have input and a place at the table. That did not happen here.

Beyond my concerns about the lack of transparency and failure to include diverse viewpoints from those who would be affected by these changes, I take particular issue with the changes related to the varicella vaccination requirements contained in Rule 1 and Rule 5. Rule 1 would change the "substantial outbreak" classification in Chapter DHS 144 to include chickenpox. This would result in unvaccinated school children, without a history of chickenpox infection, being excluded from school during an outbreak. Chickenpox is generally mild, and parents can easily identify the infection and keep their children home until they are recovered to prevent it from spreading, as with any other mild infection. As such, it does not warrant "substantial outbreak" classification.

Under current law, moms and dads can report on the school registration form whether their children have a history of chickenpox infection. Rule 5 would remove this ability, instead requiring a report of previous infection by a healthcare provider. As the rationale for this change, DHS points to recent studies showing a high incidence of reported positive chickenpox history in non-immune children. Thus, the intent of this change is apparently to assist schools in identifying immune and non-immune students, presumably to exclude non-immune students during an outbreak. If the changes were enacted, schools would classify students as immune to chickenpox if they either: (1) are up-to-date on the recommended doses of chickenpox vaccination; or (2) present a report of a previous chickenpox infection by a healthcare provider. However, being up-to-date on the varicella vaccination is not a perfect proxy for establishing immunity to chickenpox because the varicella vaccination is sometimes ineffective at provoking an adequate immune response. Varicella outbreaks in immunized children suggest that even after two doses

of varicella vaccine, 12-14% of vaccinated individuals may nevertheless be susceptible to chickenpox infection.[1] In addition, vaccine-induced immunity to varicella can wane over time. A 2017 study of over 10,000 recent military recruits found that of the recruits who had been vaccinated, only 72.4% had a positive titer, indicating immunity to Varicella Zoster Virus, in early adulthood, whereas of those with a history of chickenpox infection, 95.4% had titer results indicating immunity to chickenpox.[2] That study found that the odds of a vaccinated individual being immune to chickenpox decrease by as much as 8% for each year that elapses after vaccination.[3] Such vaccine failure contributed to a varicella outbreak at a New Hampshire daycare center, where a previously immunized child became infected with chickenpox and spread the infection to his classmates.[4] Twenty-five of the eighty-eight daycare children were infected in the outbreak, and the vaccine was found to be only 44% effective during that outbreak at preventing chickenpox infection in children who had received it.[5] Because of vaccine failure, it is not surprising that the Wisconsin Department of Health Services reported that for the year 2018, the majority of individuals under 18 who experienced varicella infection in Wisconsin, were vaccinated.[6] Indeed, "[a]mong persons with varicella aged 1–3 years, 65% were up to date for age and had received one dose of varicella vaccine. Among persons with varicella aged 4–18 years, 56% were up to date for age and had received two doses of varicella vaccine, 10% had received one dose of varicella vaccine, and 32% had not been vaccinated with varicella vaccine."[7] Therefore, if a "substantial outbreak" of chickenpox were to occur at a Wisconsin school, some of the vaccinated students would nevertheless be susceptible to chickenpox infection, even though the student immunization law treats vaccinated students as though they are immune.

Moreover, it is well established that recently vaccinated individuals are capable of shedding the vaccine strain varicella virus for up-to-six weeks after vaccination. Section 5.4 of the manufacturer's insert for Varivax, one of the available chickenpox vaccines, states that

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[1] Duncan, Joshua R., et al. "Varicella Seroepidemiology in United States Air Force Recruits: A Retrospective Cohort Study Comparing Immunogenicity of Varicella Vaccination and Natural Infection." *Vaccine*, 35, 27 Mar. 2017, 2352, https://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1190&context=usuhs (noting that "varicella outbreaks in immunized children with attack rates of 10–13% suggest varicella vaccine effectiveness of 82–85% among one-dose recipients and 86–88% among two-dose recipients").

[2] Duncan, "Varicella Seroepidemiology," 2353

[3] Duncan, "Varicella Seroepideniology," 2354

[4] https://www.nejm.org/doi/10.1056/NEJMoa021662?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov

[5] https://www.nejm.org/doi/10.1056/NEJMoa021662?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov

[6] https://www.dhs.wisconsin.gov/publications/p02321-18.pdf

[7] https://www.dhs.wisconsin.gov/publications/p02321-18.pdf

"Post-marketing experience suggests that transmission of vaccine virus may occur rarely between healthy vaccinees who develop a varicella-like rash and healthy susceptible contacts. Transmission of vaccine virus from a mother who did not develop a varicella-like rash to her newborn infant has been reported. Due to the concern for transmission of vaccine virus, vaccine recipients should attempt to avoid whenever possible close association with susceptible high-risk individuals for up to six weeks following vaccination with VARIVAX. . . ."[8] Thus, recently vaccinated students may be a source of chickenpox outbreaks, yet it would only be unvaccinated students, some of whom may be immune to chickenpox, who would be excluded from school during an outbreak.

Although DHS states that parents are incorrectly reporting a history of chickenpox infection in their children, DHS cannot cite a single example where a Wisconsin parent has incorrectly reported varicella infection. According to the CDC, "[c]omplications from chickenpox can occur, but they are not common in healthy people who get the disease."[9] For this reason, many childhood cases of chickenpox are treated at home without the need for medical care. Yet this rule change would subject Wisconsin parents to paying for doctor visits to diagnose mild chickenpox infections. And it leaves Wisconsin parents who did not seek medical attention for their children's past mild chickenpox infections, in an unclear and potentially financially burdensome position because the rule change would require them to provide medical proof of prior infection, but titer testing is not specifically enumerated as an acceptable means of establishing a history of infection. Thus, due to the challenge of obtaining a medical report of prior varicella infection in some instances, this rule change may result in some students who are immune to varicella because of a prior chickenpox infection, being excluded from school during an outbreak anyway.

If DHS's goal is to stop varicella outbreaks at schools by excluding non-immune and/or contagious students during an outbreak, Rule 1 and Rule 5 cannot accomplish this because these rules fail to address vaccine shedding and vaccine failure, both of which make vaccinated individuals potential sources of chickenpox infection. And it opens up the possibility that unvaccinated students who are immune to chickenpox from a prior infection may have significant challenges to proving their immunity. Moreover, because chickenpox is typically mild, it is not necessary to include it among the infections in the "substantial outbreak" classification in the first place. If enacted, these rules would primarily serve to punish unvaccinated children by excluding them from schools during varicella outbreaks, regardless of the ineffectiveness of this approach at containing outbreaks. For all of the foregoing reasons, I respectfully request that you vote against Rules 1, 2, 4, & 5 contained in CR 19-079.

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[8] https://www.fda.gov/media/119865/download

[9] https://www.cdc.gov/chickenpox/about/complications.html

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Varicella seroepidemiology in United States air force recruits: A retrospective cohort study comparing immunogenicity of varicella vaccination and natural infection

Joshua R. Duncan
Uniformed Services University of the Health Sciences

Catherine T. Witkop
Uniformed Services University of the Health Sciences

Bryant J. Webber
Trainee Health Surveillance

Amy A. Costello
Uniformed Services University of the Health Sciences

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Varicella seroepidemiology in United States air force recruits: A retrospective cohort study comparing immunogenicity of varicella vaccination and natural infection

Joshua R. Duncan [a,*], Catherine T. Witkop [a], Bryant J. Webber [b], Amy A. Costello [a]

[a] Uniformed Services University of the Health Sciences, 4301 Jones Bridge Rd, Building A, Room 1040A, Bethesda, MD, USA
[b] Trainee Health Surveillance, 559th Medical Group, Lackland Air Force Base, TX, USA

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ABSTRACT

Background/Objectives: Infection with varicella zoster virus (VZV) produces lifelong immunity, but duration of post-vaccination immunity has not been established. The purpose of this study is to determine if a difference exists in the long-term seropositivity of anti-VZV antibodies in a cohort of young adults who were vaccinated against varicella as compared to a similar cohort with a history of chickenpox disease, and to determine which variables best predict waning seropositivity following varicella vaccination.
Methods: This retrospective cohort study captures immunization and serology data from approximately 10,000 recruits who entered basic military training between January 1, 2008, and December 31, 2015, and who have childhood immunization records in the Air Force Aeromedical Services Information Management System. Varicella vaccine immunogenicity was determined relative to the immunogenicity of chickenpox disease, as measured by multiplex flow immunoassay. Among vaccine recipients, waning seroimmunity was modeled and adjusted for several important covariates.
Results: Basic military trainees who received varicella vaccine in childhood were 24% less likely to be seropositive to VZV than trainees who were exempt from vaccine due to a history of chickenpox disease. There was no significant difference in seropositivity between male and female trainees. The odds of a vaccinated trainee being seropositive to VZV decreased by 8% with each year elapsed since vaccination. Seroprevalence declined below estimated herd immunity thresholds in vaccinated trainees born after 1994, and in the cohort as a whole for trainees born after 1995.
Conclusion: Despite prior vaccination, seroimmunity in a large cohort of young adults unexposed to wild-type VZV failed to meet the estimated threshold for herd immunity. If vaccination in accordance with the current US VZV vaccination schedule is inadequate to maintain herd immunity, young adults not previously exposed to wild-type VZV may be at increased risk for varicella outbreaks.
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1. Background

Varicella vaccine was first licensed in the United States in 1995, and the Advisory Committee on Immunization Practices (ACIP) published its initial recommendations in 1996, advising one vaccine dose to susceptible children under 12 years of age [1]. The incidence of varicella decreased by 90% over the next 10 years, from approximately 4 million yearly cases seen before the vaccine was available [2,3]. However, varicella outbreaks continued to occur in populations of highly-vaccinated schoolchildren, and ACIP recommended a second dose of varicella vaccine in 2006 [4]. By 2012, two-dose varicella vaccination coverage levels approached the two-dose coverage levels of 82–94% seen for measles, mumps, and rubella (MMR), and wider adoption of two-dose varicella vaccination requirements for school entry have been instrumental in progression toward the Healthy People 2020 (HP2020) target of 95% of kindergarten children receiving two doses of varicella vaccine [5]. Despite this progress, estimated 2015 two-dose varicella vaccination coverage of 84.6% for adolescents aged 13–15 falls below the HP2020 target of 90% [6].

As the increased utilization of the varicella vaccine leads to reductions in circulating wild-type varicella-zoster virus (VZV), inadequately immunized children may acquire infection at an older age when they are at increased risk for severe infection [7]. This can be prevented by targeted vaccination of susceptible adolescents. ACIP criteria for evidence of immunity to varicella include documentation of age-appropriate vaccination, laboratory

* Corresponding author.
E-mail address: joshua.duncan@usuhs.edu (J.R. Duncan).

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also confound the relationship between exposure status and serologic immunity in the setting of variable vaccine availability, evolving vaccination recommendations, and decreasing exposure to wild-type VZV since the introduction of the varicella vaccine. Therefore, data on subjects' sex, HBGA expression, and year of birth were included in the analysis. Furthermore, data on the number of varicella vaccines received and the time elapsed between last varicella vaccine dose and serologic outcome determination were included in the model of waning immunity following varicella vaccine administration.

2.6. Statistical analysis

Descriptive epidemiological information was determined by stratification of the two exposure types. Continuous variables were analyzed using unpaired two sample Student's *t*-tests, and categorical variables were analyzed using Pearson's chi-square tests.

Risk ratios were computed to compare the long-term seroprevalence following vaccine administration to that of natural infection, and chi-square tests or Fischer exact tests with 5% two-sided significance levels were used to determine statistical significance, as appropriate for the covariate pattern. Effect modification was evaluated through stratification by sex, HBGA expression, and birth cohort. The Cochran-Mantel-Haenszel test was used to evaluate the presence of effect modification, and stratified results were presented where there was heterogeneity of risk ratios across strata.

For those in the vaccine exposure group, logistic regression was used to evaluate long-term seroprevalence based on the time elapsed since the last varicella vaccine dose. The dependent variable for the logistic regression model was varicella seropositivity. Independent variables included time elapsed since last vaccination dose, year of birth, sex, HBGA expression, and number of varicella vaccines received. Where the linearity assumption was reasonably met, covariates were modeled as continuous variables. Multiplex flow immunoassay-adjusted herd immunity thresholds were derived using the methods described by Plans [29] for determining enzyme immunoassay-based herd immunity thresholds, using the following equation:

$$p_c = I_c S_e + [(1 - I_c)(1 - S_p)]$$

For this equation, p_c is the critical prevalence for herd immunity, I_c is the accepted herd immunity threshold, S_e is the sensitivity of the test, and S_p is the specificity of the test. A varicella transmissibility factor of 7.32 was used to compute the accepted herd immunity threshold [30]. Duration of protective immunity following vaccine administration was estimated by comparing model-predicted values to these threshold estimates.

For all statistical tests used, two-tailed statistical significance was evaluated using an alpha of 0.05. Statistical analyses were performed using STATA/IC v13.1 for Windows.

3. Results

3.1. Descriptive epidemiology

Of the 15,210 recruits with a childhood immunization record in ASIMS, varicella exposure status was ascertained for 10,174 recruits (Table 1). A slight majority (52.3%) of included recruits had a documented history of chickenpox, with the remainder having received at least one varicella vaccination in childhood. The mean year of birth was significantly different between these two exposure groups ($p < 0.0001$), with vaccine recipients born a mean difference of three years after those with a history of chickenpox. The chickenpox and vaccine exposure groups were similar with respect to sex and HBGA expression ($p = 0.144$ and $p = 0.781$, respectively), but they were significantly different when stratified by year of birth ($p < 0.001$). Sensitivity analysis was performed to evaluate the effects of including subjects who had both history of chickenpox and received vaccine ($n = 352$, 90.9% seropositive), and all resulting descriptive statistics and measures of effect were similar when these recruits were included in the chickenpox exposure group.

3.2. Relative immunogenicity

Overall, 72.4% of vaccine recipients had a positive titer to VZV, compared to 95.4% of those with a history of chickenpox disease (Table 2). Among the vaccinated cohort, 46% had received only one vaccine dose, and seroprevalence was similar regardless of number of vaccine doses received ($p = 0.0710$). Varicella seropositivity was significantly lower in vaccine recipients compared to those with a history of chickenpox (RR = 0.76 [95% CI: 0.75–0.77]). These findings were homogeneous when stratified by sex and HBGA expression ($p = 0.2483$ and $p = 0.1774$, respectively). However, there was significant heterogeneity of relative immunogenicity when stratified by birth cohort ($p < 0.0001$), with varicella vaccination being least immunogenic compared to chickenpox for the birth cohort born after 1995 (RR = 0.69 [95% CI: 0.62–0.77]). Because of this heterogeneity, results from this study should be

Table 1
Comparison of demographic and clinical characteristics by exposure group.

	Chickenpox	Vaccine	Total	p-value[a]
Number of subjects	5323 (52.3%)	4851 (47.6%)	10,174	
Year of birth, Mean (SD)	1990 (2.9)	1993 (2.8)	1991 (3.4)	<0.001
Sex, n (%)				
Male	4009 (75.3)	3593 (74.1)	7602 (74.7)	
Female	1313 (24.7)	1258 (25.9)	2571 (25.3)	0.144
Histo-blood group antigen, n (%)				
A	1742 (37.0)	1657 (36.9)	3399 (36.9)	
B	583 (12.4)	535 (11.9)	1118 (12.2)	
AB	168 (3.6)	174 (3.9)	342 (3.7)	
O	2210 (47.0)	2127 (47.3)	4337 (47.2)	0.781
Year of birth, n (%)				
<1986	165 (3.1)	45 (1.0)	211 (2.1)	
1986–1990	2580 (48.5)	823 (17.0)	3403 (33.5)	
1991–1995	2462 (46.2)	3085 (63.6)	5547 (54.5)	
1996+	116 (2.2)	893 (18.4)	1009 (9.9)	<0.001

[a] Two-sample *t*-test for year of birth; chi-square test for sex, histo-blood group antigen, and year of birth strata.

Table 2
Relative immunogenicity of the varicella vaccine compared to chickenpox, for the overall cohort and stratified by immunogenic variable.

	Number of subjects	(+) Titers to VZV	Risk ratio [95% CI]	p-value[a]
Overall				
Vaccine only (pooled)	4802	72.4%	0.76 [0.75–0.77]	<0.0001
1 dose	2299	71.2%	0.75 [0.73–0.77]	<0.0001
2+ doses	2505	73.5%	0.77 [0.75–0.79]	<0.0001
Chickenpox	5253	95.4%	1.0 [reference]	–
Total	10,055	84.4%	–	–
Subgroup analysis				
Sex				
Male	7521	84.1%	0.75 [0.74–0.77]	
Female	2533	85.3%	0.77 [0.75–0.80]	0.2483
Histo-blood group antigen				
A	3383	82.8%	0.76 [0.73–0.78]	
B	1112	84.3%	0.76 [0.72–0.81]	
AB	340	79.4%	0.67 [0.59–0.75]	
O	4321	83.9%	0.74 [0.72–0.77]	0.1774
Year of birth				
<1986	492	94.9%	0.84 [0.72–0.98]	
1986–1990	5687	94.1%	0.91 [0.89–0.93]	
1991–1995	7614	82.3%	0.78 [0.76–0.80]	
1996+	1236	57.6%	0.69 [0.62–0.77]	<0.0001

[a] Chi-square test for overall cohort, Mantel-Haenszel test for homogeneity when stratified by subgroup.

interpreted by birth cohort rather than using the aforementioned pooled estimate of relative immunogenicity.

The relative immunogenicity conferred by both varicella vaccine and chickenpox disease declines with successive birth year, although the decline is more precipitous with the vaccine only cohort (Fig. 1). Varicella seroprevalence remains at or above levels estimated to provide herd immunity among those with a history of chickenpox disease, regardless of birth year, while seroprevalence fails to achieve herd immunity thresholds for vaccine recipients born after 1993.

3.3. Multivariate modeling of waning immunity

Of the 4802 recruits who received the varicella vaccine in childhood, 4584 (95.4%) received the varicella vaccine in accordance with standard US practices and with at least three weeks lapsing between vaccine administration and titer measurement. These subjects were included in the logistic regression model of waning immunity following varicella vaccination. Among these vaccine recipients, seroprevalence fell below estimated levels required for herd immunity when more than four years had elapsed since the last varicella vaccine dose (Fig. 2).

The odds of a positive varicella titer decreased by 8% for each successive year that elapsed since administration of the last vaccine dose, after adjusting for year of birth, number of vaccines received, sex, and HBGA expression (adjusted OR = 0.92 [$p < 0.001$]) (Table 3). The covariate-adjusted odds of a positive varicella titer decreased by 21% with each successive year of birth (adjusted OR = 0.79 [$p < 0.001$]). Modeling the interaction between year of birth and time elapsed since last vaccine dose did not improve the predictive value of the model. Compared to vaccine recipients who only received one varicella vaccine dose, the unadjusted odds of a positive varicella titer increased when subjects received two (OR = 1.22 [$p = 0.003$]) or three (OR = 2.92 [$p = 0.005$]) vaccine doses, but this relationship did not remain statistically significant after covariate adjustment. Sex did not significantly affect varicella seropositivity in either the crude or adjusted models.

Among the vaccine recipients included in this model, an additional 284 subjects had unknown HBGA expression. Sensitivity analysis was performed to evaluate the effects of excluding subjects with missing HBGA data, and resulting adjusted measures of effect for all variables included in the model were similar after excluding those with missing HBGA data. Subjects with type AB blood had 32% lower covariate-adjusted odds of a positive varicella titer compared to those with type A blood (adjusted OR = 0.68 [$p = 0.033$]). There was no significant difference in the covariate-adjusted odds of a positive varicella titer for those with type B or type O blood compared to those with type A blood. There was no statistically significant interaction between HBGA expression and any of the other covariates included in this model.

4. Discussion

This study demonstrates that the varicella vaccine produces shorter-lived seropositivity, as compared with natural infection, and the relative seropositivity decreases with later birth cohorts. With the declining incidence of chickenpox since the introduction of the varicella vaccine in the United States in 1995 [2,3], the decreasing seropositivity among younger birth cohorts may be due to reduced natural immunity boosting from exposure to wild-type VZV. Despite vaccination in accordance with ACIP recommendations, 15.6% of this study cohort were found to have no serologic evidence of varicella immunity. Although serostatus may underestimate true immunity among vaccinated individuals, the relationship found in this study between seropositivity and time elapsed since last varicella vaccination suggests that vaccinated populations previously unexposed to wild-type VZV may be at increased risk for varicella outbreaks. Clinical and public health personnel in these settings may benefit from access to VZV antibody assays that can reliably predict immunity secondary to chickenpox disease and varicella vaccination—assays which currently are not commercially available.

Among vaccine recipients with no history of chickenpox disease, year of birth and time elapsed since last vaccine dose are the most important predictors of varicella seropositivity. Since seroprevalence may fall below herd immunity thresholds four years after vaccination, additional varicella booster vaccinations may be required to maintain herd immunity in congregate settings, such as schools and military training sites, and for women of child-bearing age to minimize the risk of congenital varicella syndrome and neonatal transmission.

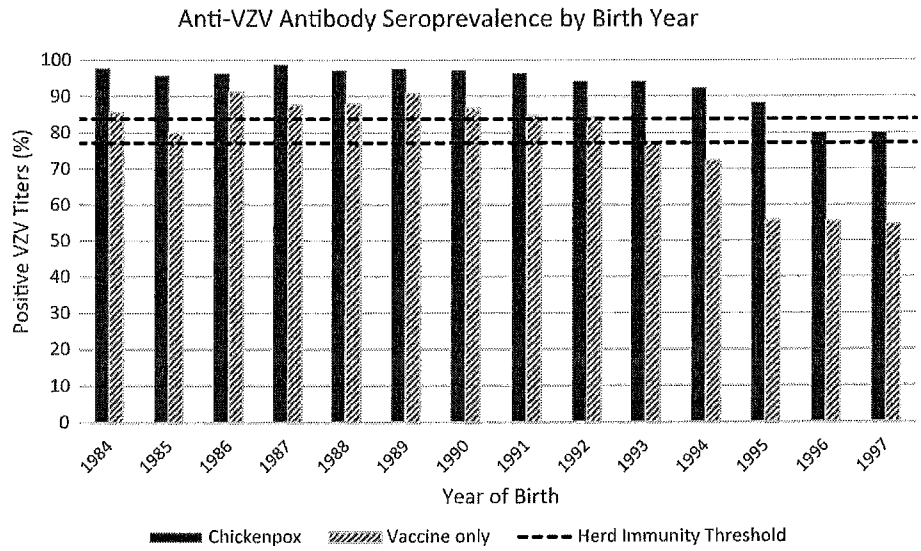

Fig. 1. Anti-VZV antibody seroprevalence by birth year. Dashed lines represent the estimated threshold to provide herd immunity, adjusted for the sensitivity and specificity of the multiplex flow immunoassay used to measure varicella titers.

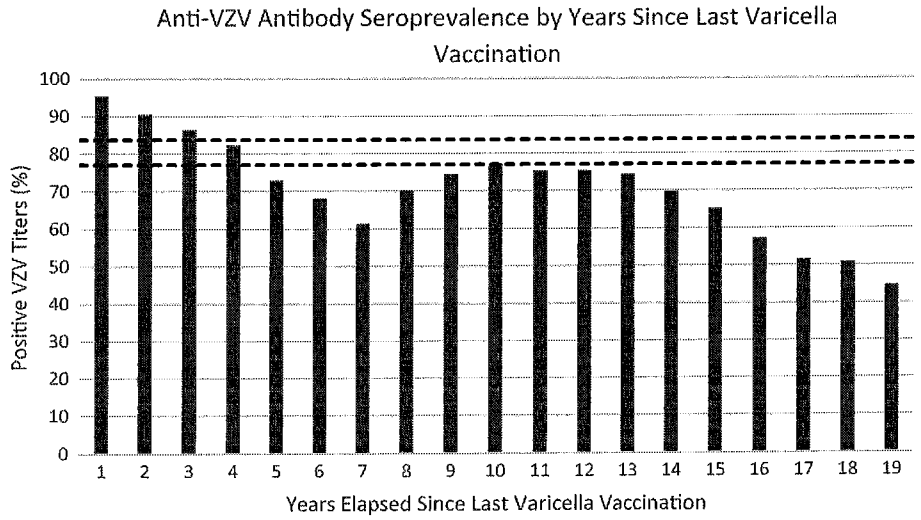

Fig. 2. Anti-VZV antibody seroprevalence in vaccine recipients by years elapsed since last varicella vaccine dose, rounded to the nearest year. Dashed lines represent the estimated threshold needed to maintain herd immunity, adjusted for the sensitivity and specificity of the multiplex flow immunoassay used to measure varicella titers.

While sex has been previously reported to modify the effects of influenza vaccine immunogenicity [26], sex was not shown in this study to affect either the relative immunogenicity of the varicella vaccine or the duration of seropositivity following varicella vaccine administration. Histo-blood group antigens are thought to affect vaccine and viral immunogenicity, especially among enteric pathogens [27,28,31–33], and the relationship between HBGAs and immunogenicity to varicella vaccine has not been previously described. The significant association identified in this study may warrant further research.

4.1. Strengths and limitations

The most significant strengths of this study were the large cohort size permitting subgroup analyses and the database's longitudinal nature with accurate serologic outcomes. Additionally, this study has good internal validity as the study cohort is composed of former military dependents, of similar socioeconomic status with assured access to reliable medical care. The only significant difference between the vaccinated and disease exposure groups was their year of birth. As a condition of entry into military service, all members of this cohort are free of immunocompromising conditions at the time of serologic outcome determination. In addition, this large cohort of young adult military recruits is sufficiently diverse to be generalizable to other US populations.

This study also has several limitations. First, given the sensitivity of the immunoassay used to assess serostatus, some false negatives were likely. Outcome misclassification would be non-differential with respect to exposure status, however, thus biasing results toward the null. While herd immunity threshold estimates were adjusted for the test characteristics of the assay [29], further studies are needed to assess the longevity of anti-VZV antibodies post-vaccination using more sensitive measures of seroimmunity. Second, since dates of chickenpox disease were unknown, the dataset did not permit characterization of waning immunity following a history of disease. Third, although the study incorporated several important covariates, other variables that may influence vaccine immunogenicity (e.g., genetic factors [34,35]) were unavailable.

Table 3
Multivariate logistic regression model characterizing waning immunity in varicella vaccine recipients.

	Positive VZV titer n = 3271	Negative VZV titer n = 1313	Crude OR [95% CI][a]	Adjusted OR [95% CI][b]
Years since last vaccine dose, mean (SD)[c]	7.9 (5.0)	10.0 (5.1)	0.92 [0.91–0.93][e]	0.92 [0.90–0.93][e]
Year of birth, mean (SD)[d]	1992 (2.6)	1994 (2.2)	0.77 [0.75–0.80][e]	0.79 [0.77–0.82][e]
Number of varicella vaccines received, n (%)				
1	1456 (44.5)	654 (49.8)	1.0 [reference]	1.0 [reference]
2	1763 (53.9)	651 (49.6)	1.22 [1.07–1.38][e]	0.81 [0.65–1.01]
3	52 (1.6)	8 (0.6)	2.92 [1.38–6.18][e]	1.86 [0.85–4.11]
Sex, n (%)				
Male	2397 (73.3)	997 (75.9)	1.0 [reference]	1.0 [reference]
Female	874 (26.7)	316 (24.1)	1.15 [0.99–1.33]	1.02 [0.86–1.19]
Histo-blood group antigen, n (%)				
A	1117 (37.1)	474 (36.9)	1.0 [reference]	1.0 [reference]
B	370 (12.3)	145 (11.3)	1.08 [0.87–1.35]	1.06 [0.85–1.34]
AB	106 (3.5)	62 (4.8)	0.73 [0.52–1.01]	0.68 [0.48–0.97][e]
O	1421 (47.1)	605 (7.0)	1.0 [0.86–1.15]	0.99 [0.85–1.15]

[a] Unadjusted odds of having a positive anti-VZV titer.
[b] Covariate-adjusted odds of having a positive anti-VZV titer. Co-variables include years since last varicella vaccine dose, year of birth, number of varicella vaccines received, sex, and histo-blood group antigen expression. Subjects with missing histo-blood group antigen data (n = 284) were censored from analysis.
[c] Modeled as a continuous variable. Odds ratios represent the odds of a positive anti-VZV titer for each successive year that has elapsed since the last vaccine dose.
[d] Modeled as a continuous variable. Odds ratios represent the odds of a positive anti-VZV titer for a given birth year cohort compared to the birth cohort of the previous birth year.
[e] $p < 0.05$.

Fourth, this study relied on parental report for history of chickenpox disease; verification was infeasible. Finally, this study relied on measures of humoral immunity, which may less reliably predict disease risk than measures of cell-mediated immunity [36–38]. However, serologic evidence of immunity is the international standard by which vaccine immunogenicity is currently measured [37–41], and although seronegativity and disease susceptibility are not identical, loss of detectible antibody is associated with an increased risk of breakthrough disease [42].

5. Conclusion

This study was conducted in a large population of US adults who have accessible, accurate electronic childhood immunization records, and who had varicella titers drawn in early adulthood. Seroprevalence as measured by multiplex flow immunoassay in the cohort of study subjects born after implementation of the US varicella vaccination program in 1995 is below the threshold estimated to provide herd immunity. Additional studies which reliably measure long-term immune response to vaccination are needed. If vaccination in accordance with the current US VZV vaccination schedule is inadequate to maintain herd immunity, young adults not previously exposed to wild-type VZV may be at increased risk for varicella outbreaks.

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Contributors

JRD designed the study, analyzed data, wrote and revised the manuscript. CTW, BJW, and AAC designed the study, wrote and revised the manuscript.

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Conflicts of interest

None.

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ORIGINAL ARTICLE

Outbreak of Varicella at a Day-Care Center despite Vaccination

Karin Galil, M.D., M.P.H., Brent Lee, M.D., M.P.H., Tara Strine, M.P.H., Claire Carraher, R.N., Andrew L. Baughman, Ph.D., M.P.H., Melinda Eaton, D.V.M., Jose Montero, M.D., and Jane Seward, M.B., B.S., M.P.H.et al.

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Abstract

BACKGROUND

In seven studies of the effectiveness of the varicella vaccine conducted since it was licensed, the effectiveness was 71 to 100 percent against disease of any severity and 95 to 100 percent against moderate and severe disease. We investigated an outbreak of varicella in a population of children with a high proportion of vaccinees who were attending a day-care center in a small community in New Hampshire.

METHODS

Using standardized questionnaires, we collected information about the children's medical and vaccination history from parents and health care providers. The analysis of the effectiveness of the vaccine and of risk factors for vaccine failure was restricted to children who were enrolled in the day-care center continuously during the outbreak and attended for one week or more and who were cared for in the building that represented the epicenter of the outbreak, since transmission was not documented in a second building.

RESULTS

Varicella developed in 25 of 88 children (28.4 percent) between December 1, 2000, and January 11, 2001. The index case occurred in a healthy child who had been vaccinated three years previously and who infected more than 50 percent of his classmates who had no history of varicella. The effectiveness of the vaccine was 44.0 percent (95 percent confidence interval, 6.9 to 66.3 percent) against disease of any severity and 86.0 percent (95 percent confidence interval, 38.7 to 96.8 percent) against moderate or severe disease. Children who had been vaccinated three years or more before the outbreak were at greater risk for vaccine failure than those who had been vaccinated more recently (relative risk, 2.6 [95 percent confidence interval, 1.3 to 5.3]).

CONCLUSIONS

In this outbreak, vaccination provided poor protection against varicella, although there was good protection against moderate or severe disease. A longer interval since vaccination was associated with an increased risk of vaccine failure. Breakthrough infections in vaccinated, healthy persons can be as infectious as varicella in unvaccinated persons.

Introduction

SINCE THE LICENSURE OF THE VARICELLA VACCINE IN 1995, SEVEN INVESTIGATIONS OF the effectiveness of the vaccine have been published.[1-6] Effectiveness ranged from 71 to 100 percent against varicella disease of any severity and 95 to 100 percent against moderate-to-severe varicella disease. Those findings are similar to results from prelicensure trials that used both the currently formulated vaccine and other formulations of the Oka-strain varicella virus to immunize children.[7-14] In the United States, there is clear evidence from three active surveillance sites that the incidence of varicella disease and the rate of related hospitalizations have declined by 80 percent since the introduction of the vaccine.[15]

Although the vaccine affords excellent protection against moderate and severe varicella, a modified form of varicella develops in some vaccinated persons after exposure to someone with an infectious case. By definition, these breakthrough cases occur more than 42 days after vaccination and are usually caused by wild-type virus. Rashes occurring less than 14 days after vaccination are typically due to previously incubating wild-type disease, and rashes occurring 14 to 42 days after vaccination may be attributable to either strain and can be classified only by molecular typing. Breakthrough disease is typically mild, with fewer lesions (usually fewer than 50),[11,12,16,17] complications, and systemic symptoms.[17,18] To date, there is no evidence of an increase over time in the rate of breakthrough disease that would suggest waning immunity after vaccination. We describe an outbreak of varicella at a day-care center in New Hampshire, where vaccination coverage in 2000 was 66 percent[19] — similar to the national average of 68 percent.

Methods

STUDY SETTING

The outbreak occurred in a private, licensed day-care center in a small community (population, 4500) near Concord, New Hampshire, that enrolled 92 children and employed 14 staff members. The day-care center was housed in two separate buildings approximately 20 yards apart. Building A housed children in the preschool, kindergarten, and before- and after-school programs, who mixed freely and shared common air flow. Building B, which housed the younger children, provided less opportunity for transmission, since children spent most of the day in one of four separate classrooms. Occasionally, parents with children in both buildings would have one child with them when they collected a sibling in the other building.

CASE DEFINITION

We defined a case of natural varicella as an illness involving a pruritic, maculopapulovesicular rash with no other apparent cause beginning from December 1, 2000, through January 11, 2001, in a child attending the day-care center who had not received varicella vaccine or who had been vaccinated less than 14 days before the onset of rash. Breakthrough disease was defined as varicella in a child who had been vaccinated more than 42 days before the onset of rash. Illness was classified as mild (fewer than 50 lesions without complications), moderate (51 to 500 lesions), or severe (more than 500 lesions or the occurrence of any serious complications, such as varicella pneumonitis, encephalitis, fever [temperature, >38.5°C] for five days, hospitalization, or death). Children were considered to have asthma if they had a reported history of asthma and were being treated with any asthma medication.

QUESTIONNAIRES

A self-administered questionnaire for parents was used to collect demographic information, medical and vaccination history, and information about health care providers for all children, as well as detailed information about illnesses and exposure to varicella outside the day-care center for children in whom illness involving a rash developed on or after November 1, 2000 (one month before the onset of the index case). We distributed questionnaires to health care providers to verify the child's health status, medication and vaccination history, and remote or recent history of varicella.

LABORATORY INVESTIGATIONS

An enzyme-linked immunosorbent assay testing for IgG antibody against whole-cell varicella–zoster virus in a filter-paper blood spot from a finger prick was offered for any child who did not have a history of either varicella disease or varicella vaccination. Children with rash were offered testing to determine whether varicella–zoster virus was present and to distinguish wild-type virus from the strain in the vaccine. Polymerase-chain-reaction analysis and restriction-fragment–length polymorphism analysis of varicella–zoster virus were performed with the use of the ORF62 primer pair according to the methods of Loparev et al.[20] and LaRussa et al.[21]

INVESTIGATION OF SECONDARY CASES AND SURVEILLANCE

The secondary attack rate from the index case was calculated as the proportion of susceptible, exposed children who were in Building A on at least one day when transmission could have occurred — that is, November 29 through December 1 — in whom varicella developed within 21 days after exposure. Enhanced

surveillance for illness involving rash was continued at the day-care center until one incubation period (21 days) after the last case was identified.

VACCINE LOTS, STORAGE, AND HANDLING

Lot numbers were verified with the manufacturer, and the expiration date for each lot of vaccine was obtained. Information from periodic evaluations of the storage and handling of vaccine in the offices of vaccine providers, which have been conducted by the health department since 1995, were reviewed, and further evaluations were undertaken as a result of the outbreak.

STATISTICAL ANALYSIS

Data were entered into Epi Info (version 6.04b, Centers for Disease Control and Prevention) and analyzed with the use of SAS software (release 8.0, SAS Institute). Fisher's exact test was used for the comparison of proportions, and the exact Wilcoxon rank-sum test was used for the comparison of medians. All P values are two-sided, with a significance level of $P<0.05$. Because the numbers were small, multivariate models were unstable, and their results are not presented.

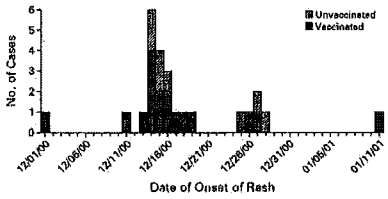
Vaccine effectiveness rates and 95 percent confidence intervals were calculated by the cohort method.[22] We excluded children with a history of varicella disease and children less than 12 months of age. We calculated the attack rates in unvaccinated children (ARU) and vaccinated children (ARV); we then estimated the percentage effectiveness of the vaccine as $[(ARU - ARV) \div ARU] \times 100$. The effectiveness of the vaccine against moderate-to-severe disease was calculated by classifying mild cases as noncases. Analysis of vaccine effectiveness and analysis of risk factors were limited to children in Building A (the epicenter of the outbreak) who were enrolled throughout the outbreak period and had attended day care for at least one week during the exposure period (from two days before the onset of rash in the index case — November 29, 2000 — to the date of the onset of rash in the last case — January 11, 2001). Children were considered to have been vaccinated if more than 42 days had elapsed since vaccination. Two children who were vaccinated on December 26, 2000, were classified as unvaccinated. Vaccination coverage at the start of the outbreak was defined as the proportion of children eligible for vaccination (at least 12 months of age and without a history of varicella) who had received the vaccine.

Results

STUDY SUBJECTS

Between December 1, 2000, and January 11, 2001, 92 children were enrolled in the day-care center. Four children attended for less than one week and were excluded from the analyses. Parents and health care providers returned questionnaires for 88 attendees (100 percent). Attendees ranged in age from 6 months to 8.9 years (median, 4.1 years) at the start of the outbreak; 61 of them (69.3 percent) were boys. At the start of the outbreak, vaccination coverage among children old enough to be eligible was 73.1 percent (49 of 67). Lot numbers of vaccine were verified for 93.9 percent of vaccinated children (46 of 49). Children were

Figure 1.



Cases of Varicella in a New Hampshire Day-Care Center in December 2000 and January 2001, According to the Vaccination Status of the Children and the Date of Onset of Rash.

The outbreak lasted from December 1, 2000, to January 11, 2001 (Figure 1). There were a total of 25 cases of varicella. Seventeen cases (68.0 percent) occurred in vaccinated children and eight cases (32.0 percent) in unvaccinated children at least 12 months of age. There were no cases in infants or children with a history of varicella disease. The median age of children with varicella was 4.4 years (range, 13 months to 7.6 years), and 19 of these children (76.0 percent) were boys (Table 1).

Table 2.

TABLE 2. CHARACTERISTICS OF ILLNESS AMONG VACCINATED CHILDREN WITH VARICELLA AND UNVACCINATED CHILDREN WITH VARICELLA.

CHARACTERISTIC	VACCINATED CHILDREN (N=17)	UNVACCINATED CHILDREN (N=8)	P VALUE*
Severity of illness — no. (%)			
Mild	15 (88.2)	2 (25.0)	0.004
Moderate or severe	2 (11.8)	6 (75.0)	
Subjective assessment of illness — no. (%)			
Did not appear ill	10 (58.8)	1 (12.5)	0.04
Mildly to severely ill	7 (41.2)	7 (87.5)	
Person who made the diagnosis — no. (%)			
Health care provider	10 (58.8)	4 (50.0)	1.0
Other	7 (41.2)	4 (50.0)	
Presence of fever — no. (%)†			
Yes	3 (30.0)	7 (87.5)	0.006
No	12 (80.0)	1 (13.6)	
No. of days until no new lesions erupted			
Median	2	5	<0.001
Range	0–12	4–12	
No. of days until rash crusted fully			
Median	4	9	0.02
Range	0–20	5–12	
No. of days sick in bed			
Median	0	1	0.06
Range	0–2	0–4	
No. of days unable to play			
Median	0	1	0.20
Range	0–4	0–4	
No. of days of day care missed			
Median	3	5	0.04
Range	0–7	3–14	
No. of days parent or guardian missed work to care for child			
Median	1	4	0.27
Range	0–7	0–14	

*P values for severity of illness, subjective assessment of illness, person who made the diagnosis, and presence of fever were calculated by a two-sided Fisher's exact test; all other P values were calculated by an exact, two-sided Wilcoxon rank-sum test.

†Data were missing for two vaccinated children.

Characteristics of Illness among Vaccinated Children with Varicella and Unvaccinated Children with Varicella.

Overall, 17 cases of varicella were mild, and 8 cases were moderate or severe. No child had a severe complication of varicella or required hospitalization. As compared with unvaccinated children, those who had been vaccinated had milder disease, had new lesions on fewer days, had rash that crusted more quickly, missed fewer days of day care, and were less likely to have fever (Table 2).

The outbreak began and was centered in Building A, where 19 cases (76.0 percent) occurred. Of the six cases in children in Building B, three occurred within one incubation period after the index case in Building A, and two other cases were more likely to have resulted from secondary household transmission than transmission at the day-care center — evidence that little if any transmission occurred in Building B. Both cases presumed to have resulted from household transmission occurred in younger siblings of patients who

attended day care in Building A, and in both cases, varicella developed 13 to 14 days after the onset of rash in the older sibling. In one family, transmission occurred between unvaccinated siblings, whereas in the other, it occurred between vaccinated siblings.

VACCINE EFFECTIVENESS

The cumulative attack rate among continuously enrolled, unvaccinated, susceptible children at least 12 months of age who had attended day care for at least one week was 85.7 percent (6 of 7) in Building A and 18.2 percent (2 of 11) in Building B. When corrected for transmission occurring outside of the building, the attack rate in Building B was 9.1 percent (1 of 11). The attack rate among vaccinated children in Building A was 48.0 percent (12 of 25). Vaccine effectiveness for children in Building A was 44.0 percent (95 percent confidence interval, 6.9 to 66.3 percent) against disease of any severity and 86.0 percent (95 percent confidence interval, 38.7 to 96.8 percent) against moderate-to-severe disease (which occurred in two vaccinated and four unvaccinated children in Building A).

RISK FACTORS FOR VACCINE FAILURE

Table 3.

TABLE 3. RISK FACTORS FOR FAILURE OF VARICELLA VACCINE AMONG VACCINATED CHILDREN IN BUILDING A CONTINUOUSLY ENROLLED AND IN ATTENDANCE FOR AT LEAST ONE WEEK DURING THE VARICELLA OUTBREAK.

VARIABLE	CHILDREN WITH VARICELLA (N=12)	CHILDREN WITHOUT VARICELLA (N=13)	P VALUE*
Age at start of outbreak — mo			
Median	54.0	53.7	0.73
Mean	57.3	56.6	
Sex — no. (%)			
Male	8 (66.7)	7 (53.8)	0.69
Female	4 (33.3)	6 (46.2)	
Age at vaccination			
<14 mo — no. (%)	2 (16.7)	1 (7.7)	0.59
≥14 mo — no. (%)	10 (83.3)	12 (92.3)	
Median — mo	18.4	24.7	0.04
Mean — mo	21.8	32.2	
Time since vaccination			
<36 mo — no. (%)	6 (50.0)	12 (92.3)	0.03
≥36 mo — no. (%)	6 (50.0)	1 (7.7)	
Median — mo	35.7	29.0	0.02
Mean — mo	35.5	24.5	
Asthma — no. (%)	1 (8.3)	2 (15.4)	1.0

*P values for age at the start of the outbreak, median age at vaccination, and median time since vaccination were calculated by an exact, two-sided Wilcoxon rank-sum test. All other P values were calculated by a two-sided Fisher's exact test.

Risk Factors for Failure of Varicella Vaccine among Vaccinated Children in Building A Continuously Enrolled and in Attendance for at Least One Week during the Varicella Outbreak.

Two continuous variables — time since vaccination and age at vaccination — were associated with the risk of vaccine failure (Table 3). Children vaccinated three or more years before the start of the outbreak had more than twice the risk of disease found among those vaccinated within three years before the outbreak (relative risk, 2.6 [95 percent confidence interval, 1.3 to 5.3]). Age at vaccination did not remain significantly associated with vaccine failure when it was dichotomized into vaccination at less than 14 months of age and vaccination at older ages (P=0.59).

LABORATORY ANALYSIS

Two cases were confirmed by laboratory testing, and the remainder were epidemiologically linked. Wild-type varicella was cultured from an unvaccinated child in Building A with an onset of rash on December 25, 2000, and wild-type varicella was detected by polymerase-chain-reaction analysis of a papule from the vaccinated child in Building B who had the last case in the outbreak.

RELIABILITY OF THE ABSENCE OF A HISTORY OF VARICELLA

Seven children who did not have varicella were reported by parents to be susceptible to it. All four whose parents agreed to serologic testing were seronegative, including the only child in Building A whose history suggested susceptibility but in whom varicella did not develop.

STORAGE AND HANDLING OF VACCINE

Periodic evaluation of the storage and handling of vaccine in the offices of vaccine providers, conducted by the state health department since the licensure of the vaccine, did not identify substantial problems. The vaccine is distributed directly from the manufacturer to the clinics and offices that provide vaccination without reliance on redistribution centers.

Discussion

In this outbreak, the effectiveness of the varicella vaccine was 44 percent against disease of any severity and 86 percent against moderate and severe disease — significantly lower than that found in any previous investigation. We found an increased risk of vaccine failure among children vaccinated three or more years previously. The index patient was a healthy vaccinated child who infected more than 50 percent of susceptible classmates, indicating that breakthrough disease can be highly infectious.

The reasons for the poor performance of the vaccine are not apparent. The thermolability of the vaccine raised concern about lapses in vaccine storage and handling, although no substantial deficiencies were detected over time or after the outbreak was recognized. Furthermore, we found no clustering of breakthrough cases according to the lot number of the vaccine used, the year of vaccination, the clinic, or the medical provider that might suggest the use of an ineffective lot of vaccine or problems with storage, handling, or administration.

Univariate analysis identified time since vaccination as a risk factor for vaccine failure. Children vaccinated three or more years before the start of the outbreak had a risk of breakthrough disease that was more than twice as high as that among children vaccinated more recently. A younger age at vaccination (less than 14 months), which has previously been identified as a risk factor,[5,6] was not associated with an increased risk of vaccine failure, nor did we detect an association with asthma or other coexisting conditions. However, in Building A, only three children were vaccinated at less than 14 months of age, three children with varicella had asthma, and two children with varicella had coexisting conditions (one had IgA deficiency, and the other had epilepsy).

We used data from Building A to estimate vaccine effectiveness and determine risk factors for vaccine failure. The cumulative attack rate among unvaccinated, susceptible children 12 months of age or older was approximately 86 percent in Building A and 9 percent in Building B. The low attack rate in Building B suggests that most children in this building were never exposed to varicella. Since the calculation of vaccine effectiveness relies on an assumption of equal exposure to disease, data from children in Building B were excluded from the calculations. The cases in children in Building B probably resulted from contact that occurred outside the classroom or from household exposure.

This outbreak began with disease in a vaccinated child who infected more than half his classmates who had no history of varicella. His attendance at day care for two days before the onset of rash and only brief attendance on the morning on which his rash erupted suggest that transmission occurred by airborne spread. Our findings also suggest that it is not possible to identify in advance persons who could be highly infectious were they to have breakthrough disease, a fact of particular concern in hospitals and other settings that rely on vaccine-derived immunity to protect against the acquisition and transmission of varicella. It is possible that vaccinated persons in whom a large number of vesicular lesions develop when they are exposed to a patient with an infectious case of varicella or herpes zoster may be more infectious than persons who have nonvesicular lesions or fewer lesions overall, although this question requires further study.

There are a number of limitations to our study. This outbreak and others that come to the attention of public health officials may represent extreme situations and result in underestimates of the effectiveness of the vaccine.[23] Even so, the upper confidence limit of our estimate was below the lower limit of the expected range of effectiveness for varicella vaccine. We relied on reports of rash by parents or physicians for diagnosis in most cases, a method that may have resulted in an overestimate or underestimate of the effectiveness of the vaccine. Incorrect diagnosis of conditions commonly mistaken for breakthrough disease (such as insect bites or enteroviral infections) could have falsely lowered the estimate of vaccine effectiveness, although these conditions occur infrequently in midwinter. Subtle presentations of breakthrough disease that were not clinically recognized could have led to a false elevation of the estimate of vaccine effectiveness. Finally, the small number of children in the day-care center limited our ability to explore the independent effects of the time since vaccination and the age at vaccination in multivariate analyses.

Although policy cannot be established on the basis of one outbreak, the findings in this investigation raise concern that the current vaccination strategy may not protect all children adequately. Further investigations are needed to define more clearly the range of effectiveness of the vaccine and risk factors for vaccine failure. In a number of prelicensure studies, persons who did not have an adequate immune response after vaccination were revaccinated,[13] excluded from the analysis of vaccine efficacy,[10,14] or analyzed separately,[11] potentially inflating the estimate by the removal of persons who had primary vaccine failure.

Although the vaccine provided suboptimal protection against varicella in this outbreak, it provided robust protection against moderate and severe varicella and has reduced the incidence of varicella dramatically in

the United States.[14] Given the approximately 11,000 hospitalizations[24] and 100 deaths[25] due to varicella that occurred annually in the era before vaccination, vaccination remains the most effective strategy for protecting children and adults against illness and death due to varicella.

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Author Affiliations

From the Centers for Disease Control and Prevention, Atlanta (K.G., B.L., T.S., A.L.B., J.S.); the New Hampshire Department of Health and Human Services, Concord (C.C., J.M.); and the College of Veterinary Medicine, Washington State University, Pullman (M.E.).

Address reprint requests to Dr. Galil at 65 Hayden Ave., Lexington, MA 02421, or at karin.galil@cubist.com.

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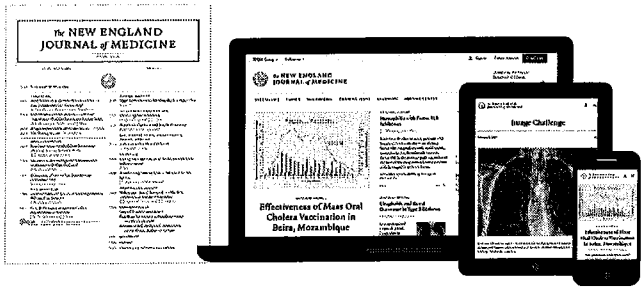

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Vaccine-Preventable Diseases Surveillance Summary
Wisconsin, 2018

This report summarizes information on vaccine-preventable diseases among Wisconsin residents reported to the Wisconsin Department of Health Services through the Wisconsin Electronic Disease Surveillance System.

Measles

Trends

After measles vaccine was introduced in 1963, the number of measles cases decreased significantly in Wisconsin (Figure 1) and in the United States.

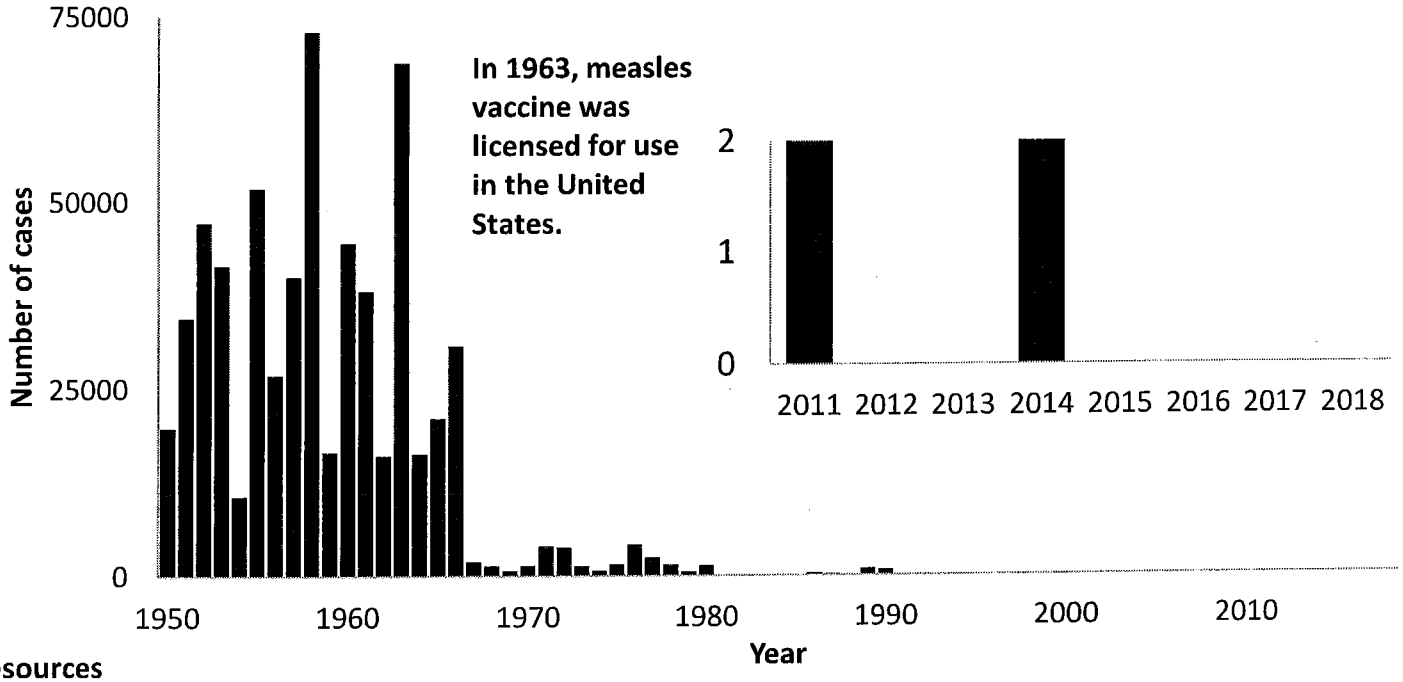
2018

During 2018, no measles cases were reported among Wisconsin residents.

Summary

Although measles is now rare in Wisconsin, measles is still common in many parts of the world, including some countries in Europe, Asia, and Africa. Travelers continue to bring measles to the United States and to Wisconsin. In 2018, the US experienced 17 outbreaks of measles and 372 confirmed cases. In 2014, two Wisconsin residents were infected with measles. One was believed to be infected at a U.S. airport while waiting for a domestic flight, and the other had travelled internationally. It is important to prevent measles because measles spreads quickly among unvaccinated people and can cause serious illness and complications, especially for children. The measles vaccine is the most effective method for preventing measles.

Figure 1. Number of reported confirmed measles cases, by year, Wisconsin, 1950–2018



Resources

DHS measles page: https://www.dhs.wisconsin.gov/immunization/measles.htm
United States cases and outbreaks: https://www.cdc.gov/measles/cases-outbreaks.html
Measles vaccine: https://www.cdc.gov/measles/vaccination.html

Mumps

Trends

After the live attenuated mumps vaccine was introduced in 1967, the number of mumps cases decreased significantly in Wisconsin (Figure 2) and in the United States. However, cases and outbreaks still occur.

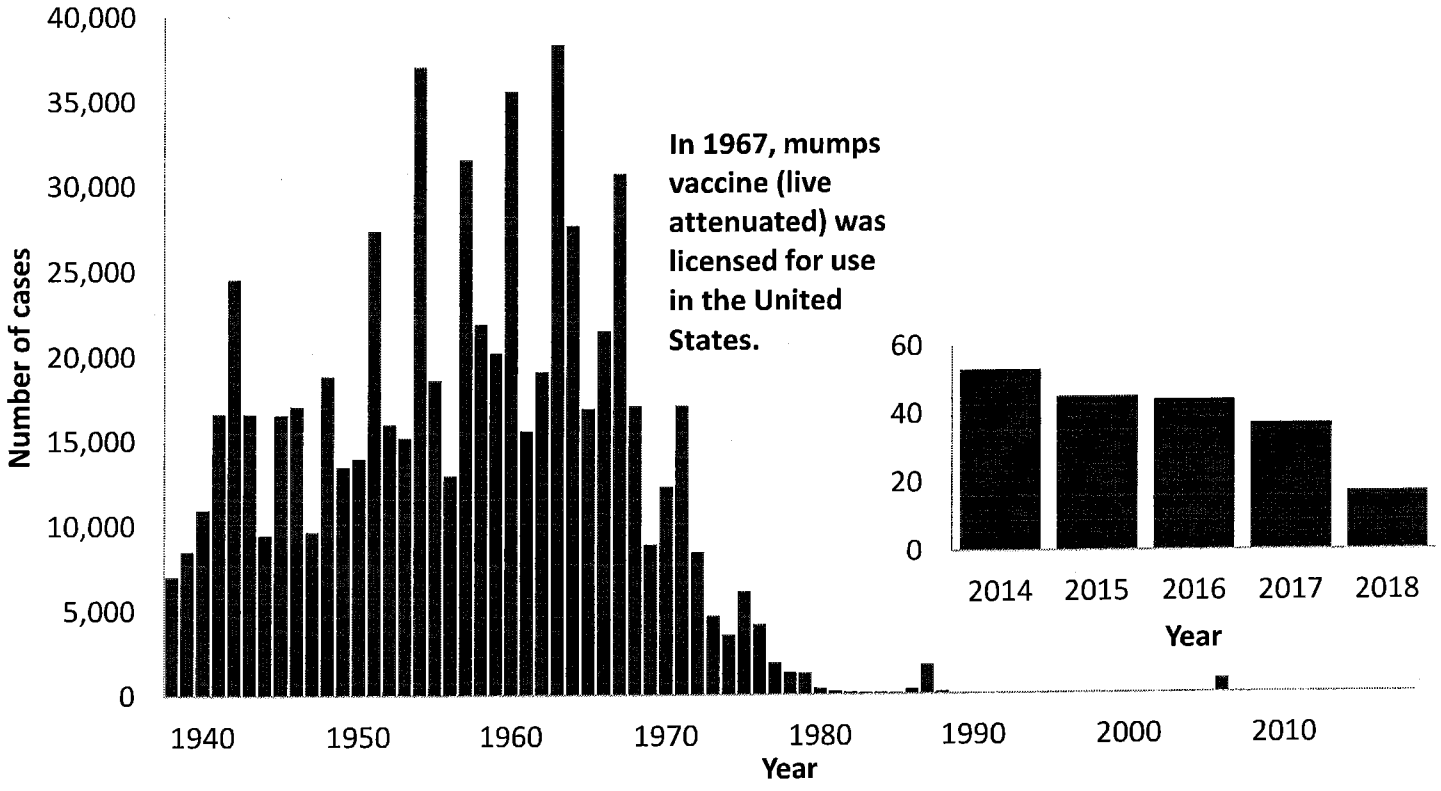
2018

- During 2018, 17 confirmed mumps cases were reported among Wisconsin residents of 6 counties.
- Ages ranged from 10 to 59 years (median age: 31 years) with 35% female and 65% male.
- Vaccination status was known for 10 (59%) cases. Of cases with known vaccination status, 90% had received two doses and 10% had received one dose.
- Three cases (18%) were associated with two outbreaks.
- Two (12%) cases were known to have had contact with another mumps case.
- One (6%) had a recent history of travel outside of Wisconsin. None travelled internationally.

Summary

Cases and outbreaks of mumps continue to occur in Wisconsin and the United States, often among young adults in close-contact settings. It is important to prevent mumps because mumps can cause serious complications, especially among adults. The mumps vaccine prevents most mumps cases and complications.

Figure 2. Number of reported confirmed mumps cases, by year, Wisconsin, 1950–2018



Resources

Update on recent Wisconsin mumps cases: https://www.dhs.wisconsin.gov/immunization/mumps-report.pdf
DHS mumps page: https://www.dhs.wisconsin.gov/immunization/mumps.htm
United States cases and outbreaks: https://www.cdc.gov/mumps/outbreaks.html
Mumps vaccine: https://www.cdc.gov/mumps/vaccination.html

Pertussis (Whooping Cough)

Trends

After whole cell pertussis vaccine was introduced during the 1940s, the number of pertussis cases decreased significantly in Wisconsin (Figure 3) and in the United States. During the 1990s a new diagnostic test (PCR) was introduced that allowed for more pertussis cases to be detected and reported. Additionally, during the 1990s whole cell vaccine was replaced by acellular pertussis vaccine (DTaP) and recent studies indicate it provides a shorter duration of protection from pertussis than whole cell vaccine. A booster vaccine, Tdap, was introduced in 2006. Recent studies indicate the protection from Tdap vaccination wanes in 3-4 years.

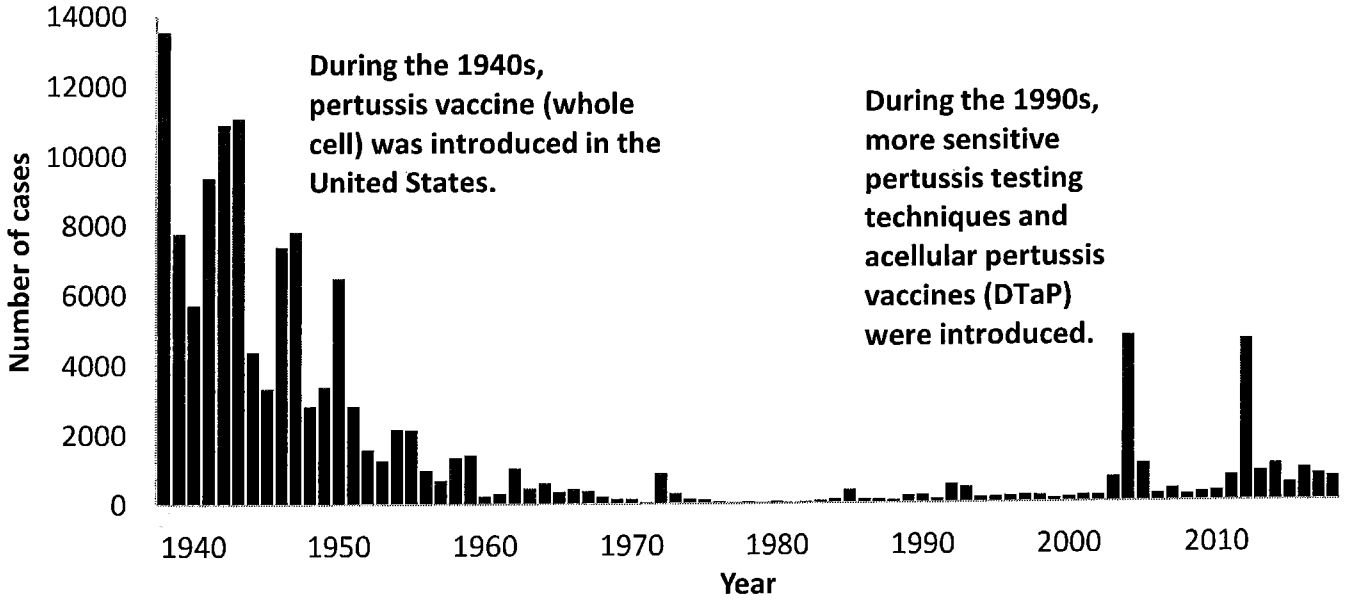
2018

- During 2018, 388 confirmed and 312 probable pertussis cases were reported among Wisconsin residents in 60 counties. Persons with pertussis ranged in age from <1 month to 88 years (median age: 1 year).
- Thirty-five (5%) cases were hospitalized.
- Among cases aged 2 months through 10 years, 55% were up to date with pertussis vaccinations, and 79% of cases aged 11–18 years had previously received the Tdap booster dose.
- For the full 2018 annual summary: https://www.dhs.wisconsin.gov/publications/p01263-18.pdf

Summary

Pertussis continues to affect people of all ages in Wisconsin and the United States. Large and small outbreaks continue to occur. Infants too young to be fully vaccinated are at highest risk of pertussis and its serious complications, including death. Routine vaccination with pertussis vaccine is the most effective method for preventing pertussis. Newborn infants are best protected from pertussis when their mothers are vaccinated with Tdap vaccine during the third trimester of pregnancy. These infants are born with passive protection from pertussis.

Figure 3. Number of reported confirmed pertussis cases, by year, Wisconsin, 1938–2018



Resources

Update on recent Wisconsin pertussis cases: https://www.dhs.wisconsin.gov/immunization/pert-report.pdf
DHS annual surveillance summaries: pertussis page | 2017| 2016 | 2015 | 2014 | 2013 | 2012
National pertussis trends: https://www.cdc.gov/pertussis/surv-reporting.html
Pertussis vaccine: https://www.cdc.gov/vaccines/vpd/pertussis/index.html

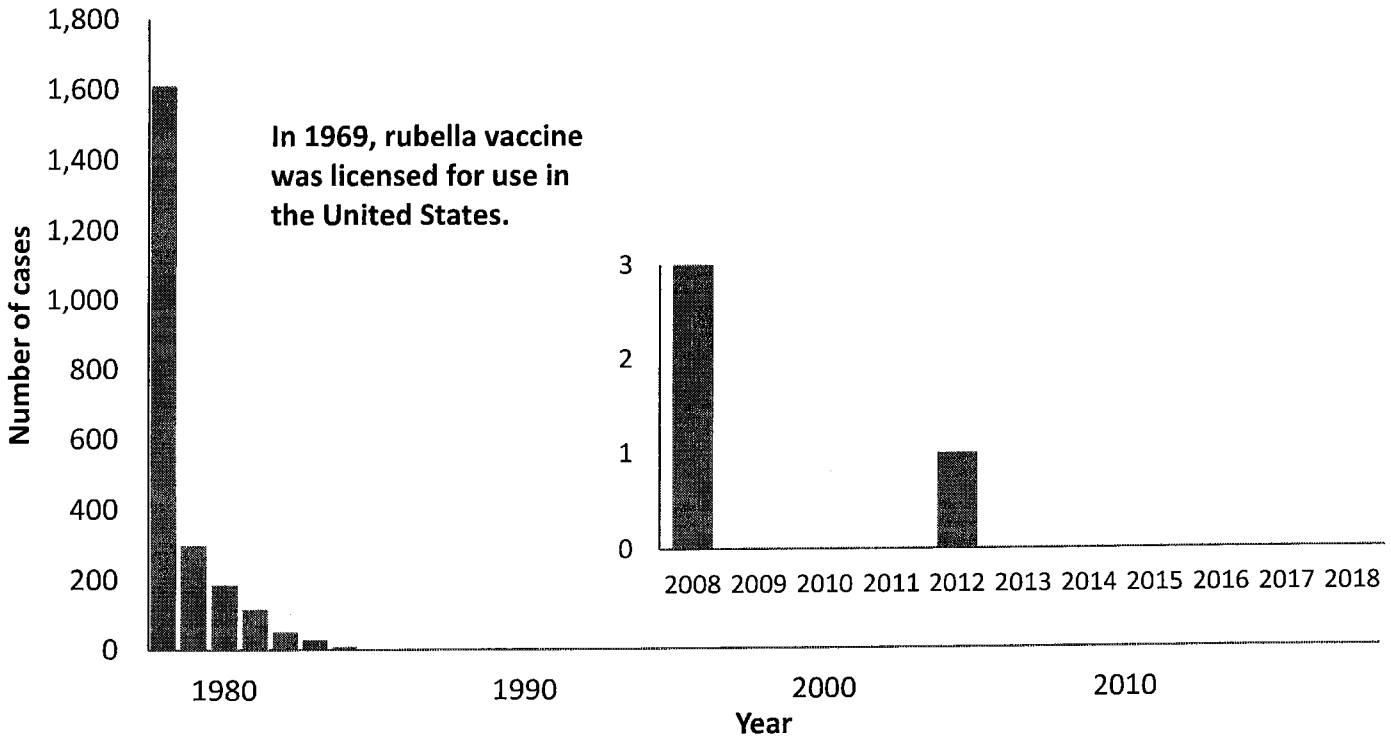
Rubella

Trends
After rubella vaccine was introduced in 1969, the number of rubella cases decreased significantly in Wisconsin (Figure 4) and in the United States.

2018
During 2018, no rubella cases were reported among Wisconsin residents.

Summary
Rubella is no longer constantly present in the United States. However, because rubella is still common in many parts of the world, including Southeast Asia, Africa, and the Eastern Mediterranean region, travelers to affected areas can bring rubella to the United States and Wisconsin. For example, in 2012 a Wisconsin resident developed rubella after having contact with family members who recently arrived from an affected country. It is important to prevent rubella because rubella can cause serious complications, and women who are infected with rubella during pregnancy are at risk for miscarriage, stillbirth, and of having a baby with severe birth defects, a condition known as congenital rubella syndrome. Vaccination with rubella vaccine is the most effective method for preventing rubella. To prevent congenital rubella syndrome, before women become pregnant, they should be vaccinated with rubella vaccine.

Figure 4. Number of reported confirmed rubella cases, by year, Wisconsin, 1978–2018



Resources
DHS rubella page: https://www.dhs.wisconsin.gov/immunization/rubella.htm
CDC rubella page: https://www.cdc.gov/rubella/about/index.html
Congenital rubella syndrome: https://www.cdc.gov/rubella/pregnancy.html
Information for travelers: https://wwwnc.cdc.gov/travel/diseases/rubella
Rubella vaccine: https://www.cdc.gov/vaccines/vpd/mmr/public/index.html

Tetanus

Trends

After tetanus vaccine was introduced for routine childhood vaccination during the late 1940s, the number of tetanus cases decreased steadily in Wisconsin (Figure 5) and in the United States.

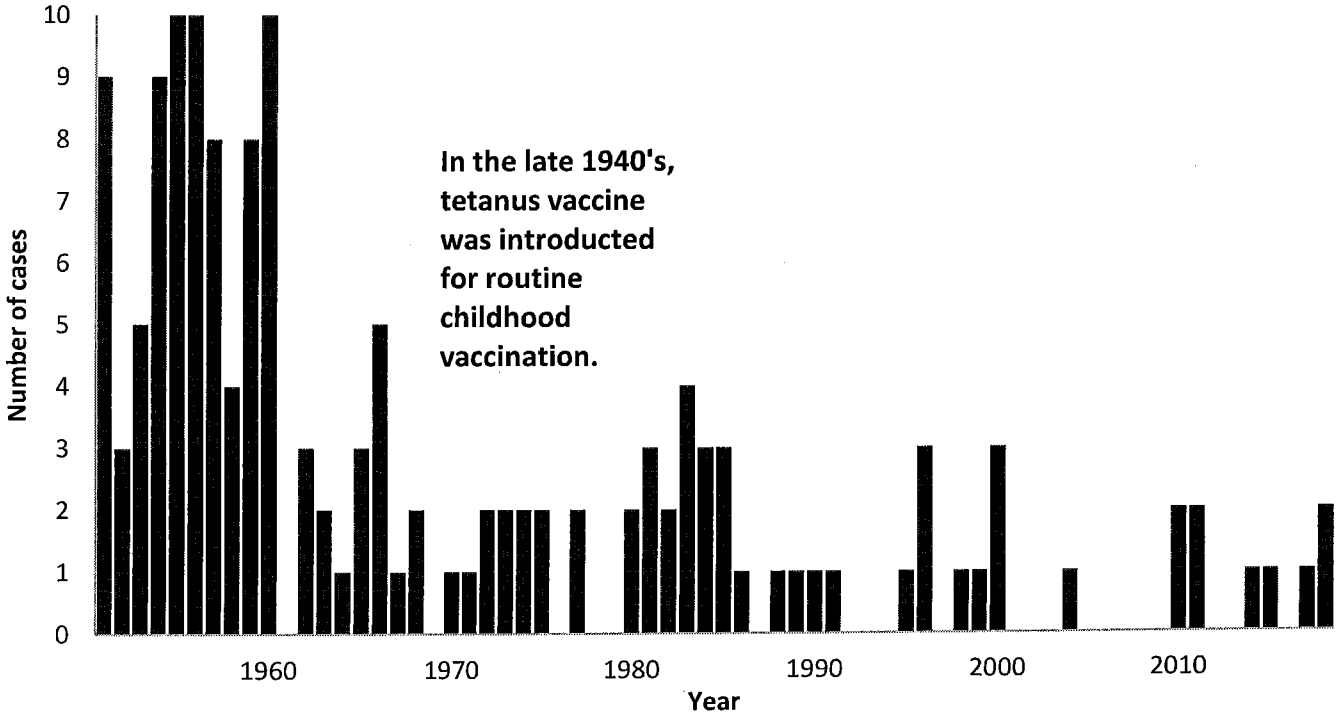
2017

During 2018, there were two tetanus cases reported among Wisconsin residents.

Summary

Because the bacteria that cause tetanus live in soil, unvaccinated people and people overdue for a tetanus booster shot are at risk for tetanus when they have a contaminated wound or other breaks in the skin. Tetanus cases continue to occur among Wisconsin residents. For example, in 2015 an unvaccinated Wisconsin child was diagnosed with tetanus requiring hospitalization for 33 days (including 15 days in intensive care). Preventing tetanus is important because tetanus can cause severe symptoms and complications, including breathing difficulty that can lead to death. Vaccination with tetanus vaccine is the most effective method for preventing tetanus.

Figure 5. Number of reported tetanus cases, by year, Wisconsin, 1951–2018



Resources

DHS tetanus page: https://www.dhs.wisconsin.gov/immunization/tetanus.htm
CDC tetanus page: https://www.cdc.gov/tetanus/about/index.html
Tetanus vaccine: https://www.cdc.gov/tetanus/vaccination.html

Diphtheria

Trends

After use of diphtheria vaccine became routine and widespread during the late 1940s, the number of diphtheria cases decreased significantly in Wisconsin (Figure 6) and in the United States.

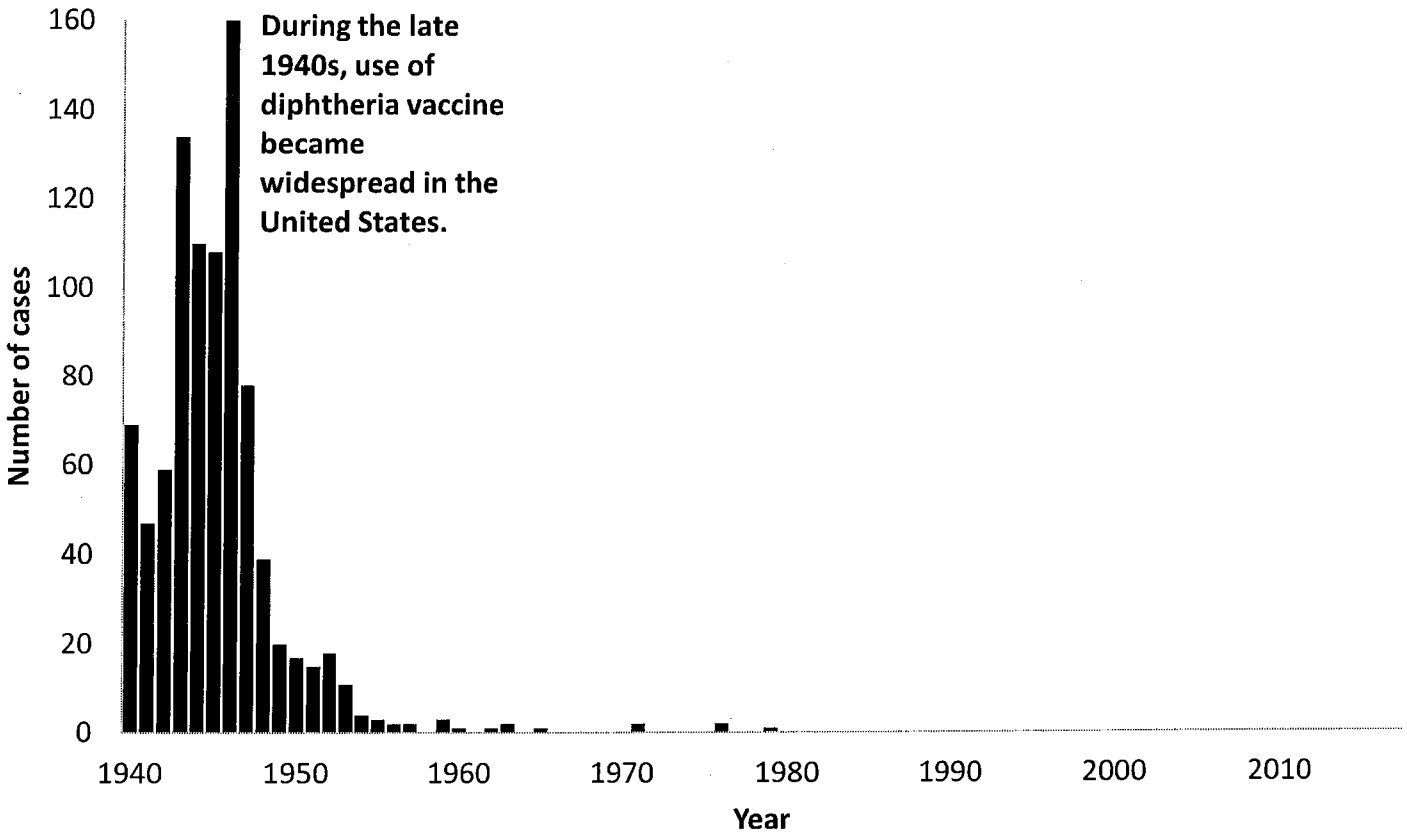
2018

During 2018, no diphtheria cases were reported among Wisconsin residents.

Summary

Diphtheria infection is rare in the United States, but continues to occur in many developing countries in Asia, the Middle East, Eastern Europe, Haiti, and the Dominican Republic. Travelers to these areas are at risk of diphtheria infection. It is important to prevent diphtheria because diphtheria can cause serious complications, including death. Vaccination with diphtheria vaccine is the most effective method for preventing diphtheria.

Figure 6. Number of reported confirmed diphtheria cases, by year, Wisconsin, 1943–2018



Resources

DHS diphtheria page: https://www.dhs.wisconsin.gov/immunization/diphtheria.htm
CDC diphtheria page: https://www.cdc.gov/diphtheria/index.html
Information for travelers: https://wwwnc.cdc.gov/travel/diseases/diphtheria
Diphtheria vaccine: https://www.cdc.gov/diphtheria/vaccination.html

Polio

Trends

After the first polio vaccine was introduced in 1955, the number of polio cases decreased significantly in Wisconsin (Figure 7) and in the United States.

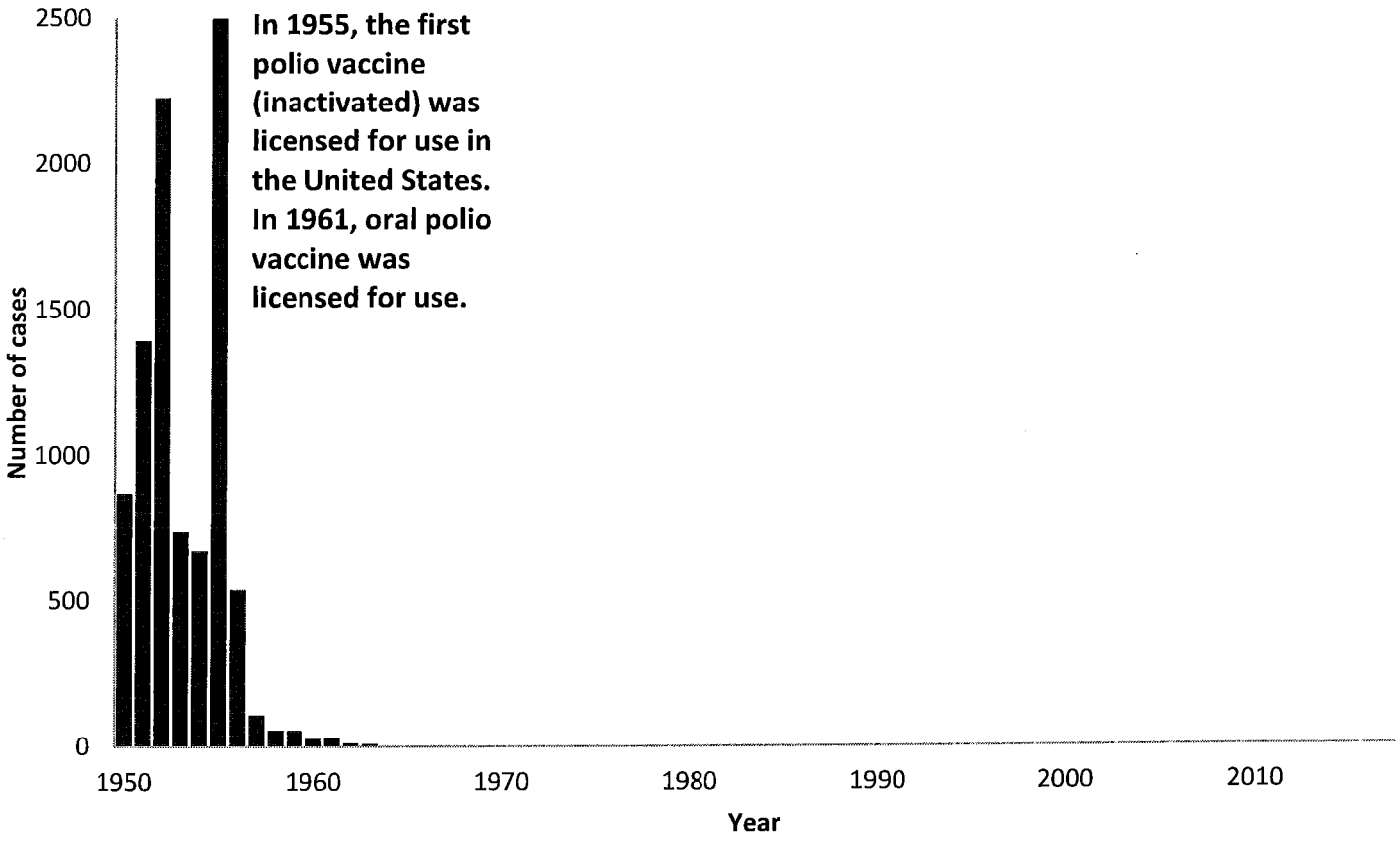
2018

During 2018, no polio cases were reported among Wisconsin residents.

Summary

Health officials from around the globe have been working intently to eradicate polio. Only a few countries remain where polio cases continue to occur, but travelers can and have spread polio to other previously polio-free countries. Travelers to affected areas, including some parts of Africa and Asia, are at risk for polio. Vaccination with polio vaccine prevents polio, its serious complications, and reduces polio transmission to other countries.

Figure 7. Number of reported confirmed polio cases, by year, Wisconsin, 1950–2018



Resources

DHS polio page: https://www.dhs.wisconsin.gov/immunization/polio.htm
CDC polio page: https://www.cdc.gov/polio/about/index.htm
Information for travelers: https://wwwnc.cdc.gov/travel/diseases/poliomyelitis
Polio vaccine: https://www.cdc.gov/vaccines/vpd/polio/index.html

Varicella (Chickenpox)

Trends

After varicella vaccine was introduced in 1995, the number of varicella cases decreased significantly in Wisconsin (Figure 8) and in the United States. In response to outbreaks among vaccinated children, in 2006 a second dose of varicella vaccine was routinely recommended. Varicella cases and outbreaks continue to occur. Surveillance for varicella is challenging because most cases are not laboratory confirmed and the clinical presentation of varicella can be confused with other rash illnesses.

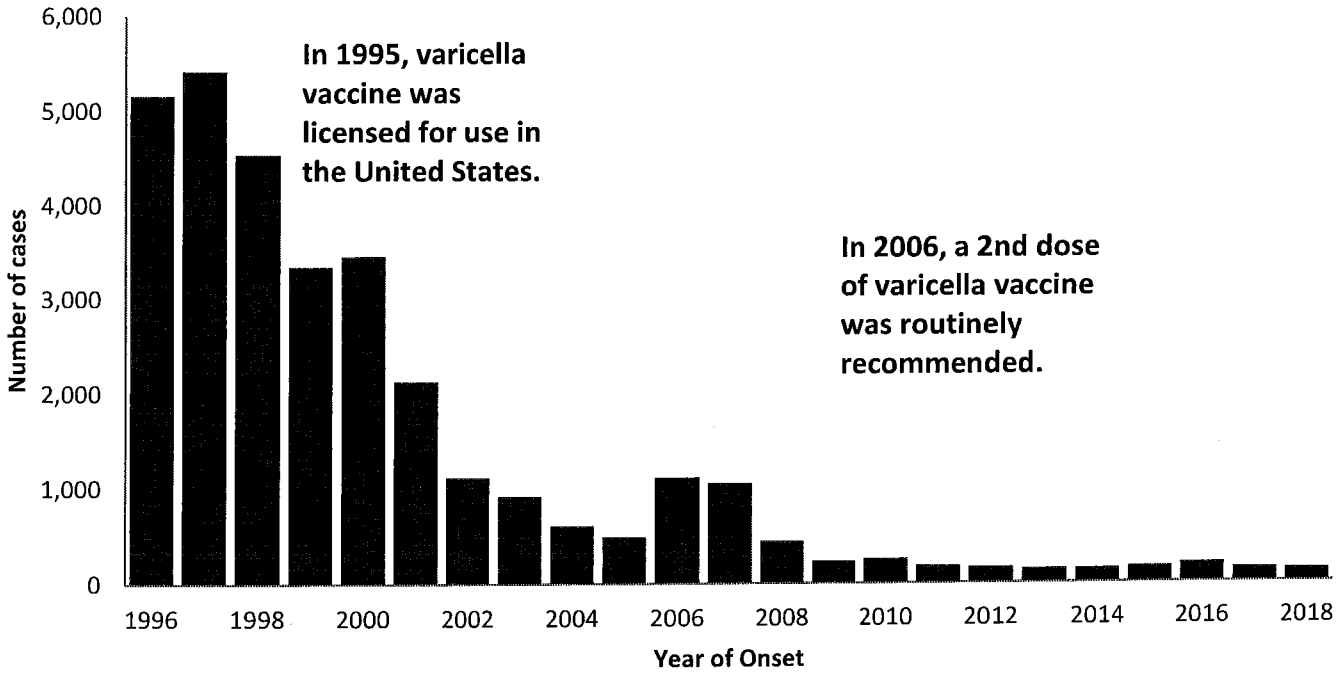
2018

- During 2018, 136 confirmed and 154 probable varicella cases were reported among Wisconsin residents.
- Cases of varicella were reported from 56 of Wisconsin's 72 counties.
- Persons with varicella ranged in age from 2 months to 90 years (median age: 6 years).
- Seven (2%) persons with varicella were hospitalized, including one infant.
- Among persons with varicella aged 1–3 years, 65% were up to date for age and had received one dose of varicella vaccine. Among persons with varicella aged 4–18 years, 56% were up to date for age and had received two doses of varicella vaccine, 10% had received one dose of varicella vaccine, and 32% had not been vaccinated with varicella vaccine.

Summary

Varicella continues to affect persons of all ages in Wisconsin and the United States. It is important to prevent varicella because varicella can result in serious complications, especially for infants, adolescents, adults, pregnant women, and immunocompromised persons. Vaccination with varicella vaccine prevents most varicella cases and complications.

Figure 8. Number of reported confirmed varicella cases, by year, Wisconsin, 1996–2018



Resources

DHS varicella page: https://www.dhs.wisconsin.gov/immunization/varicella.htm
CDC varicella page: https://www.cdc.gov/chickenpox/index.html
Varicella vaccine: https://www.cdc.gov/chickenpox/vaccination.html

Notes

Additional Resources

Vaccination rates for Wisconsin: https://www.dhs.wisconsin.gov/immunization/data.htm
Vaccine-preventable diseases by year: https://www.dhs.wisconsin.gov/immunization/vpdsbyyear.pdf
Recommended vaccination schedules
Children: https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html
Adults: https://www.cdc.gov/vaccines/schedules/hcp/adult.html

References

Epidemiology and Prevention of Vaccine-Preventable Diseases: The Pink Book:
https://www.cdc.gov/vaccines/pubs/pinkbook/index.html
Measles transmission at a domestic terminal gate in an international airport – United States, January 2014:
https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6350a9.htm

Data Source

The diseases included in this report have significant public health impact and are required by law to be reported to the local health officer when suspected in a Wisconsin resident. This information is collected and reported to DHS through the Wisconsin Electronic Disease Surveillance System:
https://www.dhs.wisconsin.gov/wiphin/wedss.htm
More information on disease reporting: https://www.dhs.wisconsin.gov/disease/diseasereporting.htm

Limitations

Monitoring trends in disease occurrence depends on complete and consistent reporting of diseases to DHS through the Wisconsin Electronic Disease Surveillance System. This report only includes information on the cases that were reported to WDPH. Therefore, to the extent that diseases are underreported or misreported to WDPH, the results depicted in this report might differ from the true burden of these diseases in Wisconsin.

Abbreviations

CDC: Centers for Disease Control and Prevention
DTaP: diphtheria, tetanus, acellular pertussis vaccine
Tdap: tetanus, diphtheria, acellular pertussis vaccine
DHS: Wisconsin Division of Public Health

Wisconsin Immunization Program, Division of Public Health
Wisconsin Department of Health Services
P-02321 (April 2019)

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VARIVAX safely and effectively. See full prescribing information for VARIVAX.

VARIVAX®
Varicella Virus Vaccine Live
Suspension for subcutaneous injection
Initial U.S. Approval: 1995

----------INDICATIONS AND USAGE----------
VARIVAX is a vaccine indicated for active immunization for the prevention of varicella in individuals 12 months of age and older. (1)

---------- DOSAGE AND ADMINISTRATION ----------
Each dose is approximately 0.5 mL after reconstitution and is administered by subcutaneous injection. (2.1)
Children (12 months to 12 years of age)
- If a second dose is administered, there should be a minimum interval of 3 months between doses. (2.1)

Adolescents (≥13 years of age) and Adults
- Two doses, to be administered a minimum of 4 weeks apart. (2.1)

---------- DOSAGE FORMS AND STRENGTHS ----------
Suspension for injection (approximately 0.5-mL dose) supplied as a lyophilized vaccine to be reconstituted using the accompanying sterile diluent. (2.2, 3, 16)

----------CONTRAINDICATIONS----------
- History of severe allergic reaction to any component of the vaccine (including neomycin and gelatin) or to a previous dose of varicella vaccine. (4.1)
- Primary or acquired immunodeficiency states. (4.2)
- Any febrile illness or active infection, including untreated tuberculosis. (4.3)
- Pregnancy. (4.4, 8.1, 17)

---------- WARNINGS AND PRECAUTIONS----------
- Evaluate individuals for immune competence prior to administration of VARIVAX if there is a family history of congenital or hereditary immunodeficiency. (5.2)
- Avoid contact with high-risk individuals susceptible to varicella because of possible transmission of varicella vaccine virus. (5.4)
- Defer vaccination for at least 5 months following blood or plasma transfusions, or administration of immune globulins (IG). (5.5, 7.2)
- Avoid use of salicylates for 6 weeks following administration of VARIVAX to children and adolescents. (5.6, 7.1)

---------- ADVERSE REACTIONS ----------
- Frequently reported (≥10%) adverse reactions in children ages 1 to 12 years include:
  - fever ≥102.0°F (38.9°C) oral: 14.7%
  - injection-site complaints: 19.3% (6.1)
- Frequently reported (≥10%) adverse reactions in adolescents and adults ages 13 years and older include:
  - fever ≥100.0°F (37.8°C) oral: 10.2%
  - injection-site complaints: 24.4% (6.1)
- Other reported adverse reactions in all age groups include:
  - varicella-like rash (injection site)
  - varicella-like rash (generalized) (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

----------DRUG INTERACTIONS----------
- Reye syndrome has been reported in children and adolescents following the use of salicylates during wild-type varicella infection. (5.6, 7.1)
- Passively acquired antibodies from blood, plasma, or immunoglobulin potentially may inhibit the response to varicella vaccination. (5.5, 7.2)
- Tuberculin skin testing may be performed before VARIVAX is administered or on the same day, or six weeks following vaccination with VARIVAX. (7.3)

---------- USE IN SPECIFIC POPULATIONS ----------
Pregnancy: Do not administer VARIVAX to females who are pregnant. Pregnancy should be avoided for 3 months following vaccination with VARIVAX. (4.4, 8.1, 17)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: XX/XXXX

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

VARIVAX® is a vaccine indicated for active immunization for the prevention of varicella in individuals 12 months of age and older.

2 DOSAGE AND ADMINISTRATION

Subcutaneous administration only

2.1 Recommended Dose and Schedule

VARIVAX is administered as an approximately 0.5-mL dose by subcutaneous injection into the outer aspect of the upper arm (deltoid region) or the anterolateral thigh.

Do not administer this product intravascularly or intramuscularly.

Children (12 months to 12 years of age)

If a second dose is administered, there should be a minimum interval of 3 months between doses *[see Clinical Studies (14.1)]*.

Adolescents (≥13 years of age) and Adults

Two doses of vaccine, to be administered with a minimum interval of 4 weeks between doses *[see Clinical Studies (14.1)]*.

2.2 Reconstitution Instructions

When reconstituting the vaccine, use only the sterile diluent supplied with VARIVAX. The sterile diluent does not contain preservatives or other anti-viral substances which might inactivate the vaccine virus.

Use a sterile syringe free of preservatives, antiseptics, and detergents for each reconstitution and injection of VARIVAX because these substances may inactivate the vaccine virus.

To reconstitute the vaccine, first withdraw the total volume of provided sterile diluent into a syringe. Inject all of the withdrawn diluent into the vial of lyophilized vaccine and gently agitate to mix thoroughly. Withdraw the entire contents into the syringe and inject the total volume (approximately 0.5 mL) of reconstituted vaccine subcutaneously. VARIVAX, when reconstituted, is a clear, colorless to pale yellow liquid.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use the product if particulates are present or if it appears discolored.

To minimize loss of potency, administer VARIVAX immediately after reconstitution. Discard if reconstituted vaccine is not used within 30 minutes.

Do not freeze reconstituted vaccine.

Do not combine VARIVAX with any other vaccine through reconstitution or mixing.

3 DOSAGE FORMS AND STRENGTHS

VARIVAX is a suspension for injection supplied as a single-dose vial of lyophilized vaccine to be reconstituted using the accompanying sterile diluent *[see Dosage and Administration (2.2) and How Supplied/Storage and Handling (16)]*. A single dose after reconstitution is approximately 0.5 mL.

4 CONTRAINDICATIONS

4.1 Severe Allergic Reaction

Do not administer VARIVAX to individuals with a history of anaphylactic or severe allergic reaction to any component of the vaccine (including neomycin and gelatin) or to a previous dose of a varicella-containing vaccine.

4.2 Immunosuppression

Do not administer VARIVAX to immunosuppressed or immunodeficient individuals, including those with a history of primary or acquired immunodeficiency states, leukemia, lymphoma or other malignant

neoplasms affecting the bone marrow or lymphatic system, AIDS, or other clinical manifestations of infection with human immunodeficiency virus (HIV).

Do not administer VARIVAX to individuals receiving immunosuppressive therapy, including individuals receiving immunosuppressive doses of corticosteroids.

VARIVAX is a live, attenuated varicella-zoster vaccine (VZV) and may cause an extensive vaccine-associated rash or disseminated disease in individuals who are immunosuppressed or immunodeficient.

4.3 Concurrent Illness

Do not administer VARIVAX to individuals with any febrile illness. Do not administer VARIVAX to individuals with active, untreated tuberculosis.

4.4 Pregnancy

Do not administer VARIVAX to individuals who are pregnant because the effects of the vaccine on fetal development are unknown. Wild-type varicella (natural infection) is known to sometimes cause fetal harm. If vaccination of postpubertal females is undertaken, pregnancy should be avoided for three months following vaccination *[see Use in Specific Populations (8.1) and Patient Counseling Information (17)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Allergic Reactions

Adequate treatment provisions, including epinephrine injection (1:1000), should be available for immediate use should anaphylaxis occur.

5.2 Family History of Immunodeficiency

Vaccination should be deferred in patients with a family history of congenital or hereditary immunodeficiency until the patient's immune status has been evaluated and the patient has been found to be immunocompetent.

5.3 Use in HIV-Infected Individuals

The Advisory Committee for Immunization Practices (ACIP) has recommendations on the use of varicella vaccine in HIV-infected individuals.

5.4 Risk of Vaccine Virus Transmission

Post-marketing experience suggests that transmission of vaccine virus may occur rarely between healthy vaccinees who develop a varicella-like rash and healthy susceptible contacts. Transmission of vaccine virus from a mother who did not develop a varicella-like rash to her newborn infant has been reported.

Due to the concern for transmission of vaccine virus, vaccine recipients should attempt to avoid whenever possible close association with susceptible high-risk individuals for up to six weeks following vaccination with VARIVAX. Susceptible high-risk individuals include:

- Immunocompromised individuals;
- Pregnant women without documented history of varicella or laboratory evidence of prior infection;
- Newborn infants of mothers without documented history of varicella or laboratory evidence of prior infection and all newborn infants born at <28 weeks gestation regardless of maternal varicella immunity.

5.5 Immune Globulins and Transfusions

Immunoglobulins should not be given concomitantly with VARIVAX. Vaccination should be deferred for at least 5 months following blood or plasma transfusions, or administration of immune globulin(s) {1}.

Following administration of VARIVAX, immune globulin(s) should not be given for 2 months thereafter unless its use outweighs the benefits of vaccination {1}. *[See Drug Interactions (7.2).]*

5.6 Salicylate Therapy

Avoid use of salicylates (aspirin) or salicylate-containing products in children and adolescents 12 months through 17 years of age for six weeks following vaccination with VARIVAX because of the association of Reye syndrome with aspirin therapy and wild-type varicella infection. *[See Drug Interactions (7.1).]*

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in clinical practice. Vaccine-related adverse reactions reported during clinical trials were assessed by the study investigators to be possibly, probably, or definitely vaccine-related and are summarized below.

In clinical trials {2-9}, VARIVAX was administered to over 11,000 healthy children, adolescents, and adults.

In a double-blind, placebo-controlled study among 914 healthy children and adolescents who were serologically confirmed to be susceptible to varicella, the only adverse reactions that occurred at a significantly ($p<0.05$) greater rate in vaccine recipients than in placebo recipients were pain and redness at the injection site {2}.

Children 1 to 12 Years of Age

One-Dose Regimen in Children

In clinical trials involving healthy children monitored for up to 42 days after a single dose of VARIVAX, the frequency of fever, injection-site complaints, or rashes were reported as shown in Table 1:

Table 1: Fever, Local Reactions, and Rashes (%) in Children 1 to 12 Years of Age 0 to 42 Days After Receipt of a Single Dose of VARIVAX

Reaction	N	% Experiencing Reaction	Peak Occurrence During Postvaccination Days
Fever ≥102.0°F (38.9°C) Oral	8827	14.7%	0 to 42
Injection-site complaints (pain/soreness, swelling and/or erythema, rash, pruritus, hematoma, induration, stiffness)	8916	19.3%	0 to 2
Varicella-like rash (injection site)	8916	3.4%	8 to 19
Median number of lesions		2	
Varicella-like rash (generalized)	8916	3.8%	5 to 26
Median number of lesions		5	

In addition, adverse events occurring at a rate of ≥1% are listed in decreasing order of frequency: upper respiratory illness, cough, irritability/nervousness, fatigue, disturbed sleep, diarrhea, loss of appetite, vomiting, otitis, diaper rash/contact rash, headache, teething, malaise, abdominal pain, other rash, nausea, eye complaints, chills, lymphadenopathy, myalgia, lower respiratory illness, allergic reactions (including allergic rash, hives), stiff neck, heat rash/prickly heat, arthralgia, eczema/dry skin/dermatitis, constipation, itching.

Pneumonitis has been reported rarely (<1%) in children vaccinated with VARIVAX.

Febrile seizures have occurred at a rate of <0.1% in children vaccinated with VARIVAX.

Two-Dose Regimen in Children

Nine hundred eighty-one (981) subjects in a clinical trial received 2 doses of VARIVAX 3 months apart and were actively followed for 42 days after each dose. The 2-dose regimen of varicella vaccine had a safety profile comparable to that of the 1-dose regimen. The overall incidence of injection-site clinical complaints (primarily erythema and swelling) observed in the first 4 days following vaccination was 25.4% Postdose 2 and 21.7% Postdose 1, whereas the overall incidence of systemic clinical complaints in the 42-day follow-up period was lower Postdose 2 (66.3%) than Postdose 1 (85.8%).

Adolescents (13 Years of Age and Older) and Adults

In clinical trials involving healthy adolescents and adults, the majority of whom received two doses of VARIVAX and were monitored for up to 42 days after any dose, the frequencies of fever, injection-site complaints, or rashes are shown in Table 2.

Table 2: Fever, Local Reactions, and Rashes (%) in Adolescents and Adults 0 to 42 Days After Receipt of VARIVAX

Reaction	N	% Post Dose 1	Peak Occurrence in Postvaccination Days	N	% Post Dose 2	Peak Occurrence in Postvaccination Days
Fever ≥100.0°F (37.8°C) Oral	1584	10.2%	14 to 27	956	9.5%	0 to 42
Injection-site complaints (soreness, erythema, swelling, rash, pruritus, pyrexia, hematoma, induration, numbness)	1606	24.4%	0 to 2	955	32.5%	0 to 2
Varicella-like rash (injection site)	1606	3%	6 to 20	955	1%	0 to 6
Median number of lesions		2			2	
Varicella-like rash (generalized)	1606	5.5%	7 to 21	955	0.9%	0 to 23
Median number of lesions		5			5.5	

In addition, adverse events reported at a rate of ≥1% are listed in decreasing order of frequency: upper respiratory illness, headache, fatigue, cough, myalgia, disturbed sleep, nausea, malaise, diarrhea, stiff neck, irritability/nervousness, lymphadenopathy, chills, eye complaints, abdominal pain, loss of appetite, arthralgia, otitis, itching, vomiting, other rashes, constipation, lower respiratory illness, allergic reactions (including allergic rash, hives), contact rash, cold/canker sore.

6.2 Post-Marketing Experience

Broad use of VARIVAX could reveal adverse events not observed in clinical trials.

The following additional adverse events, regardless of causality, have been reported during post-marketing use of VARIVAX:

Body as a Whole

Anaphylaxis (including anaphylactic shock) and related phenomena such as angioneurotic edema, facial edema, and peripheral edema.

Eye Disorders

Necrotizing retinitis (in immunocompromised individuals).

Hemic and Lymphatic System

Aplastic anemia; thrombocytopenia (including idiopathic thrombocytopenic purpura (ITP)).

Infections and Infestations

Varicella (vaccine strain).

Nervous/Psychiatric

Encephalitis; cerebrovascular accident; transverse myelitis; Guillain-Barré syndrome; Bell's palsy; ataxia; non-febrile seizures; aseptic meningitis; meningitis; dizziness; paresthesia.

Cases of encephalitis or meningitis caused by vaccine strain varicella virus have been reported in immunocompetent individuals previously vaccinated with VARIVAX months to years after vaccination. Reported cases were commonly associated with preceding or concurrent herpes zoster rash. *[See Clinical Pharmacology (12.2)].*

Respiratory

Pharyngitis; pneumonia/pneumonitis.

Skin

Stevens-Johnson syndrome; erythema multiforme; Henoch-Schönlein purpura; secondary bacterial infections of skin and soft tissue, including impetigo and cellulitis; herpes zoster.

7 DRUG INTERACTIONS

7.1 Salicylates

No cases of Reye syndrome have been observed following vaccination with VARIVAX. Vaccine recipients should avoid use of salicylates for 6 weeks after vaccination with VARIVAX, as Reye syndrome has been reported following the use of salicylates during wild-type varicella infection *[see Warnings and Precautions (5.6)].*

7.2 Immune Globulins and Transfusions

Blood, plasma, and immune globulins contain antibodies that may interfere with vaccine virus replication and decrease the immune response to VARIVAX. Vaccination should be deferred for at least 5 months following blood or plasma transfusions, or administration of immune globulin(s) {1}.

Following administration of VARIVAX, immune globulin(s) should not be given for 2 months thereafter unless its use outweighs the benefits of vaccination {1}. *[See Warnings and Precautions (5.5).]*

7.3 Tuberculin Skin Testing

Tuberculin skin testing, with tuberculin purified protein derivative (PPD), may be performed before VARIVAX is administered or on the same day, or at least 4 weeks following vaccination with VARIVAX, as other live virus vaccines may cause a temporary depression of tuberculin skin test sensitivity leading to false negative results.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

VARIVAX is contraindicated for use in pregnant women because the vaccine contains live, attenuated varicella virus, and it is known that wild-type varicella virus, if acquired during pregnancy, can cause congenital varicella syndrome *[see Contraindications (4.4) and Patient Counseling Information (17)]*. No increased risk for miscarriage, major birth defect or congenital varicella syndrome was observed in a pregnancy exposure registry that monitored outcomes after inadvertent use. There are no relevant animal data.

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4%, and 15% to 20%, respectively.

Human Data

A pregnancy exposure registry was maintained from 1995 to 2013 to monitor pregnancy and fetal outcomes following inadvertent administration of VARIVAX. The registry prospectively enrolled 1522 women who received a dose of VARIVAX during pregnancy or within three months prior to conception. After excluding elective terminations (n=60), ectopic pregnancies (n=1) and those lost to follow-up (n=556), there were 905 pregnancies with known outcomes. Of these 905 pregnancies, 271 (30%) were in women who were vaccinated within the three months prior to conception. Miscarriage was reported for 10% of pregnancies (95/905), and major birth defects were reported for 2.6% of live born infants (21/819). These rates of assessed outcomes were consistent with estimated background rates. None of the women who received VARIVAX vaccine delivered infants with abnormalities consistent with congenital varicella syndrome.

8.2 Lactation

Risk Summary

It is not known whether varicella vaccine virus is excreted in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VARIVAX, and any potential adverse effects on the breastfed child from VARIVAX or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

No clinical data are available on safety or efficacy of VARIVAX in children less than 12 months of age.

8.5 Geriatric Use

Clinical studies of VARIVAX did not include sufficient numbers of seronegative subjects aged 65 and over to determine whether they respond differently from younger subjects.

11 DESCRIPTION

VARIVAX [Varicella Virus Vaccine Live] is a preparation of the Oka/Merck strain of live, attenuated varicella virus. The virus was initially obtained from a child with wild-type varicella, then introduced into human embryonic lung cell cultures, adapted to and propagated in embryonic guinea pig cell cultures and finally propagated in human diploid cell cultures (WI-38). Further passage of the virus for varicella vaccine was performed at Merck Research Laboratories (MRL) in human diploid cell cultures (MRC-5) that were

free of adventitious agents. This live, attenuated varicella vaccine is a lyophilized preparation containing sucrose, phosphate, glutamate, and processed gelatin as stabilizers.

VARIVAX, when reconstituted as directed, is a sterile preparation for subcutaneous injection. Each approximately 0.5-mL dose contains a minimum of 1350 plaque-forming units (PFU) of Oka/Merck varicella virus when reconstituted and stored at room temperature for a maximum of 30 minutes. Each 0.5-mL dose also contains approximately 25 mg of sucrose, 12.5 mg hydrolyzed gelatin, 3.2 mg of sodium chloride, 0.5 mg of monosodium L-glutamate, 0.45 mg of sodium phosphate dibasic, 0.08 mg of potassium phosphate monobasic, and 0.08 mg of potassium chloride. The product also contains residual components of MRC-5 cells including DNA and protein and trace quantities of sodium phosphate monobasic, EDTA, neomycin and fetal bovine serum. The product contains no preservative.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

VARIVAX induces both cell-mediated and humoral immune responses to varicella-zoster virus. The relative contributions of humoral immunity and cell-mediated immunity to protection from varicella are unknown.

12.2 Pharmacodynamics

Transmission

In the placebo-controlled efficacy trial, transmission of vaccine virus was assessed in household settings (during the 8-week postvaccination period) in 416 susceptible placebo recipients who were household contacts of 445 vaccine recipients. Of the 416 placebo recipients, three developed varicella and seroconverted, nine reported a varicella-like rash and did not seroconvert, and six had no rash but seroconverted. If vaccine virus transmission occurred, it did so at a very low rate and possibly without recognizable clinical disease in contacts. These cases may represent either wild-type varicella from community contacts or a low incidence of transmission of vaccine virus from vaccinated contacts *[see Warnings and Precautions (5.4)]* {2,12}. Post-marketing experience suggests that transmission of vaccine virus may occur rarely between healthy vaccinees who develop a varicella-like rash and healthy susceptible contacts. Transmission of vaccine virus from a mother who did not develop a varicella-like rash to her newborn infant has also been reported.

Herpes Zoster

Overall, 9454 healthy children (12 months to 12 years of age) and 1648 adolescents and adults (13 years of age and older) have been vaccinated with VARIVAX in clinical trials. Eight cases of herpes zoster have been reported in children during 42,556 person-years of follow-up in clinical trials, resulting in a calculated incidence of at least 18.8 cases per 100,000 person-years. The completeness of this reporting has not been determined. One case of herpes zoster has been reported in the adolescent and adult age group during 5410 person-years of follow-up in clinical trials, resulting in a calculated incidence of 18.5 cases per 100,000 person-years. All 9 cases were mild and without sequelae. Two cultures (one child and one adult) obtained from vesicles were positive for wild-type VZV as confirmed by restriction endonuclease analysis {13}. The long-term effect of VARIVAX on the incidence of herpes zoster, particularly in those vaccinees exposed to wild-type varicella, is unknown at present.

In children, the reported rate of herpes zoster in vaccine recipients appears not to exceed that previously determined in a population-based study of healthy children who had experienced wild-type varicella {14}. The incidence of herpes zoster in adults who have had wild-type varicella infection is higher than that in children.

The vaccine virus (Oka/Merck strain) contained in VARIVAX may establish latency of varicella zoster virus in immunocompetent individuals, with the potential for later development of herpes zoster *[see Adverse Reactions (6.2)]*.

12.6 Duration of Protection

The duration of protection of VARIVAX is unknown; however, long-term efficacy studies have demonstrated continued protection up to 10 years after vaccination {15} *[see Clinical Studies (14.1)]*. A boost in antibody levels has been observed in vaccinees following exposure to wild-type varicella which could account for the apparent long-term protection after vaccination in these studies.

14 CLINICAL STUDIES

14.1 Clinical Efficacy

The protective efficacy of VARIVAX was established by: (1) a placebo-controlled, double-blind clinical trial, (2) comparing varicella rates in vaccinees versus historical controls, and (3) assessing protection from disease following household exposure.

Clinical Data in Children

One-Dose Regimen in Children

Although no placebo-controlled trial was carried out with VARIVAX using the current vaccine, a placebo-controlled trial was conducted using a formulation containing 17,000 PFU per dose {2,16}. In this trial, a single dose of VARIVAX protected 96 to 100% of children against varicella over a two-year period. The study enrolled healthy individuals 1 to 14 years of age (n=491 vaccine, n=465 placebo). In the first year, 8.5% of placebo recipients contracted varicella, while no vaccine recipient did, for a calculated protection rate of 100% during the first varicella season. In the second year, when only a subset of individuals agreed to remain in the blinded study (n=163 vaccine, n=161 placebo), 96% protective efficacy was calculated for the vaccine group as compared to placebo.

In early clinical trials, a total of 4240 children 1 to 12 years of age received 1000 to 1625 PFU of attenuated virus per dose of VARIVAX and have been followed for up to nine years post single-dose vaccination. In this group there was considerable variation in varicella rates among studies and study sites, and much of the reported data were acquired by passive follow-up. It was observed that 0.3 to 3.8% of vaccinees per year reported varicella (called breakthrough cases). This represents an approximate 83% (95% confidence interval [CI], 82%, 84%) decrease from the age-adjusted expected incidence rates in susceptible subjects over this same period {14}. In those who developed breakthrough varicella postvaccination, the majority experienced mild disease (median of the maximum number of lesions <50). In one study, a total of 47% (27/58) of breakthrough cases had <50 lesions compared with 8% (7/92) in unvaccinated individuals, and 7% (4/58) of breakthrough cases had >300 lesions compared with 50% (46/92) in unvaccinated individuals {17}.

Among a subset of vaccinees who were actively followed in these early trials for up to nine years postvaccination, 179 individuals had household exposure to varicella. There were no reports of breakthrough varicella in 84% (150/179) of exposed children, while 16% (29/179) reported a mild form of varicella (38% [11/29] of the cases with a maximum total number of <50 lesions; no individuals with >300 lesions). This represents an 81% reduction in the expected number of varicella cases utilizing the historical attack rate of 87% following household exposure to varicella in unvaccinated individuals in the calculation of efficacy.

In later clinical trials, a total of 1114 children 1 to 12 years of age received 2900 to 9000 PFU of attenuated virus per dose of VARIVAX and have been actively followed for up to 10 years post single-dose vaccination. It was observed that 0.2% to 2.3% of vaccinees per year reported breakthrough varicella for up to 10 years post single-dose vaccination. This represents an estimated efficacy of 94% (95% CI, 93%, 96%), compared with the age-adjusted expected incidence rates in susceptible subjects over the same period {2,14,18}. In those who developed breakthrough varicella postvaccination, the majority experienced mild disease, with the median of the maximum total number of lesions <50. The severity of reported breakthrough varicella, as measured by number of lesions and maximum temperature, appeared not to increase with time since vaccination.

Among a subset of vaccinees who were actively followed in these later trials for up to 10 years postvaccination, 95 individuals were exposed to an unvaccinated individual with wild-type varicella in a household setting. There were no reports of breakthrough varicella in 92% (87/95) of exposed children, while 8% (8/95) reported a mild form of varicella (maximum total number of lesions <50; observed range, 10 to 34). This represents an estimated efficacy of 90% (95% CI, 82%, 96%) based on the historical attack rate of 87% following household exposure to varicella in unvaccinated individuals in the calculation of efficacy.

Two-Dose Regimen in Children

In a clinical trial, a total of 2216 children 12 months to 12 years of age with a negative history of varicella were randomized to receive either 1 dose of VARIVAX (n=1114) or 2 doses of VARIVAX (n=1102) given 3 months apart. Subjects were actively followed for varicella, any varicella-like illness, or herpes zoster and any exposures to varicella or herpes zoster on an annual basis for 10 years after

vaccination. Persistence of VZV antibody was measured annually for 9 years. Most cases of varicella reported in recipients of 1 dose or 2 doses of vaccine were mild {15}. The estimated vaccine efficacy for the 10-year observation period was 94% for 1 dose and 98% for 2 doses ($p<0.001$). This translates to a 3.4-fold lower risk of developing varicella >42 days postvaccination during the 10-year observation period in children who received 2 doses than in those who received 1 dose (2.2% vs. 7.5%, respectively).

Clinical Data in Adolescents and Adults

Two-Dose Regimen in Adolescents and Adults

In early clinical trials, a total of 796 adolescents and adults received 905 to 1230 PFU of attenuated virus per dose of VARIVAX and have been followed for up to six years following 2-dose vaccination. A total of 50 clinical varicella cases were reported >42 days following 2-dose vaccination. Based on passive follow-up, the annual varicella breakthrough event rate ranged from <0.1 to 1.9%. The median of the maximum total number of lesions ranged from 15 to 42 per year.

Although no placebo-controlled trial was carried out in adolescents and adults, the protective efficacy of VARIVAX was determined by evaluation of protection when vaccinees received 2 doses of VARIVAX 4 or 8 weeks apart and were subsequently exposed to varicella in a household setting. Among the subset of vaccinees who were actively followed in these early trials for up to six years, 76 individuals had household exposure to varicella. There were no reports of breakthrough varicella in 83% (63/76) of exposed vaccinees, while 17% (13/76) reported a mild form of varicella. Among 13 vaccinated individuals who developed breakthrough varicella after a household exposure, 62% (8/13) of the cases reported maximum total number of lesions <50, while no individual reported >75 lesions. The attack rate of unvaccinated adults exposed to a single contact in a household has not been previously studied. Utilizing the previously reported historical attack rate of 87% for wild-type varicella following household exposure to varicella among unvaccinated children in the calculation of efficacy, this represents an approximate 80% reduction in the expected number of cases in the household setting.

In later clinical trials, a total of 220 adolescents and adults received 3315 to 9000 PFU of attenuated virus per dose of VARIVAX and have been actively followed for up to six years following 2-dose vaccination. A total of 3 clinical varicella cases were reported >42 days following 2-dose vaccination. Two cases reported <50 lesions and none reported >75. The annual varicella breakthrough event rate ranged from 0 to 1.2%. Among the subset of vaccinees who were actively followed in these later trials for up to five years, 16 individuals were exposed to an unvaccinated individual with wild-type varicella in a household setting. There were no reports of breakthrough varicella among the exposed vaccinees.

There are insufficient data to assess the rate of protective efficacy of VARIVAX against the serious complications of varicella in adults (*e.g.*, encephalitis, hepatitis, pneumonitis) and during pregnancy (congenital varicella syndrome).

14.2 Immunogenicity

In clinical trials, varicella antibodies have been evaluated following vaccination with formulations of VARIVAX containing attenuated virus ranging from 1000 to 50,000 PFU per dose in healthy individuals ranging from 12 months to 55 years of age {2,9}.

One-Dose Regimen in Children

In prelicensure efficacy studies, seroconversion was observed in 97% of vaccinees at approximately 4 to 6 weeks postvaccination in 6889 susceptible children 12 months to 12 years of age. Titers ≥5 gpELISA units/mL were induced in approximately 76% of children vaccinated with a single dose of vaccine at 1000 to 17,000 PFU per dose. Rates of breakthrough disease were significantly lower among children with VZV antibody titers ≥5 gpELISA units/mL compared with children with titers <5 gpELISA units/mL.

Two-Dose Regimen in Children

In a multicenter study, 2216 healthy children 12 months to 12 years of age received either 1 dose of VARIVAX or 2 doses administered 3 months apart. The immunogenicity results are shown in Table 3.

Table 3: Summary of VZV Antibody Responses at 6 Weeks Postdose 1 and 6 Weeks Postdose 2 in Initially Seronegative Children 12 Months to 12 Years of Age (Vaccinations 3 Months Apart)

	VARIVAX 1-Dose Regimen (N=1114)	VARIVAX 2-Dose Regimen (3 months apart) (N=1102)	
	6 Weeks Postvaccination (n=892)	6 Weeks Postdose 1 (n=851)	6 Weeks Postdose 2 (n=769)

Seroconversion Rate	98.9%	99.5%	99.9%
Percent with VZV Antibody Titer ≥5 gpELISA units/mL	84.9%	87.3%	99.5%
Geometric mean titers in gpELISA units/mL (95% CI)	12.0 (11.2, 12.8)	12.8 (11.9, 13.7)	141.5 (132.3, 151.3)

N = Number of subjects vaccinated.
n = Number of subjects included in immunogenicity analysis.

The results from this study and other studies in which a second dose of VARIVAX was administered 3 to 6 years after the initial dose demonstrate significant boosting of the VZV antibodies with a second dose. VZV antibody levels after 2 doses given 3 to 6 years apart are comparable to those obtained when the 2 doses are given 3 months apart.

Two-Dose Regimen in Adolescents and Adults

In a multicenter study involving susceptible adolescents and adults 13 years of age and older, 2 doses of VARIVAX administered 4 to 8 weeks apart induced a seroconversion rate of approximately 75% in 539 individuals 4 weeks after the first dose and of 99% in 479 individuals 4 weeks after the second dose. The average antibody response in vaccinees who received the second dose 8 weeks after the first dose was higher than that in vaccinees who received the second dose 4 weeks after the first dose. In another multicenter study involving adolescents and adults, 2 doses of VARIVAX administered 8 weeks apart induced a seroconversion rate of 94% in 142 individuals 6 weeks after the first dose and 99% in 122 individuals 6 weeks after the second dose.

14.3 Persistence of Immune Response

One-Dose Regimen in Children

In clinical studies involving healthy children who received 1 dose of vaccine, detectable VZV antibodies were present in 99.0% (3886/3926) at 1 year, 99.3% (1555/1566) at 2 years, 98.6% (1106/1122) at 3 years, 99.4% (1168/1175) at 4 years, 99.2% (737/743) at 5 years, 100% (142/142) at 6 years, 97.4% (38/39) at 7 years, 100% (34/34) at 8 years, and 100% (16/16) at 10 years postvaccination.

Two-Dose Regimen in Children

In recipients of 1 dose of VARIVAX over 9 years of follow-up, the geometric mean titers (GMTs) and the percent of subjects with VZV antibody titers ≥5 gpELISA units/mL generally increased. The GMTs and percent of subjects with VZV antibody titers ≥5 gpELISA units/mL in the 2-dose recipients were higher than those in the 1-dose recipients for the first year of follow-up and generally comparable thereafter. The cumulative rate of VZV antibody persistence with both regimens remained very high at year 9 (99.0% for the 1-dose group and 98.8% for the 2-dose group).

Two-Dose Regimen in Adolescents and Adults

In clinical studies involving healthy adolescents and adults who received 2 doses of vaccine, detectable VZV antibodies were present in 97.9% (568/580) at 1 year, 97.1% (34/35) at 2 years, 100% (144/144) at 3 years, 97.0% (98/101) at 4 years, 97.4% (76/78) at 5 years, and 100% (34/34) at 6 years postvaccination.

A boost in antibody levels has been observed in vaccinees following exposure to wild-type varicella, which could account for the apparent long-term persistence of antibody levels in these studies.

14.4 Studies with Other Vaccines

Concomitant Administration with M-M-R II

In combined clinical studies involving 1080 children 12 to 36 months of age, 653 received VARIVAX and M-M-R II concomitantly at separate injection sites and 427 received the vaccines six weeks apart. Seroconversion rates and antibody levels to measles, mumps, rubella, and varicella were comparable between the two groups at approximately six weeks postvaccination.

Concomitant Administration with Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP) and Oral Poliovirus Vaccine (OPV)

In a clinical study involving 318 children 12 months to 42 months of age, 160 received an investigational varicella-containing vaccine (a formulation combining measles, mumps, rubella, and varicella in one syringe) concomitantly with booster doses of DTaP and OPV (no longer licensed in the United States). The comparator group of 144 children received M-M-R II concomitantly with booster doses of DTaP and OPV followed by VARIVAX six weeks later. At six weeks postvaccination, seroconversion rates for measles, mumps, rubella, and VZV and the percentage of vaccinees whose titers were boosted for diphtheria, tetanus, pertussis, and polio were comparable between the two groups.

Anti-VZV levels were decreased when the investigational vaccine containing varicella was administered concomitantly with DTaP {19}. No clinically significant differences were noted in adverse reactions between the two groups.

Concomitant Administration with PedvaxHIB®

In a clinical study involving 307 children 12 to 18 months of age, 150 received an investigational varicella-containing vaccine (a formulation combining measles, mumps, rubella, and varicella in one syringe) concomitantly with a booster dose of PedvaxHIB [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)], while 130 received M-M-R II concomitantly with a booster dose of PedvaxHIB followed by VARIVAX 6 weeks later. At six weeks postvaccination, seroconversion rates for measles, mumps, rubella, and VZV, and GMTs for PedvaxHIB were comparable between the two groups. Anti-VZV levels were decreased when the investigational vaccine containing varicella was administered concomitantly with PedvaxHIB {20}. No clinically significant differences in adverse reactions were seen between the two groups.

Concomitant Administration with M-M-R II and COMVAX

In a clinical study involving 822 children 12 to 15 months of age, 410 received COMVAX, M-M-R II, and VARIVAX concomitantly at separate injection sites, and 412 received COMVAX followed by M-M-R II and VARIVAX given concomitantly at separate injection sites, 6 weeks later. At 6 weeks postvaccination, the immune responses for the subjects who received the concomitant doses of COMVAX, M-M-R II, and VARIVAX were similar to those of the subjects who received COMVAX followed 6 weeks later by M-M-R II and VARIVAX with respect to all antigens administered. There were no clinically important differences in reaction rates when the three vaccines were administered concomitantly versus six weeks apart.

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16 HOW SUPPLIED/STORAGE AND HANDLING

No. 4827/4309 —VARIVAX is supplied as follows:
(1) a box of 10 single-dose vials of lyophilized vaccine (package A), NDC 0006-4827-00
(2) a box of 10 vials of diluent (package B).

Storage

Vaccine Vial

During shipment, maintain the vaccine at a temperature between −58°F and +5°F (−50°C and −15°C). Use of dry ice may subject VARIVAX to temperatures colder than −58°F (−50°C).

Before reconstitution, store the lyophilized vaccine in a freezer at a temperature between −58°F and +5°F (−50°C and −15°C). Any freezer (*e.g.*, chest, frost-free) that reliably maintains an average temperature between −58°F and +5°F (−50°C and −15°C) and has a separate sealed freezer door is acceptable for storing VARIVAX. Routine defrost cycling of a frost-free freezer is acceptable.

VARIVAX may be stored at refrigerator temperature (36°F to 46°F, 2°C to 8°C) for up to 72 continuous hours prior to reconstitution. Vaccine stored at 2°C to 8°C which is not used within 72 hours of removal from +5°F (−15°C) storage should be discarded.

Before reconstitution, protect from light.

DISCARD IF RECONSTITUTED VACCINE IS NOT USED WITHIN 30 MINUTES.

Diluent Vial

The vial of diluent should be stored separately at room temperature (68°F to 77°F, 20°C to 25°C), or in the refrigerator.

For information regarding the product or questions regarding storage conditions, call 1-800-9-VARIVAX (1-800-982-7482).

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Discuss the following with the patient:

- Question the patient, parent, or guardian about reactions to previous vaccines.
- Provide a copy of the patient information (PPI) located at the end of this insert and discuss any questions or concerns.

- Inform patient, parent, or guardian that vaccination with VARIVAX may not result in protection of all healthy, susceptible children, adolescents, and adults.
- Inform female patients to avoid pregnancy for three months following vaccination.
- Inform patient, parent, or guardian of the benefits and risks of VARIVAX.
- Instruct patient, parent, or guardian to report any adverse reactions or any symptoms of concern to their healthcare professional.

The U.S. Department of Health and Human Services has established a Vaccine Adverse Event Reporting System (VAERS) to accept all reports of suspected adverse events after the administration of any vaccine. For information or a copy of the vaccine reporting form, call the VAERS toll-free number at 1-800-822-7967, or report online at http://www.vaers.hhs.gov.

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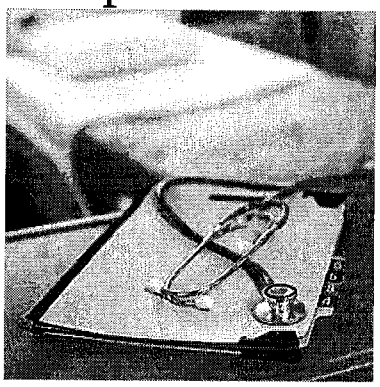
Centers for Disease Control and Prevention

Chickenpox (Varicella)

Complications



Complications from chickenpox can occur, but they are not common in healthy people who get the disease.

People who may get a serious case of chickenpox and may be at high risk for complications include:

- Infants
- Adolescents
- Adults
- Pregnant women
- People with weakened immune systems because of illness or medications, for example,
  - People with HIV/AIDS or cancer
  - Patients who have had transplants, and
  - People on chemotherapy, immunosuppressive medications, or long-term use of steroids.

Serious complications from chickenpox include:

- Bacterial infections of the skin and soft tissues in children, including Group A streptococcal infections
- Infection of the lungs (pneumonia)
- Infection or inflammation of the brain (encephalitis, cerebellar ataxia)
- Bleeding problems (hemorrhagic complications)
- Bloodstream infections (sepsis)
- Dehydration

Some people with serious complications from chickenpox can become so sick that they need to be hospitalized. Chickenpox can also cause death.

Deaths are very rare now due to the vaccine program. However, some deaths from chickenpox continue to occur in healthy, unvaccinated children and adults. In the past, many of the healthy adults who died from chickenpox contracted the disease from their unvaccinated children.

Related Pages

For Healthcare Professionals

Page last reviewed: December 31, 2018

Children's Wisconsin

TO: **Constitution and Ethics Committee**
FROM: **Robert Rohloff, MD, Director of Quality & Patient Safety of Children's Medical Group at Children's Wisconsin**
DATE: **Tuesday, March 3, 2020**
RE: **Support for Clearinghouse Rule 19-079: Immunization of students**

Good morning Chairman Wichgers and members of the committee. My name is Dr. Bob Rohloff and I am the Director of Quality & Patient Safety of Children's Medical Group at Children's Wisconsin (Children's). Thank you for holding this hearing today and allowing me this opportunity to testify today in support of **Clearinghouse Rule 19-079: Immunization of students.**

I am here to ask for your support of the Wisconsin Department of Health Services' (DHS) proposed updates to the student immunization regulations in DHS 144, as they are necessary to bring those regulations into alignment with current recommendations put forward by the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP) and current evidence-based practices. The proposed changes streamline existing regulations and reporting requirements between state entities and include necessary updates.

Children's is supportive of all of the updates listed in the rule but today I want to focus my comments on items 3-5.

Starting with item number 3 which would move the current recommendation for Tdap from 6th grade to 7th grade to ensure that children are old enough to meet this age minimum (some children are 10 years old when starting 6th grade).

Item 3 is a great addition and Children's is very supportive. The ACIP just recently amended their recommendations to allow 10 year olds to receive the Tdap and have it count towards the adolescent series. Before that change, anyone receiving the Tdap at 10 had to have it repeated after they turned 11. Because of that, we are giving the Tdap at 11 and running into a problem with the school requirement. Number 3 is imperative to better align school requirements with the previous ACIP recommendation.

Item 4 would add the meningococcal vaccine to the list of vaccines required for students entering the 7th grade and proposes a booster dose for students entering 12th grade which is in accordance with ACIP recommendations.

This is a very welcomed addition. Currently our rates of vaccination for Tdap and Meningococcus (types A,C,Y,W) at our Children's Primary Care clinics is well over 90%. Aligning the ages for Tdap requirement at 7th grade would allow us to sign one form for both vaccines (Tdap and Meningococcus) which streamlines the process for providers and parents.

Children's complies with Federal civil rights laws. We do not discriminate based on race, color, national origin, age, disability or sex. Si no habla inglés, se programarán servicios de idiomas en forma gratuita. Llame al (414) 266-7848 (TTY: 414-266-2465). Yog hais tias koj tsis txawj hais lus Askiv, peb yuav teem sij hawm muab kev pab txhais lus pub dawb rau koj. Hu rau (414) 266-7848 (TTY: 414-266-2465).

*Meningococcus causes several significant infections including blood infections called bacteremia, pneumonia and meningitis, an infection of the lining of the brain and spinal cord. Fortunately, Meningococcus is a fairly uncommon infection. Unfortunately about 15 % of people who get infected will die despite our best efforts. Of those who survive nearly 20% will have lifelong devastating sequelae including loss of limb, deafness and cognitive problems. This is not an infection to be trifled with. The vaccine is about 85% effective in the year after it is given but the effectiveness decreases over time so that by 3-5 years after the first vaccine it is about 50% effective. Which is why a second dose is so important. One of the peak times for infection is when students are attending college.

Item 5 would allow the varicella vaccination exception only when a history of varicella disease has been reported by a health care provider. This is an important addition.

When I was a child almost everyone got chicken pox. It may seem like a common, mild childhood illness. In fact over 10,000 children per year were hospitalized due to chicken pox and over 100 children in the US with chicken pox died every year. Since the introduction of the chicken pox vaccine hospitalizations have declined by 70% and deaths have declined by 88%. At the same time, chicken pox has decreased by 97%. These are remarkable numbers. Getting chickenpox is much less likely today. If a person is infected with chickenpox they are immune for life and do not need the vaccine. Unfortunately, other infections can look like chicken pox making the diagnosis a bit confusing. Also, as chickenpox has become less common it can be harder to diagnose. We recommend contacting a health care provider if a child is suspected of having chickenpox to discuss symptoms and treatment.

Immunization has always been an important factor in the health of kids and is consistently recommended by pediatricians and providers at Children's Wisconsin and health systems worldwide. Children's treats the most vulnerable and immune-challenged kids who cannot get vaccinated and are most at-risk if a communicable disease outbreak occurs. At Children's, we have cared for over 2,600 patients in the last couple of years with immune system problems. In fact the risk to these patients is enormous, up to a third of kids who have problems with their immune systems who are exposed to and catch chickenpox may have a rapidly progressive course with multiple organ system involvement. The reality is that kids who do not get vaccinated can acquire – and just as importantly, spread – dangerous diseases. Potential outbreaks can be avoided if there are fewer unimmunized children and if children stay up-to-date with recommended school vaccine schedules. Herd immunity is important to protect children who cannot be vaccinated as well as infants who are too young and those who are too ill battling diseases like cancer.

Now, I will turn it over to my physician colleague Dr. Heather Paradis who will share a letter written by a Children's patient family who finds themselves in one of these situations.

Dr. Paradis:

Thank you. This letter is from Linda Bevec from Kenosha.

I am a mother writing to you asking for your support of the changes outlined in the **Wisconsin Department of Health Services 144 – Immunization of Students.** I feel these proposed updates are imperative to the health and wellness of all children assuring they have an equal chance of growing up healthy.

As a state, it is crucial we protect all of our children, especially the weakest among us. It is so important to bring these immunization regulations into alignment with current recommendations established by the Centers for Disease Control and Prevention, the Advisory Committee on Immunization Practices, the American Academy of Pediatrics and current evidence-based practices.

Immunizations save lives. And to disregard the chance of saving lives when we have that chance is to disregard our collective responsibility and service to one another. We live in community and not in isolation from one another; we are a collective society, a global society...and diseases are spread through day-to-day interaction and contact that we all have with one another and that cannot be avoided. Vaccines keep our schools healthy, our workplaces healthy, our communities and our state healthy.

I have an 18-year old daughter, Claire, who has lived her entire life with a rare genetic kidney and liver disease called Auto Recessive Polycystic Kidney Disease and Congenital Hepatic Fibrosis. Due to her chronic illness she has lived with a weakened immune system since birth. We have done everything in our power to protect her and keep her safe and healthy in every way we possibly can, but we have also relied on certain regulations and laws to ensure protection in her schools and in our communities. When she was 9 years old she received a kidney transplant and was out of school for 5 months so she could recover and avoid contact with anyone who might be sick. Organ transplant patients have especially weakened immune systems due to the immunosuppression medications that prevent their body from rejecting the transplanted organ. Claire couldn't wait to return to school to see her teachers and friends, to learn and return to a normal 4th grade life. I trusted my school and the families who went there to abide by the vaccine regulations that help keep my daughter, and all children, healthy. She is now a freshman in college and we are still constantly vigilant and careful of her exposure to infectious diseases and individuals who might NOT be vaccinated. Recently, a young woman with my daughter's same disease died from meningococcal septicemia because of someone she came into contact with who had not been vaccinated against this completely PREVENTABLE disease. It is heartbreaking and so unnecessary. We live in a time when medicine has given us so many advances and the ability to prevent diseases and keep them from spreading.

In summary, we are only as healthy as the weakest among us. If we fail to care about the least and the weakest among us, we fail to care about all. I sincerely hope you will understand this and do what is right and just by providing protection in the form of laws and regulations ensuring the health of all in our great state of Wisconsin.

Chairman Wichgers and committee members, we thank you again for the opportunity to testify in support. Children's is glad to serve as a resource on this important public health matter facing our state. We are happy to answer any questions now.

As you know, Children's Wisconsin (Children's) serves children and families in every county across the state. We have inpatient hospitals in Milwaukee and the Fox Valley. We care for every part of a child's health, from critical care at one of our hospitals, to routine checkups in our primary care clinics. Children's Hospital also provides specialty care, urgent care, emergency care, dental care, school health nurses, foster care and adoption services, family resource centers, child health advocacy, health education, family preservation and support, mental health services, pediatric medical research and the statewide poison hotline.

Wisconsin United for Freedom
P.O. Box 894
Cedarburg, WI 53012
info@wisconsinunitedforfreedom.org

Oral Testimony for CR 19-079

Tara Czachor of Wisconsin United For Freedom

Good morning! Thank you, sincerely, Mr. Chairman and committee members for the opportunity to speak at today's hearing.

My name is Tara Czachor and I live in the Town of Lawrence. I have a Bachelor's Degree from the University of Wisconsin Green Bay. My husband and I have four thriving and healthy daughters, all of whom are in public school and would be affected by these rule changes. I am speaking to you today first and foremost as a mother, and also as one of the directors of Wisconsin United For Freedom - the state's leading health freedom advocacy organization, with a community of over 2,500 individuals and parents who support medical choice, especially as it pertains to the use of liability-free pharmaceutical products such as vaccines.

Firstly, I wanted to mention that as soon as I found out there would be a public hearing hosted by DHS on these rule changes in July 2019, I was very concerned that many members of the public would not be able to attend. I was so concerned that I emailed and left phone messages with DHS to inquire about getting a phone number to attend the meeting by phone. After many days, I was emailed a Skype number to join the meeting by phone, however, the public notice that was posted was not amended or updated with this phone number despite my questioning.

I attended the public hearing by phone. There were grave technological issues surrounding the Skype call. There was approximately 20 minutes of time spent troubleshooting technical issues, and that time was not given back to the people either in person or attending via phone. The rest of those Wisconsinites in attendance at the hearing could not hear phone attendees. It is not acceptable to have a public hearing where all those in attendance, no matter how they were in attendance, could not hear all speakers.

While I am in opposition to rule 1, 2, 4 and 5 of CR-19-079, the focus of my public testimony will be on Rule change number 4, the mandate that would require that all 11-12-year old students receive the meningococcal vaccine, or MenACWY vaccine, and would additionally require a 2nd dose of the vaccine at age 16.

Meningococcal disease is a devastating disease, and we are fortunate that this disease is very rare. But as previously mentioned, the rates of this disease had already dropped to historical lows prior to the CDC's recommendation for use of the vaccine in all 11 and 12-year old students. Rates have continued to drop and in 2018, there were approximately 330 cases in the United States.[1] Please keep in mind, there are about 900,000 children in the Wisconsin public school system.

I am certain that when Wisconsin DHS authored rule number 4, they never once considered vaccine injury. Vaccine injury is real and many people are unaware of this fact. It is acknowledged by the federal government and there have been payouts made to families with vaccine injuries. But we'll get in-depth on that later. Vaccine injuries are extremely important, especially as it pertains to this meningococcal mandate.

Even if it is acknowledged that the rare vaccine injury occurs, the number of injuries could cancel out the benefit of the vaccine. Let's explore that idea.

Within 9 months of the approval of the meningococcal vaccine, the CDC issued a health alert warning of an association between the vaccine and Guillain Barre Syndrome or GBS, a serious and devastating neurological disorder that causes paralysis and even deaths.[2] Additional reports of GBS occurring after vaccination continued to be reported, and this prompted the vaccine manufacturer to list GBS as a possible side effect of the vaccine.[3]

GBS is not the only serious reaction that has been linked to meningococcal vaccines. There are many reactions, some of the more serious reactions associated with this vaccine as listed in the vaccine package insert for the 2 available MenACWY vaccines include – anaphylaxis, convulsions, transverse myelitis and acute disseminated encephalomyelitis.[4] [5]

In fact, for the 2 available MenACWY vaccines, Menactra and Menveo, as of December 31st, 2019, there have been 1,596 SERIOUS adverse events reported to the Vaccine Adverse Events Reporting System or VAERS. These are not the reports of a sore arm or swelling at the injection site. These are serious events that include GBS, transverse myelitis, and even death.[6]

There have been 71 deaths reported to VAERS linked to the meningococcal vaccine, and while a report to VAERS does not mean that the vaccine was responsible for the death, it also doesn't rule out an association. Several of the death reports to VAERS were in individuals who died from meningococcal disease even though they were fully vaccinated. Several who did die, died from strain C, which is a strain that is targeted by the MenACYW vaccine. These reports indicate that the vaccine failed and did not protect against one of the few strains it was supposed to protect against.[7]

It is entirely possible that serious reactions occurring after the MenACWY vaccine are significantly higher because vaccine reactions are rarely reported. A 2011 report by Harvard Pilgrim Health Care, Inc. for the U.S. Department of Health and Human Services (HHS) stated that fewer than one percent of all vaccine adverse events are reported to the government. This report states the following -

> *"Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed."*[8]

A logical next step would be to figure out how to implement new surveillance methods, but instead government officials stopped corresponding with Harvard Pilgrim Health Care and we have yet to see any improvements in reporting systems.

According to the VAERS reports, this means that instead of nearly 1,600 serious adverse events following MenACWY vaccines, the number could actually be 160,000. The more alarming number is that instead of 71 deaths, the death toll could be as high as 7,100.

In 1982, due to the unrelenting onslaught of civil suits over vaccine injuries and deaths, the four biggest vaccine makers at the time, Merck, Lederle, Connaugt, and Wyeth, went to Congress and threatened to stop selling vaccines in the United States unless they were granted liability from civil lawsuits.[9]

The National Childhood Vaccine Injury Act of 1986, which acknowledged that vaccines and deaths were real and that individuals and their families should be financially compensated, made it *extremely difficult* for individuals and families to sue in civil court for vaccine injuries and death. One of the provisions of the 1986 law was that a compensation program be set up to pay for injuries and deaths caused by vaccines and that U.S. taxpayers pay for it, through a 75-cent tax levied on all vaccines. In other words, even though the National Childhood Vaccine Injury Act of 1986 acknowledged that vaccine products caused harm and death, the makers of these products should not be held financially responsible for the harm their products cause.[10] [11]

The National Vaccine Injury Compensation Program (NVICP) was touted as a less expensive and quicker alternative to civil suits to compensate children and families who were ultimately harmed by vaccines. Individuals were still supposed to retain the right to sue a vaccine maker in civil court if they were denied compensation through the NVICP or if there was evidence that a vaccine maker could have made a vaccine safer – but chose not to. [12]

However, in February 2011, the U.S. Supreme Court, in *Bruesewitz v. Wyeth*, ruled that vaccines were *"unavoidable unsafe"* and granted pharmaceutical companies a complete liability shield.[13]

You can no longer sue a pharmaceutical company for damages caused by a vaccine - even if there is evidence that the drug maker knew that their product was defective and chose not to make it less harmful.

Instead, you must go through a highly adversarial claims process with the federal government for compensation and nearly 2 out of 3 claims are denied. Despite this, since 1998, over $4.2 billion dollars has been paid out to vaccine victims.[14]

Since 1988, there have been 95 claims filed in the federal Vaccine Injury Compensation Program (VICP) for the injuries and deaths following meningococcal vaccination, including 2 deaths and 93 serious injuries. 48 cases have been compensated, 10 dismissed, and the remaining are still pending. I do want to make this committee aware that persons injured or who die as a result of vaccination cannot sue in a court of law for damages.

Given that meningococcal disease is rare, it is possible that the risks associated with this particular vaccine might outweigh the benefit. This vaccine *must not be mandated*. Health care providers and public health officials *must* ensure that parents are aware of the risks of this vaccine and allow them to make an educated decision based on the risks along with their child's personal health history.

In conclusion, I would like to thank this committee for the opportunity to speak and I respectfully request that you vote against rule 1, 2, 4, and 5 of CR-19-079.

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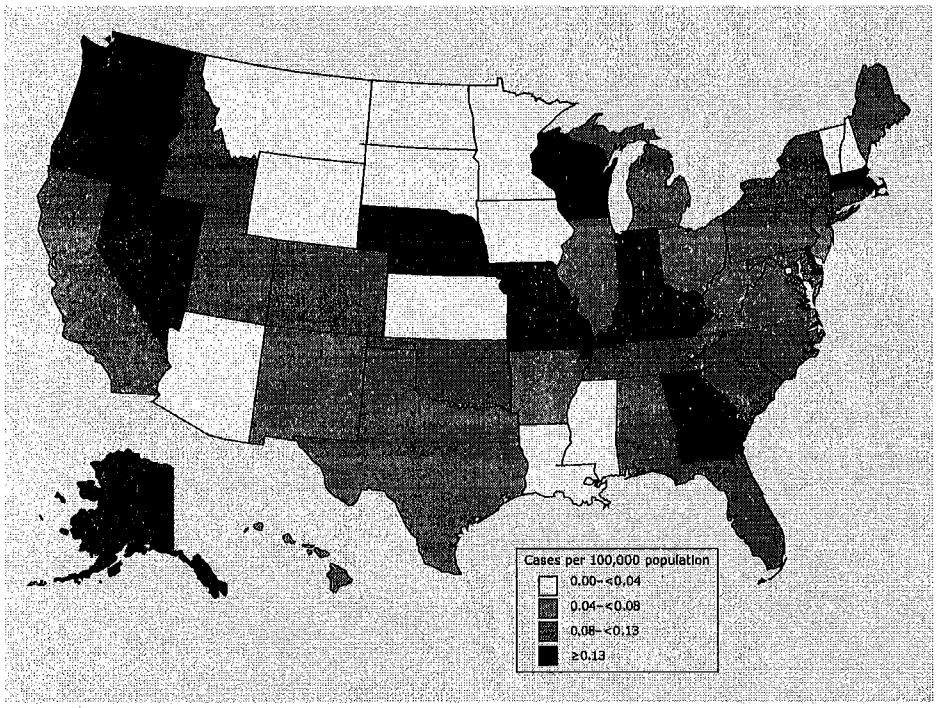
[10] U.S. Code 42 USC CHAPTER 6A, SUBCHAPTER XIX, Part 2: From Title 42—THE PUBLIC HEALTH AND WELFARE - CHAPTER 6A—PUBLIC HEALTH SERVICE SUBCHAPTER XIX—VACCINES
[11] U.S. Code 42 USC CHAPTER 6A, SUBCHAPTER XIX, Part 2: National Vaccine Injury Compensation Program From Title 42—THE PUBLIC HEALTH AND WELFARE - CHAPTER 6A—PUBLIC HEALTH SERVICE SUBCHAPTER XIX—VACCINES
[12] U.S. Code 42 USC CHAPTER 6A, SUBCHAPTER XIX, Part 2: From Title 42—THE PUBLIC HEALTH AND WELFARE - CHAPTER 6A—PUBLIC HEALTH SERVICE SUBCHAPTER XIX—VACCINES
[13] U.S. Supreme Court. Bruesewitz v. Wyeth 09-152; Feb. 22, 2011.
[14] Health Resources & Services Administration (HRSA) Vaccine Injury Compensation Data through February 1, 2020. Feb. 18, 2020

Reference #1

Enhanced Meningococcal Disease Surveillance Report, 2018*

Confirmed and Probable Cases Reported to the National Notifiable Diseases Surveillance System, 2018



As part of Enhanced Meningococcal Disease Surveillance (EMDS), additional data and isolates were collected from 45 state and 3 large jurisdiction health departments. In 2018, the population under surveillance was 320,863,137 or 98 % of the U.S. population. EMDS focuses on: (1) collecting isolates from all cases; and (2) collecting complete case information, with an emphasis on college attendance for cases 15–24 years; history of sex with men for male cases ≥16 years; and HIV infection status for all cases.**

CSTE case definition: A confirmed case was defined as isolation of *Neisseria meningitidis* or detection of *N. meningitidis* by PCR from a normally sterile body site.

A probable case was defined as detection of *N. meningitidis* antigen by latex agglutination or immunohistochemistry.

*Delaware, Hawaii, Idaho, South Dakota, Wyoming, and the District of Columbia did not participate in EMDS; cases reported from these jurisdictions are only included in the map, incidence, and CFR tables (n=5). All other information is for cases from participating EMDS jurisdictions only (n=324).

**Funding for EMDS is provided by CDC through the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement.

Meningococcal Disease Cases and Incidence by Serogroup and Age

Age (years)	B No. (Incidence†)	C No. (Incidence†)	W No. (Incidence†)	Y No. (Incidence†)	Nongroupable No. (Incidence†)	Other‡/Unknown No. (Incidence†)	Total No. (Incidence†)
<1	21 (0.55)	6 (0.16)	2 (0.05)	1 (0.03)	2 (0.05)	0 (0.00)	32 (0.83)
1–4	12 (0.08)	10 (0.06)	1 (0.01)	4 (0.03)	1 (0.01)	1 (0.01)	29 (0.18)
5–10	2 (0.01)	4 (0.02)	0 (0.00)	1 (0.00)	2 (0.01)	0 (0.00)	9 (0.04)
11–15	6 (0.03)	1 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	7 (0.03)
16–23	21 (0.06)	3 (0.01)	0 (0.00)	0 (0.00)	8 (0.02)	2 (0.01)	34 (0.10)
24–44	16 (0.02)	21 (0.02)	3 (0.00)	9 (0.01)	6 (0.01)	10 (0.01)	65 (0.07)
45–64	25 (0.03)	22 (0.03)	7 (0.01)	14 (0.02)	3 (0.00)	8 (0.01)	79 (0.09)
≥65	16 (0.03)	23 (0.04)	4 (0.01)	19 (0.04)	5 (0.01)	7 (0.01)	74 (0.14)
Total	**119 (0.04)**	**90 (0.03)**	**17 (0.01)**	**48 (0.01)**	**27 (0.01)**	**28 (0.01)**	**329 (0.10)**

Includes all confirmed and probable cases reported from all jurisdictions; †Cases per 100,000 population; and ‡includes 1 serogroup E case.

National Center for Immunization and Respiratory Diseases
Office of Infectious Diseases

CDC

Case Fatality

Serogroup	No. deaths	CFR†
B	9	7.6
C	13	14.8
W	4	23.5
Y	7	14.6
NG	2	7.4
Unknown	4	16.7
Overall	**39**	**12.0**

Age (years)	No. deaths	CFR†
<1	4	12.9
1–4	0	0.0
5–10	0	0.0
11–15	0	0.0
16–23	0	0.0
24–44	7	10.9
45–64	11	14.1
≥65	17	23.3
Overall	**39**	**12.0**

Includes all confirmed and probable cases reported from all jurisdictions; †Case fatality ratio (CFR): deaths per 100 cases with known outcome; 4 (1%) cases with unknown outcome.

Laboratory Confirmation Method

89.7% (287/320) of confirmed cases were confirmed by culture; of those 250 (87.1%) had isolates submitted to CDC.
6.3% (20/320) of confirmed cases were confirmed by PCR.
3.1% (10/320) of confirmed cases had unknown laboratory confirmation method.

Outbreaks

97.2% (315/324) of cases had information on association with an outbreak; of those, 18 (5.7%) were part of an outbreak.

Complement inhibitor use

77.8% (252/324) of cases had information on use of a complement component inhibitor; of those, 4 (1.2%) were taking eculizumab.

Homelessness

95.1% (308/324) of cases had information on homelessness; of those, 16 (5.2%) were identified as homeless.

History of sex with men among male cases

Among male cases aged ≥16 years, 73.0% (84/115) had information on history of sex with men; of those, 5 (6.0%) were identified as men who had sex with men (MSM).

College attendance among cases 18-24 years

Among cases in patients aged 18-24 years, 100% (34/34) had information on college attendance; 18 (52.9%) were attending college.

Symptoms

69.1% (224/324) of cases had symptom information available; of those 5 (2.2%) had gastrointestinal symptoms (nausea, vomiting, or diarrhea) in the absence of typical meningococcal symptoms (headache, fever, neck stiffness, rash).

Meningococcal Disease Cases and Incidence by Serogroup and College Attendance*

	B No. (Incidence†)	C No. (Incidence†)	W No. (Incidence†)	Y No. (Incidence†)	Nongroupable No. (Incidence†)	Total** No. (Incidence†)
Attending college‡	11 (0.10)	0 (0.00)	0 (0.00)	0 (0.00)	6 (0.05)	**18 (0.16)**
Not attending college‡	9 (0.05)	5 (0.03)	0 (0.00)	0 (0.00)	1 (0.01)	**16 (0.08)**

*Among cases 18-24 years. **Includes 1 case with unknown serogroup and 1 serogroup E case. †Cases per 100,000 population; and ‡assumes 38.3% of 18–24 year olds attending college[1]

Vaccination Status among cases 18-24 years

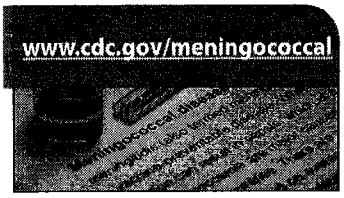
MenACWY* vaccine receipt:

College students: 100% (18/18) had information on MenACWY receipt; of those 94.4% received MenACWY.
Persons not attending college: 50.0% (8/16) had information on MenACWY receipt; of those 75.0% received MenACWY.

MenB** vaccine receipt:

College students: 77.8% (14/18) had information on MenB receipt; of those 14.3% received MenB.
Persons not attending college: 50.0% (8/16) had information on MenB receipt; of those 0 received MenB.

*MenACWY = meningococcal conjugate vaccine, **MenB = serogroup B meningococcal vaccine.



HIV Infection among Meningococcal Disease Cases*

Data collected on HIV status will allow CDC to assess the impact of the recent Advisory Committee on Immunization Practices recommendation for use of MenACWY vaccination in HIV-infected persons.[2]

55.9% (181/324) of cases had information on HIV status; of those, 5 (2.8%) were identified as HIV-infected.

[1]U.S. Department of Education. Institute of Education Sciences NCfES. Integrated Postsecondary Education Data System Fall Enrollment Survey. https://nces.ed.gov/ipeds/Home/UseTheData, 2015.

[2]MacNeil JR, Rubin LG, Patton M, Ortega-Sanchez IR, Martin SW. Recommendations for Use of Meningococcal Conjugate Vaccines in HIV-infected Persons — Advisory Committee on Immunization Practices, 2016. *MMWR Morb Mortal Wkly Rep* 2016;65:1189–1194. DOI: http://dx.doi.org/10.15585/mmwr.mm6543a3.

Reference #2

This is an official
CDC HEALTH ADVISORY

Distributed via Health Alert Network
Friday, September 30, 2005, 19:00 EDT (7:00 PM EDT)
CDCHAN-00237-2005-09-30-ADV-N

FDA and CDC Issue Alert on Menactra Meningococcal Vaccine and Guillain Barre Syndrome

The Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) are alerting consumers and health care providers to five reports of Guillain Barre Syndrome (GBS) following administration of Meningococcal Conjugate Vaccine A, C, Y, and W135 (trade name Menactra), manufactured by Sanofi Pasteur. It is not known yet whether these cases were caused by the vaccine or are coincidental. FDA and CDC are sharing this information with the public now and actively investigating the situation because of its potentially serious nature.

Guillain Barre Syndrome (GBS) is a serious neurological disorder that can occur, often in healthy individuals, either spontaneously or after certain infections. GBS typically causes increasing weakness in the legs and arms that can be severe and require hospitalization.

Meningococcal infection, which Menactra prevents, is a major cause of bacterial meningitis, affecting approximately 1 in 100,000 people annually. The infection can be life threatening:

10-14 percent of cases are fatal and 11-19 percent of survivors may have permanent disability.

According to Jesse Goodman, MD, Director of FDA's Center for Biologics Evaluation and Research, at the present time there are no changes in recommendations for vaccination; individuals should continue to follow their doctors' recommendations. FDA and CDC are not able to determine if any or all of the cases were due to vaccination. The current information is very preliminary and the two agencies are continuing to evaluate the situation.

Because of the potentially serious nature of this matter, FDA and CDC are asking any persons with knowledge of any possible cases of GBS occurring after Menactra to report them to the Vaccine Adverse Event Reporting System (VAERS) to help the agencies further evaluate the matter. Individuals can report to VAERS on the web at www.vaers.hhs.gov or by phone at 1-800-822-7967.

The five cases of GBS reported following administration of Menactra occurred in individuals living in NY, OH, PA, and NJ. All five patients were 17 or 18 years of age and developed weakness or abnormal sensations in the arms or legs, two-four weeks after vaccination. All individuals are reported to be recovering or to have recovered. More than 2.5 million doses of Menactra vaccine have been distributed to date. The rate of GBS based on the number of cases reported following administration of Menactra is similar to what might have been expected to occur by coincidence, that is, even without vaccination. However, the timing of the events is of concern. Also, vaccine adverse events are not always reported to FDA so there may be additional cases of which we are unaware at this time.

Prelicensure studies conducted by Sanofi Pasteur of more than 7000 recipients of Menactra showed no GBS cases. CDC conducted a rapid study using available health care organization databases and found that no cases of GBS have been reported to date among 110,000 Menactra recipients.

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national and international organizations.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Reference #3

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6. Puerto Rico Health Department. Population by age and sex groups. San Juan, PR: Auxiliary Secretariat for Planning and Development, Division of Statistical Analysis; 2005.
7. Buvinic M, Morrison A, Shifter M. Violence in Latin America and the Caribbean: a framework for action. Washington, DC: InterAmerican Development Bank; 1999.
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Update: Guillain-Barré Syndrome Among Recipients of Menactra® Meningococcal Conjugate Vaccine — United States, October 2005–February 2006

In October 2005, a possible association between Guillain-Barré Syndrome (GBS) and receipt of meningococcal conjugate vaccine (i.e., meningococcal polysaccharide diphtheria toxoid conjugate vaccine [Menactra®])* (MCV4) was reported (*1*). GBS is a serious neurologic disorder involving inflammatory demyelination of the peripheral nerves. At the time of the first report, five confirmed cases of GBS after receipt of MCV4 had been reported to the Vaccine Adverse Events Reporting System (VAERS). During the 4 months since, three additional confirmed cases of GBS have been reported. This report describes two of these recent cases and provides additional data collected through February 2006. Because available evidence neither proves nor disproves a causal relation between MCV4 and GBS, further monitoring and studies are ongoing within VAERS and the Vaccine Safety Datalink (VSD). CDC continues to recommend use of MCV4 for persons for whom vaccination is indicated (*1*); the additional reported cases have not resulted in any change to that recommendation.

Case Reports

Brief clinical and epidemiologic descriptions of two of the newly reported cases follow. The third case is undergoing detailed clinical investigation but meets the provisional case definition for GBS.†

Case 1. On August 8, 2005, a male aged 19 years from Arizona was vaccinated with MCV4. Approximately 25 days later, he experienced numbness and tingling in his hands and feet, followed by weakness in his legs, difficulty running, and decreased dexterity in his hands. In the month before neurologic symptom onset, he had no defined episode of respiratory or gastrointestinal illness. He had traveled to Mexico twice during the preceding 3 months. Electrophysiology studies revealed a diffuse neuropathic process with both demyelinating and axonal features, consistent with GBS. Testing for Epstein-Barr virus capsid IgG and IgM antibodies was negative. Testing for cytomegalovirus IgG and IgM antibodies also was negative, as were serologic studies for hepatitis A, B, and C to rule out other probable causes of GBS. The patient was treated with intravenous immunoglobulin. At follow-up examination 8 weeks after onset, he had fully recovered.

Case 2. On November 4, 2005, a male aged 17 years from Ohio received MCV4. Eleven days later, he experienced numbness and tingling in his right foot, followed by the same symptoms in the left foot, which progressed proximally during the next 5 days. He also described a neck hyperextension injury sustained while playing sports 2 days before the start of sensory symptoms and sore throat and congestion 1 day before sensory symptoms. He had no gastrointestinal illness during the 6 weeks before hospital admission, which occurred 6 days after symptom onset. Cervical spine radiographs revealed no fractures; magnetic resonance imaging (MRI) of the spine revealed mild enhancement along the surface of distal cord and lumbar nerve roots, consistent with GBS. Nerve conduction studies also were consistent with GBS. Polymerase chain reaction (PCR) assays for enterovirus were negative, as were tests for *Mycoplasma pneumoniae* IgG and IgM. The patient was treated with intravenous immunoglobulin. At follow-up examination 2 weeks after admission, he had completely recovered.

In the two cases described in this report, the period from MCV4 vaccination to symptom onset was less than 6 weeks. This is the time window of elevated risk noted for GBS after administration of certain other vaccines (*2*).

To determine whether the reporting rate of GBS after MCV4 vaccination was higher than the expected incidence rate of GBS for the appropriate age group population, the reporting rate was calculated by dividing the eight confirmed GBS cases with onset within 6 weeks of vaccination by the number of vaccine doses distributed as provided by the manufacturer (approximately 3.77 million doses of MCV4 were distributed during March 2005–February 2006). The eight cases were divided by the 3.77 million distributed doses to provide the reporting rate for GBS after MCV4. The expected incidence rate of GBS was estimated from a multistate hospital discharge

* Sanofi Pasteur (Swiftwater, Pennsylvania).
† Available at http://www.cdc.gov/nip/vacsafe/concerns/gbs/gbs_case_defs.pdf.

database (Health Care Utilization Project).[§] For the years 2000–2003, the incidence rate of GBS among persons aged 11–19 years was estimated to be 1.4 per 100,000 population per year or 0.17 per 100,000 population during a 6-week period. Therefore, the ratio of the reporting rate of GBS after MCV4 vaccination to the expected incidence rate was 1.4 (95% confidence interval = 0.7–2.8), suggesting that the occurrence of eight cases of GBS within 6 weeks of MCV4 administration is similar to what might be expected to occur by chance alone.

As part of the investigation, other possible causes of GBS, such as *Campylobacter jejuni*, were assessed. *C. jejuni* is a leading cause of gastroenteritis globally and the most frequent antecedent pathogen in GBS (*3*). No evidence of *C. jejuni* was observed in any of the eight cases reported; however, many *C. jejuni* infections are asymptomatic. No serum samples from GBS cases reported after MCV4 vaccination were available for testing. To further assess the possibility that *C. jejuni* was a precipitating cause, unpublished data were collected and analyzed from all five state health departments involved in initial GBS case reports to VAERS (Arizona, New Jersey, New York, Ohio, and Pennsylvania). Despite an expected seasonal peak of GBS cases from June to October 2005 (CDC, unpublished data, 2005), none of the involved states reported outbreaks of *C. jejuni* during this period.

Reported by: *Center for Biologics Evaluation and Research, Food and Drug Admin. Arizona State Health Dept. New Jersey Dept of Health and Senior Svcs. New York State Dept of Health. Columbus City Health Dept, Columbus, Ohio. Pennsylvania Dept Health. Immunization Safety Office, National Immunization Program; National Center for Infectious Diseases; F Soud, PhD, EIS Officer, CDC.*

Editorial Note: In October 2005, CDC and the Food and Drug Administration (FDA) alerted health-care providers about a possible association between GBS and MCV4 and encouraged reporting of adverse events to VAERS (*1*). Since that time, three additional confirmed cases of GBS with onset within 6 weeks of MCV4 vaccination have been reported. However, even with these reported cases, the reported incidence remains similar to the expected incidence. In addition, three other cases of GBS have been reported, with symptom onsets at >6 weeks (107 days, 116 days, and 125 days) after vaccination with MCV4; these three cases were not included in calculation of GBS rates. Because VAERS is a voluntary reporting system, the completeness of reporting of GBS remains unknown. Only three cases were reported since October 2005, suggesting that MCV4 might not be causally related to GBS. The background incidence rate of GBS is one to two cases per 100,000 population. However, the timing of onset of neurologic symptoms within 2–5 weeks of vaccination is still a concern.

Additional preliminary data from VSD,[¶] a collaborative project between CDC and eight managed care organizations in the United States, have not identified GBS cases in MCV4 recipients. However, VSD has a limited ability to detect rare health events such as GBS. To further evaluate any potential risk, additional controlled studies of GBS after MCV4 are being planned.

The case definition developed for the initial investigation has been refined by an extended working group of the Brighton Collaboration,[**] an international voluntary collaboration of scientists. The Clinical Immunization Safety Assessment Network,[††] in collaboration with CDC, continues to research and conduct standardized clinical evaluation of affected vaccinees to better understand the pathophysiology of select adverse events after vaccination, such as GBS. In response to the evaluation of the reported cases to VAERS, Sanofi Pasteur and FDA updated the Menactra vaccine package insert to list previous GBS as a contraindication and provide a warning of the temporal relation between GBS and MCV4 (*4*).

In October 2005, CDC recommended continuing use of MCV4 for persons for whom vaccination is recommended; the additional cases reported in this update do not affect that recommendation (*1*). In December 2005, the Global Advisory Committee on Vaccine Safety also recommended no change in MCV4 vaccination policies (*5*).

The Advisory Committee on Immunization Practices has recommended that persons with a history of GBS should not be vaccinated with MCV4 unless they are at elevated risk for meningococcal disease (*6*). Persons at elevated risk for meningococcal disease include first-year college students living in dormitories, military recruits, travelers to areas in which meningococcal disease is hyperendemic or epidemic, microbiologists who are routinely exposed to isolates of *Neisseria meningitidis*, patients with anatomic or functional asplenia, and patients with terminal complement deficiency. Information regarding the current investigation should be shared with adolescents and caregivers before MCV4 vaccination. A Vaccine Information Statement and fact sheet noting the information on the reported GBS cases is available at http://www.cdc.gov/nip/publications/vis/default.htm. An updated fact sheet for health-care workers is available at http://www.cdc.gov/nip/vacsafe/concerns/gbs/menactra.htm. CDC continues to recommend that health-care workers and any other persons aware of adverse events associated with MCV4 or any other vaccination report to VAERS cases of GBS or any other

[§] Available at http://www.ahrq.gov/hcupnet.

[¶] Available at http://www.cdc.gov/nip/vacsafe/vsd.

[**] Information available at http://www.brightoncollaboration.org.

[††] Available at http://www.vaccinesafety.org/cisa/index.htm.

clinically significant adverse events. Reports may be submitted securely online at http://www.vaers.hhs.gov or by fax at 877-721-0366. Reporting forms and additional information is available at telephone, 800-822-7967.

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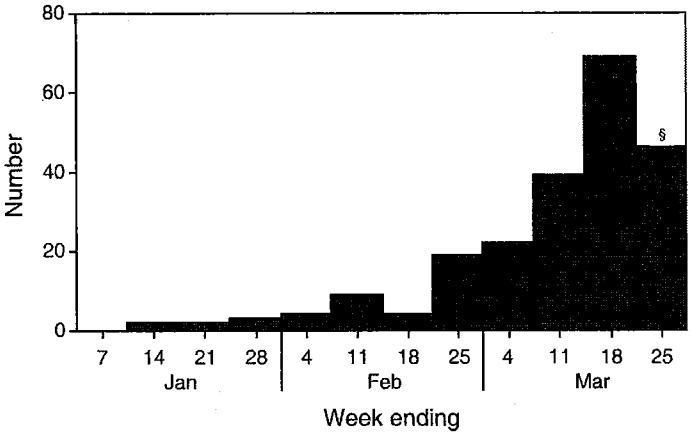
Mumps Epidemic — Iowa, 2006

On March 30, this report was posted as an MMWR Dispatch *on the* MMWR *website* (http://www.cdc.gov/mmwr).

In the United States, since 2001, an average of 265 mumps cases (range: 231–293 cases) have been reported each year,* and in Iowa, an average of five cases have been reported annually since 1996.† However, in 2006, by March 28, a total of 219 mumps cases§ had been reported in Iowa (Figure 1), and an additional 14 persons with clinically compatible symptoms were being investigated in three neighboring states (11 in Illinois, two in Nebraska, and one in Minnesota) in what has become the largest epidemic of mumps in the United States since 1988 (*1*). This report summarizes and characterizes the ongoing mumps epidemic in Iowa, the public health response, and recommendations for preventing further transmission.

FIGURE 1. Number* of mumps cases,† by week of onset — Iowa, 2006



* N = 219.
† Includes confirmed, probable, and suspect cases. Case definitions were modified from Council of State and Territorial Epidemiologists/CDC mumps case definitions for use in this outbreak. *Confirmed:* case that meets the clinical case definition (i.e., unilateral or bilateral tender, self-limited, swelling of the parotid or other salivary gland, lasting >2 days and without other apparent cause) and is laboratory confirmed (i.e., by a positive IgM test result or positive viral culture) or epidemiologically linked to a confirmed case. A confirmed case can be asymptomatic if a mumps viral culture is positive. *Probable:* case that meets the clinical case definition but has noncontributory or no serologic or virologic testing and is not epidemiologically linked to a confirmed or probable case. *Suspect:* case with a positive IgM test result but no confirmation of the clinical definition.
§ Provisional data; cases being assessed for the week ending March 25, 2006.

Mumps is an acute viral infection characterized by fever and nonsuppurative swelling of the salivary glands; an estimated 20%–30% of cases are asymptomatic. Complications can include inflammation of the testicles or ovaries, meningitis/encephalitis, spontaneous abortion, and deafness. During the prevaccine era, nearly everyone in the United States experienced mumps, and 90% of cases occurred among children aged <15 years. In 1977, Iowa law mandated 1 dose of measles, mumps, and rubella (MMR) vaccine for entry to public schools; in 1991, the mandate became 2 doses. For the 2004–05 school year, 97% of children entering school in Iowa had received 2 doses of MMR vaccine (*2*).

The first reports to the Iowa Department of Public Health (IDPH) of mumps-like illness occurred in December 2005 at a university in eastern Iowa, where several students with glandular swelling were tested; two tested positive for mumps-specific IgM antibodies. In mid-January 2006, an isolate from an unrelated patient was cultured and identified as mumps virus at the University Hygienic Laboratory (Iowa's state public health laboratory). Viral isolates were sent to CDC, and the mumps strain was identified as genotype G. By mid-February, active surveillance had been initiated in seven geographic areas, including the campuses of the three largest universities in Iowa.

* Data available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5511md.htm#tab1.
† Data available at http://www.idph.state.ia.us/adper/common/pdf/cade/decades.pdf.
§ Includes 150 confirmed, nine probable, and 60 suspect cases. Case definitions were modified from Council of State and Territorial Epidemiologists/CDC mumps case definitions for use in this outbreak. *Confirmed:* case that meets the clinical case definition (i.e., unilateral or bilateral tender, self-limited, swelling of the parotid or other salivary gland, lasting >2 days and without other apparent cause) and is laboratory confirmed (i.e., by a positive IgM test result or positive viral culture) or epidemiologically linked to a confirmed case. A confirmed case can be asymptomatic if a mumps viral culture is positive. *Probable:* case that meets the clinical case definition but has noncontributory or no serologic or virologic testing and is not epidemiologically linked to a confirmed or probable case. *Suspect:* case with a positive IgM test result but no confirmation of the clinical definition.

Reference #4

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MENVEO safely and effectively. See full prescribing information for MENVEO.

MENVEO [Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM_{197} Conjugate Vaccine]
for injection, for intramuscular use
Initial U.S. Approval: 2010

RECENT MAJOR CHANGES

Dosage and Administration (2.1, 2.2)	09/2019
Dosage and Administration, Dosing Schedule (2.3)	12/2019

INDICATIONS AND USAGE

MENVEO is a vaccine indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135. MENVEO is approved for use in persons aged 2 months through 55 years. MENVEO does not prevent *N. meningitidis* serogroup B infections. (1)

DOSAGE AND ADMINISTRATION

- For intramuscular injection only (0.5 mL). (2)
- MENVEO is supplied in 2 vials that must be combined prior to administration: reconstitute the MenA lyophilized conjugate vaccine component with the MenCYW-135 liquid conjugate vaccine component immediately before administration. (2.1)

Primary Vaccination

- In children initiating vaccination at 2 months of age, MENVEO is to be administered as a 4-dose series at 2, 4, 6, and 12 months of age. (2.3)
- In children initiating vaccination at 7 months through 23 months of age, MENVEO is to be administered as a 2-dose series with the second dose administered in the second year of life and at least 3 months after the first dose. (2.3)
- In individuals aged 2 through 55 years MENVEO is to be administered as a single dose. (2.3)

Booster Vaccination

- A single booster dose of MENVEO may be administered to individuals aged 15 through 55 years who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of a meningococcal (serogroups A, C, Y, W-135) conjugate vaccine. (2.3)

DOSAGE FORMS AND STRENGTHS

Solution for intramuscular injection supplied as a lyophilized MenA conjugate vaccine component to be reconstituted with the accompanying MenCYW-135 liquid conjugate vaccine component. A single dose after reconstitution is 0.5 mL. (3)

CONTRAINDICATIONS

Severe allergic reaction (e.g., anaphylaxis) after a previous dose of MENVEO, any component of this vaccine, or any other CRM_{197}-, diphtheria toxoid-, or meningococcal-containing vaccine is a contraindication to administration of MENVEO. (4)

WARNINGS AND PRECAUTIONS

- Appropriate medical treatment must be available should an acute allergic reaction, including an anaphylactic reaction, occur following administration of MENVEO. (5.1)
- Syncope, sometimes resulting in falling injury, has been reported following vaccination with MENVEO. Vaccinees should be observed for at least 15 minutes after vaccine administration. (5.2)
- Apnea following intramuscular vaccination has been observed in some infants born prematurely. The decision about when to administer an intramuscular vaccine, including MENVEO, to an infant born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination. (5.5)

ADVERSE REACTIONS

- Common solicited adverse reactions (≥10%) among children initiating vaccination at 2 months of age and receiving the 4-dose series were tenderness (24% to 41%) and erythema at injection site (11% to 15%), irritability (42% to 57%), sleepiness (29% to 50%), persistent crying (21% to 41%), change in eating habits (17% to 23%), vomiting (5% to 11%), and diarrhea (8% to 16%). (6.1)
- Common solicited adverse reactions (≥10%) among children initiating vaccination at 7 months through 23 months of age and receiving the 2-dose series were tenderness (10% to 16%) and erythema at injection site (12% to 15%), irritability (27% to 40%), sleepiness (17% to 29%), persistent crying (12-21%), change in eating habits (12% to 20%), and diarrhea (10% to 16%). (6.1)
- Common solicited adverse reactions (≥10%) among children aged 2 through 10 years who received MENVEO were injection site pain (31%), erythema (23%), irritability (18%), induration (16%), sleepiness (14%), malaise (12%), and headache (11%). (6.1)
- Common solicited adverse reactions (≥10%) among adolescents and adults who received a single dose of MENVEO were pain at the injection site (41%), headache (30%), myalgia (18%), malaise (16%), and nausea (10%). Similar rates of solicited adverse reactions were observed following a single booster dose. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

DRUG INTERACTIONS

Do not mix MENVEO or any of its components with any other vaccine or diluent in the same syringe or vial. (7.1)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 01/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

MENVEO is a vaccine indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135. MENVEO is approved for use in persons aged 2 months through 55 years.

MENVEO does not prevent *N. meningitidis* serogroup B infections.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Reconstitution

MENVEO is supplied in 2 vials that must be combined prior to administration. Use the MenCYW-135 liquid conjugate vaccine component (Vial 1) to reconstitute the MenA lyophilized conjugate vaccine component (Vial 2) to form MENVEO. Invert the vial and shake well until the vaccine is dissolved and then withdraw 0.5 mL of reconstituted product. Following reconstitution, the vaccine is a clear, colorless solution, free from visible foreign particles. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If any of these conditions exist, MENVEO should not be administered.

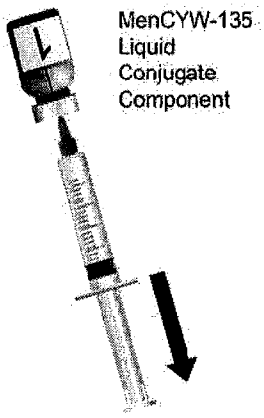


Figure 1. Cleanse both vial stoppers. Using a sterile needle and sterile graduated syringe, withdraw the entire contents of Vial 1 containing the MenCYW-135 liquid conjugate component while slightly tilting the vial.

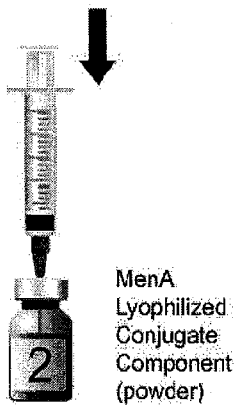


Figure 2. Slowly transfer entire contents of the syringe into Vial 2 containing the MenA lyophilized conjugate component (powder).

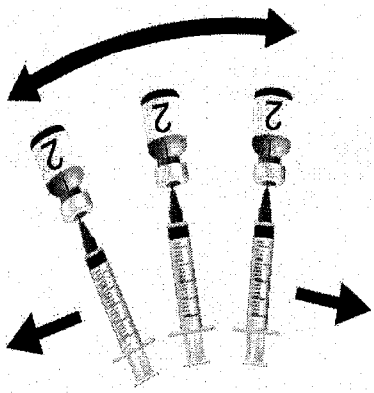


Figure 3. Invert the vial and shake well until powder is completely dissolved.

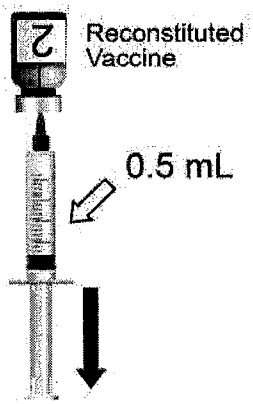


Figure 4. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine. Administer **intramuscularly**.

Please note that it is normal for a small amount of liquid to remain in the vial following withdrawal of the dose. Discard unused portion.

2.2 Administration Instructions

For intramuscular injection only.

After reconstitution, administer MENVEO immediately or store between 36°F and 77°F (2°C and 25°C) for up to 8 hours. Shake well before using. Do not freeze. Discard reconstituted vaccine if it has been frozen or not used within 8 hours.

Use a separate sterile needle and sterile syringe for each individual. Each dose of MENVEO should be administered as a single 0.5-mL intramuscular injection, preferably into the anterolateral aspect of the thigh in infants or into the deltoid muscle (upper arm) in toddlers, adolescents, and adults. Do not administer MENVEO intravenously, subcutaneously, or intradermally.

2.3 Dosing Schedule

The dosing schedule is as follows:

Primary Vaccination

Infants Aged 2 Months: MENVEO is to be administered as a 4-dose series at 2, 4, 6, and 12 months of age.

Children Aged 7 through 23 Months: MENVEO is to be administered as a 2-dose series with the second dose administered in the second year of life and at least 3 months after the first dose.

Children Aged 2 through 10 Years: MENVEO is to be administered as a single dose. For children aged 2 through 5 years at continued high risk of meningococcal disease, a second dose may be administered 2 months after the first dose.

Adolescents and Adults Aged 11 through 55 Years: MENVEO is to be administered as a single dose.

Booster Vaccination

Adolescents and Adults Aged 15 through 55 Years: A single booster dose of MENVEO may be administered to individuals who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of a meningococcal (serogroups A, C, Y, W-135) conjugate vaccine.

3 DOSAGE FORMS AND STRENGTHS

MENVEO is a solution for intramuscular injection supplied as a lyophilized MenA conjugate vaccine component to be reconstituted with the accompanying MenCYW-135 liquid conjugate vaccine component. A single dose, after reconstitution, is 0.5 mL. *[See Dosage and Administration (2), How Supplied/Storage and Handling (16).]*

4 CONTRAINDICATIONS

Severe allergic reaction (e.g., anaphylaxis) after a previous dose of MENVEO, any component of this vaccine, or any other CRM_{197}-, diphtheria toxoid-, or meningococcal-containing vaccine is a contraindication to administration of MENVEO. *[See Description (11).]*

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment must be available should an acute allergic reaction, including an anaphylactic reaction, occur following administration of MENVEO.

5.2 Syncope

Syncope, sometimes resulting in falling injury associated with seizure-like movements, has been reported following vaccination with MENVEO. Vaccinees should be observed for at least 15 minutes after vaccine administration to prevent and manage syncopal reactions.

5.3 Altered Immunocompetence

Reduced Immune Response

Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to MENVEO.

Complement Deficiency

Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by *N. meningitidis*, including invasive disease caused by serogroups A, C, Y, and W, even if they develop antibodies following vaccination with MENVEO. *[See Clinical Pharmacology (12.1).]*

5.4 Guillain-Barré Syndrome

Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of another U.S.-licensed meningococcal quadrivalent polysaccharide conjugate vaccine. The decision to administer MENVEO to subjects with a known history of Guillain-Barré Syndrome should take into account the potential benefits and risks.

5.5 Apnea in Premature Infants

Apnea following intramuscular vaccination has been observed in some infants born prematurely. The decision about when to administer an intramuscular vaccine, including MENVEO, to an infant born prematurely should be based on consideration of the individual infant's medical status, and the potential benefits and possible risks of vaccination.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Primary Vaccination Studies

Children Aged 2 through 23 Months: The safety of MENVEO in infants vaccinated at 2, 4, 6, and 12 months of age was evaluated in 3 randomized multicenter clinical studies[1-3] conducted in the U.S., Australia, Canada, Taiwan, and several countries of Latin America in which 8,735 infants received at least 1 dose of MENVEO and routine infant vaccines (diphtheria toxoid;

acellular pertussis; tetanus toxoid; inactivated polio types 1, 2, and 3; hepatitis B; *Haemophilus influenzae* type b (Hib) antigens; pentavalent rotavirus; and 7-valent pneumococcal conjugate). With Dose 4 of MENVEO, toddlers received concomitantly the following vaccines: 7-valent pneumococcal conjugate; measles, mumps, rubella, and varicella; and inactivated hepatitis A. A total of 2,864 infants in these studies received the routine infant/toddler vaccines only. The infants who received MENVEO were Caucasian (33%), Hispanic (44%), African American (8%), Asian (8%), and other racial/ethnic groups (7%); 51% were male, with a mean age of 65.1 days (Standard Deviation [SD]: 7.5 days) at the time of first vaccination.

Safety data for administration of 2 doses of MENVEO in children aged 6 through 23 months are available from 3 randomized studies[1,4,5] conducted in the U.S., Latin America, and Canada, of which one U.S. study specifically addressed the safety of MENVEO administered concomitantly with measles, mumps, rubella, and varicella vaccine (MMRV). The 1,985 older infants and toddlers who received 2 doses of MENVEO were Caucasian (49%), Hispanic (32%), African American (11%), and other racial/ethnic groups (8%), 51% male, with a mean age of 10.1 months (SD: 2.0 months).

Children Aged 2 through 10 Years: The safety of MENVEO in children aged 2 through 10 years was evaluated in 4 clinical trials[6-9] conducted in North America (66%), Latin America (28%), and Europe (6%) in which 3,181 subjects received MENVEO and 2,116 subjects received comparator vaccines (either Meningococcal Polysaccharide Vaccine, Groups A, C, Y, and W-135 Combined - MENOMUNE, Sanofi Pasteur [n = 861], or Meningococcal (Groups A, C, Y, and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine - MENACTRA, Sanofi Pasteur [n = 1,255]). The subjects aged 2 through 10 years who received MENVEO were Caucasian (69%), Hispanic (13%), African American (7%), and other racial/ethnic groups (6%), 51% male, with a mean age of 5.2 years. The safety of a second dose of MENVEO administered 2 months following a first dose was studied in 351 children aged 2 through 5 years.

Adolescents and Adults: The safety of MENVEO in individuals aged 11 through 55 years was evaluated in 5 randomized controlled clinical trials[10-14] in which 6,185 participants received MENVEO alone (5,286 participants), MENVEO concomitant with other vaccine(s) (899 participants), or a U.S.-licensed comparator vaccine (1,966 participants). In the concomitant trials[11,14] MENVEO was given with vaccines containing: tetanus toxoid, diphtheria toxoid, and pertussis (Tdap), or Tdap with human papillomavirus (HPV). The comparator vaccine was either MENOMUNE (209 participants) or MENACTRA (1,757 participants). The trials were conducted in North America (46%), Latin America (41%), and Europe (13%). In 2 of the studies, subjects received concomitant vaccination with Tdap or with Tdap plus HPV. Overall, subjects were Caucasian (50%), followed by Hispanic (40%), African American (7%), and other racial/ethnic groups (3%). Among recipients of MENVEO, 61%, 17%, and 22% were in the 11- through 18-year, 19- through 34-year, and 35- through 55-year age groups, respectively, with a mean age of 23.5 years (SD: 12.9 years). Among recipients of MENACTRA, 31%, 32%, and 37% were in the 11- through 18-year, 19- through 34-year, and 35- through 55-year age groups,

respectively, with a mean age of 29.2 years (SD: 13.4 years). Among MENOMUNE recipients, 100% were in the 11- through 18-year age group, and the mean age was 14.2 years (SD: 1.8 years).

Booster Vaccination Study

In a multicenter, open-label trial (NCT02986854)[15] conducted in the U.S., 601 subjects aged 15 to 51 years received a single booster dose of MENVEO 4 to 6 years after prior vaccination with MENVEO (n = 301; median age: 16 years) or MENACTRA (n = 300; median age: 16 years). Across booster groups of MENVEO, 81% of subjects were white and 50% were female.

In most trials, solicited local and systemic adverse reactions were monitored daily for 7 days following each (one or more) vaccination and recorded on a diary card. Participants were monitored for unsolicited adverse events which included adverse events requiring a physician visit or Emergency Department visit (i.e., medically-attended) or which led to a subject's withdrawal from the study. Among children, adolescents, and adults aged 2 to 55 years, medically significant adverse events and serious adverse events (SAE) were monitored for 6 months after vaccination. Across the studies of infants and toddlers aged 2 through 23 months, either all medically-attended or all medically-significant adverse events were collected in the period between the infant dose(s) and the toddler doses and during the 6-month period after the toddler dose.

Solicited Adverse Reactions in the Primary Vaccination Studies

The reported frequencies of solicited local and systemic adverse reactions from U.S. infants in the largest multinational safety study of MENVEO[2] are presented in Table 1. Among the U.S. participants in the group receiving MENVEO with routine vaccines, 51% were female; 64% were Caucasian, 12% were African American, 15% were Hispanic, 2% were Asian, and 7% were of other racial/ethnic groups.

In infants initiating vaccination at 2 months of age and receiving the 4-dose series, common solicited adverse reactions (≥10%) were tenderness (24% to 41%) and erythema at injection site (11% to 15%), irritability (42% to 57%), sleepiness (29% to 50%), persistent crying (21% to 41%), change in eating habits (17% to 23%), vomiting (5% to 11%), and diarrhea (8% to 16%). The rates of solicited adverse reactions reported for subjects aged 2 months and older receiving MENVEO with routine vaccines at 2, 4, 6, and 12 months of age were comparable to rates among subjects who only received routine vaccines.

Table 1. Rates of Solicited Adverse Reactions Reported in U.S. Infants, Aged 2 Months and Older, during the 7 Days following Each Vaccination of MENVEO Administered with Routine Infant/Toddler Vaccines, or Routine Infant/Toddler Vaccines Alone at 2, 4, 6, and 12 Months of Age[a]

	Dose 1		Dose 2		Dose 3		Dose 4	
Adverse Reactions	**MENVEO with Routine[b] %**	**Routine Vaccines[b] %**	**MENVEO with Routine[b] %**	**Routine Vaccines[b] %**	**MENVEO with Routine[b] %**	**Routine Vaccines[b] %**	**MENVEO with Routine[b] %**	**Routine Vaccines[b] %**
Local Adverse Reactions[c]	**n = 1,250-1,252**	**n = 428**	**n = 1,205-1,207**	**n = 399**	**n = 1,056-1,058**	**n = 351-352**	**n = 1,054-1,055**	**n = 334-337**
Tenderness, any	41	45	31	36	24	32	29	39
Tenderness, severe[d]	3	5	2	2	1	3	1	1
Erythema, any	11	14	12	21	14	23	15	25
Erythema, >50 mm	<1	<1	0	0	0	0	0	0
Induration, any	8	16	9	17	8	19	8	21
Induration, >50 mm	0	<1	0	0	0	0	0	0
Systemic Adverse Reactions	**n = 1,246-1,251**	**n = 427-428**	**n = 1,119-1,202**	**n = 396-398**	**n = 1,050-1,057**	**n = 349-350**	**n = 1,054-1,056**	**n = 333-337**
Irritability, any	57	59	48	46	42	38	43	42
Irritability, severe[e]	2	2	1	3	1	1	2	1
Sleepiness, any	50	50	37	36	30	30	29	27
Sleepiness, severe[f]	2	1	1	1	<1	<1	1	0
Persistent crying, any	41	38	28	24	22	17	21	18
Persistent crying, ≥3 hours	2	2	2	2	1	1	1	1
Change in eating habits, any	23	24	18	17	17	13	19	16
Change in eating habits, severe[g]	1	1	1	1	1	<1	1	0
Vomiting, any	11	9	7	6	6	4	5	4
Vomiting, severe[h]	<1	0	<1	0	<1	0	<1	0
Diarrhea, any	16	11	11	8	8	6	13	9
Diarrhea, severe[i]	<1	<1	<1	<1	1	<1	1	1
Rash[j]	3	3	3	4	3	3	4	3
Fever ≥38.0°C[k]	3	2	4	6	7	6	9	7
Fever 38.0-38.9°C	3	2	4	5	7	6	6	5
Fever 39.0-39.9°C	0	0	1	1	<1	0	2	2

Fever≥40.0°C	0	<1	0	<1	0	0	<1	0

Clinicaltrials.gov Identifier NCT00806195.[2]

n = Number of subjects who completed the diary card for a given symptom at the specified vaccination.

[a] As-Treated Safety Subpopulation = U.S. children who received at least 1 dose of study vaccine and whose diary cards were completed per protocol and returned to the site.

[b] Routine infant/toddler vaccines include DTaP-IPV-Hib and PCV7 at Doses 1, 2, 3, and PCV7, MMRV, and Hepatitis A vaccines at Dose 4. HBV and rotavirus vaccines were allowed according to Advisory Committee on Immunization Practices (ACIP) recommendations.

[c] Local reactogenicity of MENVEO and PCV7 was assessed.

[d] Tenderness, severe = Cried when injected limb moved.

[e] Irritability, severe = Unable to console.

[f] Sleepiness, severe = Sleeps most of the time, hard to arouse.

[g] Change in eating habits, severe = Missed >2 feeds.

[h] Vomiting, severe = Little/no intake for more prolonged time.

[i] Diarrhea, severe = ≥6 liquid stools, no solid consistency.

[j] Rash was assessed only as present or not present, without a grading for severity.

[k] Axillary temperature.

The safety of a second dose of MENVEO administered at 12 months of age concomitantly with MMRV was investigated in a randomized, controlled, multicenter study[5] conducted in the U.S. The rates of solicited adverse reactions reported were comparable between the concomitantly administered group (MENVEO with MMRV) and the group which received MMRV alone or MENVEO alone. The frequency and severity of solicited local and systemic reactions occurring within 7 days following vaccination at 12 months of age are shown in Table 2. In subjects who received both MENVEO and MMRV at 12 months of age local reactions at both injection sites were evaluated separately. Body temperature measurements were collected for 28 days following the 12-months-of-age visit, when MMRV was administered to the vaccinees. Common solicited adverse reactions (≥10%) among children initiating vaccination at 7 months through 23 months of age and receiving the 2-dose series were tenderness (10% to 16%) and erythema at injection site (12% to 15%), irritability (27% to 40%), sleepiness (17% to 29%), persistent crying (12% to 21%), change in eating habits (12% to 20%), and diarrhea (10% to 16%). An examination of the fever profile during this period showed that MENVEO administered with MMRV did not increase the frequency or intensity of fever above that observed for the MMRV-only group.

Table 2. Rates of Solicited Adverse Reactions Reported in U.S. Toddlers during the 7 Days following Vaccination with MENVEO Administered at 7-9 Months and 12 Months of Age, MENVEO Administered Alone at 7-9 Months and with MMRV at 12 Months of Age, and MMRV Administered Alone at 12 Months of Age[a]

	MENVEO		MENVEO + MMRV		MMRV
Adverse Reactions	**MENVEO 7-9 Months %**	**MENVEO 12 Months %**	**MENVEO 7-9 Months %**	**MENVEO with MMRV 12 Months %**	**MMRV 12 Months %**
Local Adverse Reactions– MENVEO	**n = 460-462**	**n = 381-384**	**n = 430-434**	**n = 386-387**	
Tenderness, any	11	10	11	16	N/A
Tenderness, severe[b]	<1	<1	<1	0	N/A
Erythema, any	15	13	13	12	N/A
Erythema, >50 mm	<1	<1	0	1	N/A
Induration, any	8	8	7	8	N/A
Induration, >50 mm	<1	<1	0	1	N/A
Local Adverse Reactions– MMRV				**n = 382-383**	**n = 518-520**
Tenderness, any	N/A	N/A	N/A	16	19
Tenderness, severe[b]	N/A	N/A	N/A	0	<1
Erythema, any	N/A	N/A	N/A	15	14
Erythema, >50 mm	N/A	N/A	N/A	1	<1
Induration, any	N/A	N/A	N/A	13	8
Induration, >50 mm	N/A	N/A	N/A	<1	0
Systemic Adverse Reactions	**n = 461-463**	**n = 385-386**	**n = 430-434**	**n = 387-389**	**n = 522-524**
Irritability, any	40	27	37	37	44
Irritability, severe[c]	2	2	2	1	3
Sleepiness, any	26	17	29	26	32
Sleepiness, severe[d]	2	1	1	1	2
Persistent crying, any	21	12	20	19	20
Persistent crying, ≥3 hours	2	1	1	1	2
Change in eating habits, any	17	12	17	20	20
Change in eating habits, severe[e]	<1	1	1	2	1
Vomiting, any	9	6	9	6	6
Vomiting, severe[f]	<1	<1	<1	<1	<1
Diarrhea, any	16	10	15	15	20
Diarrhea, severe[g]	2	1	<1	1	2
Rash[h]	3	5	6	6	8
Fever ≥38.0°C[i]	5	5	6	9	7
Fever 38.0-38.9°C	3	3	5	7	7
Fever 39.0-39.9°C	2	2	1	1	1
Fever ≥40.0°C	<1	1	<1	<1	0

Clinicaltrials.gov Identifier NCT00626327.[5]

n = Number of subjects who completed the diary card for a given symptom at the specified vaccination.

[a] As-Treated Safety Subpopulation = U.S. children who received at least 1 dose of study vaccine and whose diary cards were completed per protocol and returned to the site.

[b] Tenderness, severe = Cried when injected limb moved.

[c] Irritability, severe = Unable to console.

[d] Sleepiness, severe = Sleeps most of the time, hard to arouse.

[e] Change in eating habits, severe = Missed >2 feeds.

[f] Vomiting, severe = Little/no intake for more prolonged time.

[g] Diarrhea, severe = ≥6 liquid stools, no solid consistency.

[h] Rash was assessed only as present or not present, without a grading for severity.

[i] Axillary temperature.

In clinical trials of children aged 2 through 10 years,[6-9] the most frequently occurring adverse reactions (≥10%) among all subjects who received MENVEO were injection site pain (31%), erythema (23%), irritability (18%), induration (16%), sleepiness (14%), malaise (12%), and headache (11%). Among subjects aged 11 through 55 years, the most frequently occurring adverse reactions (≥10%) among all subjects who received MENVEO were pain at the injection site (41%), headache (30%), myalgia (18%), malaise (16%), and nausea (10%).

The rates of solicited adverse reactions reported for subjects aged 2 through 5 years and 6 through 10 years who received a single dose of MENVEO or MENACTRA in a randomized, controlled, multicenter study[9] conducted in the U.S. and Canada are shown in Table 3. Following a second dose of MENVEO administered to children aged 2 through 5 years, the most common solicited adverse reactions (≥10%) were pain at injection site (28%), erythema (22%), irritability (16%), induration (13%), and sleepiness (12%). The solicited adverse reactions from a separate randomized, controlled, multicenter study conducted in the U.S. in adolescents and adults[12] are provided in Tables 4 and 5, respectively. In neither study were concomitant vaccines administered with the study vaccines.

Table 3. Rates of Solicited Adverse Reactions within 7 Days following a Single Vaccination in Children Aged 2 through 5 Years and 6 through 10 Years

	Participants Aged 2 through 5 Years					
	MENVEO n = 693 %			**MENACTRA n = 684 %**		
Adverse Reactions	**Any**	**Moderate**	**Severe**	**Any**	**Moderate**	**Severe**
Local Adverse Reactions						
Injection site pain[a]	33	6	1	35	8	0.4
Erythema[b]	27	5	1	25	3	0.3
Induration[b]	18	2	0.4	18	2	0.3
Systemic Adverse Reactions[e]						
Irritability[a]	21	6	1	22	7	1
Sleepiness[a]	16	3	1	18	5	1
Change in eating[a]	9	2	1	10	2	0.3

Diarrhea[a]	7	1	0.1	8	1	0
Headache[a]	5	1	0	6	1	0.3
Rash[c]	4	-	-	5	-	-
Arthralgia[a]	3	1	0.1	4	1	0
Vomiting[a]	3	1	0.1	3	1	0
Fever[d]	2	0.4	0	2	0.3	0
Participants Aged 6 through 10 Years						
	MENVEO n = 582 %			**MENACTRA n = 571 %**		
Adverse Reactions	**Any**	**Moderate**	**Severe**	**Any**	**Moderate**	**Severe**
Local Adverse Reactions						
Injection site pain[a]	39	8	1	45	10	2
Erythema[b]	28	5	1	22	2	0.2
Induration[b]	17	2	0.3	13	2	0
Systemic Adverse Reactions[e]						
Headache[a]	18	3	1	13	2	1
Malaise[a]	14	3	1	11	3	1
Myalgia[a]	10	2	1	10	2	1
Nausea[a]	8	2	1	6	2	0.4
Arthralgia[a]	6	1	0	4	1	0.4
Chills[a]	5	1	0	5	1	0.4
Rash[c]	5	-	-	3	-	-
Fever[d]	2	1	0	2	0	0.4

Clinicaltrials.gov Identifier NCT00616421.[9]

[a] Moderate: Some limitation in normal daily activity, Severe: Unable to perform normal daily activity.

[b] Moderate: ≥50-100 mm, Severe: >100 mm.

[c] Rash was assessed only as present or not present, without a grading for severity.

[d] Fever grading: Any: ≥38°C, Moderate: 39-39.9°C, Severe: ≥40°C. Parents reported the use of antipyretic medication to treat or prevent symptoms in 11% and 13% of subjects aged 2 through 5 years, 9% and 10% of subjects aged 6 through 10 years for MENVEO and MENACTRA, respectively.

[e] Different systemic reactions were solicited in different age groups.

Table 4. Rates of Solicited Adverse Reactions within 7 Days following Vaccination in Individuals Aged 11 through 18 Years

Adverse Reactions	MENVEO n = 1,631 %			MENACTRA n = 539 %		
	Any	Moderate	Severe	Any	Moderate	Severe
Local Adverse Reactions						
Injection site pain[a]	44	9	1	53	11	1
Erythema[b]	15	2	0.4	16	1	0
Induration[b]	12	2	0.2	11	1	0
Systemic Adverse Reactions						
Headache[a]	29	8	2	28	7	1
Myalgia[a]	19	4	1	18	5	0.4
Nausea[a]	12	3	1	9	2	1
Malaise[a]	11	3	1	12	5	1
Chills[a]	8	2	1	7	1	0.2
Arthralgia[a]	8	2	0.4	6	1	0
Rash[c]	3	-	-	3	-	-
Fever[d]	1	0.4	0	1	0	0

Clinicaltrials.gov Identifier NCT00450437.[12]

[a] Moderate: Some limitation in normal daily activity, Severe: Unable to perform normal daily activity.

[b] Moderate: ≥50-100 mm, Severe: >100 mm.

[c] Rash was assessed only as present or not present, without a grading for severity.

[d] Fever grading: Any: ≥38°C, Moderate: 39-39.9°C, Severe: ≥40°C.

Table 5. Rates of Solicited Adverse Reactions within 7 Days following Vaccination in Individuals Aged 19 through 55 Years

Adverse Reactions	MENVEO n = 1,018 %			MENACTRA n = 336 %		
	Any	Moderate	Severe	Any	Moderate	Severe
Local Adverse Reactions						
Injection site pain[a]	38	7	0.3	41	6	0
Erythema[b]	16	2	1	12	1	0
Induration[b]	13	1	0.4	9	0.3	0
Systemic Adverse Reactions						
Headache[a]	25	7	2	25	7	1
Myalgia[a]	14	4	0.5	15	3	1

Malaise[a]	10	3	1	10	2	1
Nausea[a]	7	2	0.4	5	1	0.3
Arthralgia[a]	6	2	0.4	6	1	1
Chills[a]	4	1	0.1	4	1	0
Rash[c]	2	-	-	1	-	-
Fever[d]	1	0.3	0	1	0.3	0

Clinicaltrials.gov Identifier NCT00450437.[12]

[a] Moderate: Some limitation in normal daily activity, Severe: Unable to perform normal daily activity.

[b] Moderate: ≥50-100 mm, Severe: >100 mm.

[c] Rash was assessed only as present or not present, without a grading for severity.

[d] Fever grading: Any: ≥38°C, Moderate: 39-39.9°C, Severe: ≥40°C.

Solicited Adverse Reactions in the Booster Vaccination Study (Adolescents and Adults)

A multicenter, open-label clinical trial (NCT02986854)[15] was conducted in the U.S. in subjects aged 15 through 55 years *[see Clinical Studies (14.2)]*. The methodology for evaluating solicited adverse reactions, unsolicited adverse events, and serious adverse events after a booster dose of MENVEO was similar to the primary vaccination studies. The most common solicited local and systemic adverse reactions within 7 days of vaccination were pain at injection site (36%) and fatigue (38%), respectively.

Solicited Adverse Reactions following Concomitant Vaccine Administration

The safety of 4-dose series of MENVEO administered concomitantly with U.S.-licensed routine infant and toddler vaccines was evaluated in one pivotal trial[2]. The safety of a 2-dose series of MENVEO initiated at 7-9 months of age, with the second dose administered concomitantly with U.S.-licensed MMR and V vaccine at 12 months of age, was evaluated in one pivotal trial.[5] Rates of solicited adverse reactions which occurred 7 days following vaccination are shown in Tables 1 and 2, respectively. There was no significant increase in the rates of solicited systemic or local reactions observed in recipients of routine childhood vaccines when concomitantly vaccinated with MENVEO. *[See Drug Interactions (7.1).]*

The safety of MENVEO administered concomitantly with Tdap and HPV was evaluated in a single-center study[14] conducted in Costa Rica. Solicited local and systemic adverse reactions were reported as noted above. In this study, subjects aged 11 through 18 years received MENVEO concomitantly with Tdap and HPV (n = 540), or MENVEO followed 1 month later by Tdap and then 1 month later by HPV (n = 541), or Tdap followed 1 month later by MENVEO and then 1 month later by HPV (n = 539). Some solicited systemic adverse reactions were more frequently reported in the group that received MENVEO, Tdap, and HPV concomitantly, (headache 40%, malaise 25%, myalgia 27%, and arthralgia 17%) compared with the group that first received MENVEO alone (headache 36%, malaise 20%, myalgia 19%, and arthralgia 11%). Among subjects administered MENVEO alone (1 month prior to Tdap), 36% reported headache,

20% malaise, and 16% myalgia. Among subjects administered MENVEO 1 month after Tdap, 27% reported headache, 18% malaise, and 16% myalgia.

Serious Adverse Events in All Safety Studies

Serious adverse events in subjects receiving a 4-dose series of MENVEO at 2, 4, 6, and 12 months were evaluated in 3 randomized, multicenter clinical studies.[1-3] In the 2 controlled studies,[2,3] the proportions of infants randomized to receive the 4-dose series of MENVEO concomitantly with routine vaccinations and infants who received routine vaccinations alone that reported serious adverse events during different study periods were, respectively: a) 2.7% and 2.2% during the infant series, b) 2.5% and 2.5% between the infant series and the toddler dose, c) 0.3% and 0.3% in the 1 month following the toddler dose, and d) 1.6% and 2.2% during the 6-month follow-up period after the last dose. In the third study,[1] which was controlled up to the toddler dose, the proportions of infants randomized to dosing regimens that included receiving 4 doses of MENVEO concomitantly with routine vaccinations at 2, 4, 6, and 12 months and infants who received routine vaccinations alone that reported serious adverse events during different study periods were, respectively: a) 3.5% and 3.6% during the infant series, and b) 2.8% and 3.3% between the infant series and the toddler dose, and c) 0.5% and 0.7% in the 1 month following the toddler dose. In the same study, 1.9% of infants randomized to receive the 4-dose series of MENVEO concomitantly with routine vaccinations reported serious adverse events during the 6-month follow-up period after the toddler dose. The most common serious adverse events reported in these 3 studies were wheezing, pneumonia, gastroenteritis, and convulsions, and most occurred at highest frequency after the infant series.

In a study of older infants[5] randomized to receive the 2-dose series of MENVEO concomitantly with MMRV at 12 months of age, the rates of serious adverse events during the study, including the 6-month follow-up period after the last dose, were 3.6% and 3.8% for the groups receiving MENVEO with MMRV and MENVEO only, respectively. Infants receiving MMRV alone, who had a shorter period of study participation as they were enrolled at 12 months of age, had a lower rate of serious adverse events (1.5%). Among 1,597 study subjects included in the safety population, the most commonly reported serious adverse events in all study arms combined were dehydration (0.4%) and gastroenteritis (0.3%). Across the submitted studies of individuals aged 2 through 23 months within 28 days of vaccination, 2 deaths were reported in the groups receiving MENVEO (one case of sudden death and one case of sepsis), while no deaths were reported in the control group. None of the deaths was assessed as related to vaccination. Among subjects with symptom onset within 42 days of vaccination (Days 12, 25, 29), 3/12,049 (0.02%, 95% CI: [0.01%, 0.07%]) recipients of MENVEO and 0/2,877 (0%, 95% CI: [0%, 0.13%]) control recipients were diagnosed with Kawasaki Disease. One case of acute disseminated encephalomyelitis with symptom onset 29 days post Dose 4 was observed in a participant given MENVEO coadministered with routine U.S. childhood vaccines at 12 months of age (including MMR and varicella vaccines).

The information regarding serious adverse events in subjects aged 2 through 10 years was derived from 3 randomized, controlled clinical trials.[7-9] Safety follow-up ranged from 6 through 12 months and included 2,883 subjects administered MENVEO. Serious adverse events reported during the safety follow-up periods occurred in 21/2,883 (0.7%) subjects receiving MENVEO, in 7/1,255 (0.6%) MENACTRA subjects, and 2/861 (0.2%) MENOMUNE subjects. In the subjects receiving either 1 or 2 doses of MENVEO, there were 6 subjects with pneumonia, 3 subjects with appendicitis, and 2 subjects with dehydration; all other events were reported to occur in one subject. Among 1,255 subjects administered a single dose of MENACTRA and 861 subjects administered MENOMUNE, there were no events reported to occur in more than 1 subject. The serious adverse events occurring within the first 30 days after receipt of each vaccine were as follows: MENVEO (6/2,883 [0.2%]) — appendicitis, pneumonia, staphylococcal infection, dehydration, febrile convulsion, and tonic convulsion; MENACTRA (1/1255 [0.1%]) — inguinal hernia; MENOMUNE (2/861 [0.2%]) — abdominal pain, lobar pneumonia. In a supportive study,[6] 298 subjects received 1 or 2 doses of MENVEO and 22 (7%) had serious adverse events over a 13-month follow-up period including 13 subjects with varicella and 2 subjects with laryngitis. All other events were reported to occur in 1 subject. During the 30 days post vaccination in this study, 1 limb injury and 1 case of varicella were reported.

The information regarding serious adverse events in subjects aged 11 through 55 years was derived from 5 randomized, controlled clinical trials.[10-14] Serious adverse events reported within 6 months of vaccination occurred in 40/6,185 (0.6%) subjects receiving MENVEO, 13/1,757 (0.7%) MENACTRA subjects, and 5/209 (2.4%) MENOMUNE subjects. During the 6 months following immunization, serious adverse events reported by more than 1 subject were as follows: MENVEO - appendicitis (3 subjects), road traffic accident (3 subjects), and suicide attempt (5 subjects); MENACTRA - intervertebral disc protrusion (2 subjects); MENOMUNE - none. Serious adverse events that occurred within 30 days of vaccination were reported by 7 of 6,185 (0.1%) subjects in the group receiving MENVEO, 4 of 1,757 (0.2%) subjects in the MENACTRA group, and by none of 209 subjects in the MENOMUNE group. The events that occurred during the first 30 days post immunization with MENVEO were: vitello-intestinal duct remnant, Cushing's syndrome, viral hepatitis, pelvic inflammatory disease, intentional multiple-drug overdose, simple partial seizure, and suicidal depression. The events that occurred during the first 30 days post immunization with MENACTRA were: herpes zoster, fall, intervertebral disc protrusion, and angioedema.

6.2 Postmarketing Experience

In addition to reports in clinical trials, the following adverse reactions have been identified during postapproval use of MENVEO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

Ear and Labyrinth Disorders

Hearing impaired, ear pain, vertigo, vestibular disorder.

Eye Disorders

Eyelid ptosis.

General Disorders and Administration Site Conditions

Injection site pruritus; pain; erythema; inflammation; and swelling, including extensive swelling of the vaccinated limb; fatigue; malaise; pyrexia.

Immune System Disorders

Hypersensitivity reactions, including anaphylaxis.

Infections and Infestations

Vaccination site cellulitis.

Injury, Poisoning, and Procedural Complications

Fall, head injury.

Investigation

Alanine aminotransferase increased, body temperature increased.

Musculoskeletal and Connective Tissue Disorders

Arthralgia, bone pain.

Nervous System Disorders

Dizziness, syncope, tonic convulsion, headache, facial paresis, balance disorder.

Respiratory, Thoracic, and Mediastinal Disorders

Oropharyngeal pain.

Skin and Subcutaneous Tissue Disorders

Skin exfoliation.

Postmarketing Observational Safety Study

In a postmarketing observational safety study conducted in a U.S. health maintenance organization, data from electronic health records of 48,899 persons aged 11 through 21 years were used to evaluate pre-specified events of interest following vaccination with MENVEO. Using a self-controlled case series method, Bell's palsy showed a statistically significant increased risk in the period 1 to 84 days post vaccination compared with the control period, with an overall adjusted relative incidence of 2.9 (95% CI: 1.1-7.5). Among the 8 reported cases of Bell's palsy, 6 cases occurred in persons who received MENVEO concomitantly with one or

more of the following vaccines: Tdap, HPV, and Influenza vaccine. All reported Bell's palsy cases resolved.

7 DRUG INTERACTIONS

7.1 Concomitant Administration with Other Vaccines

Do not mix MENVEO or any of its components with any other vaccine or diluent in the same syringe or vial.

In 2 clinical trials of infants initiating vaccination at 2 months of age,[1,3] MENVEO was given concomitantly at 2, 4, and 6 months with routine infant vaccines: diphtheria toxoid; acellular pertussis; tetanus toxoid; inactivated polio types 1, 2, and 3; hepatitis B; *Haemophilus influenzae* type b (Hib) antigens; pentavalent rotavirus; and 7-valent pneumococcal conjugate vaccine. For Dose 4 given at 12 months of age, MENVEO was given concomitantly with the following vaccines: 7-valent pneumococcal conjugate, MMRV, or MMR+V, and inactivated hepatitis A. In a clinical trial of older infants (aged 7 months and older) and toddlers,[5] MENVEO was administered concomitantly with MMRV or MMR+V vaccine(s) at 12 months of age. No immune interference was observed for the concomitantly administered vaccines, including most pneumococcal vaccine serotypes (post Dose 3); no immune interference was observed post Dose 4 for any pneumococcal vaccine serotypes.[1,3] *[See Clinical Studies (14.3).]*

For children aged 2 through 10 years, no data are available to evaluate safety and immunogenicity of other childhood vaccines when administered concomitantly with MENVEO.

In a clinical trial in adolescents,[14] MENVEO was given concomitantly with the following: Tdap and HPV; no interference was observed in meningococcal immune responses when compared with MENVEO given alone. Lower geometric mean antibody concentrations (GMCs) for antibodies to the pertussis antigens filamentous hemagglutinin (FHA) and pertactin were observed when MENVEO was administered concomitantly with Tdap and HPV as compared with Tdap alone. *[See Clinical Studies (14.3).]*

7.2 Immunosuppressive Treatments

Immunosuppressive therapies, such as irradiation, antimetabolite medications, alkylating agents, cytotoxic drugs, and corticosteroids (when used in greater than physiologic doses) may reduce the immune response to MENVEO *[see Warnings and Precautions (5.3)]*. The immunogenicity of MENVEO has not been evaluated in persons receiving such therapies.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

There are no adequate and well-controlled studies of MENVEO in pregnant women in the U.S. There was a pregnancy exposure registry conducted from 2014-2017 that included 82 subjects. Available data do not suggest an increased risk of major birth defects and miscarriage in women who received MENVEO within 28 days prior to conception or during pregnancy *(see Data)*.

A developmental toxicity study was performed in female rabbits administered 0.5 mL (at each occasion) of MENVEO prior to mating and during gestation. A single human dose is 0.5 mL. This study revealed no adverse effects on fetal or pre-weaning development *(see Data)*.

Data

Human Data: A pregnancy exposure registry (2014 to 2017) included 82 pregnancies with known outcomes with exposure within 28 days prior to conception or during pregnancy. Miscarriage was reported for 12.2% of pregnancies with exposure to MENVEO within 28 days prior to conception or during pregnancy (10/82). Major birth defects were reported for 3.6% of live born infants whose mothers were exposed within 28 days prior to conception or during pregnancy (2/55). The rates of miscarriage and major birth defects were consistent with estimated background rates.

Animal Data: In a developmental toxicity study, female rabbits were administered MENVEO by intramuscular injection on Days 29, 15, and 1 prior to mating and on Gestation Days 7 and 20. The total dose was 0.5 mL at each occasion (a single human dose is 0.5 mL). No adverse effects on pre-weaning development up to Postnatal Day 29 were observed. There were no vaccine-related fetal malformations or variations observed.

8.2 Lactation

Risk Summary

It is not known whether the vaccine components of MENVEO are excreted in human milk. Data are not available to assess the effects of MENVEO in the breastfed infant or on milk production/excretion.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for MENVEO and any potential adverse effects on the breastfed child from MENVEO or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

Reference #5

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Menactra® safely and effectively. See full prescribing information for Menactra vaccine.

Menactra®, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine
Solution for Intramuscular Injection

Initial U.S. Approval: 2005

----------RECENT MAJOR CHANGES ----------
Warnings and Precautions, Altered Immunocompetence (5.3) 4/2018

----------INDICATIONS AND USAGE----------
Menactra is indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135. Menactra is approved for use in individuals 9 months through 55 years of age. Menactra does not prevent *N meningitidis* serogroup B disease. (1)

----------DOSAGE AND ADMINISTRATION----------
A 0.5 mL dose for intramuscular injection. (2)

Primary Vaccination:
- Children 9 through 23 months of age: Two doses, three months apart.
- Individuals 2 through 55 years of age: A single dose.

Booster Vaccination:
- A single booster dose may be given to individuals 15 through 55 years of age at continued risk for meningococcal disease, if at least 4 years have elapsed since the prior dose.

----------DOSAGE FORMS AND STRENGTHS----------
Solution supplied in 0.5 mL single-dose vials (3)

----------CONTRAINDICATIONS----------
- Severe allergic reaction (eg, anaphylaxis) after a previous dose of a meningococcal capsular polysaccharide-, diphtheria toxoid- or CRM_{197}-containing vaccine, or to any component of Menactra. (4)

----------WARNINGS AND PRECAUTIONS----------
- Persons previously diagnosed with Guillain-Barré syndrome (GBS) may be at increased risk of GBS following receipt of Menactra. The decision to give Menactra should take into account the potential benefits and risks. (5.1)

----------ADVERSE REACTIONS----------
- Common (≥10%) solicited adverse events in infants and toddlers 9 and 12 months of age were injection site tenderness, erythema, and swelling; irritability, abnormal crying, drowsiness, appetite loss, vomiting, and fever. (6)
- Common (≥10%) solicited adverse events in individuals 2 through 55 years of age who received a single dose were injection site pain, redness, induration, and swelling; anorexia and diarrhea. Other common solicited adverse events were irritability and drowsiness (2-10 years of age), headache, fatigue, malaise, and arthralgia (11-55 years of age). (6)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Pasteur Inc. at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 or http://vaers.hhs.gov.

----------DRUG INTERACTIONS----------
- When Menactra and DAPTACEL® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) are to be administered to children 4 through 6 years of age, preference should be given to simultaneous administration of the 2 vaccines or administration of Menactra prior to DAPTACEL. Administraton of Menactra one month after DAPTACEL has been shown to reduce meningococcal antibody responses to Menactra. (7.1)
- Pneumococcal antibody responses to some serotypes in Prevnar (PCV7) were decreased following co-administration of Menactra and PCV7. (7.1)

----------USE IN SPECIFIC POPULATIONS----------
- Safety and effectiveness of Menactra have not been established in children younger than 9 months of age, pregnant women, nursing mothers, and adults older than 55 years of age. (8.1, 8.2, 8.4, 8.5)
- A pregnancy registry is available. Contact Sanofi Pasteur Inc. at 1-800-822-2463. (8.1)

See **17 PATIENT_COUNSELING_INFORMATION.**
Revised: April 2018

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION:

1 INDICATIONS AND USAGE

Menactra®, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine, is indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135. Menactra is approved for use in individuals 9 months through 55 years of age. Menactra does not prevent *N meningitidis* serogroup B disease.

2 DOSAGE AND ADMINISTRATION

2.1 Preparation for Administration

Menactra is a clear to slightly turbid solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If any of these conditions exist, the vaccine should not be administered.

Withdraw the 0.5 mL dose of vaccine from the single-dose vial using a sterile needle and syringe.

2.2 Dose and Schedule

Menactra is administered as a 0.5 mL dose by intramuscular injection. Do not administer this product intravenously or subcutaneously.

Primary Vaccination:

- In children 9 through 23 months of age, Menactra is given as a 2-dose series three months apart.

- Individuals 2 through 55 years of age, Menactra is given as a single dose.

Booster Vaccination:

- A single booster dose may be given to individuals 15 through 55 years of age at continued risk for meningococcal disease, if at least 4 years have elapsed since the prior dose.

3 DOSAGE FORMS AND STRENGTHS

Menactra is a solution supplied in 0.5 mL single-dose vials. [See *Description (11)* for a complete listing of ingredients.]

4 CONTRAINDICATIONS

Severe allergic reaction (eg, anaphylaxis) after a previous dose of a meningococcal capsular polysaccharide-, diphtheria toxoid- or CRM_{197}-containing vaccine, or to any component of Menactra [see *Description (11)*].

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome

Persons previously diagnosed with Guillain-Barré syndrome (GBS) may be at increased risk of GBS following receipt of Menactra. The decision to give Menactra should take into account the potential benefits and risks.

GBS has been reported in temporal relationship following administration of Menactra (1) (2). The risk of GBS following Menactra vaccination was evaluated in a post-marketing retrospective cohort study [see *Post-Marketing Experience (6.2)*].

5.2 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions to allow an assessment of benefits and risks. Epinephrine and other appropriate agents used for the control of immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur.

5.3 Altered Immunocompetence

- *Reduced Immune Response*

Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to Menactra.

- *Complement Deficiency*

Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by *N meningitidis*, including invasive disease caused by serogroups A, C, Y and W-135, even if they develop antibodies following vaccination with Menactra. [See *Clinical Pharmacology (12).*]

5.4 Limitations of Vaccine Effectiveness

Menactra may not protect all recipients.

5.5 Syncope

Syncope (fainting) has been reported following vaccination with Menactra. Procedures should be in place to prevent falling injury and manage syncopal reactions.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Children 9 Through 12 Months of Age

The safety of Menactra was evaluated in four clinical studies that enrolled 3721 participants who received Menactra at 9 and 12 months of age. At 12 months of age these children also received one or more other recommended vaccines [Measles, Mumps, Rubella and Varicella Virus Vaccine Live (MMRV) or Measles, Mumps, and Rubella Virus Vaccine (MMR) and Varicella Virus Vaccine Live (V) each manufactured by Merck & Co., Inc., Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM_{197} Protein) manufactured by Wyeth Pharmaceuticals Inc. (PCV7), Hepatitis A Vaccine manufactured by Merck & Co., Inc. (HepA). A control group of 997 children

was enrolled at 12 months of age and received two or more childhood vaccines [MMRV (or MMR+V), PCV7, HepA] at 12 months of age [see *Concomitant Vaccine Administration (14.3)*]. Three percent of individuals received MMR and V, instead of MMRV, at 12 months of age.

The primary safety study was a controlled trial that enrolled 1256 children who received Menactra at 9 and 12 months of age. At 12 months of age these children received MMRV (or MMR+V), PCV7 and HepA. A control group of 522 children received MMRV, PCV7 and HepA. Of the 1778 children, 78% of participants (Menactra, N=1056; control group, N=322) were enrolled at United States (US) sites and 22% at a Chilean site. (Menactra, N=200; control group, N=200).

Individuals 2 Through 55 Years of Age

The safety of Menactra was evaluated in eight clinical studies that enrolled 10,057 participants aged 2-55 years who received Menactra and 5,266 participants who received Menomune® – A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined. There were no substantive differences in demographic characteristics between the vaccine groups. Among Menactra recipients 2-55 years of age 24.0%, 16.2%, 40.4% and 19.4% were in the 2-10, 11-14, 15-25 and 26-55-year age groups, respectively. Among Menomune – A/C/Y/W-135 recipients 2-55 years of age 42.3%, 9.3%, 30.0% and 18.5% were in the 2-10, 11-14, 15-25 and 26-55-year age groups, respectively. The three primary safety studies were randomized, active-controlled trials that enrolled participants 2-10 years of age (Menactra, N=1713; Menomune – A/C/Y/W-135, N=1519), 11-18 years of age (Menactra, N=2270; Menomune – A/C/Y/W-135, N=972) and 18-55 years of age (Menactra, N=1384; Menomune – A/C/Y/W-135, N=1170), respectively. Of the 3232 children 2-10 years of age, 68% of participants (Menactra, N=1164;

Menomune – A/C/Y/W-135, N=1031) were enrolled at US sites and 32% (Menactra, N=549; Menomune – A/C/Y/W-135, N=488) of participants at a Chilean site. The median ages in the Chilean and US subpopulations were 5 and 6 years, respectively. All adolescents and adults were enrolled at US sites. As the route of administration differed for the two vaccines (Menactra given intramuscularly, Menomune – A/C/Y/W-135 given subcutaneously), study personnel collecting the safety data differed from personnel administering the vaccine.

Booster Vaccination Study

In an open-label trial conducted in the US, 834 individuals were enrolled to receive a single dose of Menactra 4-6 years after a prior dose. The median age of participants was 17.1 years at the time of the booster dose.

Safety Evaluation

Participants were monitored after each vaccination for 20 or 30 minutes for immediate reactions, depending on the study. Solicited injection site and systemic reactions were recorded in a diary card for 7 consecutive days after each vaccination. Participants were monitored for 28 days (30 days for infants and toddlers) for unsolicited adverse events and for 6 months post-vaccination for visits to an emergency room, unexpected visits to an office physician, and serious adverse events. Unsolicited adverse event information was obtained either by telephone interview or at an interim clinic visit. Information regarding adverse events that occurred in the 6-month post-vaccination time period was obtained via a scripted telephone interview.

Serious Adverse Events in All Safety Studies

Serious adverse events (SAEs) were reported during a 6-month time period following vaccinations in individuals 9 months through 55 years of age. In children who received Menactra at 9 months and at 12 months of age, SAEs occurred at a rate of 2.0% - 2.5%. In participants who received one or more childhood vaccine(s) (without co-administration of Menactra) at 12 months of age, SAEs occurred at a rate of 1.6% - 3.6%, depending on the number and type of vaccines received. In children 2-10 years of age, SAEs occurred at a rate of 0.6% following Menactra and at a rate of 0.7% following Menomune – A/C/Y/W-135. In adolescents 11 through 18 years of age and adults 18 years through 55 years of age, SAEs occurred at a rate of 1.0% following Menactra and at a rate of 1.3% following Menomune – A/C/Y/W-135. In adolescents and adults, SAEs occurred at a rate of 1.3% following booster vaccination with Menactra.

Solicited Adverse Events in the Primary Safety Studies

The most frequently reported solicited injection site and systemic adverse reactions within 7 days following vaccination in children 9 months and 12 months of age (Table 1) were injection site tenderness and irritability.

The most frequently reported solicited injection site and systemic adverse reactions in US children aged 2-10 years of age (Table 2) were injection site pain and irritability. Diarrhea, drowsiness, and anorexia were also common.

The most commonly reported solicited injection site and systemic adverse reactions in adolescents, ages 11-18 years (Table 3), and adults, ages 18-55 years (Table 4), after a single dose

were injection site pain, headache and fatigue. Except for redness in adults, injection site reactions were more frequently reported after Menactra vaccination than after Menomune – A/C/Y/W-135 vaccination.

Table 1: Percentage of US Participants Reporting Solicited Adverse Reactions Within 7 Days Following Vaccine Administration at 9 Months and 12 Months of Age

	Menactra at 9 months of age N[d]=998 - 1002			Menactra + PCV7[a]+ MMRV[b] + HepA[c] at 12 months of age N[d]=898 - 908			PCV7[a] + MMRV[b] + HepA[c] at 12 months of age N[d]=302 - 307		
Reaction	**Any**	**Grade 2**	**Grade 3**	**Any**	**Grade 2**	**Grade 3**	**Any**	**Grade 2**	**Grade 3**
Local/Injection Site									
Tenderness[e]									
Menactra Site	37.4	4.3	0.6	48.5	7.5	1.3	-	-	-
PCV7 Site	-	-	-	45.6	9.4	1.6	45.7	8.3	0.3
MMRV Site	-	-	-	38.9	7.1	1.0	43.0	5.2	0.0
HepA Site	-	-	-	43.4	8.7	1.4	40.9	4.6	0.3
Erythema[f]									
Menactra Site	30.2	2.5	0.3	30.1	1.3	0.1	-	-	-
PCV7 Site	-	-	-	29.4	2.6	0.2	32.6	3.0	0.7
MMRV Site	-	-	-	22.5	0.9	0.3	33.2	5.9	0.0
HepA Site	-	-	-	25.1	1.1	0.0	26.6	0.7	0.0
Swelling[f]									
Menactra Site	16.8	0.9	0.2	16.2	0.9	0.1	-	-	-
PCV7 Site	-	-	-	19.5	1.3	0.4	16.6	1.3	0.7
MMRV Site	-	-	-	12.1	0.4	0.1	14.1	0.3	0.0
HepA Site	-	-	-	16.4	0.7	0.2	13.5	0.0	0.3
Systemic									
Irritability[g]	56.8	23.1	2.9	62.1	25.7	3.7	64.8	28.7	4.2
Abnormal crying[h]	33.3	8.3	2.0	40.0	11.5	2.4	39.4	10.1	0.7
Drowsiness[i]	30.2	3.5	0.7	39.8	5.3	1.1	39.1	5.2	0.7
Appetite loss[j]	30.2	7.1	1.2	35.7	7.6	2.6	31.9	6.5	0.7
Vomiting[k]	14.1	4.6	0.3	11.0	4.4	0.2	9.8	2.0	0.0
Fever[l]	12.2	4.5	1.1	24.5	11.9	2.2	21.8	7.3	2.6

[a] PCV7 (Prevnar®) = Pneumococcal 7-valent Conjugate Vaccine

[b] MMRV (ProQuad®) = Measles, Mumps, Rubella and Varicella Virus Vaccine Live

[c] HepA (VAQTA®) = Hepatitis A Vaccine, Inactivated

[d] N = The number of participants with available data.

[e] Grade 2: cries and protests when injection site is touched, Grade 3: cries when injected limb is moved, or the movement of the injected limb is reduced.

[f] Grade 2: ≥1.0 inches to <2.0 inches, Grade 3: ≥2.0 inches.

[g] Grade 2: requires increased attention, Grade 3: inconsolable.

[h] Grade 2: 1 to 3 hours, Grade 3: >3 hours.

[i] Grade 2: not interested in surroundings or did not wake up for a feed/meal, Grade 3: sleeping most of the time or difficult to wake up.

[j] Grade 2: missed 1 or 2 feeds/meals completely, Grade 3: refuses ≥3 feeds/meals or refuses most feeds/meals.

[k] Grade 2: 2 to 5 episodes per 24 hours, Grade 3: ≥6 episodes per 24 hours or requiring parenteral hydration.

[l] Grade 2: >38.5°C to ≤39.5°C, Grade 3: >39.5°C.

Table 2: Percentage of US Participants 2 Years Through 10 Years of Age Reporting Solicited Adverse Reactions Within 7 Days Following Vaccine Administration

	Menactra N[a]=1156 - 1157			Menomune – A/C/Y/W-135 N[a]=1027		
Reaction	**Any**	**Grade 2**	**Grade 3**	**Any**	**Grade 2**	**Grade 3**
Local/Injection Site						
Pain[b]	45.0	4.9	0.3	26.1	2.5	0.0
Redness[c]	21.8	4.6	3.9	7.9	0.5	0.0
Induration[c]	18.9	3.4	1.4	4.2	0.6	0.0
Swelling[c]	17.4	3.9	1.9	2.8	0.3	0.0
Systemic						
Irritability[d]	12.4	3.0	0.3	12.2	2.6	0.6
Diarrhea[e]	11.1	2.1	0.2	11.8	2.5	0.3
Drowsiness[f]	10.8	2.7	0.3	11.2	2.5	0.5
Anorexia[g]	8.2	1.7	0.4	8.7	1.3	0.8
Arthralgia[h]	6.8	0.5	0.2	5.3	0.7	0.0
Fever[i]	5.2	1.7	0.3	5.2	1.7	0.2
Rash[j]	3.4	-	-	3.0	-	-
Vomiting[k]	3.0	0.7	0.3	2.7	0.7	0.6
Seizure[j]	0.0	-	-	0.0	-	-

[a] N = The total number of participants reporting at least one solicited reaction. The median age of participants was 6 years in both vaccine groups.

[b] Grade 2: interferes with normal activities, Grade 3: disabling, unwilling to move arm.

[c] Grade 2: 1.0-2.0 inches, Grade 3: >2.0 inches.

[d] Grade 2: 1-3 hours duration, Grade 3: >3 hours duration.

[e] Grade 2: 3-4 episodes, Grade 3: ≥5 episodes.

[f] Grade 2: interferes with normal activities, Grade 3: disabling, unwilling to engage in play or interact with others.

[g] Grade 2: skipped 2 meals, Grade 3: skipped ≥3 meals.

[h] Grade 2: decreased range of motion due to pain or discomfort, Grade 3: unable to move major joints due to pain.

[i] Oral equivalent temperature; Grade 2: 38.4°C to 39.4°C, Grade 3: ≥39.5°C.

[j] These solicited adverse events were reported as present or absent only.

[k] Grade 2: 2 episodes, Grade 3: ≥3 episodes.

Note: During the study Grade 1, Grade 2, and Grade 3 were collected as Mild, Moderate, and Severe respectively.

Table 3: Percentage of Participants 11 Years Through 18 Years of Age Reporting Solicited Adverse Reactions Within 7 Days Following Vaccine Administration With a Single Dose

	Menactra N[a]=2264 - 2265			Menomune – A/C/Y/W-135 N[a]=970		
Reaction	**Any**	**Grade 2**	**Grade 3**	**Any**	**Grade 2**	**Grade 3**
Local/Injection Site						
Pain[b]	59.2[c]	12.8[c]	0.3	28.7	2.6	0.0
Induration[d]	15.7[c]	2.5[c]	0.3	5.2	0.5	0.0
Redness[d]	10.9[c]	1.6[c]	0.6[c]	5.7	0.4	0.0
Swelling[d]	10.8[c]	1.9[c]	0.5[c]	3.6	0.3	0.0
Systemic						
Headache[e]	35.6[c]	9.6[c]	1.1	29.3	6.5	0.4
Fatigue[e]	30.0[c]	7.5	1.1[c]	25.1	6.2	0.2
Malaise[e]	21.9[c]	5.8[c]	1.1	16.8	3.4	0.4
Arthralgia[e]	17.4[c]	3.6[c]	0.4	10.2	2.1	0.1
Diarrhea[f]	12.0	1.6	0.3	10.2	1.3	0.0
Anorexia[g]	10.7[c]	2.0	0.3	7.7	1.1	0.2
Chills[e]	7.0[c]	1.7[c]	0.2	3.5	0.4	0.1
Fever[h]	5.1[c]	0.6	0.0	3.0	0.3	0.1
Vomiting[i]	1.9	0.4	0.3	1.4	0.5	0.3
Rash[j]	1.6	-	-	1.4	-	-
Seizure[j]	0.0	-	-	0.0	-	-

[a] N = The number of participants with available data.

[b] Grade 2: interferes with or limits usual arm movement, Grade 3: disabling, unable to move arm.

[c] Denotes $p < 0.05$ level of significance. The p-values were calculated for each category and severity using Chi Square test.

[d] Grade 2: 1.0-2.0 inches, Grade 3: >2.0 inches.

[e] Grade 2: interferes with normal activities, Grade 3: requiring bed rest.

[f] Grade 2: 3-4 episodes, Grade 3: ≥5 episodes.

[g] Grade 2: skipped 2 meals, Grade 3: skipped ≥3 meals.

[h] Oral equivalent temperature; Grade 2: 38.5°C to 39.4°C, Grade 3: ≥39.5°C.

[i] Grade 2: 2 episodes, Grade 3: ≥3 episodes.

[j] These solicited adverse events were reported as present or absent only.

Note: During the study Grade 1, Grade 2, and Grade 3 were collected as Mild, Moderate, and Severe respectively.

Table 4: Percentage of Participants 18 Years Through 55 Years of Age Reporting Solicited Adverse Reactions Within 7 Days Following Vaccine Administration With a Single Dose

	Menactra N[a]=1371			Menomune – A/C/Y/W-135 N[a]=1159		
Reaction	**Any**	**Grade 2**	**Grade 3**	**Any**	**Grade 2**	**Grade 3**
Local/Injection Site						
Pain[b]	53.9[c]	11.3[c]	0.2	48.1	3.3	0.1
Induration[d]	17.1[c]	3.4[c]	0.7[c]	11.0	1.0	0.0
Redness[d]	14.4	2.9	1.1[c]	16.0	1.9	0.1
Swelling[d]	12.6[c]	2.3[c]	0.9[c]	7.6	0.7	0.0
Systemic						
Headache[e]	41.4	10.1	1.2	41.8	8.9	0.9
Fatigue[e]	34.7	8.3	0.9	32.3	6.6	0.4
Malaise[e]	23.6	6.6[c]	1.1	22.3	4.7	0.9
Arthralgia[e]	19.8[c]	4.7[c]	0.3	16.0	2.6	0.1
Diarrhea[f]	16.0	2.6	0.4	14.0	2.9	0.3
Anorexia[g]	11.8	2.3	0.4	9.9	1.6	0.4
Chills[e]	9.7[c]	2.1[c]	0.6[c]	5.6	1.0	0.0
Vomiting[h]	2.3	0.4	0.2	1.5	0.2	0.4
Fever[i]	1.5[c]	0.3	0.0	0.5	0.1	0.0
Rash[j]	1.4	-	-	0.8	-	-
Seizure[j]	0.0	-	-	0.0	-	-

[a] N = The number of participants with available data.

[b] Grade 2: interferes with or limits usual arm movement, Grade 3: disabling, unable to move arm.

[c] Denotes $p < 0.05$ level of significance. The p-values were calculated for each category and severity using Chi Square test.

[d] Grade 2: 1.0-2.0 inches, Grade 3: >2.0 inches.

[e] Grade 2: interferes with normal activities, Grade 3: requiring bed rest.

[f] Grade 2: 3-4 episodes, Grade 3: ≥5 episodes.

[g] Grade 2: skipped 2 meals, Grade 3: skipped ≥3 meals.

[h] Grade 2: 2 episodes, Grade 3: ≥3 episodes.

[i] Oral equivalent temperature; Grade 2: 39.0°C to 39.9°C, Grade 3: ≥40.0°C.

[j] These solicited adverse events were reported as present or absent only.

Note: During the study Grade 1, Grade 2, and Grade 3 were collected as Mild, Moderate, and Severe respectively.

Solicited Adverse Events in a Booster Vaccination Study

For a description of the study design and number of participants, [see *Clinical Trials Experience, Booster Vaccination Study (6.1)*]. The most common solicited injection site and systemic reactions within 7 days of vaccination were pain (60.2%) and myalgia (42.8%), respectively. Overall rates of solicited injection site reactions and solicited systemic reactions were similar to those observed in adolescents and adults after a single Menactra dose. The majority of solicited reactions were Grade 1 or 2 and resolved within 3 days.

Adverse Events in Concomitant Vaccine Studies

Solicited Injection Site and Systemic Reactions when Given with Routine Pediatric Vaccines

For a description of the study design and number of participants, [see *Clinical Trials Experience (6.1), Concomitant Vaccine Administration (14.3)*]. In the primary safety study, 1378 US children were enrolled to receive Menactra alone at 9 months of age and Menactra plus one or more other routinely administered vaccines (MMRV, PCV7 and HepA) at 12 months of age (N=961). Another group of children received two or more routinely administered vaccines (MMRV, PCV7 and HepA) (control group, n=321) at 12 months of age. The frequency of occurrence of solicited adverse events is presented in Table 1. Participants who received Menactra and the concomitant

vaccines at 12 months of age described above reported similar frequencies of tenderness, redness and swelling at the Menactra injection site and at the concomitant vaccine injection sites. Tenderness was the most frequent injection site reaction (48%, 39%, 46% and 43% at the Menactra, MMRV, PCV7 and HepA sites, respectively). Irritability was the most frequent systemic reaction, reported in 62% of recipients of Menactra plus concomitant vaccines, and 65% of the control group. [See *Concomitant Vaccine Administration (14.3).*]

In a randomized, parallel group, US multi-center clinical trial conducted in children 4 through 6 years of age, Menactra was administered as follows: 30 days after concomitant DAPTACEL®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, (DTaP), manufactured by Sanofi Pasteur Limited + IPOL®, Poliovirus Vaccine Inactivated, (IPV), manufactured by Sanofi Pasteur SA [Group A]; concomitantly with DAPTACEL followed 30 days later by IPV [Group B]; concomitantly with IPV followed 30 days later by DAPTACEL [Group C]. Solicited injection site and systemic reactions were recorded in a diary card for 7 consecutive days after each vaccination. For all study groups, the most frequently reported solicited local reaction at the Menactra site was pain: 52.2%, 60.9% and 56.0% of participants in Groups A, B and C, respectively. For all study groups, the most frequently reported systemic reaction following the administration of Menactra alone or with the respective concomitant vaccines was myalgia: 24.2%, 37.3% and 26.7% of participants in Groups A, B and C, respectively. Fever >39.5°C occurred at <1.0% in all groups. [See *Concomitant Vaccine Administration (14.3).*]

Solicited Injection Site and Systemic Reactions when Given with Tetanus and Diphtheria Toxoid Adsorbed Vaccine

In a clinical study, rates of local and systemic reactions after Menactra and Tetanus and Diphtheria Toxoid Adsorbed (Td) vaccine manufactured by Sanofi Pasteur Inc. were compared [see *Drug Interactions (7)*, and *Concomitant Vaccine Administration (14.3)* for study description]. Injection site pain was reported more frequently after Td vaccination than after Menactra vaccination (71% versus 53%). The overall rate of systemic adverse events was higher when Menactra and Td vaccines were given concomitantly than when Menactra was administered 28 days after Td vaccine (59% versus 36%). In both groups, the most common reactions were headache (Menactra + Td vaccine, 36%; Td vaccine + Placebo, 34%; Menactra alone, 22%) and fatigue (Menactra + Td vaccine, 32%; Td vaccine + Placebo, 29%; Menactra alone, 17%). Fever ≥40.0°C occurred at ≤0.5% in all groups.

Solicited Injection Site and Systemic Reactions when Given with Typhoid Vi Polysaccharide Vaccine

In a clinical study, rates of local and systemic reactions after Menactra and Typhim Vi® [Typhoid Vi Polysaccharide Vaccine] (Typhoid), produced by Sanofi Pasteur SA were compared [see *Drug Interactions (7)* and *Concomitant Vaccine Administration (14.3)*] for a description of the concomitantly administered vaccine, study design and number of participants. More participants experienced pain after Typhoid vaccination than after Menactra vaccination (Typhoid + Placebo, 76% versus Menactra + Typhoid, 47%). The majority (70%-77%) of injection site solicited reactions for both groups at either injection site were reported as Grade 1 and resolved within 3 days post-vaccination. In both groups, the most common systemic reaction was headache (Menactra +

Typhoid, 41%; Typhoid + Placebo, 42%; Menactra alone, 33%) and fatigue (Menactra + Typhoid, 38%; Typhoid + Placebo, 35%; Menactra alone, 27%). Fever ≥40.0°C and seizures were not reported in either group.

6.2 Post-Marketing Experience

In addition to reports in clinical trials, worldwide voluntary adverse events reports received since market introduction of Menactra are listed below. This list includes serious events and/or events which were included based on severity, frequency of reporting or a plausible causal connection to Menactra. Because these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to vaccination.

- *Blood and Lymphatic System Disorders*

  Lymphadenopathy

- *Immune System Disorders*

  Hypersensitivity reactions such as anaphylaxis/anaphylactic reaction, wheezing, difficulty breathing, upper airway swelling, urticaria, erythema, pruritus, hypotension

- *Nervous System Disorders*

  Guillain-Barré syndrome, paraesthesia, vasovagal syncope, dizziness, convulsion, facial palsy, acute disseminated encephalomyelitis, transverse myelitis

- *Musculoskeletal and Connective Tissue Disorders*

Myalgia

- *General Disorders and Administrative Site Conditions*

  Large injection site reactions, extensive swelling of the injected limb (may be associated with erythema, warmth, tenderness or pain at the injection site).

Post-marketing Safety Study

The risk of GBS following receipt of Menactra was evaluated in a US retrospective cohort study using healthcare claims data from 9,578,688 individuals 11 through 18 years of age, of whom 1,431,906 (15%) received Menactra. Of 72 medical chart-confirmed GBS cases, none had received Menactra within 42 days prior to symptom onset. An additional 129 potential cases of GBS could not be confirmed or excluded due to absent or insufficient medical chart information. In an analysis that took into account the missing data, estimates of the attributable risk of GBS ranged from 0 to 5 additional cases of GBS per 1,000,000 vaccinees within the 6-week period following vaccination.

7 DRUG INTERACTIONS

7.1 Concomitant Administration with Other Vaccines

Menactra vaccine was concomitantly administered with Typhim Vi® [Typhoid Vi Polysaccharide Vaccine] (Typhoid) and Tetanus and Diphtheria Toxoids Adsorbed, For Adult Use (Td) vaccine, in individuals 18 through 55 and 11 through 17 years of age, respectively. In children 4 through 6 years of age, Menactra was co-administered with DAPTACEL, and in children younger than 2

years of age, Menactra was co-administered with one or more of the following vaccines: PCV7, MMR, V, MMRV, or HepA [see *Clinical Studies (14)* and *Adverse Reactions (6)*].

When Menactra and DAPTACEL are to be administered to children 4 through 6 years of age, preference should be given to simultaneous administration of the 2 vaccines or administration of Menactra prior to DAPTACEL. Administration of Menactra one month after DAPTACEL has been shown to reduce meningococcal antibody responses to Menactra. Data are not available to evaluate the immune response to Menactra administered to younger children following DAPTACEL or to Menactra administered to persons <11 years of age following other diphtheria toxoid-containing vaccines [see *Clinical Studies (14.3)*].

Pneumococcal antibody responses to some serotypes in PCV7 were decreased following co-administration of Menactra and PCV7 [see *Concomitant Vaccine Administration (14.3)*].

Do not mix Menactra with other vaccines in the same syringe. When Menactra is administered concomitantly with other injectable vaccines, the vaccines should be administered with different syringes and given at separate injection sites.

7.2 Immunosuppressive Therapies

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses) may reduce the immune response to vaccines.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Menactra during pregnancy. To enroll in or obtain information about the registry, call Sanofi Pasteur at 1-800-822-2463.

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. There are no adequate and well-controlled studies of Menactra administration in pregnant women in the US. Available data suggest that rates of major birth defects and miscarriage in women who received Menactra 30 days prior to pregnancy or during pregnancy are consistent with estimated background rates.

A developmental toxicity study was performed in female mice given 0.1 mL (in divided doses) of Menactra prior to mating and during gestation (a single human dose is 0.5 mL). The study revealed no evidence of harm to the fetus due to Menactra [see *Animal Data (8.1)*].

Data

Human Data

A pregnancy registry spanning 11 years (2005-2016) included 222 reports of exposure to Menactra from 30 days before or at any time during pregnancy. Of these reports, 87 had known

pregnancy outcomes available and were enrolled in the pregnancy registry prior to the outcomes being known. Outcomes among these prospectively followed pregnancies included 2 major birth defects and 6 miscarriages.

Animal Data

A developmental toxicity study was performed in female mice. The animals were administered 0.1 mL of Menactra (in divided doses) at each of the following time points: 14 days prior to mating, and on Days 6 and 18 of gestation (a single human dose is 0.5 mL). There were no vaccine-related fetal malformations or variations, and no adverse effects on pre-weaning development observed in the study.

8.2 Lactation

Risk Summary

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Menactra and any potential adverse effects on the breastfed child from Menactra. Data are not available to assess the effects of Menactra on the breastfed infant or on milk production/excretion.

8.4 Pediatric Use

Menactra is not approved for use in infants under 9 months of age. Available data show that infants administered three doses of Menactra (at 2, 4, and 6 months of age) had diminished responses to each meningococcal vaccine serogroup compared to older children given two doses at 9 and 12 months of age.

Reference #6

VAERS Vaccine Adverse Event Reporting System

www.vaers.hhs.gov

Search Results

Found 1,596 cases where Vaccine is MNC or MNQ and Serious and Vaccination Date on/before '2019-12-31'

Table

Age	Count	Percent
< 3 Years	162	10.15%
3-6 Years	20	1.25%
6-9 Years	8	0.5%
9-12 Years	217	13.6%
12-17 Years	487	30.51%
17-44 Years	446	27.94%
44-65 Years	49	3.07%
65-75 Years	9	0.56%
Unknown	198	12.41%
TOTAL	1596	100%

MNC – Menveo (Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine)

MNQ – Menactra (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine)

Vaccine Adverse Events Reporting System (VAERS) accessed with Medalerts. Serious Adverse Events following Menactra and Menveo vaccination through Dec. 31, 2019 (Accessed Mar. 1, 2020)

Reference 7

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Found 71 cases where Vaccine is MNC or MNQ and Patient Died and Vaccination Date on/before '2019-12-31'

Table

Age	Count	Percent
< 3 Years	11	15.49%
3-6 Years	1	1.41%
9-12 Years	8	11.27%
12-17 Years	14	19.72%
17-44 Years	23	32.39%
65-75 Years	1	1.41%
Unknown	13	18.31%
TOTAL	71	100%

MNC – Menveo (Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine)

MNQ – Menactra (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine)

Vaccine Adverse Events Reporting System (VAERS) accessed with Medalerts Deaths reported following Menactra and Menveo vaccination through Dec. 31, 2019 (Accessed Mar. 1, 2020)

Reference 8

Grant Final Report

Grant ID: R18 HS 017045

Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS)

Inclusive dates: 12/01/07 - 09/30/10

Principal Investigator:
Lazarus, Ross, MBBS, MPH, MMed, GDCompSci

Team members:
Michael Klompas, MD, MPH

Performing Organization:
Harvard Pilgrim Health Care, Inc.

Project Officer:
Steve Bernstein

Submitted to:
The Agency for Healthcare Research and Quality (AHRQ)
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Abstract

Purpose: To develop and disseminate HIT evidence and evidence-based tools to improve healthcare decision making through the use of integrated data and knowledge management.

Scope: To create a generalizable system to facilitate detection and clinician reporting of vaccine adverse events, in order to improve the safety of national vaccination programs.

Methods: Electronic medical records available from all ambulatory care encounters in a large multi-specialty practice were used. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions were evaluated for values suggestive of an adverse event.

Results: Restructuring at CDC and consequent delays in terms of decision making have made it challenging despite best efforts to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial and comparison of ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. However, Preliminary data were collected and analyzed and this initiative has been presented at a number of national symposia.

Key Words: electronic health records, vaccinations, adverse event reporting

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Final Report

Purpose

This research project was funded to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS), via the following aims:

Aim 1. Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration.

Aim 2. Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS).

Aim 3. Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.

Aim 4. Distribute documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems.

Scope

Public and professional confidence in vaccination depends on reliable postmarketing surveillance systems to ensure that rare and unexpected adverse effects are rapidly identified. The goal of this project is to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS). This project is serving as an extension of the Electronic Support for Public Health (ESP) project, an automated system using electronic health record (EHR) data to detect and securely report cases of certain diseases to a local public health authority. ESP provides a ready-made platform for automatically converting clinical, laboratory, prescription, and demographic data from almost any EHR system into database tables on a completely independent server, physically located and secured by the same logical and physical security as the EHR data itself. The ESP:VAERS project developed criteria and algorithms to identify important adverse events related to vaccinations in ambulatory care EHR data, and made attempts at formatting and securely sending electronic VAERS reports directly to the Centers for Disease Control and Prevention (CDC).

Patient data were available from Epic System's Certification Commission for Health Information Technology-certified EpicCare system at all ambulatory care encounters within Atrius Health, a large multispecialty group practice with over 35 facilities. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions are evaluated for values

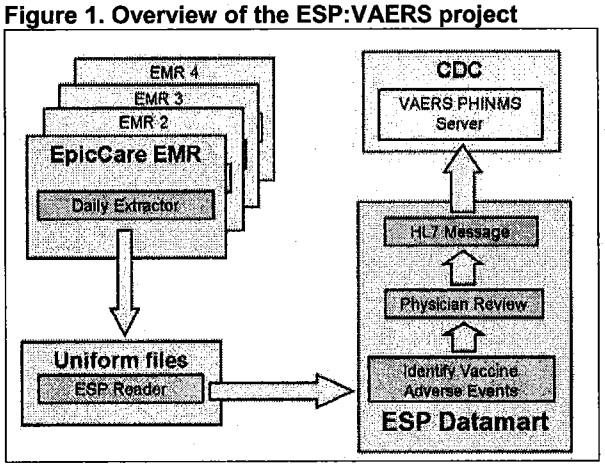
suggestive of an adverse vaccine event. When a possible adverse event was detected, it was recorded, and the appropriate clinician was to be notified electronically.

Clinicians in-basket messaging was designed to provide a preview a pre-populated report with information from the EHR about the patient, including vaccine type, lot number, and possible adverse effect, to inform their clinical judgment regarding whether they wish to send a report to VAERS. Clinicians would then have the option of adding free-text comments to pre-populated VAERS reports or to document their decision not to send a report. The CDC's Public Health Information Network Messaging System (PHIN-MS) software was installed within the facilities so that the approved reports could be securely transferred to VAERS as electronic messages in an interoperable health data exchange format using Health Level 7 (HL7).

Methods

The goal of Aim 1: *Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration*, and Aim 2: *Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS)*, was to construct the below flow of data in order to support the first two Aims:

Figure 1. Overview of the ESP:VAERS project



Existing and functioning ESP components are shown on the left, and Aims 1 and 2 on the right. ESP:VAERS flags every vaccinated patient, and prospectively accumulate that patient's diagnostic codes, laboratory tests, allergy lists, vital signs, and medication prescriptions. A main component of Aim 1 was to *Develop AE criteria to assess these parameters for new or abnormal values that might be suggestive of an adverse effect.* A reporting protocol & corresponding algorithms were developed to detect potential adverse event cases using diagnostic codes, and methods were tested to identify prescriptions or abnormal laboratory values that might be suggestive of an adverse effect. These algorithms were designed to seek both expected and unexpected adverse effects.

This reporting protocol was approved by both internal & external partners. We initially prepared a draft document describing the elements, algorithms, interval of interest after vaccination, and actions for broad classes of post-vaccination events, including those to be reported immediately without delay (such as acute anaphylactic reaction following vaccination), those never to be reported (such as routine check-ups following vaccination) and those to be reported at the discretion and with additional information from the attending physician through a feedback mechanism. The draft was then widely circulated as an initial / working draft for comment by relevant staff in the CDC and among our clinical colleagues at Atrius. In addition to review by the internal CDC Brighton Collaboration liaison, this protocol has also received review & comment via the CDC's Clinical Immunization Safety Assessment (CISA) Network.

The goal of Aim 2 was the *Development of HL7 messages code for ESP:VAERS to ensure secure transmission to CDC via PHIN-MS.* The HL7 specification describing the elements for an electronic message to be submitted to Constella, the consultants engaged by CDC for this project was implemented. Synthetic and real test data was been generated and transmitted between Harvard and Constella. However, real data transmissions of non-physician approved reports to the CDC was unable to commence, as by the end of this project, the CDC had yet to respond to multiple requests to partner for this activity.

The goal of Aim 3 was to *Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.*

We had initially planned to evaluate the system by comparing adverse event findings to those in the Vaccine Safety Datalink project—a collaborative effort between CDC's Immunization Safety Office and eight large managed care organizations. Through a randomized trial, we would also test the hypothesis that the combination of secure, computer-assisted, clinician-approved, adverse event detection, and automated electronic reporting will substantially increase the number, completeness, validity, and timeliness of physician-approved case reports to VAERS compared to the existing spontaneous reporting system; however, due to restructuring at CDC and consequent delays in terms of decision making, it became impossible to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial, and compare ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. Therefore, the components under this particular Aim were not achieved.

Aim 4 *Distribution of documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems* has been successfully completed. Functioning source code is available to share under an approved open source license. ESP:VAERS source code is available as part of the ESP source code distribution. It is licensed under the LGPL, an open source license compatible with commercial use. We have added the ESP:VAERS code, HL7 and other specifications and documentation to the existing ESP web documentation and distribution resource center http://esphealth.org, specifically, the Subversion repository available at:
http://esphealth.org/trac/ESP/wiki/ESPVAERS.

Results

Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6 percent of vaccinations) were identified. This is an average of 890 possible events, an average of 1.3 events per clinician, per month. These data were presented at the 2009 AMIA conference.

In addition, ESP:VAERS investigators participated on a panel to explore the perspective of clinicians, electronic health record (EHR) vendors, the pharmaceutical industry, and the FDA towards systems that use proactive, automated adverse event reporting.

Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.

Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.

Inclusion of AHRQ Priority Populations

The focus of our project was the Atrius Health (formerly HealthOne) provider & patient community. This community serves several AHRQ inclusion populations, specifically low-income and minority populations in primarily urban settings.

Atruis currently employs approximately 700 physicians to serve 500,000 patients at more than 18 office sites spread throughout the greater Metropolitan Boston area. The majority of Atruis physicians are primary care internal medicine physicians or pediatricians but the network also includes physicians from every major specialty.

The entire adult and pediatric population served by Atruis was included in our adverse event surveillance system (ESP:VAERS). Atruis serves a full spectrum of patients that reflects the broad diversity of Eastern Massachusetts. A recent analysis suggests that the population served by Atruis is 56% female, 16.6% African American, 4% Hispanic. The prevalence of type 2 diabetes in the adult population is 5.7%. About a quarter of the Atruis population is under age 18.

List of Publications and Products

ESP:VAERS [source code available as part of the ESP source code distribution]. Licensed under the GNU Lesser General Public License (LGPL), an open source license compatible with commercial use. Freely available under an approved open source license at: http://esphealth.org.

Lazarus, R, Klompas M, Hou X, Campion FX, Dunn J, Platt R. Automated Electronic Detection & Reporting of Adverse Events Following Vaccination: ESP:VAERS. The CDC Vaccine Safety Datalink (VSD) Annual Meeting. Atlanta, GA; April, 2008.

Lazarus R, Klompas M Automated vaccine adverse event detection and reporting from electronic medical records. CDC Public Health Informatics Network (PHIN) Conference August 27, 2008.

Klompas M, Lazarus R ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 17th.

Lazarus R, Klompas M, Kruskal B, Platt R Temporal patterns of fever following immunization in ambulatory care data identified by ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Linder J, Klompas M, Cass B, et al. Spontaneous Electronic Adverse Event Reporting: Perspectives from Clinicians, EHR Vendors, Biopharma, and the FDA. Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Reference 10 of 12

42 USC CHAPTER 6A, SUBCHAPTER XIX: VACCINES

From Title 42—THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A—PUBLIC HEALTH SERVICE

SUBCHAPTER XIX—VACCINES

PRIOR PROVISIONS

A prior subchapter XIX (§300aa et seq.), comprised of title XXI of the Public Health Service Act, act July 1, 1944, ch. 373, §§2101 to 2116, was renumbered title XXIII, §§2301 to 2316, of the Public Health Service Act, and transferred to subchapter XXI (§300cc et seq.) of this chapter, renumbered title XXV, §§2501 to 2514, of the Public Health Service Act, and transferred to subchapter XXV (§300aaa et seq.) of this chapter, renumbered title XXVI, §§2601 to 2614, of the Public Health Service Act, renumbered title XXVII, §§2701 to 2714, of the Public Health Service Act, and renumbered title II, part B, §§231 to 244, of the Public Health Service Act, and transferred to part B (§238 et seq.) of subchapter I of this chapter.

Part 1—National Vaccine Program

§300aa–1. Establishment

The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

(July 1, 1944, ch. 373, title XXI, §2101, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3756.)

PRIOR PROVISIONS

A prior section 300aa–1, act July 1, 1944, §2102, was successively renumbered by subsequent acts and transferred, see section 238a of this title.

A prior section 2101 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238 of this title.

EFFECTIVE DATE

Pub. L. 99–660, title III, §323, Nov. 14, 1986, 100 Stat. 3784, as amended by Pub. L. 100–203, title IV, §4302(a), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 102–168, title II, §201(a), Nov. 26, 1991, 105 Stat. 1102, provided that: "Subtitle 1 of title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] shall take effect on the date of the enactment of this Act [Nov. 14, 1986] and parts A and B of subtitle 2 of such title [42 U.S.C. 300aa–10 et seq., 300aa–21 et seq.] shall take effect on October 1, 1988 and parts C and D of such title [42 U.S.C. 300aa–25 et seq., 300aa–31 et seq.] and this title [probably means provisions of title III of Pub. L. 99–660 other than those that enacted this subchapter and redesignated former sections 300aa to 300aa–15 of this title as sections 300cc to 300cc–15 of this title; these other provisions amended sections 218, 242c, 262, 286, and 289f of this title and enacted provisions set out as notes under sections 201, 300aa–1, and 300aa–4 of this title] shall take effect on the date of the enactment of the Vaccine Compensation Amendments of 1987 [Dec. 22, 1987]."

SEVERABILITY

Pub. L. 99–660, title III, §322, Nov. 14, 1986, 100 Stat. 3783, as amended by Pub. L. 101–239, title VI, §6602, Dec. 19, 1989, 103 Stat. 2293; Pub. L. 101–502, §5(g)(1), Nov. 3, 1990, 104 Stat.

1288, provided that:

"(a) In General.—Except as provided in subsection (b), if any provision [of] part A or B of subtitle 2 of title XXI of the Public Health Service Act [42 U.S.C. 300aa–10 et seq., 300aa–21 et seq.], as added by section 311(a), or the application of such a provision to any person or circumstance is held invalid by reason of a violation of the Constitution, both such parts shall be considered invalid.

"(b) Special Rule.—If any amendment made by section 6601 of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239, amending sections 300aa–10 to 300aa–17, 300aa–21, 300aa–23, 300aa–26, and 300aa–27 of this title] to title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] or the application of such a provision to any person or circumstance is held invalid by reason of the Constitution, subsection (a) shall not apply and such title XXI of the Public Health Service Act without such amendment shall continue in effect."

[Amendment by section 5(g)(1) of Pub. L. 101–502 to section 322(a) of Pub. L. 99–660, set out above, effective Nov. 14, 1986, see section 5(h) of Pub. L. 101–502, set out as an Effective Date of 1990 Amendment note under section 300aa–11 of this title.]

EVALUATION OF PROGRAM; STUDY AND REPORT TO CONGRESS

Pub. L. 101–239, title VI, §6601(t), Dec. 19, 1989, 103 Stat. 2293, as amended by Pub. L. 102–168, title II, §201(b), Nov. 26, 1991, 105 Stat. 1103, directed the Secretary of Health and Human Services to evaluate the National Vaccine Injury Compensation Program under this subchapter and report results of such study to Committee on Energy and Commerce of House of Representatives and Committee on Labor and Human Resources of Senate not later than Jan. 1, 1993.

RELATED STUDIES

Pub. L. 99–660, title III, §312, Nov. 14, 1986, 100 Stat. 3779, directed Secretary of Health and Human Services, not later than 3 years after the effective date of this title (see Effective Date note above), to conduct, through studies by the Institute of Medicine of the National Academy of Sciences or other appropriate nonprofit private groups or associations, a review of pertussis vaccines and related illnesses and conditions and MMR vaccines, vaccines containing material intended to prevent or confer immunity against measles, mumps, and rubella disease, and related illnesses and conditions, make specific findings and report these findings in the Federal Register not later than 3 years after the effective date of this title, and at the same time these findings are published in the Federal Register, propose regulations as a result of such findings, and not later than 42 months after the effective date of this title, promulgate such proposed regulations with such modifications as may be necessary after opportunity for public hearing.

STUDY OF OTHER VACCINE RISKS

Pub. L. 99–660, title III, §313, Nov. 14, 1986, 100 Stat. 3781, provided that:

"(a) Study.—

"(1) Not later than 3 years after the effective date of this title [see Effective Date note above], the Secretary shall, after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [42 U.S.C. 300aa–19]—

"(A) arrange for a broad study of the risks (other than the risks considered under section 102 [21 U.S.C. 382]) to children associated with each vaccine set forth in the Vaccine Injury Table under section 2114 of such Act [42 U.S.C. 300aa–14], and

"(B) establish guidelines, after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, respecting the administration of such vaccines which shall include—

"(i) the circumstances under which any such vaccine should not be administered,

"(ii) the circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration, and

"(iii) the groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher risk of major adverse reactions to such vaccine than the general population of potential recipients.

"(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the

Secretary.

"(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study.

"(C) The Institute of Medicine or other group or association conducting the study required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [42 U.S.C. 300aa–19].

"(b) Revision of Guidelines.—The Secretary shall periodically, but at least every 3 years after establishing guidelines under subsection (a), review and revise such guidelines after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, unless the Secretary finds that on the basis of all relevant information no revision of such guidelines is warranted and publishes such finding in the Federal Register.

"(c) Factors Affecting Guidelines.—Guidelines under subsection (a) shall take into account—

"(1) the risk to potential recipients of the vaccines with respect to which the guidelines are established,

"(2) the medical and other characteristics of such potential recipients, and

"(3) the risks to the public of not having such vaccines administered.

"(d) Dissemination.—The Secretary shall widely disseminate the guidelines established under subsection (a) to—

"(1) physicians and other health care providers,

"(2) professional health associations,

"(3) State and local governments and agencies, and

"(4) other relevant entities."

REVIEW OF WARNINGS, USE INSTRUCTIONS, AND PRECAUTIONARY INFORMATION

Pub. L. 99–660, title III, §314, Nov. 14, 1986, 100 Stat. 3782, directed Secretary of Health and Human Services, not later than 1 year after the effective date of this title (see Effective Date note above) and after consultation with Advisory Commission on Childhood Vaccines and with other appropriate entities, to review the warnings, use instructions, and precautionary information presently issued by manufacturers of vaccines set forth in the Vaccine Injury Table set out in section 300aa–14 of this title and by rule determine whether such warnings, instructions, and information adequately warn health care providers of the nature and extent of dangers posed by such vaccines, and, if any such warning, instruction, or information is determined to be inadequate for such purpose in any respect, require at the same time that the manufacturers revise and reissue such warning, instruction, or information as expeditiously as practical, but not later than 18 months after the effective date of this title.

STUDY OF IMPACT ON SUPPLY OF VACCINES

Pub. L. 99–660, title III, §316, Nov. 14, 1986, 100 Stat. 3786, provided that: "On June 30, 1987, and on June 30 of each second year thereafter, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources [now Committee on Health, Education, Labor, and Pensions] of the Senate—

"(1) an assessment of the impact of the amendments made by this title [enacting this subchapter, amending sections 218, 242c, 262, 286, and 289f of this title, redesignating former sections 300aa to 300aa–15 of this title as sections 300cc to 300cc–15 of this title, and enacting provisions set out as notes under this section and sections 201 and 300aa–1 of this title] on the supply of vaccines listed in the Vaccine Injury Table under section 2114 of the Public Health Service Act [42 U.S.C. 300aa–14], and

"(2) an assessment of the ability of the administrators of vaccines (including public clinics and private administrators) to provide such vaccines to children."

WAIVER OF PAPERWORK REDUCTION

Pub. L. 99–660, title III, §321, Nov. 14, 1986, 100 Stat. 3783, provided that: "Chapter 35 of title 44, United States Code, shall not apply to information required for purposes of carrying out this title and

implementing the amendments made by this title [enacting this subchapter, amending sections 218, 242c, 262, 286, and 289f of this title, redesignating former sections 300aa to 300aa–15 of this title as sections 300cc to 300cc–15 of this title, and enacting provisions set out as notes under sections 201, 300aa–1, and 300aa–4 of this title]."

§300aa–2. Program responsibilities

(a) The Director of the Program shall have the following responsibilities:

(1) Vaccine research

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.

(2) Vaccine development

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development to develop the techniques needed to produce safe and effective vaccines.

(3) Safety and efficacy testing of vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

(4) Licensing of vaccine manufacturers and vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for the allocation of resources in the implementation of the licensing program under section 263a of this title.

(5) Production and procurement of vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

(6) Distribution and use of vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction to the Centers for Disease Control and Prevention and assistance to States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.

(7) Evaluating the need for and the effectiveness and adverse effects of vaccines and immunization activities

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Centers for Medicare & Medicaid Services in monitoring the need for and the effectiveness and adverse effects of vaccines and immunization activities.

(8) Coordinating governmental and non-governmental activities

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, provide for the exchange of information between Federal agencies involved in the implementation of the Program and non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental activities under the Program.

(9) Funding of Federal agencies

The Director of the Program shall make available to Federal agencies involved in the implementation of the

plan issued under section 300aa–3 of this title funds appropriated under section 300aa–6 of this title to supplement the funds otherwise available to such agencies for activities under the plan.

(b) In carrying out subsection (a) and in preparing the plan under section 300aa–3 of this title, the Director shall consult with all Federal agencies involved in research on and development, testing, licensing, production, procurement, distribution, and use of vaccines.

(July 1, 1944, ch. 373, title XXI, §2102, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3756; amended Pub. L. 102–531, title III, §312(d)(13), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 108–173, title IX, §900(e)(2)(F), Dec. 8, 2003, 117 Stat. 2372.)

PRIOR PROVISIONS

A prior section 300aa–2, act July 1, 1944, §2103, was successively renumbered by subsequent acts and transferred, see section 238b of this title.

A prior section 2102 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238a of this title.

AMENDMENTS

2003—Subsec. (a)(7). Pub. L. 108–173 substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".

1992—Subsec. (a)(1), (3), (6), (7). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

ENCOURAGING VACCINE INNOVATION; MEETINGS

Pub. L. 114–255, div. A, title III, §3093(a), Dec. 13, 2016, 130 Stat. 1151, provided that: "The Director of the Centers for Disease Control and Prevention shall ensure that appropriate staff within the relevant centers and divisions of the Office of Infectious Diseases, and others, as appropriate, coordinate with respect to the public health needs, epidemiology, and program planning and implementation considerations related to immunization, including with regard to meetings with stakeholders related to such topics."

GRANTS FOR RESEARCH ON VACCINE AGAINST VALLEY FEVER

Pub. L. 109–432, div. B, title IV, §402, Dec. 20, 2006, 120 Stat. 2994, authorized the Secretary of Health and Human Services to make grants for research on the development of a vaccine against coccidioidomycosis (commonly known as Valley Fever) before Oct. 1, 2012.

DEMONSTRATION PROJECTS FOR OUTREACH PROGRAMS

Pub. L. 101–502, §2(b), Nov. 3, 1990, 104 Stat. 1285, provided that:

"(1) In general.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, may make grants to public and nonprofit private entities for the purpose of carrying out demonstration projects—

"(A) to provide, without charge, immunizations against vaccine-preventable diseases to children not more than 2 years of age who reside in communities whose population includes a significant number of low-income individuals; and

"(B) to provide outreach services to identify such children and to inform the parents (or other guardians) of the children of the availability from the entities of the immunizations specified in subparagraph (A).

"(2) Authorization of appropriations.—For the purpose of carrying out paragraph (1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1993."

[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.]

SUPPLY OF VACCINES

Pub. L. 101–502, §3, Nov. 3, 1990, 104 Stat. 1285, provided that:

"(a) In General.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall acquire and maintain a supply of vaccines sufficient to provide vaccinations throughout a 6-month period. Any proceeds received by the Secretary from the sale of

vaccines from such supply shall be available to the Secretary for the purpose of purchasing vaccines for the supply. Such proceeds shall remain available for such purpose until expended.

"(b) Authorization of Appropriations.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $5,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995."

[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.]

Pub. L. 100–177, title I, §110(b), Dec. 1, 1987, 101 Stat. 991, provided that:

"(1) In general.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall acquire and maintain a supply of vaccines sufficient to provide vaccinations throughout a 6-month period.

"(2) Authorization of Appropriations.—There are authorized to be appropriated to carry out paragraph (1) $5,000,000 for fiscal year 1988, and such sums as may be necessary for each of the fiscal years 1989 and 1990."

[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.]

§300aa–3. Plan

The Director of the Program shall prepare and issue a plan for the implementation of the responsibilities of the Director under section 300aa–2 of this title. The plan shall establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines, describe an optimal use of resources to carry out such priorities, and describe how each of the various departments and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with such priorities. The first plan under this section shall be prepared not later than January 1, 1987, and shall be revised not later than January 1 of each succeeding year.

(July 1, 1944, ch. 373, title XXI, §2103, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3757.)

PRIOR PROVISIONS

A prior section 300aa–3, act July 1, 1944, §2104, which was renumbered section 2304 by Pub. L. 99–660, was transferred to section 300cc–3 of this title, prior to repeal by Pub. L. 98–621, §10(s), Nov. 8, 1984, 98 Stat. 3381.

A prior section 2103 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238b of this title.

§300aa–4. Repealed. Pub. L. 105–362, title VI, §601(a)(1)(H), Nov. 10, 1998, 112 Stat. 3285

Section, act July 1, 1944, ch. 373, title XXI, §2104, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3757, related to national vaccine program report.

A prior section 300aa–4, act July 1, 1944, §2105, was repealed by Pub. L. 99–117, §12(f), Oct. 7, 1985, 99 Stat. 495. See section 300cc–4 of this title.

A prior section 2104 of act July 1, 1944, was renumbered section 2304 by Pub. L. 99–660 and classified to section 300cc–3 of this title, and was repealed by Pub. L. 98–621, §10(s), Nov. 8, 1984, 98 Stat. 3381.

§300aa–5. National Vaccine Advisory Committee

(a) There is established the National Vaccine Advisory Committee. The members of the Committee shall be appointed by the Director of the Program, in consultation with the National Academy of Sciences, from among individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations.

(b) The Committee shall—

(1) study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States,

(2) recommend research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines,

(3) advise the Director of the Program in the implementation of sections 300aa–2, 300aa–3, and 300aa–4 [1] of this title, and

(4) identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 300aa–2, 300aa–3, and 300aa–4 [1] of this title.

(July 1, 1944, ch. 373, title XXI, §2105, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758.)

REFERENCES IN TEXT

Section 300aa–4 of this title, referred to in subsec. (b)(3), (4), was repealed by Pub. L. 105–362, title VI, §601(a)(1)(H), Nov. 10, 1998, 112 Stat. 3285.

PRIOR PROVISIONS

A prior section 300aa–5, act July 1, 1944, §2106, was successively renumbered by subsequent acts and transferred, see section 238c of this title.

A prior section 2105 of act July 1, 1944, was repealed by Pub. L. 99–117, §12(f), Oct. 7, 1985, 99 Stat. 495. See section 300cc–4 of this title.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

[1] *See References in Text note below.*

§300aa–6. Authorization of appropriations

(a) To carry out this part other than section 300aa–2(9) of this title there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.

(b) To carry out section 300aa–2(9) of this title there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.

(July 1, 1944, ch. 373, title XXI, §2106, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 101–502, §4, Nov. 3, 1990, 104 Stat. 1286; Pub. L. 108–276, §2(c), July 21, 2004, 118 Stat. 842.)

PRIOR PROVISIONS

A prior section 300aa–6, act July 1, 1944, §2107, was successively renumbered by subsequent acts and transferred, see section 238d of this title.

A prior section 2106 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238c of this title.

Prior sections 300aa–7 to 300aa–9, act July 1, 1944, §§2108–2110, respectively, were successively renumbered by subsequent acts and transferred, see sections 238e to 238g, respectively, of this title.

AMENDMENTS

2004—Pub. L. 108–276 substituted provisions authorizing appropriations for fiscal years 2004 and

2005 for provisions authorizing appropriations for fiscal years 1991 through 1995 in subsecs. (a) and (b).

1990—Pub. L. 101–502 substituted provisions authorizing appropriations for fiscal years 1991 through 1995 for provisions authorizing appropriations for fiscal years 1987 through 1991 in subsecs. (a) and (b).

Part 2—National Vaccine Injury Compensation Program

subpart a—program requirements

§300aa–10. Establishment of program

(a) Program established

There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

(b) Attorney's obligation

It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program [1] for such injury or death.

(c) Publicity

The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

(July 1, 1944, ch. 373, title XXI, §2110, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 101–239, title VI, §6601(b), Dec. 19, 1989, 103 Stat. 2285.)

PRIOR PROVISIONS

A prior section 300aa–10, act July 1, 1944, §2111, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

A prior section 2110 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238g of this title.

AMENDMENTS

1989—Subsec. (c). Pub. L. 101–239 added subsec. (c).

EFFECTIVE DATE OF 1989 AMENDMENT

Section 6601(s) of Pub. L. 101–239, as amended by Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa–11 to 300aa–17, 300aa–21, 300aa–23, 300aa–26, and 300aa–27 of this title] shall apply as follows:

"(A) Petitions filed after the date of enactment of this section [Dec. 19, 1989] shall proceed under the National Vaccine Injury Compensation Program under title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] as amended by this section.

"(B) Petitions currently pending in which the evidentiary record is closed shall continue to proceed under the Program in accordance with the law in effect before the date of the enactment of this section, except that if the United States Court of Federal Claims is to review the findings of fact and conclusions of law of a special master on such a petition, the court may receive further evidence in conducting such review.

"(C) Petitions currently pending in which the evidentiary record is not closed shall proceed under the Program in accordance with the law as amended by this section.

All pending cases which will proceed under the Program as amended by this section shall be immediately suspended for 30 days to enable the special masters and parties to prepare for

proceeding under the Program as amended by this section. In determining the 240-day period prescribed by section 2112(d) of the Public Health Service Act [42 U.S.C. 300aa–12(d)], as amended by this section, or the 420-day period prescribed by section 2121(b) of such Act [42 U.S.C. 300aa–21(b)], as so amended, any period of suspension under the preceding sentence shall be excluded.

"(2) The amendments to section 2115 of the Public Health Service Act [42 U.S.C. 300aa–15] shall apply to all pending and subsequently filed petitions."

EFFECTIVE DATE

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99–660, as amended, set out as a note under section 300aa–1 of this title.

[1] *So in original. Probably should be capitalized.*

§300aa–11. Petitions for compensation

(a) General rule

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) with the United States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa–12 (d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—

(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa–12 of this title on such petition, and

(II) such person elects under section 300aa–21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa–21(b) of this title or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa–16 of this title, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988.

(4) If in a civil action brought against a vaccine administrator or manufacturer before October 1, 1988, damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) for such injury or death.

(5)(A) A plaintiff who on October 1, 1988, has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after October 1, 1988, or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) for such injury or death.

(6) If a person brings a civil action after November 15, 1988 for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under subsection (b) for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) for such injury or death.

(8) If on October 1, 1988, there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who

brought such action may file a petition under subsection (b) for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court [2] is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) Petitioners

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1), file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before October 1, 1988, if compensation has been paid under this part for 3500 petitions for such injuries or deaths.

(2) Only one petition may be filed with respect to each administration of a vaccine. A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine.

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) Additional information

A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) Schedule

The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

(f) Maternal immunization

(1) In general

Notwithstanding any other provision of law, for purposes of this subpart, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

(2) Definition

As used in this subsection, the term "child" shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1 except that, for purposes of this subsection, such section 8 shall be applied as if the term "include" in subsection (a) of such section were replaced with the term "mean".

(July 1, 1944, ch. 373, title XXI, §2111, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 100–203, title IV, §§4302(b), 4304(a), (b), 4306, 4307(1), (2), Dec. 22, 1987, 101 Stat. 1330–221, 1330-223, 1330-224; Pub. L. 101–239, title VI, §6601(c)(1)–(7), Dec. 19, 1989, 103 Stat. 2285, 2286; Pub. L. 101–502, §5(a), Nov. 3, 1990, 104 Stat. 1286; Pub. L. 102–168, title II, §201(h)(1), Nov. 26, 1991, 105 Stat. 1104; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–43, title XX, §2012, June 10, 1993, 107 Stat. 214; Pub. L. 105–277, div. C, title XV, §1502, Oct. 21, 1998, 112 Stat. 2681–741; Pub. L. 106–310, div. A, title XVII, §1701(a), Oct. 17, 2000, 114 Stat. 1151; Pub. L. 114–255, div. A, title III, §3093(c)(2), (3), Dec. 13, 2016, 130 Stat. 1152.)

CODIFICATION

In subsecs. (a)(2)(A), (3), (4), (5)(A), (8), and (b)(1)(B), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

PRIOR PROVISIONS

A prior section 300aa–11, act July 1, 1944, §2112, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

A prior section 2111 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

AMENDMENTS

2016—Subsec. (b)(2). Pub. L. 114–255, §3093(c)(3), inserted at end "A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine."

Subsec. (f). Pub. L. 114–255, §3093(c)(2), added subsec. (f).

2000—Subsec. (c)(1)(D)(iii). Pub. L. 106–310 added cl. (iii).

1998—Subsec. (c)(1)(D)(i). Pub. L. 105–277 struck out "and incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than $1,000" before ", or (ii) died".

1993—Subsec. (a)(10). Pub. L. 103–43 added par. (10).

1992—Subsec. (a)(1), (2)(A)(i)(I). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" wherever appearing.

1991—Subsec. (a)(2)(A)(i), (ii). Pub. L. 102–168 realigned margins of cls. (i) and (ii).

1990—Subsec. (a)(2)(A). Pub. L. 101–502, §5(a)(1), substituted "unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—" and cls. (i) and (ii) for "unless—

"(i) a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death,

"(ii) the United States Claims Court has issued a judgment under section 300aa–12 of this title on such petition, and

"(iii) such person elects under section 300aa–21(a) of this title to file such an action."

Subsec. (a)(5)(A). Pub. L. 101–502, §5(a)(2), struck out "without prejudice" after "without prejudice or costs".

Subsec. (a)(5)(B). Pub. L. 101–502, §5(a)(3), substituted "plaintiff" for "plaintiff who".

Subsec. (d). Pub. L. 101–502, §5(a)(4), struck out "(d) except as provided in paragraph (3)," before "(d) Additional information".

Subsec. (e). Pub. L. 101–502, §5(a)(5), substituted "(e) Schedule" for "(e)(e) Schedule".

1989—Subsec. (a)(1). Pub. L. 101–239, §6601(c)(1), substituted "filing of a petition containing the matter prescribed in subsection (c)" for "filing of a petition" and inserted at end "The clerk of the United States Claims Court shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa–12(d)(1) of this title."

Subsec. (a)(2)(A)(i). Pub. L. 101–239, §6601(c)(2), struck out "under subsection (b) of this section" after "section 300aa–16 of this title,".

Subsec. (a)(5)(A). Pub. L. 101–239, §6601(c)(3)(A), substituted "petition to have such action dismissed without prejudice or costs" for "elect to withdraw such action".

Subsec. (a)(5)(B). Pub. L. 101–239, §6601(c)(3)(B), substituted "has pending" for "on October 1, 1988, had pending" and struck out "does not withdraw the action under subparagraph (A)" after "vaccine-related injury or death".

Subsec. (a)(6). Pub. L. 101–239, §6601(c)(4), substituted "November 15, 1988" for "the effective date of this subpart" in two places.

Subsec. (a)(8). Pub. L. 101–239, §6601(c)(5), added par. (8). Former par. (8) redesignated (9).

Subsec. (a)(9). Pub. L. 101–239, §6601(c)(5), (7), redesignated par. (8) as (9) and realigned margin.

Subsec. (c)(1). Pub. L. 101–239, §6601(c)(6)(A), inserted "except as provided in paragraph (3)," after "(1)" in introductory provisions.

Subsec. (c)(2). Pub. L. 101–239, §6601(c)(6)(B), (C), added par. (2) and redesignated former par. (2) as subsec. (d).

Pub. L. 101–239, §6601(c)(6)(A), inserted "except as provided in paragraph (3)," after "(2)".

Subsec. (c)(3). Pub. L. 101–239, §6601(c)(6)(C), (D), added par. (3). Former par. (3) redesignated subsec. (e).

Subsec. (d). Pub. L. 101–239, §6601(c)(6)(B), redesignated former subsec. (c)(2) as subsec. (d), expanded margin to full measure, inserted subsec. designation and heading, substituted "A petition may also include other available" for "all available", struck out "(including autopsy reports, if any)" after "relevant medical records", and substituted "administration of the vaccine." for "administration of the vaccine and an identification of any unavailable records known to the petitioner and the reasons for their unavailability, and".

Subsec. (e). Pub. L. 101–239, §6601(c)(6)(D), redesignated former subsec. (c)(3) as subsec. (e), expanded margin to full measure, inserted subsec. designation and heading, and substituted "The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition" for "appropriate".

1987—Subsec. (a)(1). Pub. L. 100–203, §4307(1), which directed that par. (1) be amended by substituting "with the United States Claims Court" for "with the United States district court for the district in which the petitioner resides or the injury or death occurred", was executed making the substitution for "with the United States district court for the district in which the petitioner resides or in which the injury or death occurred", as the probable intent of Congress.

Subsec. (a)(2)(A). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(2)(A)(ii). Pub. L. 100–203, §4307(2), substituted "the United States Claims Court" for "a district court of the United States".

Subsec. (a)(3). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this

part".

Subsec. (a)(4). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(5)(A). Pub. L. 100–203, §4302(b)(2), substituted "after the effective date of this subpart" for "after the effective date of this subchapter".

Pub. L. 100–203, §4302(b)(1), substituted "who on the effective date of this subpart" for "who on the effective date of this part".

Subsec. (a)(5)(B). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(6). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part" in two places.

Subsec. (a)(7). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Subsec. (a)(8). Pub. L. 100–203, §4304(a), added par. (8).

Subsec. (b)(1)(A). Pub. L. 100–203, §4304(b)(1), substituted "may, if the person meets the requirements of subsection (c)(1), file" for "may file".

Subsec. (b)(1)(B). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (c)(1)(D). Pub. L. 100–203, §4304(b)(2), substituted "for more than 6 months" for "for more than 1 year", "and incurred" for ", (ii) incurred", and "(ii)" for "(iii)".

CHANGE OF NAME

References to United States Claims Court deemed to refer to United States Court of Federal Claims, see section 902(b) of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–310, div. A, title XVII, §1701(b), Oct. 17, 2000, 114 Stat. 1151, provided that: "The amendment made by subsection (a) [amending this section] takes effect upon the date of the enactment of this Act [Oct. 17, 2000], including with respect to petitions under section 2111 of the Public Health Service Act [42 U.S.C. 300aa–11] that are pending on such date."

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Pub. L. 102–168, title II, §201(i), Nov. 26, 1991, 105 Stat. 1104, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa–12, 300aa–15, 300aa–16, 300aa–19, and 300aa–21 of this title and provisions set out as a note under section 300aa–1 of this title] shall take effect on the date of the enactment of this Act [Nov. 26, 1991].

"(2) The amendments made by subsections (d) and (f) [amending sections 300aa–12, 300aa–15, 300aa–16, and 300aa–21 of this title] shall take effect as if the amendments had been in effect on and after October 1, 1988."

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–502, §5(h), Nov. 3, 1990, 104 Stat. 1289, provided that: "The amendments made by subsections (f)(1) and (g) [amending section 300aa–21 of this title and provisions set out as a note under section 300aa–1 of this title and enacting provisions set out as a note under section 300aa–12 of this title] shall take effect as of November 14, 1986, and the amendments made by subsections (a) through (e) and subsection (f)(2) [amending this section and sections 300aa–12, 300aa–13, 300aa–15, 300aa–16, and 300aa–21 of this title] shall take effect as of September 30, 1990."

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

[2] *See Change of Name note below.*

§300aa–12. Court jurisdiction

(a) General rule

The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa–11 of this title is entitled to compensation under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) In all proceedings brought by the filing of a petition under section 300aa–11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa–11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) shall afford all interested persons an opportunity to submit relevant, written information—

(A) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title.

(c) United States Court of Federal Claims special masters

(1) There is established within the United States Court of Federal Claims an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Court of Federal Claims shall appoint the special masters, 1 of whom, by designation of the judges of the United States Court of Federal Claims, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Court of Federal Claims for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Court of Federal Claims determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters on December 19, 1989, shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on December 19, 1989, shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States Court of Federal Claims, upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, title 5. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, title 5.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts [1] judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The

Conference rules and regulations pertaining to United States magistrate judges shall be applied to the special masters.

(D) Coordinating with the United States Court of Federal Claims the use of services, equipment, personnel, information, and facilities of the United States Court of Federal Claims without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Court of Federal Claims on the number of petitions filed under section 300aa–11 of this title and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) Special masters

(1) Following the receipt and filing of a petition under section 300aa–11 of this title, the clerk of the United States Court of Federal Claims shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of title 28. Such rules shall—

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.

(3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall—

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Court of Federal Claims in accordance with subsection (e).

(B) In conducting a proceeding on a petition a special master—

(i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) shall afford all interested persons an opportunity to submit relevant written information—

(I) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(II) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title, and

(v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before October 1, 1988, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information—

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) Action by United States Court of Federal Claims

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Court of Federal Claims a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Court of Federal Claims no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals

The findings of fact and conclusions of law of the United States Court of Federal Claims on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the date of entry of the United States Claims Court's [2] judgment with such court of appeals.

(g) Notice

If—

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)), or

(2) the United States Court of Federal Claims fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa–21(b) of this title or the petitioner may choose under section 300aa–21(b) of this title to have the petition remain before the special master or court, as the case may be.

(July 1, 1944, ch. 373, title XXI, §2112, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3761; amended Pub. L. 100–203, title IV, §§4303(d)(2)(A), 4307(3), 4308(a), (b), Dec. 22, 1987, 101 Stat. 1330–222, 1330-224; Pub. L. 100–360, title IV, §411(o)(2), (3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(d)–(i), Dec. 19, 1989, 103 Stat. 2286–2290; Pub. L. 101–502, §5(b), Nov. 3, 1990, 104 Stat. 1286; Pub. L. 101–650, title III, §321, Dec. 1, 1990, 104 Stat. 5117; Pub. L. 102–168, title II, §201(c), (d)(1), (h)(2), (3), Nov. 26, 1991, 105 Stat. 1103, 1104; Pub. L. 102–572, title IX, §902(b), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–66, title XIII, §13632(c), Aug. 10, 1993, 107 Stat. 646.)

CODIFICATION

In subsec. (c)(4), "on December 19, 1989," substituted for "upon the date of the enactment of this subsection" and "on the date of the enactment of this subsection".

In subsec. (d)(3)(D), "October 1, 1988," substituted for "the effective date of this part".

PRIOR PROVISIONS

A prior section 300aa–12, act July 1, 1944, §2113, was successively renumbered by subsequent

acts and transferred, see section 238j of this title.

A prior section 2112 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

AMENDMENTS

1993—Subsec. (d)(3)(D). Pub. L. 103–66 substituted "30 months (but for not more than 6 months at a time)" for "540 days".

1992—Subsecs. (a), (c) to (g). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" and "Court of Federal Claims" for "Claims Court", wherever appearing.

1991—Subsec. (d)(3)(D). Pub. L. 102–168, §201(c), (h)(2), realigned margin and substituted "540 days" for "180 days".

Subsec. (g). Pub. L. 102–168, §201(h)(3), made technical amendment to underlying provisions of original Act.

Pub. L. 102–168, §201(d)(1), substituted "or the petitioner may choose under section 300aa–21(b) of this title to have the petition remain before the special master or court, as the case may be" for "and the petition will be considered withdrawn under such section if the petitioner, the special master, or the court do not take certain actions" before period at end.

1990—Subsec. (d)(3)(D). Pub. L. 101–502, §5(b)(1), added subpar. (D).

Subsec. (g). Pub. L. 101–502, §5(b)(2), added subsec. (g).

1989—Subsec. (a). Pub. L. 101–239, §6601(d), substituted "and the United States Claims Court special masters shall, in accordance with this section, have jurisdiction" for "shall have jurisdiction (1)", ". The United States Claims Court may issue" for ", and (2) to issue", and "deems" for "deem".

Subsec. (b)(1). Pub. L. 101–239, §6601(f), substituted "In all proceedings brought by the filing of a petition under section 300aa–11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28." for "The Secretary shall be named as the respondent in all proceedings brought by the filing of a petition under section 300aa–11(b) of this title. Except as provided in paragraph (2), no other person may intervene in any such proceeding."

Subsec. (c). Pub. L. 101–239, §6601(e)(2), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 101–239, §6601(e)(1), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (e).

Subsec. (d)(1). Pub. L. 101–239, §6601(g)(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Following receipt of a petition under subsection (a) of this section, the United States Claims Court shall designate a special master to carry out the functions authorized by paragraph (2)."

Subsec. (d)(2) to (4). Pub. L. 101–239, §6601(g)(2), added pars. (2) to (4) and struck out former par. (2) which prescribed functions of special masters.

Subsec. (e). Pub. L. 101–239, §6601(h), substituted "Action by United States Claims Court" for "Action by court" as heading and amended text generally. Prior to amendment, text read as follows:

"(1) Upon objection by the petitioner or respondent to the proposed findings of fact or conclusions of law prepared by the special master or upon the court's own motion, the court shall undertake a review of the record of the proceedings and may thereafter make a de novo determination of any matter and issue its judgment accordingly, including findings of fact and conclusions of law, or remand for further proceedings.

"(2) If no objection is filed under paragraph (1) or if the court does not choose to review the proceeding, the court shall adopt the proposed findings of fact and conclusions of law of the special master as its own and render judgment thereon.

"(3) The court shall render its judgment on any petition filed under the Program as expeditiously as practicable but not later than 365 days after the date on which the petition was filed."

Pub. L. 101–239, §6601(e)(1), redesignated subsec. (d) as (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 101–239, §6601(i), inserted "within 60 days of the date of entry of the United States Claims Court's judgment with such court of appeals" after "with such court of appeals".

Pub. L. 101–239, §6601(e)(1), redesignated subsec. (e) as (f).

1988—Subsec. (c)(2). Pub. L. 100–360, §411(o)(3)(A), added Pub. L. 100–203, §4308(a), see 1987 Amendment note below.

Subsec. (e). Pub. L. 100–360, §411(o)(2), made technical amendment to directory language of Pub. L. 100–203, §4307(3)(C), see 1987 Amendment note below.

Pub. L. 100–360, §411(o)(3)(A), added Pub. L. 100–203, §4308(b), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4307(3)(A), substituted "United States Claims Court" for "district courts of the United States" and "the court" for "the courts".

Subsec. (c)(1). Pub. L. 100–203, §4307(3)(B), substituted "the United States Claims Court" for "the district court of the United States in which the petition is filed".

Subsec. (c)(2). Pub. L. 100–203, §4308(a), as added by Pub. L. 100–360, §411(o)(3)(A), inserted ", shall prepare and submit to the court proposed findings of fact and conclusions of law," in introductory provisions and struck out subpar. (E) which read as follows: "prepare and submit to the court proposed findings of fact and conclusions of law."

Subsec. (e). Pub. L. 100–203, §4308(b), as added by Pub. L. 100–360, §411(o)(3)(A), inserted "within 60 days of the date of the judgment" after "petition filed".

Pub. L. 100–203, §4307(3)(C), as amended by Pub. L. 100–360, §411(o)(2), substituted "the United States Claims Court" for "a district court of the United States" and "for the Federal Circuit" for "for the circuit in which the court is located".

Pub. L. 100–203, §4303(d)(2)(A), redesignated subsec. (g) as (e) and struck out former subsec. (e) relating to administration of an award.

Subsec. (f). Pub. L. 100–203, §4303(d)(2)(A), struck out subsec. (f) which related to revision of an award.

Subsec. (g). Pub. L. 100–203, §4303(d)(2)(A), redesignated subsec. (g) as (e).

CHANGE OF NAME

"United States magistrate judges" substituted for "United States magistrates" in subsec. (c)(6)(C) pursuant to section 321 of Pub. L. 101–650, set out as a note under section 631 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by section 201(d)(1) of Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 240-day period prescribed in subsec. (d) of this section, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1,

General Provisions.

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions in subsec. (c)(6)(E) of this section relating to reporting annually to the Congress, see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 13 of House Document No. 103–7.

REVIEW BY 3-JUDGE PANEL

Section 322(c) of Pub. L. 99–660, as added by Pub. L. 101–502, §5(g)(2), Nov. 3, 1990, 104 Stat. 1288, and amended by Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that: "If the review authorized by section 2112(f) [42 U.S.C. 300aa–12(f)] is held invalid because the judgment of the United States Court of Federal Claims being reviewed did not arise from a case or controversy under Article III of the Constitution, such judgment shall be reviewed by a 3-judge panel of the United States Court of Federal Claims. Such panel shall not include the judge who participated in such judgment."

[Enactment of section 322(c) of Pub. L. 99–660 by section 5(g)(2) of Pub. L. 101–502, set out above, effective Nov. 14, 1986, see section 5(h) of Pub. L. 101–502, set out as an Effective Date of 1990 Amendment note under section 300aa–11 of this title.]

[1] *So in original. Probably should be a reference to the United States Court of Federal Claims.*

[2] *So in original. Probably should be a reference to the United States Court of Federal Claims.*

§300aa–13. Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) Matters to be considered

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or court may find the first symptom or manifestation of onset or significant aggravation

of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

(c) "Record" defined

For purposes of this section, the term "record" means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa–11 of this title.

(July 1, 1944, ch. 373, title XXI, §2113, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3763; amended Pub. L. 100–203, title IV, §4307(4), Dec. 22, 1987, 101 Stat. 1330–224; Pub. L. 101–239, title VI, §6601(j), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 101–502, §5(c), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

PRIOR PROVISIONS

A prior section 300aa–13, act July 1, 1944, §2114, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

A prior section 2113 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

AMENDMENTS

1992—Subsec. (c). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court".

1990—Subsec. (c). Pub. L. 101–502 inserted "the" after "special masters of".

1989—Subsecs. (a)(1), (b). Pub. L. 101–239, §6601(j)(1), substituted "special master or court" for "court" wherever appearing.

Subsec. (c). Pub. L. 101–239, §6601(j)(2), inserted "special masters of" after "established by the".

1987—Subsec. (c). Pub. L. 100–203 substituted "the United States Claims Court" for "a district court of the United States".

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–14. Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

.	DTP; P; DTP/Polio Combination; or Any Other Vaccine

ontaining Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	
Illness, disability, injury, or condition covered:	ime period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
A. Anaphylaxis or anaphylactic shock	24 hours
B. Encephalopathy (or encephalitis)	3 days
C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
D. Residual seizure disorder in accordance with subsection (b)(2)	3 days
E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
I. Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
A. Anaphylaxis or anaphylactic shock	24 hours
B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
C. Residual seizure disorder in accordance with subsection (b)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
II. Polio Vaccines (other than Inactivated Polio Vaccine).	
A. Paralytic polio	
—in a non-immunodeficient recipient	30 days
—in an immunodeficient recipient	6 months
—in a vaccine-associated community case	Not applicable
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
V. Inactivated Polio Vaccine.	
A. Anaphylaxis or anaphylactic shock	24 hours
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

(b) Qualifications and aids to interpretation

The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a):

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa–11 of this title for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

(c) Administrative revision of table

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) Role of Commission

Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

(e) Additional vaccines

(1) Vaccines recommended before August 1, 1993

By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) Vaccines recommended after August 1, 1993

When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which were recommended for routine administration to children,
(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and
(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(3) Vaccines recommended for use in pregnant women

The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.

(July 1, 1944, ch. 373, title XXI, §2114, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3764; amended Pub. L. 101–239, title VI, §6601(k), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 103–66, title XIII, §13632(a)(2), Aug. 10, 1993, 107 Stat. 645; Pub. L. 114–255, div. A, title III, §3093(c)(1), Dec. 13, 2016, 130 Stat. 1152.)

PRIOR PROVISIONS

A prior section 300aa–14, act July 1, 1944, §2115, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

A prior section 2114 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

AMENDMENTS

2016—Subsec. (e)(3). Pub. L. 114–255 added par. (3).

1993—Subsec. (e). Pub. L. 103–66 amended heading and text of subsec. (e) generally. Prior to amendment, text read as follows: "The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table."

1989—Subsec. (a). Pub. L. 101–239, §6601(k)(1), substituted "(b)(2)" for "(c)(2)" in items I.D. and II.C. in table.

Subsec. (b)(3)(B). Pub. L. 101–239, §6601(k)(2), substituted "300aa–11 of this title" for "300aa–11 (b) of this title".

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

REVISIONS OF VACCINE INJURY TABLE

The Vaccine Injury Table as modified by regulations promulgated by the Secretary of Health and Human Services is set out at 42 CFR 100.3.

Pub. L. 103–66, title XIII, §13632(a)(3), Aug. 10, 1993, 107 Stat. 646, provided that: "A revision by the Secretary under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa–14(a))."

§300aa–15. Compensation

(a) General rule

Compensation awarded under the Program to a petitioner under section 300aa–11 of this title for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, shall include the following:

(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—
(i) result from the vaccine-related injury for which the petitioner seeks compensation,
(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and
(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(B) Subject to section 300aa–16(a)(2) of this title, actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $250,000.

(b) Vaccines administered before effective date

Compensation awarded under the Program to a petitioner under section 300aa–11 of this title for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—

(1) lost earnings (as provided in paragraph (3) of subsection (a)),

(2) pain and suffering (as provided in paragraph (4) of subsection (a)), and

(3) reasonable attorneys' fees and costs (as provided in subsection (e)).[1]

(c) Residential and custodial care and service

The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

(d) Types of compensation prohibited

Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

(e) Attorneys' fees

(1) In awarding compensation on a petition filed under section 300aa–11 of this title the special master or court shall also award as part of such compensation an amount to cover—

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) If the petitioner, before October 1, 1988, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and petitioned under section 300aa–11(a)(5) of this title to have such action dismissed and to file a petition for compensation under the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the

costs and expenses incurred by the petitioner and the attorney of the petitioner before October 1, 1988, in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

(3) No attorney may charge any fee for services in connection with a petition filed under section 300aa–11 of this title which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(f) Payment of compensation

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 300aa–21(a) of this title to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the United States Court of Federal Claims under section 300aa–12 of this title awarding the compensation. Such compensation may not be paid after an election under section 300aa–21(a) of this title to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation under the Program and the costs of carrying out the Program shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985 [2 U.S.C. 900 et seq.].

(4)(A) Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26 in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, the compensation shall be determined on the basis of the net present value of the elements of compensation and shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 300aa–21(a) of this title shall not apply to a civil action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26, or to the appropriations account from which the funds were derived to purchase the annuity, whichever is appropriate.

(g) Program not primarily liable

Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (other than under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.]), or (2) by an entity which provides health services on a prepaid basis.

(h) Liability of health insurance carriers, prepaid health plans, and benefit providers

No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

(1) no State, and

(2) no entity which provides health services on a prepaid basis or provides health benefits,

may make the provision of health services or health benefits secondary to the payment of compensation under the Program, except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(i) Source of compensation

(1) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, shall be made by the Secretary from appropriations under subsection (j).

(2) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1988, shall be made from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(j) Authorization

For the payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, there are authorized to be appropriated to the Department of Health and Human Services $80,000,000 for fiscal year 1989, $80,000,000 for fiscal year 1990, $80,000,000 for fiscal year 1991, $80,000,000 for fiscal year 1992, $110,000,000 for fiscal year 1993, and $110,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B). Amounts appropriated under this subsection shall remain available until expended.

(July 1, 1944, ch. 373, title XXI, §2115, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3767; amended Pub. L. 100–203, title IV, §§4302(b), 4303(a)–(d)(1), (e), (g), 4307(5), (6), Dec. 22, 1987, 101 Stat. 1330–221 to 1330-223, 1330-225; Pub. L. 100–360, title IV, §411(o)(1), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(c)(8), (l), Dec. 19, 1989, 103 Stat. 2286, 2290; Pub. L. 101–502, §5(d), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(e), (f), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102–531, title III, §314, Oct. 27, 1992, 106 Stat. 3508; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–66, title XIII, §13632(b), Aug. 10, 1993, 107 Stat. 646.)

REFERENCES IN TEXT

The Balanced Budget and Emergency Deficit Control Act of 1985, referred to in subsec. (f)(3), is title II of Pub. L. 99–177, Dec. 12, 1985, 99 Stat. 1038. Part C of the Act is classified generally to subchapter I (§900 et seq.) of chapter 20 of Title 2, The Congress. For complete classification of this Act to the Code, see Short Title note set out under section 900 of Title 2 and Tables.

The Social Security Act, referred to in subsecs. (g) and (h), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Title XIX of the Social Security Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

In subsecs. (a), (b), (e)(2), (f)(4)(B), (i), and (j), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

PRIOR PROVISIONS

A prior section 300aa–15, act July 1, 1944, §2116, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

A prior section 2115 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

AMENDMENTS

1993—Subsec. (j). Pub. L. 103–66 substituted "$110,000,000 for each succeeding fiscal year" for "$80,000,000 for each succeeding fiscal year".

1992—Subsecs. (e)(1), (f)(2). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court".

Subsec. (j). Pub. L. 102–531 increased authorization for fiscal year 1993 from $80,000,000 to $110,000,000.

1991—Subsec. (f)(4)(A). Pub. L. 102–168, §201(e)(1)(A), (2), struck out "of the proceeds" after "portion" and substituted "Vaccine Injury Compensation Trust Fund established under section 9510 of title 26" for "trust fund".

Subsec. (f)(4)(B). Pub. L. 102–168, §201(e)(1)(B), which directed substitution of "shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion" for "paid in 4 equal installments of which all or portion of the proceeds" was executed by making the substitution for "paid in 4 equal annual installments of which all or a portion of the proceeds" to reflect the probable intent of Congress.

Subsec. (f)(4)(C). Pub. L. 102–168, §201(f), added subpar. (C).

1990—Subsec. (e)(2). Pub. L. 101–502, §5(d)(1), inserted "of compensation" before "limited to the costs".

Subsec. (f)(2). Pub. L. 101–502, §5(d)(2)(A), substituted "section 300aa–21(a)" for "section 300aa–21(b)".

Subsec. (f)(4)(B). Pub. L. 101–502, §5(d)(2)(B), substituted "subsection (j)" for "subsection (i)" and "the limitation on civil actions prescribed by section 300aa–21(a) of this title" for "section 300aa–11

(a) of this title".

Subsec. (j). Pub. L. 101–502, §5(d)(3), inserted before period at end of first sentence ", and $80,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B)".

1989—Subsec. (b). Pub. L. 101–239, §6601(l)(1), substituted "may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—" and cls. (1) to (3) for "may not include the compensation described in paragraph (1)(B) of subsection (a) of this section and may include attorneys' fees and other costs included in a judgment under subsection (e) of this section, except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) of this section and included as attorneys' fees and other costs under subsection (e) of this section may not exceed $30,000."

Subsec. (e)(1). Pub. L. 101–239, §6601(l)(2)(A), substituted "In awarding compensation on a petition filed under section 300aa–11 of this title the special master or court shall also award as part of such compensation an amount to cover" for "The judgment of the United States Claims Court on a petition filed under section 300aa–11 of this title awarding compensation shall include an amount to cover".

Pub. L. 101–239, §6601(l)(2)(B), (C), substituted "the special master or court may award an amount of compensation to cover" for "the court may include in the judgment an amount to cover" and "the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition" for "the court determines that the civil action was brought in good faith and there was a reasonable basis for the claim for which the civil action".

Subsec. (e)(2). Pub. L. 101–239, §6601(l)(2)(D), which directed amendment of par. (2) by substituting "the special master or court may also award an amount of compensation" for "the judgment of the court on such petition may include an amount", could not be executed because of the prior amendment by Pub. L. 101–239, §6601(c)(8)(B), see Amendment note below.

Pub. L. 101–239, §6601(c)(8), substituted "and petitioned under section 300aa–11(a)(5) of this title to have such action dismissed" for "and elected under section 300aa–11(a)(4) of this title to withdraw such action" and "in awarding compensation on such petition the special master or court may include" for "the judgment of the court on such petition may include".

Subsec. (e)(3). Pub. L. 101–239, §6601(l)(2)(E), substituted "awarded as compensation by the special master or court under paragraph (1)" for "included under paragraph (1) in a judgment on such petition".

Subsec. (f)(3). Pub. L. 101–239, §6601(l)(3)(A), inserted "under the Program and the costs of carrying out the Program" after "Payments of compensation".

Subsec. (f)(4)(A). Pub. L. 101–239, §6601(l)(3)(B), struck out "made in a lump sum" after "the Program shall be" and inserted "and shall be paid from the trust fund in a lump sum of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner" after "elements of the compensation".

Subsec. (f)(4)(B). Pub. L. 101–239, §6601(l)(3)(C), substituted "determined on the basis of the net present value of the elements of compensation and paid in 4 equal annual installments of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum" for "paid in 4 equal annual installments".

Subsec. (g). Pub. L. 101–239, §6601(l)(4)(A), inserted "(other than under title XIX of the Social Security Act)" after "State health benefits program".

Subsec. (h). Pub. L. 101–239, §6601(l)(4)(B), inserted before period at end ", except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act".

Subsec. (i)(1). Pub. L. 101–239, §6601(l)(5), which directed amendment of par. (1) by substituting "(j)" for "(i)", could not be executed because "(i)" did not appear.

Subsec. (j). Pub. L. 101–239, §6601(l)(6), struck out "and" after "fiscal year 1991," and inserted ", $80,000,000 for fiscal year 1993" after "fiscal year 1992".

1988—Subsec. (i)(1). Pub. L. 100–360, §411(o)(1)(A), substituted "by the Secretary from

appropriations under subsection (j)" for "from appropriations under subsection (i)".

Subsec. (j). Pub. L. 100–360, §411(o)(1)(B), inserted "to the Department of Health and Human Services".

1987—Subsec. (a). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Pub. L. 100–203, §4303(d)(1)(A), struck out last two sentences which read as follows: "Payments for projected expenses shall be paid on a periodic basis (but no payment may be made for a period in excess of 1 year). Payments for pain and suffering and emotional distress and incurred expenses may be paid in a lump sum."

Subsec. (a)(1). Pub. L. 100–203, §4303(c), struck out last sentence of subpars. (A) and (B) each of which read as follows: "The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 300aa–11(c)(1)(D)(ii) of this title."

Subsec. (b). Pub. L. 100–203, §4303(e), substituted "may not include the compensation described in paragraph (1)(B) of subsection (a) of this section and may include attorneys' fees and other costs included in a judgment under subsection (e) of this section, except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) of this section and included as attorneys' fees and other costs under subsection (e) of this section may not exceed $30,000" for "shall only include the compensation described in paragraphs (1)(A) and (2) of subsection (a) of this section".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (e)(1). Pub. L. 100–203, §4307(5), substituted "of the United States Claims Court" for "of a court" in two places.

Subsec. (e)(2). Pub. L. 100–203, §4302(b), substituted "effective date of this subpart, filed a" for "effective date of this subchapter, filed a" and "effective date of this subpart in preparing" for "effective date of this part in preparing".

Subsec. (f). Pub. L. 100–203, §4303(d)(1)(B), (g), added par. (4) and redesignated a second subsec. (f), relating to the Program not being primarily liable, as subsec. (g).

Subsec. (f)(2). Pub. L. 100–203, §4307(6), substituted "United States Claims Court" for "district court of the United States".

Subsecs. (g), (h). Pub. L. 100–203, §4303(g), redesignated a second subsec. (f), relating to the Program not being liable, as (g) and redesignated former subsec. (g) as (h).

Subsecs. (i), (j). Pub. L. 100–203, §4303(a), (b), added subsecs. (i) and (j).

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by section 201(f) of Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101–239 applicable to all pending and subsequently filed petitions, see section 6601(s)(2) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1,

General Provisions.

[1] *So in original. Probably should be preceded by another closing parenthesis.*

§300aa–16. Limitations of actions

(a) General rule

In the case of—

(1) a vaccine set forth in the Vaccine Injury Table which is administered before October 1, 1988, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 28 months after October 1, 1988, and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine,

(2) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

(3) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

(b) Effect of revised table

If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa–11(b)(2) of this title, file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if—

(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

(c) State limitations of actions

If a petition is filed under section 300aa–11 of this title for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date (1) an election is made under section 300aa–21(a) of this title to file the civil action or (2) an election is made under section 300aa–21(b) of this title to withdraw the petition.

(July 1, 1944, ch. 373, title XXI, §2116, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3769; amended Pub. L. 100–203, title IV, §4302(b)(2), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(m)(1), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101–502, §5(e), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(d)(2), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 103–66, title XIII, §13632(a)(1), Aug. 10, 1993, 107 Stat. 645.)

CODIFICATION

In subsec. (a)(1) to (3), "October 1, 1988" and "October 1, 1988," substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

PRIOR PROVISIONS

A prior section 2116 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

AMENDMENTS

1993—Subsec. (b). Pub. L. 103–66 substituted "or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa–11(b)(2) of this title, file" for "such person may file".

1991—Subsec. (c). Pub. L. 102–168 substituted "or (2)" for ", (2)" and struck out ", or (3) the petition is considered withdrawn under section 300aa–21(b) of this title."

1990—Subsec. (a)(1). Pub. L. 101–502, §5(e)(1), substituted "28 months" for "24 months" and inserted before comma at end "and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine".

Subsec. (c). Pub. L. 101–502, §5(e)(2), substituted "and ending on the date (1) an election is made under section 300aa–21(a) of this title to file the civil action, (2) an election is made under section 300aa–21(b) of this title to withdraw the petition, or (3) the petition is considered withdrawn under section 300aa–21(b) of this title" for "and ending on the date a final judgment is entered on the petition".

1989—Subsec. (c). Pub. L. 101–239 substituted "300aa–11 of this title" for "300aa–11(b) of this title".

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this subchapter" in pars. (1) to (3).

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201 (i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–17. Subrogation

(a) General rule

Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrogated [1] to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

(b) Disposition of amounts recovered

Amounts recovered under subsection (a) shall be collected on behalf of, and deposited in, the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(July 1, 1944, ch. 373, title XXI, §2117, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3770; amended Pub. L. 100–203, title IV, §4307(7), Dec. 22, 1987, 101 Stat. 1330–225; Pub. L. 101–239, title VI, §6601(m)(2), Dec. 19, 1989, 103 Stat. 2291.)

AMENDMENTS

1989—Subsec. (b). Pub. L. 101–239 substituted "the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26" for "the trust fund which has been established to provide compensation under the Program".

1987—Subsec. (a). Pub. L. 100–203 struck out par. (1) designation before "Upon" and struck out par. (2) which read as follows: "In any case in which it deems such action appropriate, a district court of the United States may, after entry of a final judgment providing for compensation to be paid under section 300aa–15 of this title for a vaccine-related injury or death, refer the record of such proceeding to the Secretary and the Attorney General with such recommendation as the court deems appropriate with respect to the investigation or commencement of a civil action by the Secretary under paragraph (1)."

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

[1] *So in original. Probably should be "subrogated".*

§300aa–18. Repealed. Pub. L. 100–203, title IV, §4303(d)(2)(B), Dec. 22, 1987, 101 Stat. 1330–222

Section, act July 1, 1944, ch. 373, title XXI, §2118, as added Nov. 14, 1986, Pub. L. 99–660, title III, §311(a), 100 Stat. 3771, provided for annual increases for inflation of compensation under subsections (a)(2) and (a)(4) of section 300aa–15 of this title and civil penalty under section 300aa–27(b) of this title.

§300aa–19. Advisory Commission on Childhood Vaccines

(a) Establishment

There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

(1) Nine members appointed by the Secretary as follows:

(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of October 1, 1988. The members of the Commission shall select a Chair from among the members.

(b) Term of office

Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

(c) Meetings

The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the Commission present at the meeting.

(d) Compensation

Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the Commission who are not officers or employees of the Federal Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5 for employees serving intermittently.

(e) Staff

The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

(f) Functions

The Commission shall—

(1) advise the Secretary on the implementation of the Program,

(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

(3) advise the Secretary in implementing the Secretary's responsibilities under section 300aa–27 of this title regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 300aa–25(b) of this title, and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this part.

(July 1, 1944, ch. 373, title XXI, §2119, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3771; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 102–168, title II, §201(g), Nov. 26, 1991, 105 Stat. 1104; Pub. L. 102–531, title III, §312(d)(14), Oct. 27, 1992, 106 Stat. 3505.)

CODIFICATION

In subsec. (a), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1992—Subsec. (a)(2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1991—Subsec. (c). Pub. L. 102–168 inserted "present at the meeting" before period at end.

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part" in last sentence.

TERMINATION OF ADVISORY COMMISSIONS

Advisory commissions established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a commission established by the President or an officer of the Federal Government, such commission is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a commission established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

subpart b—additional remedies

§300aa–21. Authority to bring actions

(a) Election

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under

section 300aa–12(f) of this title, after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa–11 of this title shall file with the clerk of the United States Court of Federal Claims—

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the court's final judgment with respect to which the election is to be made. If a person required to file an election with the court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered. For limitations on the bringing of civil actions for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988, see section 300aa–11(a)(2) of this title.

(b) Continuance or withdrawal of petition

A petitioner under a petition filed under section 300aa–11 of this title may submit to the United States Court of Federal Claims a notice in writing choosing to continue or to withdraw the petition if—

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 300aa–12(d)(3)(A)(ii) of this title (excluding (i) any period of suspension under section 300aa–12(d)(3)(C) or 300aa–12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title), or

(2) the court fails to enter a judgment under section 300aa–12 of this title on the petition within 420 days (excluding (i) any period of suspension under section 300aa–12(d)(3)(C) or 300aa–12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title) after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 300aa–12(g) of this title.

(c) Limitations of actions

A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 300aa–11 of this title shall, except as provided in section 300aa–16(c) of this title, be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

(July 1, 1944, ch. 373, title XXI, §2121, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3772; amended Pub. L. 100–203, title IV, §§4304(c), 4307(8), 4308(c), Dec. 22, 1987, 101 Stat. 1330–224, 1330-225; Pub. L. 100–360, title IV, §411(o)(3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(n), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101–502, §5(f), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(d)(3), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

CODIFICATION

In subsec. (a), "October 1, 1988," and "October 1, 1988" substituted for "the effective date of this part".

AMENDMENTS

1992—Subsecs. (a), (b). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" wherever appearing.

1991—Subsec. (b). Pub. L. 102–168 substituted "Continuance or withdrawal of petition" for "Withdrawal of petition" in heading, redesignated introductory provisions of par. (1) as introductory provisions of subsec. (b) and substituted "a notice in writing choosing to continue or to withdraw the petition" for "a notice in writing withdrawing the petition", redesignated subpars. (A) and (B) of former par. (1) as pars. (1) and (2), respectively, and realigned margins, struck out at end of former par. (1) "If such a notice is not filed before the expiration of such 30 days, the petition with respect to which the notice was to be filed shall be considered withdrawn under this paragraph.", and struck out par. (2) which read as follows: "If a special master or the court does not enter a decision or make a judgment on a petition filed under section 300aa–11 of this title within 30 days of the provision of the notice in accordance with section 300aa–12(g) of this title, the special master or court shall no longer have jurisdiction over such petition and such petition shall be considered as withdrawn under

paragraph (1)."

1990—Subsec. (a). Pub. L. 101–502, §5(f)(1), in closing provisions, inserted after second sentence "If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered." and inserted "for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988" after "actions" in last sentence.

Subsec. (b). Pub. L. 101–502, §5(f)(2), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "If the United States Claims Court fails to enter a judgment under section 300aa–12 of this title on a petition filed under section 300aa–11 of this title within 420 days (excluding any period of suspension under section 300aa–12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title) after the date on which the petition was filed, the petitioner may submit to the court a notice in writing withdrawing the petition. An election shall be filed under this subsection not later than 90 days after the date of the entry of the Claims Court's judgment or the appellate court's mandate with respect to which the election is to be made. A person who has submitted a notice under this subsection may, notwithstanding section 300aa–11(a)(2) of this title, thereafter maintain a civil action for damages in a State or Federal court without regard to this subpart and consistent with otherwise applicable law."

1989—Subsec. (a). Pub. L. 101–239, §6601(n)(1)(A), amended introductory provisions generally. Prior to amendment, introductory provisions read as follows: "After the judgment of the United States Claims Court under section 300aa–11 of this title on a petition filed for compensation under the Program for a vaccine-related injury or death has become final, the person who filed the petition shall file with the court—".

Pub. L. 101–239, §6601(n)(1)(B), amended last sentence generally. Prior to amendment, last sentence read as follows: "If a person elects to receive compensation under a judgment of the court or is deemed to have accepted the judgment of the court, such person may not bring or maintain a civil action for damages against a vaccine manufacturer for the vaccine-related injury or death for which the judgment was entered."

Subsec. (b). Pub. L. 101–239, §6601(n)(2), substituted "within 420 days (excluding any period of suspension under section 300aa–12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title)" for "within 365 days" in first sentence and amended second sentence generally. Prior to amendment, second sentence read as follows: "Such a notice shall be filed not later than 90 days after the expiration of such 365-day period."

1988—Subsec. (a). Pub. L. 100–360 added Pub. L. 100–203, §4308(c), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4308(c), as added by Pub. L. 100–360, substituted "the court's final judgment" for "the entry of the court's judgment" in concluding provisions.

Pub. L. 100–203, §4307(8), substituted "the United States Claims Court" for "a district court of the United States" and "the court" for "a court" in three places.

Subsecs. (b), (c). Pub. L. 100–203, §4304(c), added subsec. (b) and redesignated former subsec. (b) as (c).

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by Pub. L. 102–168 effective as in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by section 5(f)(1) of Pub. L. 101–502 effective Nov. 14, 1986, and amendment by

section 5(f)(2) of Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 420-day period prescribed in subsec. (b) of this section, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

EFFECTIVE DATE

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–22. Standards of responsibility

(a) General rule

Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa–23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction

The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

(July 1, 1944, ch. 373, title XXI, §2122, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3773;

amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

CODIFICATION

In subsecs. (b)(1), (c), "October 1, 1988" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1987—Subsecs. (b)(1), (c). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

§300aa–23. Trial

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, which is not barred by section 300aa–11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa–22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa–11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

(July 1, 1944, ch. 373, title XXI, §2123, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §§4302(b)(1), 4307(9), Dec. 22, 1987, 101 Stat. 1330–221, 1330-225; Pub. L. 101–239, title VI, §6601(o), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (d)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

CODIFICATION

In subsec. (a), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1992—Subsec. (e). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" in two places.

1989—Subsec. (e). Pub. L. 101–239 substituted "finding of fact or conclusion of law" for "finding", "special master" for "master appointed by such court", and directed substitution of "the United States Claims Court and subsequent appellate review" for "a district court of the United States" which was executed by inserting "and subsequent appellate review" after "the United States Claims Court" the second place it appeared to reflect the probable intent of Congress and the amendment by Pub. L. 100–203, §4307(a), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (e). Pub. L. 100–203, §4307(9), substituted "the United States Claims Court" for "a district court of the United States" in two places.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

subpart c—assuring a safer childhood vaccination program in united states

§300aa–25. Recording and reporting of information

(a) General rule

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

(1) the date of administration of the vaccine,

(2) the vaccine manufacturer and lot number of the vaccine,

(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(b) Reporting

(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa–14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after

December 22, 1987. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of December 22, 1987.

(c) Release of information

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, or otherwise, to any person except—

(A) the person who received the vaccine, or

(B) the legal representative of such person.

(2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

(July 1, 1944, ch. 373, title XXI, §2125, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

CODIFICATION

In subsec. (b)(1), (3), "December 22, 1987" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1987—Subsec. (b)(1), (3). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

EFFECTIVE DATE

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–26. Vaccine information

(a) General rule

Not later than 1 year after December 22, 1987, the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

(b) Development and revision of materials

Such materials shall be developed or revised—

(1) after notice to the public and 60 days of comment thereon, and

(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

(c) Information requirements

The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include—

(1) a concise description of the benefits of the vaccine,

(2) a concise description of the risks associated with the vaccine,

(3) a statement of the availability of the National Vaccine Injury Compensation Program, and
(4) such other relevant information as may be determined by the Secretary.

(d) Health care provider duties

On and after a date determined by the Secretary which is—
(1) after the Secretary develops the information materials required by subsection (a), and
(2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

(July 1, 1944, ch. 373, title XXI, §2126, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3775; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(p), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–531, title III, §312(d)(15), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–183, title VII, §708, Dec. 14, 1993, 107 Stat. 2242.)

CODIFICATION

In subsec. (a), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–183, §708(c), inserted "or to any other individual" after "to the legal representatives of any child".

Subsec. (b). Pub. L. 103–183, §708(a), struck out "by rule" after "revised" in introductory provisions and substituted "and 60" for ", opportunity for a public hearing, and 90" in par. (1).

Subsec. (c). Pub. L. 103–183, §708(b), inserted in introductory provisions "shall be based on available data and information," after "such materials", added pars. (1) to (4), and struck out former pars. (1) to (10) which read as follows:

"(1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine,

"(2) the symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider,

"(3) precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur,

"(4) early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions,

"(5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities,

"(6) a specification of when, how, and to whom legal representatives should report any major adverse reaction,

"(7) the contraindications to (and bases for delay of) the administration of the vaccine,

"(8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population,

"(9) a summary of—

"(A) relevant Federal recommendations concerning a complete schedule of childhood immunizations, and

"(B) the availability of the Program, and

"(10) such other relevant information as may be determined by the Secretary."

Subsec. (d). Pub. L. 103–183, §708(c), (d), in concluding provisions, inserted "or to any other individual" after "to the legal representatives of any child", substituted "supplemented with visual presentations or oral explanations, in appropriate cases" for "or other written information which meets the requirements of this section", and struck out "or other information" after "Such materials".

1992—Subsec. (b)(2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention"

for "Centers for Disease Control".

1989—Subsec. (c)(9). Pub. L. 101–239 amended par. (9) generally. Prior to amendment, par. (9) read as follows: "a summary of relevant State and Federal laws concerning the vaccine, including information on—

"(A) the number of vaccinations required for school attendance and the schedule recommended for such vaccinations, and

"(B) the availability of the Program, and".

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–27. Mandate for safer childhood vaccines

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

(July 1, 1944, ch. 373, title XXI, §2127, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(q), Dec. 19, 1989, 103 Stat. 2292.)

CODIFICATION

In subsecs. (a)(1), (c), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1989—Subsecs. (b), (c). Pub. L. 101–239 added subsec. (b) and redesignated former subsec. (b) as (c).

1987—Subsecs. (a)(1), (b). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–28. Manufacturer recordkeeping and reporting

(a) General rule

Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to each batch, lot, or other quantity manufactured or licensed after December 22, 1987—

(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous batches, lots, or other quantities (and, if so, the identity of the previous batches, lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test,

(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

(b) Sanction

Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall—

(1) be subject to a civil penalty of up to $100,000 per occurrence, or

(2) be fined $50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or concealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

(July 1, 1944, ch. 373, title XXI, §2128, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

CODIFICATION

In subsec. (a), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

subpart d—general provisions

§300aa–31. Citizen's actions

(a) General rule

Except as provided in subsection (b), any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this part.

(b) Notice

No action may be commenced under subsection (a) before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

(c) Costs of litigation

The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any plaintiff who substantially prevails on one or more significant issues in the action.

(July 1, 1944, ch. 373, title XXI, §2131, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 100–203, title IV, §4305, Dec. 22, 1987, 101 Stat. 1330–224.)

AMENDMENTS

1987—Subsec. (c). Pub. L. 100–203, which directed that subsec. (c) be amended by substituting "to any plaintiff who substantially prevails on one or more significant issues in the action" for "to any party, whenever the court determines that such award is appropriate", was executed by making the substitution for "to any party, whenever the court determines such award is appropriate", to reflect the probable intent of Congress.

EFFECTIVE DATE

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–32. Judicial review

A petition for review of a regulation under this part may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

(July 1, 1944, ch. 373, title XXI, §2132, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778.)

§300aa–33. Definitions

For purposes of this part:

(1) The term "health care provider" means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

(2) The term "legal representative" means a parent or an individual who qualifies as a legal guardian under State law.

(3) The term "manufacturer" means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 300aa–28 of this title, such term shall include the manufacturer of any other vaccine

covered by that section. The term "manufacture" means to manufacture, import, process, or distribute a vaccine.

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

(5) The term "vaccine-related injury or death" means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

(6)(A) The term "Advisory Commission on Childhood Vaccines" means the Commission established under section 300aa–19 of this title.

(B) The term "Vaccine Injury Table" means the table set out in section 300aa–14 of this title.

(July 1, 1944, ch. 373, title XXI, §2133, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 107–296, title XVII, §§1714–1716, Nov. 25, 2002, 116 Stat. 2320, 2321; Pub. L. 108–7, div. L, §102(a), Feb. 20, 2003, 117 Stat. 528.)

AMENDMENTS

2003—Pars. (3), (5), (7). Pub. L. 108–7 repealed Pub. L. 107–296, §§1714–1717, and provided that this chapter shall be applied as if the sections repealed had never been enacted. See 2002 Amendment notes below.

2002—Par. (3). Pub. L. 107–296, §1714, which directed amendment of first sentence by substituting "any vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine" for "under its label any vaccine set forth in the Vaccine Injury Table" and of second sentence by inserting "including any component or ingredient of any such vaccine" before period at end, was repealed by Pub. L. 108–7.

Par. (5). Pub. L. 107–296, §1715, which directed insertion of "For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label." at end, was repealed by Pub. L. 108–7.

Par. (7). Pub. L. 107–296, §1716, which directed addition of par. (7), was repealed by Pub. L. 108–7, §102(a). Par. (7) read as follows: "The term 'vaccine' means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccines's product license application and product label."

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–296, title XVII, §1717, Nov. 25, 2002, 116 Stat. 2321, which provided that the amendments made by sections 1714, 1715, and 1716 (amending this section) shall apply to all actions or proceedings pending on or after Nov. 25, 2002, unless a court of competent jurisdiction has entered judgment (regardless of whether the time for appeal has expired) in such action or proceeding disposing of the entire action or proceeding, was repealed by Pub. L. 108–7, div. L, §102 (a), Feb. 20, 2003, 117 Stat. 528.

CONSTRUCTION OF AMENDMENTS

Pub. L. 108–7, div. L, §102(b), (c), Feb. 20, 2003, 117 Stat. 528, provided that:

"(b) Application of the Public Health Service Act.—The Public Health Service Act (42 U.S.C. 201 et seq.) shall be applied and administered as if the sections repealed by subsection (a) [repealing sections 1714 to 1717 of Pub. L. 107–296, which amended this section and enacted provisions set out as a note under this section] had never been enacted.

"(c) Rule of Construction.—No inference shall be drawn from the enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107–296), or from this repeal [repealing sections 1714 to 1717 of Pub. L. 107–296], regarding the law prior to enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107–296) [Nov. 25, 2002]. Further, no inference shall be drawn that subsection (a) or (b) affects any change in that prior law, or that Leroy v. Secretary of Health and Human Services, Office of Special Master, No. 02–392V (October 11, 2002), was incorrectly decided."

§300aa–34. Termination of program

(a) Reviews

The Secretary shall review the number of awards of compensation made under the program to petitioners under section 300aa–11 of this title for vaccine-related injuries and deaths associated with the administration of vaccines on or after December 22, 1987, as follows:

(1) The Secretary shall review the number of such awards made in the 12-month period beginning on December 22, 1987.

(2) At the end of each 3-month period beginning after the expiration of the 12-month period referred to in paragraph (1) the Secretary shall review the number of such awards made in the 3-month period.

(b) Report

(1) If in conducting a review under subsection (a) the Secretary determines that at the end of the period reviewed the total number of awards made by the end of that period and accepted under section 300aa–21(a) of this title exceeds the number of awards listed next to the period reviewed in the table in paragraph (2)—

(A) the Secretary shall notify the Congress of such determination, and

(B) beginning 180 days after the receipt by Congress of a notification under paragraph (1), no petition for a vaccine-related injury or death associated with the administration of a vaccine on or after December 22, 1987, may be filed under section 300aa–11 of this title.

Section 300aa–11(a) of this title and subpart B of this part shall not apply to civil actions for damages for a vaccine-related injury or death for which a petition may not be filed because of subparagraph (B).

(2) The table referred to in paragraph (1) is as follows:

Period reviewed:	**Total number of awards by the end of the period reviewed**
12 months after December 22, 1987	150
13th through the 15th month after December 22, 1987	188
16th through the 18th month after December 22, 1987	225
19th through the 21st month after December 22, 1987	263
22nd through the 24th month after December 22, 1987	300
25th through the 27th month after December 22, 1987	338
28th through the 30th month after December 22, 1987	375
31st through the 33rd month after December 22, 1987	413
34th through the 36th month after December 22, 1987	450
37th through the 39th month after December 22, 1987	488
40th through the 42nd month after December 22, 1987	525
43rd through the 45th month after December 22, 1987	563
46th through the 48th month after December 22, 1987	600.

(July 1, 1944, ch. 373, title XXI, §2134, as added Pub. L. 100–203, title IV, §4303(f), Dec. 22, 1987, 101 Stat. 1330–222.)

CODIFICATION

In subsecs. (a) and (b), "December 22, 1987" substituted for "the effective date of this subpart" on

authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Reference 11

42 USC CHAPTER 6A, SUBCHAPTER XIX, Part 2: National Vaccine Injury Compensation Program

From Title 42—THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A—PUBLIC HEALTH SERVICE
SUBCHAPTER XIX—VACCINES

Part 2—National Vaccine Injury Compensation Program

subpart a—program requirements

§300aa–10. Establishment of program

(a) Program established

There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

(b) Attorney's obligation

It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program [1] for such injury or death.

(c) Publicity

The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

(July 1, 1944, ch. 373, title XXI, §2110, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 101–239, title VI, §6601(b), Dec. 19, 1989, 103 Stat. 2285.)

PRIOR PROVISIONS

A prior section 300aa–10, act July 1, 1944, §2111, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

A prior section 2110 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238g of this title.

AMENDMENTS

1989—Subsec. (c). Pub. L. 101–239 added subsec. (c).

EFFECTIVE DATE OF 1989 AMENDMENT

Section 6601(s) of Pub. L. 101–239, as amended by Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa–11 to 300aa–17, 300aa–21, 300aa–23, 300aa–26, and 300aa–27 of this title] shall apply as follows:

"(A) Petitions filed after the date of enactment of this section [Dec. 19, 1989] shall proceed under the National Vaccine Injury Compensation Program under title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] as amended by this section.

"(B) Petitions currently pending in which the evidentiary record is closed shall continue to proceed under the Program in accordance with the law in effect before the date of the enactment of this section, except that if the United States Court of Federal Claims is to review the findings of fact and conclusions of law of a special master on such a petition, the court may receive further evidence in conducting such review.

"(C) Petitions currently pending in which the evidentiary record is not closed shall proceed under the Program in accordance with the law as amended by this section.

All pending cases which will proceed under the Program as amended by this section shall be

immediately suspended for 30 days to enable the special masters and parties to prepare for proceeding under the Program as amended by this section. In determining the 240-day period prescribed by section 2112(d) of the Public Health Service Act [42 U.S.C. 300aa–12(d)], as amended by this section, or the 420-day period prescribed by section 2121(b) of such Act [42 U.S.C. 300aa–21(b)], as so amended, any period of suspension under the preceding sentence shall be excluded.

"(2) The amendments to section 2115 of the Public Health Service Act [42 U.S.C. 300aa–15] shall apply to all pending and subsequently filed petitions."

EFFECTIVE DATE

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99–660, as amended, set out as a note under section 300aa–1 of this title.

[1] *So in original. Probably should be capitalized.*

§300aa–11. Petitions for compensation

(a) General rule

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) with the United States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa–12 (d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—

(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa–12 of this title on such petition, and

(II) such person elects under section 300aa–21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa–21(b) of this title or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa–16 of this title, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988.

(4) If in a civil action brought against a vaccine administrator or manufacturer before October 1, 1988, damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) for such injury or death.

(5)(A) A plaintiff who on October 1, 1988, has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after October 1, 1988, or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) for such injury or death.

(6) If a person brings a civil action after November 15, 1988 for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under subsection (b) for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) for such injury or death.

(8) If on October 1, 1988, there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or

the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition under subsection (b) for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court [2] is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) Petitioners

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1), file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before October 1, 1988, if compensation has been paid under this part for 3500 petitions for such injuries or deaths.

(2) Only one petition may be filed with respect to each administration of a vaccine. A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine.

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) Additional information

A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) Schedule

The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

(f) Maternal immunization

(1) In general

Notwithstanding any other provision of law, for purposes of this subpart, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

(2) Definition

As used in this subsection, the term "child" shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1 except that, for purposes of this subsection, such section 8 shall be applied as if the term "include" in subsection (a) of such section were replaced with the term "mean".

(July 1, 1944, ch. 373, title XXI, §2111, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 100–203, title IV, §§4302(b), 4304(a), (b), 4306, 4307(1), (2), Dec. 22, 1987, 101 Stat. 1330–221, 1330-223, 1330-224; Pub. L. 101–239, title VI, §6601(c)(1)–(7), Dec. 19, 1989, 103 Stat. 2285, 2286; Pub. L. 101–502, §5(a), Nov. 3, 1990, 104 Stat. 1286; Pub. L. 102–168, title II, §201(h)(1), Nov. 26, 1991, 105 Stat. 1104; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–43, title XX, §2012, June 10, 1993, 107 Stat. 214; Pub. L. 105–277, div. C, title XV, §1502, Oct. 21, 1998, 112 Stat. 2681–741; Pub. L. 106–310, div. A, title XVII, §1701(a), Oct. 17, 2000, 114 Stat. 1151; Pub. L. 114–255, div. A, title III, §3093(c)(2), (3), Dec. 13, 2016, 130 Stat. 1152.)

CODIFICATION

In subsecs. (a)(2)(A), (3), (4), (5)(A), (8), and (b)(1)(B), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

PRIOR PROVISIONS

A prior section 300aa–11, act July 1, 1944, §2112, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

A prior section 2111 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

AMENDMENTS

2016—Subsec. (b)(2). Pub. L. 114–255, §3093(c)(3), inserted at end "A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine."

Subsec. (f). Pub. L. 114–255, §3093(c)(2), added subsec. (f).

2000—Subsec. (c)(1)(D)(iii). Pub. L. 106–310 added cl. (iii).

1998—Subsec. (c)(1)(D)(i). Pub. L. 105–277 struck out "and incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than $1,000" before ", or (ii) died".

1993—Subsec. (a)(10). Pub. L. 103–43 added par. (10).

1992—Subsec. (a)(1), (2)(A)(i)(I). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" wherever appearing.

1991—Subsec. (a)(2)(A)(i), (ii). Pub. L. 102–168 realigned margins of cls. (i) and (ii).

1990—Subsec. (a)(2)(A). Pub. L. 101–502, §5(a)(1), substituted "unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—" and cls. (i) and (ii) for "unless—

"(i) a petition has been filed, in accordance with section 300aa–16 of this title, for

compensation under the Program for such injury or death,

"(ii) the United States Claims Court has issued a judgment under section 300aa–12 of this title on such petition, and

"(iii) such person elects under section 300aa–21(a) of this title to file such an action."

Subsec. (a)(5)(A). Pub. L. 101–502, §5(a)(2), struck out "without prejudice" after "without prejudice or costs".

Subsec. (a)(5)(B). Pub. L. 101–502, §5(a)(3), substituted "plaintiff" for "plaintiff who".

Subsec. (d). Pub. L. 101–502, §5(a)(4), struck out "(d) except as provided in paragraph (3)," before "(d) Additional information".

Subsec. (e). Pub. L. 101–502, §5(a)(5), substituted "(e) Schedule" for "(e)(e) Schedule".

1989—Subsec. (a)(1). Pub. L. 101–239, §6601(c)(1), substituted "filing of a petition containing the matter prescribed in subsection (c)" for "filing of a petition" and inserted at end "The clerk of the United States Claims Court shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa–12(d)(1) of this title."

Subsec. (a)(2)(A)(i). Pub. L. 101–239, §6601(c)(2), struck out "under subsection (b) of this section" after "section 300aa–16 of this title,".

Subsec. (a)(5)(A). Pub. L. 101–239, §6601(c)(3)(A), substituted "petition to have such action dismissed without prejudice or costs" for "elect to withdraw such action".

Subsec. (a)(5)(B). Pub. L. 101–239, §6601(c)(3)(B), substituted "has pending" for "on October 1, 1988, had pending" and struck out "does not withdraw the action under subparagraph (A)" after "vaccine-related injury or death".

Subsec. (a)(6). Pub. L. 101–239, §6601(c)(4), substituted "November 15, 1988" for "the effective date of this subpart" in two places.

Subsec. (a)(8). Pub. L. 101–239, §6601(c)(5), added par. (8). Former par. (8) redesignated (9).

Subsec. (a)(9). Pub. L. 101–239, §6601(c)(5), (7), redesignated par. (8) as (9) and realigned margin.

Subsec. (c)(1). Pub. L. 101–239, §6601(c)(6)(A), inserted "except as provided in paragraph (3)," after "(1)" in introductory provisions.

Subsec. (c)(2). Pub. L. 101–239, §6601(c)(6)(B), (C), added par. (2) and redesignated former par. (2) as subsec. (d).

Pub. L. 101–239, §6601(c)(6)(A), inserted "except as provided in paragraph (3)," after "(2)".

Subsec. (c)(3). Pub. L. 101–239, §6601(c)(6)(C), (D), added par. (3). Former par. (3) redesignated subsec. (e).

Subsec. (d). Pub. L. 101–239, §6601(c)(6)(B), redesignated former subsec. (c)(2) as subsec. (d), expanded margin to full measure, inserted subsec. designation and heading, substituted "A petition may also include other available" for "all available", struck out "(including autopsy reports, if any)" after "relevant medical records", and substituted "administration of the vaccine." for "administration of the vaccine and an identification of any unavailable records known to the petitioner and the reasons for their unavailability, and".

Subsec. (e). Pub. L. 101–239, §6601(c)(6)(D), redesignated former subsec. (c)(3) as subsec. (e), expanded margin to full measure, inserted subsec. designation and heading, and substituted "The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition" for "appropriate".

1987—Subsec. (a)(1). Pub. L. 100–203, §4307(1), which directed that par. (1) be amended by substituting "with the United States Claims Court" for "with the United States district court for the district in which the petitioner resides or the injury or death occurred", was executed making the substitution for "with the United States district court for the district in which the petitioner resides or in which the injury or death occurred", as the probable intent of Congress.

Subsec. (a)(2)(A). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(2)(A)(ii). Pub. L. 100–203, §4307(2), substituted "the United States Claims Court" for "a district court of the United States".

Subsec. (a)(3). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(4). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(5)(A). Pub. L. 100–203, §4302(b)(2), substituted "after the effective date of this subpart" for "after the effective date of this subchapter".

Pub. L. 100–203, §4302(b)(1), substituted "who on the effective date of this subpart" for "who on the effective date of this part".

Subsec. (a)(5)(B). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(6). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part" in two places.

Subsec. (a)(7). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Subsec. (a)(8). Pub. L. 100–203, §4304(a), added par. (8).

Subsec. (b)(1)(A). Pub. L. 100–203, §4304(b)(1), substituted "may, if the person meets the requirements of subsection (c)(1), file" for "may file".

Subsec. (b)(1)(B). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (c)(1)(D). Pub. L. 100–203, §4304(b)(2), substituted "for more than 6 months" for "for more than 1 year", "and incurred" for ", (ii) incurred", and "(ii)" for "(iii)".

CHANGE OF NAME

References to United States Claims Court deemed to refer to United States Court of Federal Claims, see section 902(b) of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–310, div. A, title XVII, §1701(b), Oct. 17, 2000, 114 Stat. 1151, provided that: "The amendment made by subsection (a) [amending this section] takes effect upon the date of the enactment of this Act [Oct. 17, 2000], including with respect to petitions under section 2111 of the Public Health Service Act [42 U.S.C. 300aa–11] that are pending on such date."

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Pub. L. 102–168, title II, §201(i), Nov. 26, 1991, 105 Stat. 1104, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa–12, 300aa–15, 300aa–16, 300aa–19, and 300aa–21 of this title and provisions set out as a note under section 300aa–1 of this title] shall take effect on the date of the enactment of this Act [Nov. 26, 1991].

"(2) The amendments made by subsections (d) and (f) [amending sections 300aa–12, 300aa–15, 300aa–16, and 300aa–21 of this title] shall take effect as if the amendments had been in effect on and after October 1, 1988."

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–502, §5(h), Nov. 3, 1990, 104 Stat. 1289, provided that: "The amendments made by subsections (f)(1) and (g) [amending section 300aa–21 of this title and provisions set out as a note under section 300aa–1 of this title and enacting provisions set out as a note under section 300aa–12 of this title] shall take effect as of November 14, 1986, and the amendments made by subsections (a) through (e) and subsection (f)(2) [amending this section and sections 300aa–12, 300aa–13, 300aa–15, 300aa–16, and 300aa–21 of this title] shall take effect as of September 30, 1990."

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

[2] *See Change of Name note below.*

§300aa–12. Court jurisdiction

(a) General rule

The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa–11 of this title is entitled to compensation under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) In all proceedings brought by the filing of a petition under section 300aa–11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa–11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) shall afford all interested persons an opportunity to submit relevant, written information—

(A) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title.

(c) United States Court of Federal Claims special masters

(1) There is established within the United States Court of Federal Claims an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Court of Federal Claims shall appoint the special masters, 1 of whom, by designation of the judges of the United States Court of Federal Claims, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Court of Federal Claims for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Court of Federal Claims determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters on December 19, 1989, shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on December 19, 1989, shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States Court of Federal Claims, upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, title 5. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, title 5.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts [1] judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The

Conference rules and regulations pertaining to United States magistrate judges shall be applied to the special masters.

(D) Coordinating with the United States Court of Federal Claims the use of services, equipment, personnel, information, and facilities of the United States Court of Federal Claims without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Court of Federal Claims on the number of petitions filed under section 300aa–11 of this title and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) Special masters

(1) Following the receipt and filing of a petition under section 300aa–11 of this title, the clerk of the United States Court of Federal Claims shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of title 28. Such rules shall—

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.

(3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall—

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Court of Federal Claims in accordance with subsection (e).

(B) In conducting a proceeding on a petition a special master—

(i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) shall afford all interested persons an opportunity to submit relevant written information—

(I) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(II) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title, and

(v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before October 1, 1988, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information—

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) Action by United States Court of Federal Claims

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Court of Federal Claims a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Court of Federal Claims no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals

The findings of fact and conclusions of law of the United States Court of Federal Claims on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the date of entry of the United States Claims Court's [2] judgment with such court of appeals.

(g) Notice

If—

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)), or

(2) the United States Court of Federal Claims fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa–21(b) of this title or the petitioner may choose under section 300aa–21(b) of this title to have the petition remain before the special master or court, as the case may be.

(July 1, 1944, ch. 373, title XXI, §2112, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3761; amended Pub. L. 100–203, title IV, §§4303(d)(2)(A), 4307(3), 4308(a), (b), Dec. 22, 1987, 101 Stat. 1330–222, 1330-224; Pub. L. 100–360, title IV, §411(o)(2), (3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(d)–(i), Dec. 19, 1989, 103 Stat. 2286–2290; Pub. L. 101–502, §5(b), Nov. 3, 1990, 104 Stat. 1286; Pub. L. 101–650, title III, §321, Dec. 1, 1990, 104 Stat. 5117; Pub. L. 102–168, title II, §201(c), (d)(1), (h)(2), (3), Nov. 26, 1991, 105 Stat. 1103, 1104; Pub. L. 102–572, title IX, §902(b), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–66, title XIII, §13632(c), Aug. 10, 1993, 107 Stat. 646.)

CODIFICATION

In subsec. (c)(4), "on December 19, 1989," substituted for "upon the date of the enactment of this subsection" and "on the date of the enactment of this subsection".

In subsec. (d)(3)(D), "October 1, 1988," substituted for "the effective date of this part".

PRIOR PROVISIONS

A prior section 300aa–12, act July 1, 1944, §2113, was successively renumbered by subsequent

acts and transferred, see section 238j of this title.

A prior section 2112 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

AMENDMENTS

1993—Subsec. (d)(3)(D). Pub. L. 103–66 substituted "30 months (but for not more than 6 months at a time)" for "540 days".

1992—Subsecs. (a), (c) to (g). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" and "Court of Federal Claims" for "Claims Court", wherever appearing.

1991—Subsec. (d)(3)(D). Pub. L. 102–168, §201(c), (h)(2), realigned margin and substituted "540 days" for "180 days".

Subsec. (g). Pub. L. 102–168, §201(h)(3), made technical amendment to underlying provisions of original Act.

Pub. L. 102–168, §201(d)(1), substituted "or the petitioner may choose under section 300aa–21(b) of this title to have the petition remain before the special master or court, as the case may be" for "and the petition will be considered withdrawn under such section if the petitioner, the special master, or the court do not take certain actions" before period at end.

1990—Subsec. (d)(3)(D). Pub. L. 101–502, §5(b)(1), added subpar. (D).

Subsec. (g). Pub. L. 101–502, §5(b)(2), added subsec. (g).

1989—Subsec. (a). Pub. L. 101–239, §6601(d), substituted "and the United States Claims Court special masters shall, in accordance with this section, have jurisdiction" for "shall have jurisdiction (1)", ". The United States Claims Court may issue" for ", and (2) to issue", and "deems" for "deem".

Subsec. (b)(1). Pub. L. 101–239, §6601(f), substituted "In all proceedings brought by the filing of a petition under section 300aa–11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28." for "The Secretary shall be named as the respondent in all proceedings brought by the filing of a petition under section 300aa–11(b) of this title. Except as provided in paragraph (2), no other person may intervene in any such proceeding."

Subsec. (c). Pub. L. 101–239, §6601(e)(2), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 101–239, §6601(e)(1), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (e).

Subsec. (d)(1). Pub. L. 101–239, §6601(g)(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Following receipt of a petition under subsection (a) of this section, the United States Claims Court shall designate a special master to carry out the functions authorized by paragraph (2)."

Subsec. (d)(2) to (4). Pub. L. 101–239, §6601(g)(2), added pars. (2) to (4) and struck out former par. (2) which prescribed functions of special masters.

Subsec. (e). Pub. L. 101–239, §6601(h), substituted "Action by United States Claims Court" for "Action by court" as heading and amended text generally. Prior to amendment, text read as follows:

"(1) Upon objection by the petitioner or respondent to the proposed findings of fact or conclusions of law prepared by the special master or upon the court's own motion, the court shall undertake a review of the record of the proceedings and may thereafter make a de novo determination of any matter and issue its judgment accordingly, including findings of fact and conclusions of law, or remand for further proceedings.

"(2) If no objection is filed under paragraph (1) or if the court does not choose to review the proceeding, the court shall adopt the proposed findings of fact and conclusions of law of the special master as its own and render judgment thereon.

"(3) The court shall render its judgment on any petition filed under the Program as expeditiously as practicable but not later than 365 days after the date on which the petition was filed."

Pub. L. 101–239, §6601(e)(1), redesignated subsec. (d) as (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 101–239, §6601(i), inserted "within 60 days of the date of entry of the United States Claims Court's judgment with such court of appeals" after "with such court of appeals".

Pub. L. 101–239, §6601(e)(1), redesignated subsec. (e) as (f).

1988—Subsec. (c)(2). Pub. L. 100–360, §411(o)(3)(A), added Pub. L. 100–203, §4308(a), see 1987 Amendment note below.

Subsec. (e). Pub. L. 100–360, §411(o)(2), made technical amendment to directory language of Pub. L. 100–203, §4307(3)(C), see 1987 Amendment note below.

Pub. L. 100–360, §411(o)(3)(A), added Pub. L. 100–203, §4308(b), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4307(3)(A), substituted "United States Claims Court" for "district courts of the United States" and "the court" for "the courts".

Subsec. (c)(1). Pub. L. 100–203, §4307(3)(B), substituted "the United States Claims Court" for "the district court of the United States in which the petition is filed".

Subsec. (c)(2). Pub. L. 100–203, §4308(a), as added by Pub. L. 100–360, §411(o)(3)(A), inserted ", shall prepare and submit to the court proposed findings of fact and conclusions of law," in introductory provisions and struck out subpar. (E) which read as follows: "prepare and submit to the court proposed findings of fact and conclusions of law."

Subsec. (e). Pub. L. 100–203, §4308(b), as added by Pub. L. 100–360, §411(o)(3)(A), inserted "within 60 days of the date of the judgment" after "petition filed".

Pub. L. 100–203, §4307(3)(C), as amended by Pub. L. 100–360, §411(o)(2), substituted "the United States Claims Court" for "a district court of the United States" and "for the Federal Circuit" for "for the circuit in which the court is located".

Pub. L. 100–203, §4303(d)(2)(A), redesignated subsec. (g) as (e) and struck out former subsec. (e) relating to administration of an award.

Subsec. (f). Pub. L. 100–203, §4303(d)(2)(A), struck out subsec. (f) which related to revision of an award.

Subsec. (g). Pub. L. 100–203, §4303(d)(2)(A), redesignated subsec. (g) as (e).

CHANGE OF NAME

"United States magistrate judges" substituted for "United States magistrates" in subsec. (c)(6)(C) pursuant to section 321 of Pub. L. 101–650, set out as a note under section 631 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by section 201(d)(1) of Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 240-day period prescribed in subsec. (d) of this section, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1,

General Provisions.

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions in subsec. (c)(6)(E) of this section relating to reporting annually to the Congress, see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 13 of House Document No. 103–7.

REVIEW BY 3-JUDGE PANEL

Section 322(c) of Pub. L. 99–660, as added by Pub. L. 101–502, §5(g)(2), Nov. 3, 1990, 104 Stat. 1288, and amended by Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that: "If the review authorized by section 2112(f) [42 U.S.C. 300aa–12(f)] is held invalid because the judgment of the United States Court of Federal Claims being reviewed did not arise from a case or controversy under Article III of the Constitution, such judgment shall be reviewed by a 3-judge panel of the United States Court of Federal Claims. Such panel shall not include the judge who participated in such judgment."

[Enactment of section 322(c) of Pub. L. 99–660 by section 5(g)(2) of Pub. L. 101–502, set out above, effective Nov. 14, 1986, see section 5(h) of Pub. L. 101–502, set out as an Effective Date of 1990 Amendment note under section 300aa–11 of this title.]

[1] *So in original. Probably should be a reference to the United States Court of Federal Claims.*

[2] *So in original. Probably should be a reference to the United States Court of Federal Claims.*

§300aa–13. Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) Matters to be considered

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or court may find the first symptom or manifestation of onset or significant aggravation

of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

(c) "Record" defined

For purposes of this section, the term "record" means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa–11 of this title.

(July 1, 1944, ch. 373, title XXI, §2113, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3763; amended Pub. L. 100–203, title IV, §4307(4), Dec. 22, 1987, 101 Stat. 1330–224; Pub. L. 101–239, title VI, §6601(j), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 101–502, §5(c), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

PRIOR PROVISIONS

A prior section 300aa–13, act July 1, 1944, §2114, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

A prior section 2113 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

AMENDMENTS

1992—Subsec. (c). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court".

1990—Subsec. (c). Pub. L. 101–502 inserted "the" after "special masters of".

1989—Subsecs. (a)(1), (b). Pub. L. 101–239, §6601(j)(1), substituted "special master or court" for "court" wherever appearing.

Subsec. (c). Pub. L. 101–239, §6601(j)(2), inserted "special masters of" after "established by the".

1987—Subsec. (c). Pub. L. 100–203 substituted "the United States Claims Court" for "a district court of the United States".

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–14. Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

DTP; P; DTP/Polio Combination; or Any Other Vaccine	

Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	
Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
A. Anaphylaxis or anaphylactic shock	24 hours
B. Encephalopathy (or encephalitis)	3 days
C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
D. Residual seizure disorder in accordance with subsection (b)(2)	3 days
E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
I. Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
A. Anaphylaxis or anaphylactic shock	24 hours
B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
C. Residual seizure disorder in accordance with subsection (b)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
II. Polio Vaccines (other than Inactivated Polio Vaccine).	
A. Paralytic polio	
—in a non-immunodeficient recipient	30 days
—in an immunodeficient recipient	6 months
—in a vaccine-associated community case	Not applicable
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
V. Inactivated Polio Vaccine.	
A. Anaphylaxis or anaphylactic shock	24 hours
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

(b) Qualifications and aids to interpretation

The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a):

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa–11 of this title for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

(c) Administrative revision of table

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) Role of Commission

Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

(e) Additional vaccines

(1) Vaccines recommended before August 1, 1993

By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) Vaccines recommended after August 1, 1993

When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which were recommended for routine administration to children,
(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and
(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(3) Vaccines recommended for use in pregnant women

The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.

(July 1, 1944, ch. 373, title XXI, §2114, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3764; amended Pub. L. 101–239, title VI, §6601(k), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 103–66, title XIII, §13632(a)(2), Aug. 10, 1993, 107 Stat. 645; Pub. L. 114–255, div. A, title III, §3093(c)(1), Dec. 13, 2016, 130 Stat. 1152.)

PRIOR PROVISIONS

A prior section 300aa–14, act July 1, 1944, §2115, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

A prior section 2114 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

AMENDMENTS

2016—Subsec. (e)(3). Pub. L. 114–255 added par. (3).

1993—Subsec. (e). Pub. L. 103–66 amended heading and text of subsec. (e) generally. Prior to amendment, text read as follows: "The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table."

1989—Subsec. (a). Pub. L. 101–239, §6601(k)(1), substituted "(b)(2)" for "(c)(2)" in items I.D. and II.C. in table.

Subsec. (b)(3)(B). Pub. L. 101–239, §6601(k)(2), substituted "300aa–11 of this title" for "300aa–11 (b) of this title".

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

REVISIONS OF VACCINE INJURY TABLE

The Vaccine Injury Table as modified by regulations promulgated by the Secretary of Health and Human Services is set out at 42 CFR 100.3.

Pub. L. 103–66, title XIII, §13632(a)(3), Aug. 10, 1993, 107 Stat. 646, provided that: "A revision by the Secretary under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa–14(a))."

§300aa–15. Compensation

(a) General rule

Compensation awarded under the Program to a petitioner under section 300aa–11 of this title for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, shall include the following:

(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—
(i) result from the vaccine-related injury for which the petitioner seeks compensation,
(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and
(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(B) Subject to section 300aa–16(a)(2) of this title, actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $250,000.

(b) Vaccines administered before effective date

Compensation awarded under the Program to a petitioner under section 300aa–11 of this title for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—

(1) lost earnings (as provided in paragraph (3) of subsection (a)),

(2) pain and suffering (as provided in paragraph (4) of subsection (a)), and

(3) reasonable attorneys' fees and costs (as provided in subsection (e)).[1]

(c) Residential and custodial care and service

The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

(d) Types of compensation prohibited

Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

(e) Attorneys' fees

(1) In awarding compensation on a petition filed under section 300aa–11 of this title the special master or court shall also award as part of such compensation an amount to cover—

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) If the petitioner, before October 1, 1988, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and petitioned under section 300aa–11(a)(5) of this title to have such action dismissed and to file a petition for compensation under the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the

costs and expenses incurred by the petitioner and the attorney of the petitioner before October 1, 1988, in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

(3) No attorney may charge any fee for services in connection with a petition filed under section 300aa–11 of this title which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(f) Payment of compensation

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 300aa–21(a) of this title to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the United States Court of Federal Claims under section 300aa–12 of this title awarding the compensation. Such compensation may not be paid after an election under section 300aa–21(a) of this title to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation under the Program and the costs of carrying out the Program shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985 [2 U.S.C. 900 et seq.].

(4)(A) Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26 in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, the compensation shall be determined on the basis of the net present value of the elements of compensation and shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 300aa–21(a) of this title shall not apply to a civil action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26, or to the appropriations account from which the funds were derived to purchase the annuity, whichever is appropriate.

(g) Program not primarily liable

Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (other than under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.]), or (2) by an entity which provides health services on a prepaid basis.

(h) Liability of health insurance carriers, prepaid health plans, and benefit providers

No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

(1) no State, and

(2) no entity which provides health services on a prepaid basis or provides health benefits,

may make the provision of health services or health benefits secondary to the payment of compensation under the Program, except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(i) Source of compensation

(1) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, shall be made by the Secretary from appropriations under subsection (j).

(2) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1988, shall be made from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(j) Authorization

For the payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, there are authorized to be appropriated to the Department of Health and Human Services $80,000,000 for fiscal year 1989, $80,000,000 for fiscal year 1990, $80,000,000 for fiscal year 1991, $80,000,000 for fiscal year 1992, $110,000,000 for fiscal year 1993, and $110,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B). Amounts appropriated under this subsection shall remain available until expended.

(July 1, 1944, ch. 373, title XXI, §2115, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3767; amended Pub. L. 100–203, title IV, §§4302(b), 4303(a)–(d)(1), (e), (g), 4307(5), (6), Dec. 22, 1987, 101 Stat. 1330–221 to 1330-223, 1330-225; Pub. L. 100–360, title IV, §411(o)(1), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(c)(8), (l), Dec. 19, 1989, 103 Stat. 2286, 2290; Pub. L. 101–502, §5(d), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(e), (f), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102–531, title III, §314, Oct. 27, 1992, 106 Stat. 3508; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–66, title XIII, §13632(b), Aug. 10, 1993, 107 Stat. 646.)

REFERENCES IN TEXT

The Balanced Budget and Emergency Deficit Control Act of 1985, referred to in subsec. (f)(3), is title II of Pub. L. 99–177, Dec. 12, 1985, 99 Stat. 1038. Part C of the Act is classified generally to subchapter I (§900 et seq.) of chapter 20 of Title 2, The Congress. For complete classification of this Act to the Code, see Short Title note set out under section 900 of Title 2 and Tables.

The Social Security Act, referred to in subsecs. (g) and (h), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Title XIX of the Social Security Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

In subsecs. (a), (b), (e)(2), (f)(4)(B), (i), and (j), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

PRIOR PROVISIONS

A prior section 300aa–15, act July 1, 1944, §2116, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

A prior section 2115 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

AMENDMENTS

1993—Subsec. (j). Pub. L. 103–66 substituted "$110,000,000 for each succeeding fiscal year" for "$80,000,000 for each succeeding fiscal year".

1992—Subsecs. (e)(1), (f)(2). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court".

Subsec. (j). Pub. L. 102–531 increased authorization for fiscal year 1993 from $80,000,000 to $110,000,000.

1991—Subsec. (f)(4)(A). Pub. L. 102–168, §201(e)(1)(A), (2), struck out "of the proceeds" after "portion" and substituted "Vaccine Injury Compensation Trust Fund established under section 9510 of title 26" for "trust fund".

Subsec. (f)(4)(B). Pub. L. 102–168, §201(e)(1)(B), which directed substitution of "shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion" for "paid in 4 equal installments of which all or portion of the proceeds" was executed by making the substitution for "paid in 4 equal annual installments of which all or a portion of the proceeds" to reflect the probable intent of Congress.

Subsec. (f)(4)(C). Pub. L. 102–168, §201(f), added subpar. (C).

1990—Subsec. (e)(2). Pub. L. 101–502, §5(d)(1), inserted "of compensation" before "limited to the costs".

Subsec. (f)(2). Pub. L. 101–502, §5(d)(2)(A), substituted "section 300aa–21(a)" for "section 300aa–21(b)".

Subsec. (f)(4)(B). Pub. L. 101–502, §5(d)(2)(B), substituted "subsection (j)" for "subsection (i)" and "the limitation on civil actions prescribed by section 300aa–21(a) of this title" for "section 300aa–11

(a) of this title".

Subsec. (j). Pub. L. 101–502, §5(d)(3), inserted before period at end of first sentence ", and $80,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B)".

1989—Subsec. (b). Pub. L. 101–239, §6601(l)(1), substituted "may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—" and cls. (1) to (3) for "may not include the compensation described in paragraph (1)(B) of subsection (a) of this section and may include attorneys' fees and other costs included in a judgment under subsection (e) of this section, except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) of this section and included as attorneys' fees and other costs under subsection (e) of this section may not exceed $30,000."

Subsec. (e)(1). Pub. L. 101–239, §6601(l)(2)(A), substituted "In awarding compensation on a petition filed under section 300aa–11 of this title the special master or court shall also award as part of such compensation an amount to cover" for "The judgment of the United States Claims Court on a petition filed under section 300aa–11 of this title awarding compensation shall include an amount to cover".

Pub. L. 101–239, §6601(l)(2)(B), (C), substituted "the special master or court may award an amount of compensation to cover" for "the court may include in the judgment an amount to cover" and "the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition" for "the court determines that the civil action was brought in good faith and there was a reasonable basis for the claim for which the civil action".

Subsec. (e)(2). Pub. L. 101–239, §6601(l)(2)(D), which directed amendment of par. (2) by substituting "the special master or court may also award an amount of compensation" for "the judgment of the court on such petition may include an amount", could not be executed because of the prior amendment by Pub. L. 101–239, §6601(c)(8)(B), see Amendment note below.

Pub. L. 101–239, §6601(c)(8), substituted "and petitioned under section 300aa–11(a)(5) of this title to have such action dismissed" for "and elected under section 300aa–11(a)(4) of this title to withdraw such action" and "in awarding compensation on such petition the special master or court may include" for "the judgment of the court on such petition may include".

Subsec. (e)(3). Pub. L. 101–239, §6601(l)(2)(E), substituted "awarded as compensation by the special master or court under paragraph (1)" for "included under paragraph (1) in a judgment on such petition".

Subsec. (f)(3). Pub. L. 101–239, §6601(l)(3)(A), inserted "under the Program and the costs of carrying out the Program" after "Payments of compensation".

Subsec. (f)(4)(A). Pub. L. 101–239, §6601(l)(3)(B), struck out "made in a lump sum" after "the Program shall be" and inserted "and shall be paid from the trust fund in a lump sum of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner" after "elements of the compensation".

Subsec. (f)(4)(B). Pub. L. 101–239, §6601(l)(3)(C), substituted "determined on the basis of the net present value of the elements of compensation and paid in 4 equal annual installments of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum" for "paid in 4 equal annual installments".

Subsec. (g). Pub. L. 101–239, §6601(l)(4)(A), inserted "(other than under title XIX of the Social Security Act)" after "State health benefits program".

Subsec. (h). Pub. L. 101–239, §6601(l)(4)(B), inserted before period at end ", except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act".

Subsec. (i)(1). Pub. L. 101–239, §6601(l)(5), which directed amendment of par. (1) by substituting "(j)" for "(i)", could not be executed because "(i)" did not appear.

Subsec. (j). Pub. L. 101–239, §6601(l)(6), struck out "and" after "fiscal year 1991," and inserted ", $80,000,000 for fiscal year 1993" after "fiscal year 1992".

1988—Subsec. (i)(1). Pub. L. 100–360, §411(o)(1)(A), substituted "by the Secretary from

appropriations under subsection (j)" for "from appropriations under subsection (i)".

Subsec. (j). Pub. L. 100–360, §411(o)(1)(B), inserted "to the Department of Health and Human Services".

1987—Subsec. (a). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Pub. L. 100–203, §4303(d)(1)(A), struck out last two sentences which read as follows: "Payments for projected expenses shall be paid on a periodic basis (but no payment may be made for a period in excess of 1 year). Payments for pain and suffering and emotional distress and incurred expenses may be paid in a lump sum."

Subsec. (a)(1). Pub. L. 100–203, §4303(c), struck out last sentence of subpars. (A) and (B) each of which read as follows: "The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 300aa–11(c)(1)(D)(ii) of this title."

Subsec. (b). Pub. L. 100–203, §4303(e), substituted "may not include the compensation described in paragraph (1)(B) of subsection (a) of this section and may include attorneys' fees and other costs included in a judgment under subsection (e) of this section, except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) of this section and included as attorneys' fees and other costs under subsection (e) of this section may not exceed $30,000" for "shall only include the compensation described in paragraphs (1)(A) and (2) of subsection (a) of this section".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (e)(1). Pub. L. 100–203, §4307(5), substituted "of the United States Claims Court" for "of a court" in two places.

Subsec. (e)(2). Pub. L. 100–203, §4302(b), substituted "effective date of this subpart, filed a" for "effective date of this subchapter, filed a" and "effective date of this subpart in preparing" for "effective date of this part in preparing".

Subsec. (f). Pub. L. 100–203, §4303(d)(1)(B), (g), added par. (4) and redesignated a second subsec. (f), relating to the Program not being primarily liable, as subsec. (g).

Subsec. (f)(2). Pub. L. 100–203, §4307(6), substituted "United States Claims Court" for "district court of the United States".

Subsecs. (g), (h). Pub. L. 100–203, §4303(g), redesignated a second subsec. (f), relating to the Program not being liable, as (g) and redesignated former subsec. (g) as (h).

Subsecs. (i), (j). Pub. L. 100–203, §4303(a), (b), added subsecs. (i) and (j).

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by section 201(f) of Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101–239 applicable to all pending and subsequently filed petitions, see section 6601(s)(2) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1,

General Provisions.

[1] *So in original. Probably should be preceded by another closing parenthesis.*

§300aa–16. Limitations of actions

(a) General rule

In the case of—

(1) a vaccine set forth in the Vaccine Injury Table which is administered before October 1, 1988, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 28 months after October 1, 1988, and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine,

(2) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

(3) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

(b) Effect of revised table

If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa–11(b)(2) of this title, file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if—

(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

(c) State limitations of actions

If a petition is filed under section 300aa–11 of this title for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date (1) an election is made under section 300aa–21 (a) of this title to file the civil action or (2) an election is made under section 300aa–21(b) of this title to withdraw the petition.

(July 1, 1944, ch. 373, title XXI, §2116, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3769; amended Pub. L. 100–203, title IV, §4302(b)(2), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(m)(1), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101–502, §5(e), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(d)(2), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 103–66, title XIII, §13632(a)(1), Aug. 10, 1993, 107 Stat. 645.)

CODIFICATION

In subsec. (a)(1) to (3), "October 1, 1988" and "October 1, 1988," substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

PRIOR PROVISIONS

A prior section 2116 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

AMENDMENTS

1993—Subsec. (b). Pub. L. 103–66 substituted "or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa–11(b)(2) of this title, file" for "such person may file".

1991—Subsec. (c). Pub. L. 102–168 substituted "or (2)" for ", (2)" and struck out ", or (3) the petition is considered withdrawn under section 300aa–21(b) of this title."

1990—Subsec. (a)(1). Pub. L. 101–502, §5(e)(1), substituted "28 months" for "24 months" and inserted before comma at end "and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine".

Subsec. (c). Pub. L. 101–502, §5(e)(2), substituted "and ending on the date (1) an election is made under section 300aa–21(a) of this title to file the civil action, (2) an election is made under section 300aa–21(b) of this title to withdraw the petition, or (3) the petition is considered withdrawn under section 300aa–21(b) of this title" for "and ending on the date a final judgment is entered on the petition".

1989—Subsec. (c). Pub. L. 101–239 substituted "300aa–11 of this title" for "300aa–11(b) of this title".

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this subchapter" in pars. (1) to (3).

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201 (i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–17. Subrogation

(a) General rule

Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrogated [1] to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

(b) Disposition of amounts recovered

Amounts recovered under subsection (a) shall be collected on behalf of, and deposited in, the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(July 1, 1944, ch. 373, title XXI, §2117, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3770; amended Pub. L. 100–203, title IV, §4307(7), Dec. 22, 1987, 101 Stat. 1330–225; Pub. L. 101–239, title VI, §6601(m)(2), Dec. 19, 1989, 103 Stat. 2291.)

AMENDMENTS

1989—Subsec. (b). Pub. L. 101–239 substituted "the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26" for "the trust fund which has been established to provide compensation under the Program".

1987—Subsec. (a). Pub. L. 100–203 struck out par. (1) designation before "Upon" and struck out par. (2) which read as follows: "In any case in which it deems such action appropriate, a district court of the United States may, after entry of a final judgment providing for compensation to be paid under section 300aa–15 of this title for a vaccine-related injury or death, refer the record of such proceeding to the Secretary and the Attorney General with such recommendation as the court deems appropriate with respect to the investigation or commencement of a civil action by the Secretary under paragraph (1)."

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

[1] *So in original. Probably should be "subrogated".*

§300aa–18. Repealed. Pub. L. 100–203, title IV, §4303(d)(2)(B), Dec. 22, 1987, 101 Stat. 1330–222

Section, act July 1, 1944, ch. 373, title XXI, §2118, as added Nov. 14, 1986, Pub. L. 99–660, title III, §311(a), 100 Stat. 3771, provided for annual increases for inflation of compensation under subsections (a)(2) and (a)(4) of section 300aa–15 of this title and civil penalty under section 300aa–27(b) of this title.

§300aa–19. Advisory Commission on Childhood Vaccines

(a) Establishment

There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

(1) Nine members appointed by the Secretary as follows:

(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of October 1, 1988. The members of the Commission shall select a Chair from among the members.

(b) Term of office

Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

(c) Meetings

The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the Commission present at the meeting.

(d) Compensation

Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the Commission who are not officers or employees of the Federal Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5 for employees serving intermittently.

(e) Staff

The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

(f) Functions

The Commission shall—

(1) advise the Secretary on the implementation of the Program,

(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

(3) advise the Secretary in implementing the Secretary's responsibilities under section 300aa–27 of this title regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 300aa–25(b) of this title, and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this part.

(July 1, 1944, ch. 373, title XXI, §2119, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3771; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 102–168, title II, §201(g), Nov. 26, 1991, 105 Stat. 1104; Pub. L. 102–531, title III, §312(d)(14), Oct. 27, 1992, 106 Stat. 3505.)

CODIFICATION

In subsec. (a), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1992—Subsec. (a)(2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1991—Subsec. (c). Pub. L. 102–168 inserted "present at the meeting" before period at end.

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part" in last sentence.

TERMINATION OF ADVISORY COMMISSIONS

Advisory commissions established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a commission established by the President or an officer of the Federal Government, such commission is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a commission established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

subpart b—additional remedies

§300aa–21. Authority to bring actions

(a) Election

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under

section 300aa–12(f) of this title, after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa–11 of this title shall file with the clerk of the United States Court of Federal Claims—

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the court's final judgment with respect to which the election is to be made. If a person required to file an election with the court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered. For limitations on the bringing of civil actions for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988, see section 300aa–11(a)(2) of this title.

(b) Continuance or withdrawal of petition

A petitioner under a petition filed under section 300aa–11 of this title may submit to the United States Court of Federal Claims a notice in writing choosing to continue or to withdraw the petition if—

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 300aa–12(d)(3)(A)(ii) of this title (excluding (i) any period of suspension under section 300aa–12(d)(3)(C) or 300aa–12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title), or

(2) the court fails to enter a judgment under section 300aa–12 of this title on the petition within 420 days (excluding (i) any period of suspension under section 300aa–12(d)(3)(C) or 300aa–12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title) after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 300aa–12(g) of this title.

(c) Limitations of actions

A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 300aa–11 of this title shall, except as provided in section 300aa–16(c) of this title, be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

(July 1, 1944, ch. 373, title XXI, §2121, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3772; amended Pub. L. 100–203, title IV, §§4304(c), 4307(8), 4308(c), Dec. 22, 1987, 101 Stat. 1330–224, 1330-225; Pub. L. 100–360, title IV, §411(o)(3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(n), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101–502, §5(f), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(d)(3), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

CODIFICATION

In subsec. (a), "October 1, 1988," and "October 1, 1988" substituted for "the effective date of this part".

AMENDMENTS

1992—Subsecs. (a), (b). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" wherever appearing.

1991—Subsec. (b). Pub. L. 102–168 substituted "Continuance or withdrawal of petition" for "Withdrawal of petition" in heading, redesignated introductory provisions of par. (1) as introductory provisions of subsec. (b) and substituted "a notice in writing choosing to continue or to withdraw the petition" for "a notice in writing withdrawing the petition", redesignated subpars. (A) and (B) of former par. (1) as pars. (1) and (2), respectively, and realigned margins, struck out at end of former par. (1) "If such a notice is not filed before the expiration of such 30 days, the petition with respect to which the notice was to be filed shall be considered withdrawn under this paragraph.", and struck out par. (2) which read as follows: "If a special master or the court does not enter a decision or make a judgment on a petition filed under section 300aa–11 of this title within 30 days of the provision of the notice in accordance with section 300aa–12(g) of this title, the special master or court shall no longer have jurisdiction over such petition and such petition shall be considered as withdrawn under

paragraph (1)."

1990—Subsec. (a). Pub. L. 101–502, §5(f)(1), in closing provisions, inserted after second sentence "If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered." and inserted "for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988" after "actions" in last sentence.

Subsec. (b). Pub. L. 101–502, §5(f)(2), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "If the United States Claims Court fails to enter a judgment under section 300aa–12 of this title on a petition filed under section 300aa–11 of this title within 420 days (excluding any period of suspension under section 300aa–12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title) after the date on which the petition was filed, the petitioner may submit to the court a notice in writing withdrawing the petition. An election shall be filed under this subsection not later than 90 days after the date of the entry of the Claims Court's judgment or the appellate court's mandate with respect to which the election is to be made. A person who has submitted a notice under this subsection may, notwithstanding section 300aa–11(a)(2) of this title, thereafter maintain a civil action for damages in a State or Federal court without regard to this subpart and consistent with otherwise applicable law."

1989—Subsec. (a). Pub. L. 101–239, §6601(n)(1)(A), amended introductory provisions generally. Prior to amendment, introductory provisions read as follows: "After the judgment of the United States Claims Court under section 300aa–11 of this title on a petition filed for compensation under the Program for a vaccine-related injury or death has become final, the person who filed the petition shall file with the court—".

Pub. L. 101–239, §6601(n)(1)(B), amended last sentence generally. Prior to amendment, last sentence read as follows: "If a person elects to receive compensation under a judgment of the court or is deemed to have accepted the judgment of the court, such person may not bring or maintain a civil action for damages against a vaccine manufacturer for the vaccine-related injury or death for which the judgment was entered."

Subsec. (b). Pub. L. 101–239, §6601(n)(2), substituted "within 420 days (excluding any period of suspension under section 300aa–12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title)" for "within 365 days" in first sentence and amended second sentence generally. Prior to amendment, second sentence read as follows: "Such a notice shall be filed not later than 90 days after the expiration of such 365-day period."

1988—Subsec. (a). Pub. L. 100–360 added Pub. L. 100–203, §4308(c), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4308(c), as added by Pub. L. 100–360, substituted "the court's final judgment" for "the entry of the court's judgment" in concluding provisions.

Pub. L. 100–203, §4307(8), substituted "the United States Claims Court" for "a district court of the United States" and "the court" for "a court" in three places.

Subsecs. (b), (c). Pub. L. 100–203, §4304(c), added subsec. (b) and redesignated former subsec. (b) as (c).

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by Pub. L. 102–168 effective as in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by section 5(f)(1) of Pub. L. 101–502 effective Nov. 14, 1986, and amendment by

section 5(f)(2) of Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 420-day period prescribed in subsec. (b) of this section, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

EFFECTIVE DATE

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–22. Standards of responsibility

(a) General rule

Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa–23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction

The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

(July 1, 1944, ch. 373, title XXI, §2122, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3773;

amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

CODIFICATION

In subsecs. (b)(1), (c), "October 1, 1988" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1987—Subsecs. (b)(1), (c). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

§300aa–23. Trial

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, which is not barred by section 300aa–11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa–22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa–11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

(July 1, 1944, ch. 373, title XXI, §2123, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §§4302(b)(1), 4307(9), Dec. 22, 1987, 101 Stat. 1330–221, 1330-225; Pub. L. 101–239, title VI, §6601(o), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (d)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

CODIFICATION

In subsec. (a), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1992—Subsec. (e). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" in two places.

1989—Subsec. (e). Pub. L. 101–239 substituted "finding of fact or conclusion of law" for "finding", "special master" for "master appointed by such court", and directed substitution of "the United States Claims Court and subsequent appellate review" for "a district court of the United States" which was executed by inserting "and subsequent appellate review" after "the United States Claims Court" the second place it appeared to reflect the probable intent of Congress and the amendment by Pub. L. 100–203, §4307(a), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (e). Pub. L. 100–203, §4307(9), substituted "the United States Claims Court" for "a district court of the United States" in two places.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

subpart c—assuring a safer childhood vaccination program in united states

§300aa–25. Recording and reporting of information

(a) General rule

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

(1) the date of administration of the vaccine,

(2) the vaccine manufacturer and lot number of the vaccine,

(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(b) Reporting

(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa–14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after

December 22, 1987. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of December 22, 1987.

(c) Release of information

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, or otherwise, to any person except—

(A) the person who received the vaccine, or

(B) the legal representative of such person.

(2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

(July 1, 1944, ch. 373, title XXI, §2125, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

CODIFICATION

In subsec. (b)(1), (3), "December 22, 1987" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1987—Subsec. (b)(1), (3). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

EFFECTIVE DATE

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–26. Vaccine information

(a) General rule

Not later than 1 year after December 22, 1987, the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

(b) Development and revision of materials

Such materials shall be developed or revised—

(1) after notice to the public and 60 days of comment thereon, and

(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

(c) Information requirements

The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include—

(1) a concise description of the benefits of the vaccine,

(2) a concise description of the risks associated with the vaccine,

(3) a statement of the availability of the National Vaccine Injury Compensation Program, and
(4) such other relevant information as may be determined by the Secretary.

(d) Health care provider duties

On and after a date determined by the Secretary which is—
(1) after the Secretary develops the information materials required by subsection (a), and
(2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

(July 1, 1944, ch. 373, title XXI, §2126, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3775; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(p), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–531, title III, §312(d)(15), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–183, title VII, §708, Dec. 14, 1993, 107 Stat. 2242.)

CODIFICATION

In subsec. (a), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–183, §708(c), inserted "or to any other individual" after "to the legal representatives of any child".

Subsec. (b). Pub. L. 103–183, §708(a), struck out "by rule" after "revised" in introductory provisions and substituted "and 60" for ", opportunity for a public hearing, and 90" in par. (1).

Subsec. (c). Pub. L. 103–183, §708(b), inserted in introductory provisions "shall be based on available data and information," after "such materials", added pars. (1) to (4), and struck out former pars. (1) to (10) which read as follows:

"(1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine,

"(2) the symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider,

"(3) precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur,

"(4) early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions,

"(5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities,

"(6) a specification of when, how, and to whom legal representatives should report any major adverse reaction,

"(7) the contraindications to (and bases for delay of) the administration of the vaccine,

"(8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population,

"(9) a summary of—

"(A) relevant Federal recommendations concerning a complete schedule of childhood immunizations, and

"(B) the availability of the Program, and

"(10) such other relevant information as may be determined by the Secretary."

Subsec. (d). Pub. L. 103–183, §708(c), (d), in concluding provisions, inserted "or to any other individual" after "to the legal representatives of any child", substituted "supplemented with visual presentations or oral explanations, in appropriate cases" for "or other written information which meets the requirements of this section", and struck out "or other information" after "Such materials".

1992—Subsec. (b)(2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention"

for "Centers for Disease Control".

1989—Subsec. (c)(9). Pub. L. 101–239 amended par. (9) generally. Prior to amendment, par. (9) read as follows: "a summary of relevant State and Federal laws concerning the vaccine, including information on—

"(A) the number of vaccinations required for school attendance and the schedule recommended for such vaccinations, and

"(B) the availability of the Program, and".

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–27. Mandate for safer childhood vaccines

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

(July 1, 1944, ch. 373, title XXI, §2127, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(q), Dec. 19, 1989, 103 Stat. 2292.)

CODIFICATION

In subsecs. (a)(1), (c), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1989—Subsecs. (b), (c). Pub. L. 101–239 added subsec. (b) and redesignated former subsec. (b) as (c).

1987—Subsecs. (a)(1), (b). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–28. Manufacturer recordkeeping and reporting

(a) General rule

Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to each batch, lot, or other quantity manufactured or licensed after December 22, 1987—

(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous batches, lots, or other quantities (and, if so, the identity of the previous batches, lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test,

(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

(b) Sanction

Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall—

(1) be subject to a civil penalty of up to $100,000 per occurrence, or

(2) be fined $50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or concealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

(July 1, 1944, ch. 373, title XXI, §2128, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

CODIFICATION

In subsec. (a), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

subpart d—general provisions

§300aa–31. Citizen's actions

(a) General rule

Except as provided in subsection (b), any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this part.

(b) Notice

No action may be commenced under subsection (a) before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

(c) Costs of litigation

The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any plaintiff who substantially prevails on one or more significant issues in the action.

(July 1, 1944, ch. 373, title XXI, §2131, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 100–203, title IV, §4305, Dec. 22, 1987, 101 Stat. 1330–224.)

AMENDMENTS

1987—Subsec. (c). Pub. L. 100–203, which directed that subsec. (c) be amended by substituting "to any plaintiff who substantially prevails on one or more significant issues in the action" for "to any party, whenever the court determines that such award is appropriate", was executed by making the substitution for "to any party, whenever the court determines such award is appropriate", to reflect the probable intent of Congress.

EFFECTIVE DATE

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–32. Judicial review

A petition for review of a regulation under this part may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

(July 1, 1944, ch. 373, title XXI, §2132, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778.)

§300aa–33. Definitions

For purposes of this part:

(1) The term "health care provider" means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

(2) The term "legal representative" means a parent or an individual who qualifies as a legal guardian under State law.

(3) The term "manufacturer" means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 300aa–28 of this title, such term shall include the manufacturer of any other vaccine

covered by that section. The term "manufacture" means to manufacture, import, process, or distribute a vaccine.

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

(5) The term "vaccine-related injury or death" means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

(6)(A) The term "Advisory Commission on Childhood Vaccines" means the Commission established under section 300aa–19 of this title.

(B) The term "Vaccine Injury Table" means the table set out in section 300aa–14 of this title.

(July 1, 1944, ch. 373, title XXI, §2133, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 107–296, title XVII, §§1714–1716, Nov. 25, 2002, 116 Stat. 2320, 2321; Pub. L. 108–7, div. L, §102(a), Feb. 20, 2003, 117 Stat. 528.)

AMENDMENTS

2003—Pars. (3), (5), (7). Pub. L. 108–7 repealed Pub. L. 107–296, §§1714–1717, and provided that this chapter shall be applied as if the sections repealed had never been enacted. See 2002 Amendment notes below.

2002—Par. (3). Pub. L. 107–296, §1714, which directed amendment of first sentence by substituting "any vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine" for "under its label any vaccine set forth in the Vaccine Injury Table" and of second sentence by inserting "including any component or ingredient of any such vaccine" before period at end, was repealed by Pub. L. 108–7.

Par. (5). Pub. L. 107–296, §1715, which directed insertion of "For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label." at end, was repealed by Pub. L. 108–7.

Par. (7). Pub. L. 107–296, §1716, which directed addition of par. (7), was repealed by Pub. L. 108–7, §102(a). Par. (7) read as follows: "The term 'vaccine' means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccines's product license application and product label."

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–296, title XVII, §1717, Nov. 25, 2002, 116 Stat. 2321, which provided that the amendments made by sections 1714, 1715, and 1716 (amending this section) shall apply to all actions or proceedings pending on or after Nov. 25, 2002, unless a court of competent jurisdiction has entered judgment (regardless of whether the time for appeal has expired) in such action or proceeding disposing of the entire action or proceeding, was repealed by Pub. L. 108–7, div. L, §102 (a), Feb. 20, 2003, 117 Stat. 528.

CONSTRUCTION OF AMENDMENTS

Pub. L. 108–7, div. L, §102(b), (c), Feb. 20, 2003, 117 Stat. 528, provided that:

"(b) Application of the Public Health Service Act.—The Public Health Service Act (42 U.S.C. 201 et seq.) shall be applied and administered as if the sections repealed by subsection (a) [repealing sections 1714 to 1717 of Pub. L. 107–296, which amended this section and enacted provisions set out as a note under this section] had never been enacted.

"(c) Rule of Construction.—No inference shall be drawn from the enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107–296), or from this repeal [repealing sections 1714 to 1717 of Pub. L. 107–296], regarding the law prior to enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107–296) [Nov. 25, 2002]. Further, no inference shall be drawn that subsection (a) or (b) affects any change in that prior law, or that Leroy v. Secretary of Health and Human Services, Office of Special Master, No. 02–392V (October 11, 2002), was incorrectly decided."

§300aa–34. Termination of program

(a) Reviews

The Secretary shall review the number of awards of compensation made under the program to petitioners under section 300aa–11 of this title for vaccine-related injuries and deaths associated with the administration of vaccines on or after December 22, 1987, as follows:

(1) The Secretary shall review the number of such awards made in the 12-month period beginning on December 22, 1987.

(2) At the end of each 3-month period beginning after the expiration of the 12-month period referred to in paragraph (1) the Secretary shall review the number of such awards made in the 3-month period.

(b) Report

(1) If in conducting a review under subsection (a) the Secretary determines that at the end of the period reviewed the total number of awards made by the end of that period and accepted under section 300aa–21(a) of this title exceeds the number of awards listed next to the period reviewed in the table in paragraph (2)—

(A) the Secretary shall notify the Congress of such determination, and

(B) beginning 180 days after the receipt by Congress of a notification under paragraph (1), no petition for a vaccine-related injury or death associated with the administration of a vaccine on or after December 22, 1987, may be filed under section 300aa–11 of this title.

Section 300aa–11(a) of this title and subpart B of this part shall not apply to civil actions for damages for a vaccine-related injury or death for which a petition may not be filed because of subparagraph (B).

(2) The table referred to in paragraph (1) is as follows:

Period reviewed:	**Total number of awards by the end of the period reviewed**
12 months after December 22, 1987	150
13th through the 15th month after December 22, 1987	188
16th through the 18th month after December 22, 1987	225
19th through the 21st month after December 22, 1987	263
22nd through the 24th month after December 22, 1987	300
25th through the 27th month after December 22, 1987	338
28th through the 30th month after December 22, 1987	375
31st through the 33rd month after December 22, 1987	413
34th through the 36th month after December 22, 1987	450
37th through the 39th month after December 22, 1987	488
40th through the 42nd month after December 22, 1987	525
43rd through the 45th month after December 22, 1987	563
46th through the 48th month after December 22, 1987	600.

(July 1, 1944, ch. 373, title XXI, §2134, as added Pub. L. 100–203, title IV, §4303(f), Dec. 22, 1987, 101 Stat. 1330–222.)

CODIFICATION

In subsecs. (a) and (b), "December 22, 1987" substituted for "the effective date of this subpart" on

authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Reference 13

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

BRUESEWITZ ET AL. *v.* WYETH LLC, FKA WYETH, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 09–152. Argued October 12, 2010—Decided February 22, 2011

The National Childhood Vaccine Injury Act of 1986 (NCVIA or Act) created a no-fault compensation program to stabilize a vaccine market adversely affected by an increase in vaccine-related tort litigation and to facilitate compensation to claimants who found pursuing legitimate vaccine-inflicted injuries too costly and difficult. The Act provides that a party alleging a vaccine-related injury may file a petition for compensation in the Court of Federal Claims, naming the Health and Human Services Secretary as the respondent; that the court must resolve the case by a specified deadline; and that the claimant can then decide whether to accept the court's judgment or reject it and seek tort relief from the vaccine manufacturer. Awards are paid out of a fund created by an excise tax on each vaccine dose. As a *quid pro quo,* manufacturers enjoy significant tort-liability protections. Most importantly, the Act eliminates manufacturer liability for a vaccine's unavoidable, adverse side effects.

Hannah Bruesewitz's parents filed a vaccine-injury petition in the Court of Federal Claims, claiming that Hannah became disabled after receiving a diphtheria, tetanus, and pertussis (DTP) vaccine manufactured by Lederle Laboratories (now owned by respondent Wyeth). After that court denied their claim, they elected to reject the unfavorable judgment and filed suit in Pennsylvania state court, alleging, *inter alia,* that the defective design of Lederle's DTP vaccine caused Hannah's disabilities, and that Lederle was subject to strict liability and liability for negligent design under Pennsylvania common law. Wyeth removed the suit to the Federal District Court. It granted Wyeth summary judgment, holding that the relevant Pennsylvania law was preempted by 42 U. S. C. §300aa–22(b)(1), which

Syllabus

provides that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side-effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." The Third Circuit affirmed.

Held: The NCVIA preempts all design-defect claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury or death caused by a vaccine's side effects. Pp. 7–19.

(a) Section 300aa–22(b)(1)'s text suggests that a vaccine's design is not open to question in a tort action. If a manufacturer could be held liable for failure to use a different design, the "even though" clause would do no work. A vaccine side effect could always have been avoidable by use of a different vaccine not containing the harmful element. The language of the provision thus suggests the design is not subject to question in a tort action. What the statute establishes as a complete defense must be unavoidability (given safe manufacture and warning) with respect to the particular design. This conclusion is supported by the fact that, although products-liability law establishes three grounds for liability—defective manufacture, inadequate directions or warnings, and defective design—the Act mentions only manufacture and warnings. It thus seems that the Act's failure to mention design-defect liability is "by deliberate choice, not inadvertence." *Barnhart* v. *Peabody Coal Co.*, 537 U. S. 149, 168. Pp. 7–8.

(b) Contrary to petitioners' argument, there is no reason to believe that §300aa–22(b)(1)'s term "unavoidable" is a term of art incorporating Restatement (Second) of Torts §402A, Comment *k*, which exempts from strict liability rules "unavoidably unsafe products." "Unavoidable" is hardly a rarely used word, and cases interpreting comment *k* attach special significance only to the term "unavoidably unsafe products," not the word "unavoidable" standing alone. Moreover, reading the phrase "side effects that were unavoidable" to exempt injuries caused by flawed design would require treating "even though" as a coordinating conjunction linking independent ideas when it is a concessive, subordinating conjunction conveying that one clause weakens or qualifies the other. The canon against superfluity does not undermine this Court's interpretation because petitioners' competing interpretation has superfluity problems of its own. Pp. 8–12.

(c) The structure of the NCVIA and of vaccine regulation in general reinforces what §300aa–22(b)(1)'s text suggests. Design defects do not merit a single mention in the Act or in Food and Drug Administration regulations that pervasively regulate the drug manufacturing process. This lack of guidance for design defects, combined with

Syllabus

the extensive guidance for the two liability grounds specifically mentioned in the Act, strongly suggests that design defects were not mentioned because they are not a basis for liability. The Act's mandates lead to the same conclusion. It provides for federal agency improvement of vaccine design and for federally prescribed compensation, which are other means for achieving the two beneficial effects of design-defect torts—prompting the development of improved designs, and providing compensation for inflicted injuries. The Act's structural *quid pro quo* also leads to the same conclusion. The vaccine manufacturers fund an informal, efficient compensation program for vaccine injuries in exchange for avoiding costly tort litigation and the occasional disproportionate jury verdict. Taxing their product to fund the compensation program, while leaving their liability for design defect virtually unaltered, would hardly coax them back into the market. Pp. 13–16.

561 F. 3d 233, affirmed.

SCALIA, J., delivered the opinion of the Court, in which ROBERTS, C. J., and KENNEDY, THOMAS, BREYER, and ALITO, JJ., joined. BREYER, J., filed a concurring opinion. SOTOMAYOR, J., filed a dissenting opinion, in which GINSBURG, J., joined. KAGAN, J., took no part in the consideration or decision of the case.

Reference 14

HRSA
Health Resources & Services Administration

Data & Statistics

The United States has the safest, most effective vaccine supply in history. In the majority of cases, vaccines cause no side effects, however they can occur, as with any medication—but most are mild. Very rarely, people experience more serious side effects, like allergic reactions.
In those instances, the National Vaccine Injury Compensation Program (VICP) allows individuals to file a petition for compensation.

What does it mean to be awarded compensation?
Being awarded compensation for a petition does not necessarily mean that the vaccine caused the alleged injury. In fact:

- Approximately 70 percent of all compensation awarded by the VICP comes as result of a negotiated settlement between the parties in which HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury.
- Attorneys are eligible for reasonable attorneys' fees, whether or not the petitioner is awarded compensation by the Court, if certain minimal requirements are met. In those circumstances, attorneys are paid by the VICP directly. By statute, attorneys may not charge any other fee, including a contingency fee, for his or her services in representing a petitioner in the VICP.

What reasons might a petition result in a negotiated settlement?

- Consideration of prior U.S. Court of Federal Claims decisions, both parties decide to minimize risk of loss through settlement
- A desire to minimize the time and expense of litigating a case
- The desire to resolve a petition quickly

How many petitions have been awarded compensation?
According to the CDC, from 2006 to 2018 over 3.4 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 6,595 petitions were adjudicated by the Court, and of those 4,539 were compensated. This means for every 1 million doses of vaccine that were distributed, approximately 1 individual was compensated.

Since 1988, over 21,585 petitions have been filed with the VICP. Over that 30-year time period, 18,533 petitions have been adjudicated, with 7,090 of those determined to be compensable, while 11,443 were dismissed. Total compensation paid over the life of the program is approximately $4.2 billion.

This information reflects the current thinking of the United States Department of Health and Human Services on the topics addressed. This information is not legal advice and does not create or confer any rights for or on any person and does not operate to bind the Department or the public. The ultimate decision about the scope of the statutes authorizing the VICP is within the authority of the United States Court of Federal Claims, which is responsible for resolving petitions for compensation under the VICP.

VICP Adjudication Categories, by Alleged Vaccine for Petitions Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/01/2006 through 12/31/2018

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2018 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
DT	794,777	1	0	5	6	4	10
DTaP	105,474,077	21	23	109	153	119	272
DTaP-Hep B-IPV	74,255,807	5	7	28	40	55	95
DTaP-HIB	1,135,474	0	1	2	3	2	5
DTaP-IPV	27,884,804	0	0	5	5	3	8
DTap-IPV-HIB	68,409,736	4	4	9	17	35	52
DTP	0	1	1	3	5	2	7
DTP-HIB	0	1	0	2	3	1	4
Hep A-Hep B	16,923,878	2	1	15	18	6	24
Hep B-HIB	4,787,457	1	1	2	4	1	5
Hepatitis A (Hep A)	189,707,214	8	6	44	58	33	91
Hepatitis B (Hep B)	198,868,169	10	11	67	88	84	172
HIB	128,789,396	2	1	9	12	10	22
HPV	121,642,555	15	13	109	137	185	322
Influenza	1,672,400,000	814	182	2,399	3,395	591	3,986
IPV	75,537,282	0	0	4	4	4	8
Measles	135,660	0	0	1	1	0	1
Meningococcal	106,233,254	2	5	41	48	12	60
MMR	108,389,441	23	15	88	126	129	255

National Vaccine Injury Compensation Program
Monthly Statistics Report

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2018 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
MMR-Varicella	28,376,497	10	0	13	23	16	39
Mumps	110,749	0	0	0	0	0	0
Nonqualified	0	0	0	3	3	38	41
OPV	0	1	0	0	1	5	6
Pneumococcal Conjugate	250,151,136	26	3	37	66	47	113
Rotavirus	116,651,363	18	4	22	44	15	59
Rubella	422,548	0	1	1	2	0	2
Td	68,120,632	11	6	62	79	27	106
Tdap	270,851,285	105	19	294	418	85	503
Tetanus	3,836,052	11	2	41	54	20	74
Unspecified	0	1	1	4	6	590	596
Varicella	121,855,108	9	7	30	46	20	66
Grand Total	3,761,744,351	1,102	314	3,449	4,865	2,139	7,004

Notes on the Adjudication Categories Table

The date range of 01/01/2006 through 12/31/2018 was selected to reflect petitions filed since the inclusion of influenza vaccine in July 2005. Influenza vaccine now is named in the majority of all VICP petitions.

In addition to the first vaccine alleged by a petitioner, which is the vaccine listed in this table, a VICP petition may allege other vaccines, which may form the basis of compensation.

Vaccine doses are self-reported distribution data provided by US-licensed vaccine manufacturers. The data provide an estimate of the annual national distribution and do not represent vaccine administration. In order to maintain confidentiality of an individual manufacturer or brand, the data are presented in an aggregate format by vaccine type. Flu doses are derived from CDC's FluFinder tracking system, which includes data provided to CDC by US-licensed influenza vaccine manufacturers as well as their first line distributors.

"Unspecified" means insufficient information was submitted to make an initial determination. The conceded "unspecified" petition was for multiple unidentified vaccines that caused abscess formation at the vaccination site(s), and the "unspecified" settlements were for multiple vaccines later identified in the Special Masters' decisions

Definitions

Compensable – The injured person who filed a petition was paid money by the VICP. Compensation can be achieved through a concession by the U.S. Department of Health and Human Services (HHS), a decision on the merits of the petition by a special master or a judge of the U.S. Court of Federal Claims (Court), or a settlement between the parties.

- **Concession**: HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.
- **Court Decision**: A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation (e.g., that the injury was not caused by the vaccine).
  For injury petitions, compensable court decisions are based in part on one of the following determinations by the court:
  1. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or
  2. The injury is listed on, and meets all of the requirements of, the Vaccine Injury Table, and HHS has not proven that a factor unrelated to the vaccine more likely than not caused or significantly aggravated the injury. An injury listed on the Table and meeting all Table requirements is given the legal presumption of causation. It should be noted that conditions are placed on the Table for both scientific and policy reasons.
- **Settlement**: The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the Court does not determine that the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Petitions may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to minimize the time and expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.
- **Non-compensable/Dismissed**: The injured person who filed a petition was ultimately not paid money. Non-compensable Court decisions include the following:
  1. The Court determines that the person who filed the petition did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine or meet the requirements of the Table (for injuries listed on the Table).
  2. The petition was dismissed for not meeting other statutory requirements (such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute's severity requirement).
  3. The injured person voluntarily withdrew his or her petition.

Petitions Filed, Compensated and Dismissed, by Alleged Vaccine, Since the Beginning of VICP, 10/01/1988 through 2/01/2020

Vaccines	Filed Injury	Filed Death	Filed Grand Total	Compensated	Dismissed
DTaP-IPV	12	0	12	5	3
DT	69	9	78	26	52
DTP	3,287	696	3,983	1,273	2,709
DTP-HIB	20	8	28	7	21
DTaP	465	85	550	233	254
DTaP-Hep B-IPV	90	38	128	42	55
DTaP-HIB	11	1	12	7	4
DTaP-IPV-HIB	45	21	66	15	32
Td	216	3	219	125	75
Tdap	769	7	776	412	82
Tetanus	143	2	145	77	47
Hepatitis A (Hep A)	106	7	113	58	33
Hepatitis B (Hep B)	710	61	771	280	426
Hep A-Hep B	36	0	36	18	7
Hep B-HIB	8	0	8	5	3
HIB	44	3	47	19	20
HPV	426	15	441	134	172
Influenza	5,802	178	5,980	3,365	545
IPV	269	14	283	8	270
OPV	282	28	310	158	152
Measles	143	19	162	55	107
Meningococcal	93	2	95	48	10
MMR	989	62	1,051	407	585
MMR-Varicella	54	2	56	23	13
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	224	19	243	69	58
Rotavirus	98	5	103	63	25
Rubella	190	4	194	71	123
Varicella	104	9	113	66	31
Nonqualified1	106	9	115	3	104
Unspecified2	5,426	9	5,435	9	5,402
Grand Total	**20,266**	**1,319**	**21,585**	**7,090**	**11,443**

[1] Nonqualified petitions are those filed for vaccines not covered under the VICP.
[2] Unspecified petitions are those submitted with insufficient information to make a determination.

Petitions Filed

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	215
FY 2002	958
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	448
FY 2011	386
FY 2012	401
FY 2013	504
FY 2014	633
FY 2015	803
FY 2016	1,120
FY 2017	1,243
FY 2018	1,238
FY 2019	1,282
FY 2020	383
Total	**21,585**

Adjudications

Generally, petitions are not adjudicated in the same fiscal year as filed.
On average, it takes 2 to 3 years to adjudicate a petition after it is filed.

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	88	174
FY 2002	104	104	208
FY 2003	56	100	156
FY 2004	62	247	309
FY 2005	60	229	289
FY 2006	69	193	262
FY 2007	82	136	218
FY 2008	147	151	298
FY 2009	134	257	391
FY 2010	180	329	509
FY 2011	266	1,740	2,006
FY 2012	265	2,533	2,798
FY 2013	369	649	1,018
FY 2014	370	192	562
FY 2015	517	137	654
FY 2016	697	179	876
FY 2017	695	186	881
FY 2018	539	189	728
FY 2019	635	143	778
FY 2020	176	43	219
Total	**7,090**	**11,443**	**18,533**

Awards Paid

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 1989	6	$1,317,654.78	$54,107.14	0	$0.00	0	$0.00	$1,371,761.92
FY 1990	88	$53,252,510.46	$1,379,005.79	4	$57,699.48	0	$0.00	$54,689,215.73
FY 1991	114	$95,980,493.16	$2,364,758.91	30	$496,809.21	0	$0.00	$98,842,061.28
FY 1992	130	$94,538,071.30	$3,001,927.97	118	$1,212,677.14	0	$0.00	$98,752,676.41
FY 1993	162	$119,693,267.87	$3,262,453.06	272	$2,447,273.05	0	$0.00	$125,402,993.98
FY 1994	158	$98,151,900.08	$3,571,179.67	335	$3,166,527.38	0	$0.00	$104,889,607.13
FY 1995	169	$104,085,265.72	$3,652,770.57	221	$2,276,136.32	0	$0.00	$110,014,172.61
FY 1996	163	$100,425,325.22	$3,096,231.96	216	$2,364,122.71	0	$0.00	$105,885,679.89
FY 1997	179	$113,620,171.68	$3,898,284.77	142	$1,879,418.14	0	$0.00	$119,397,874.59
FY 1998	165	$127,546,009.19	$4,002,278.55	121	$1,936,065.50	0	$0.00	$133,484,353.24
FY 1999	96	$95,917,680.51	$2,799,910.85	117	$2,306,957.40	0	$0.00	$101,024,548.76
FY 2000	136	$125,945,195.64	$4,112,369.02	80	$1,724,451.08	0	$0.00	$131,782,015.74
FY 2001	97	$105,878,632.57	$3,373,865.88	57	$2,066,224.67	0	$0.00	$111,318,723.12
FY 2002	80	$59,799,604.39	$2,653,598.89	50	$656,244.79	0	$0.00	$63,109,448.07
FY 2003	65	$82,816,240.07	$3,147,755.12	69	$1,545,654.87	0	$0.00	$87,509,650.06
FY 2004	57	$61,933,764.20	$3,079,328.55	69	$1,198,615.96	0	$0.00	$66,211,708.71
FY 2005	64	$55,065,797.01	$2,694,664.03	71	$1,790,587.29	0	$0.00	$59,551,048.33
FY 2006	68	$48,746,162.74	$2,441,199.02	54	$1,353,632.61	0	$0.00	$52,540,994.37
FY 2007	82	$91,449,433.89	$4,034,154.37	61	$1,692,020.25	0	$0.00	$97,175,608.51
FY 2008	141	$75,716,552.06	$5,191,770.83	74	$2,531,394.20	2	$117,265.31	$83,556,982.40
FY 2009	131	$74,142,490.58	$5,404,711.98	36	$1,557,139.53	28	$4,241,362.55	$85,345,704.64
FY 2010	173	$179,387,341.30	$5,961,744.40	59	$1,933,550.09	22	$1,978,803.88	$189,261,439.67
FY 2011	251	$216,319,428.47	$9,572,042.87	403	$5,589,417.19	28	$2,001,770.91	$233,482,659.44
FY 2012	249	$163,491,998.82	$9,241,427.33	1,020	$8,649,676.56	37	$5,420,257.99	$186,803,360.70
FY 2013	375	$254,666,326.70	$13,543,099.70	704	$7,012,615.42	50	$1,454,851.74	$276,676,893.56
FY 2014	365	$202,084,196.12	$12,161,422.64	508	$6,824,566.68	38	$2,493,460.73	$223,563,646.17
FY 2015	508	$204,137,880.22	$14,445,776.29	118	$3,546,785.14	50	$3,089,497.68	$225,219,939.33

National Vaccine Injury Compensation Program
Monthly Statistics Report

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 2016	689	$230,140,251.20	$16,225,881.12	99	$2,741,830.10	59	$3,502,709.91	$252,610,672.33
FY 2017	706	$252,245,932.78	$22,045,785.00	131	$4,441,724.32	52	$3,363,464.24	$282,096,906.34
FY 2018	522	$199,658,492.49	$16,658,440.14	111	$5,091,269.45	58	$5,220,096.78	$226,628,298.86
FY 2019	653	$196,217,707.64	$18,991,247.55	102	$4,791,157.52	65	$5,457,545.23	$225,457,657.94
FY 2020	217	$57,786,000.28	$5,677,818.84	39	$1,668,328.60	23	$1,562,373.61	$66,694,521.33
Total	**7,059**	**$3,942,157,779.14**	**$211,741,012.81**	**5,491**	**$86,550,572.65**	**512**	**$39,903,460.56**	**$4,280,352,825.16**

NOTE: Some previous fiscal year data has been updated as a result of the receipt and entry of data from documents issued by the Court and system updates which included petitioners' costs reimbursements in outlay totals,

"Compensated" are petitions that have been paid as a result of a settlement between parties or a decision made by the U.S. Court of Federal Claims (Court). The # of awards is the number of petitioner awards paid, including the attorneys' fees/costs payments, if made during a fiscal year. However, petitioners' awards and attorneys' fees/costs are not necessarily paid in the same fiscal year as when the petitions/petitions are determined compensable. "Dismissed" includes the # of payments to attorneys and the total amount of payments for attorneys' fees/costs per fiscal year. The VICP will pay attorneys' fees/costs related to the petition, whether or not the petition/petition is awarded compensation by the Court, if certain minimal requirements are met. "Total Outlays" are the total amount of funds expended for compensation and attorneys' fees/costs from the Vaccine Injury Compensation Trust Fund by fiscal year.

Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult petitions related to that vaccine have been filed, thus changing the proportion of children to adults receiving compensation.

Children's Wisconsin

TO: **Constitution and Ethics Committee**
FROM: **Children's School Health Nurses Team**
DATE: **Tuesday, March 3, 2020**
RE: **Support for Clearinghouse Rule 19-079: Immunization of students**

Thank you Chairman Wichgers and members of the committee for holding this hearing. We are here today to express our support of **Clearinghouse Rule 19-079: Immunization of students.**

My name is Heather Fischer and I am a School Health Nurse with Children's Wisconsin and I am joined by a few of my Children's school nurse colleagues. We will share a few of our reasons for supporting this Rule.

As a teenager I had cancer. After chemo and radiation, I was given a bone marrow transplant. Although I had been vaccinated as advised by my pediatrician since birth, I was now starting my immunity from scratch. My body was not strong enough to endure revaccination for several months. Had there been as many of those who are hesitant or opposed to vaccinations as today I may not be here. Thanks to the built up herd immunity of my friends and classmates, I was able to return to school and sleep overs with friends as soon and as often as my energy level would allow. I am here today to state that I agree with every part of the rule. The updates will provide easier, more effective, safer and most importantly, better patient outcomes.

Thank you. My name is Nora Alaniz

I would like to express my support of having the current Tdap requirement from 6th to 7th grade.

The Wisconsin Student Immunization law currently requires that all students entering the 6th grade have a dose of Tdap vaccine that protects against Tetanus (lock jaw), diphtheria, and pertussis (whooping cough). Currently, students entering 6th grade may still be 10 years of age and do not qualify for the immunization at their pediatric office, causing them to be in a "behind schedule" status, which may result in wrongly excluding them from school for up to a week according to the current exclusion period for immunization non-compliance. Changing the Tdap requirement from 6th to 7th grade will also allow for more accurate data reporting of children who are actually behind schedule from each school to the school district and the state.

My name is Deanne Hauch and I support the updates to the immunization rule. Children who attend school are exposed to many illnesses and as the increase in students attending school with chronic illness, including those who may be immunocompromised, rises so does the risk for exposure to those students from others in the population who may not be immunized. To that population, a disease thought to be otherwise benign, may in fact be deadly. This causes undo stress to both the parents and the student. Parents of those students are at risk for additional loss of work hours and wages to take care of their child, and those students may be at risk from losing valuable educational hours in school, causing potential academic delays. Vaccines have been proven to decrease and or prevent disease and for that reason and the ones above, I support the proposed changes to the rule.

Children's complies with Federal civil rights laws. We do not discriminate based on race, color, national origin, age, disability or sex. Si no habla inglés, se programarán servicios de idiomas en forma gratuita. Llame al (414) 266-7848 (TTY: 414-266-2465). Yog hais tias koj tsis txawj hais lus Askiv, peb yuav teem sij hawm muab kev pab txhais lus pub dawb rau koj. Hu rau (414) 266-7848 (TTY: 414-266-2465).

Hello and thank you my name is Ashley Dingler. I will start with Rule 1 – Change in the 'substantial outbreak' classification to include chicken pox and the meningococcal disease.

I support this rule. If the incidence of chicken pox of meningococcal disease becomes an outbreak, it is imperative we take the proper steps as to not increase further spreading among non-vaccinated citizens, especially immunocompromised citizens such as the sickle cell students I work with daily.

Moving on to Rule 2 – which would change the 'substantial outbreak' definition of mumps from "an incidence of the disease exceeding 2% of the unvaccinated population" to define 'substantial outbreak' as "three or more cases linked by time and place."

I also support this rule. It is important to set clear and specific guidelines when discussing an outbreak and this would be consistent with the CDC surveillance recommendations. The primary reason for conducting an investigation of an outbreak is to identify the source in order to establish control and to institute measures that will prevent future episodes and learn more about the way the disease is transmitted.

And lastly I would like to touch on Rule 4 – Move the current recommendation for Tdap from 6th grade to 7th grade to ensure that children are old enough to meet this age minimum (some children are 10 years old when starting 6th grade).

In my experience many young 6th graders (10 years old) are unable to receive the vaccine due to the guidelines their physician follows, this creates an issue within the school system because it appears as though the student is non-compliant with their vaccinations. These student's receive calls and letters home to their parents to alert them of their non-compliance when in fact they are attempting to follow their physician's orders.

Thank you Chairman and committee members for holding this hearing. We are happy to take any questions.

Children's Wisconsin

TO: **Constitution and Ethics Committee**
FROM: **Robert Rohloff, MD, Director of Quality & Patient Safety of Children's Medical Group at Children's Wisconsin**
DATE: **Tuesday, March 3, 2020**
RE: **Support for Clearinghouse Rule 19-079: Immunization of students**

Good morning Chairman Wichgers and members of the committee. My name is Dr. Bob Rohloff and I am the Director of Quality & Patient Safety of Children's Medical Group at Children's Wisconsin. Thank you for holding this hearing today and allowing me this opportunity to testify today in support of **Clearinghouse Rule 19-079: Immunization of students.**

I am here to ask for your support of the Wisconsin Department of Health Services' (DHS) proposed updates to the student immunization regulations in DHS 144, as they are necessary to bring those regulations into alignment with current recommendations put forward by the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP) and current evidence-based practices. The proposed changes streamline existing regulations and reporting requirements between state entities and include necessary updates.

Children's is supportive of all of the updates listed in the rule but today I want to focus my comments on items 3-5.

Starting with item number 3 which would move the current recommendation for Tdap from 6th grade to 7th grade to ensure that children are old enough to meet this age minimum (some children are 10 years old when starting 6th grade).

Item 3 is a great addition and Children's is very supportive. The ACIP just recently amended their recommendations to allow 10 year olds to receive the Tdap and have it count towards the adolescent series. Before that change, anyone receiving the Tdap at 10 had to have it repeated after they turned 11. Because of that, we are giving the Tdap at 11 and running into a problem with the school requirement. Number 3 is imperative to better align school requirements with the previous ACIP recommendation.

Item 4 would add the meningococcal vaccine to the list of vaccines required for students entering the 7th grade and proposes a booster dose for students entering 12th grade which is in accordance with ACIP recommendations.

This is a very welcomed addition. Currently our rates of vaccination for Tdap and Meningococcus (types A,C,Y,W) at our Children's Primary Care clinics is well over 90%. Aligning the ages for Tdap requirement at 7th grade would allow us to sign one form for both vaccines (Tdap and Meningococcus) which streamlines the process for providers and parents.

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*Meningococcus causes several significant infections including blood infections called bacteremia, pneumonia and meningitis, an infection of the lining of the brain and spinal cord. Fortunately, Meningococcus is a fairly uncommon infection. Unfortunately about 15 % of people who get infected will die despite our best efforts. Of those who survive nearly 20% will have lifelong devastating sequelae including loss of limb, deafness and cognitive problems. This is not an infection be trifled with. The vaccine is about 85% effective in the year after it is given but the effectiveness decreases over time so that by 3-5 years after the first vaccine it is about 50% effective. Which is why a second dose is so important. One of the peak times for infection is in college students.

Item 5 would allow the varicella vaccination exception only when a history of varicella disease has been reported by a health care provider. This is an important addition.

When I was a child almost everyone got chicken pox. It may seem like a common, mild childhood illness. In fact over 10,000 children per year were hospitalized due to chicken pox and over 100 children in the US with chicken pox died every year. Since the introduction of the chicken pox vaccine hospitalizations have declined by 70% and deaths have declined by 88%. At the same time, chicken pox has decreased by 97%. These are remarkable numbers. Getting chickenpox is much less likely today. If a person is infected with chickenpox they are immune for life and do not need the vaccine. Unfortunately, other infections can look like chicken pox making the diagnosis a bit confusing. Also, as chickenpox has become less common it can be harder to diagnose. We recommend contacting a health care provider if a child is suspected of having chickenpox to discuss symptoms and treatment.

Immunization has always been an important factor in the health of kids and is consistently recommended by pediatricians and providers at Children's Wisconsin and health systems worldwide. Children's treats the most vulnerable and immune-challenged kids who cannot get vaccinated and are most at-risk if a communicable disease outbreak occurs. At children's, we have cared for over 2,600 patients in the last couple of years with immune system problems. In fact the risk to these patients is enormous., up to a third of ~~these~~ kids who have problems with their immune systems who are exposed to and catch chickenpox may have a rapidly progressive course with multiple organ system involvement. The reality is that kids who do not get vaccinated can acquire – and just as importantly, spread – dangerous diseases. Potential outbreaks can be avoided if there are fewer unimmunized children and if children stay up-to-date with recommended school vaccine schedules. Herd immunity is important to protect children who cannot be vaccinated as well as infants who are too young and those who are too ill battling diseases like cancer.

Now, I will turn it over to my physician colleague Dr. Heather Paradis who will share a letter written by a Children's patient family who finds themselves in one of these situations.

Dr. Paradis:

Thank you. This letter is from Linda Bevec from Kenosha.

I am a mother writing to you asking for your support of the changes outlined in the **Wisconsin Department of Health Services 144 – Immunization of Students.** I feel these proposed updates are

imperative to the health and wellness of all children assuring they have an equal chance of growing up healthy.

As a state, it is crucial we protect all of our children, especially the weakest among us. It is so important to bring these immunization regulations into alignment with current recommendations established by the Centers for Disease Control and Prevention, the Advisory Committee on Immunization Practices, the American Academy of Pediatrics and current evidence-based practices.

Immunizations save lives. And to disregard the chance of saving lives when we have that chance is to disregard our collective responsibility and service to one another. We live in community and not in isolation from one another; we are a collective society, a global society...and diseases are spread through day-to-day interaction and contact that we all have with one another and that cannot be avoided. Vaccines keep our schools healthy, our workplaces healthy, our communities and our state healthy.

I have an 18-year old daughter, Claire, who has lived her entire life with a rare genetic kidney and liver disease called Auto Recessive Polycystic Kidney Disease and Congenital Hepatic Fibrosis. Due to her chronic illness she has lived with a weakened immune system since birth. We have done everything in our power to protect her and keep her safe and healthy in every way we possibly can, but we have also relied on certain regulations and laws to ensure protection in her schools and in our communities. When she was 9 years old she received a kidney transplant and was out of school for 5 months so she could recover and avoid contact with anyone who might be sick. Organ transplant patients have especially weakened immune systems due to the immunosuppression medications that prevent their body from rejecting the transplanted organ. Claire couldn't wait to return to school to see her teachers and friends, to learn and return to a normal 4th grade life. I trusted my school and the families who went there to abide by the vaccine regulations that help keep my daughter, and all children, healthy. She is now a freshman in college and we are still constantly vigilant and careful of her exposure to infectious diseases and individuals who might NOT be vaccinated. Recently, a young woman with my daughter's same disease died from meningococcal septicemia because of someone she came into contact with who had not been vaccinated against this completely PREVENTABLE disease. It is heartbreaking and so unnecessary. We live in a time when medicine has given us so many advances and the ability to prevent diseases and keep them from spreading.

In summary, we are only as healthy as the weakest among us. If we fail to care about the least and the weakest among us, we fail to care about all. I sincerely hope you will understand this and do what is right and just by providing protection in the form of laws and regulations ensuring the health of all in our great state of Wisconsin.

Chairman Wichgers and committee members, we thank you again for the opportunity to testify in support. Children's is glad to serve as a resource on this important public health matter facing our state. We are happy to answer any questions now.

As you know, Children's Wisconsin (Children's) serves children and families in every county across the state. We have inpatient hospitals in Milwaukee and the Fox Valley. We care for every part of a child's health, from critical

care at one of our hospitals, to routine checkups in our primary care clinics. Children's Hospital also provides specialty care, urgent care, emergency care, dental care, school health nurses, foster care and adoption services, family resource centers, child health advocacy, health education, family preservation and support, mental health services, pediatric medical research and the statewide poison hotline.

TO: **Constitution and Ethics Committee**
FROM: **Nicholas Herrick, BSN, RN, Community Health School Nurse Supervisor, Children's Wisconsin and President, Wisconsin Association of School Nurses (WASN)**
DATE: **Tuesday, March 3, 2020**
RE: **Support for Clearinghouse Rule 19-079: Immunization of students**

Good afternoon, Chairman Wichgers and members of the committee. My name is Nicholas Herrick and I am the Community Health School Nurse Supervisor at Children's Wisconsin. I am also here representing the Wisconsin Association of School Nurses (WASN) as the organization's current president. Thank you for holding this hearing today and providing this opportunity to testify in support of **Clearinghouse Rule 19-079: regarding the Immunization of students.**

I am here today to ask for your support of Clearinghouse Rule 19-079, specific to DHS 144. One of the foundations of professional nursing practice is utilizing scientific evidence and expert recommendations to make the best decisions in providing care and ensuring safety for patients. The proposed rule changes would bring existing regulations into alignment with current expert recommendations of the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP), all following current evidence-based practices. School nurses are leaders in the school and community settings who use evidence-based immunization strategies, such as School Located Vaccine (SLV) clinics, parent/guardian reminders regarding vaccine schedules, state immunization information systems (WIR), strong support of vaccination recommendations, and vaccine education for students, staff, and families.

School nurses are committed to the health and safety of **all** school-aged children and in Wisconsin, the implementation of Wisconsin's immunization program is of particular interest and concern. Monitoring school immunization requirements for vaccine-preventable diseases generally falls under the responsibility of the school or district nurse and is just one of the many ways school nurses help provide protection for children in our communities and schools.

I'd like to share with you a few excerpts from the newly revised (2020) position statement on Immunizations posted by the National Association of School Nurses, Silver Spring, MD:

The CDC (2019a) currently recommends that U.S. children and adolescents be vaccinated against 17 diseases. Childhood immunizations have reduced the incidence of Vaccine Preventable Diseases (VPD) by more than 90%, and, in some cases, have spurred reductions as high as 99%. Smallpox, the only human disease ever eradicated, was eradicated through vaccination. Similarly, polio is near eradication as a result of widespread vaccination programs (American Academy of Pediatrics [AAP], 2018; Orenstein & Ahmed, 2017). In addition to reducing disease, disability and death, vaccines are credited with saving almost $69 billion in healthcare costs in the United States alone (Orenstein et al., 2017). Vaccines not only provide protection to those who are vaccinated, but also provide community protection or "herd immunity" where vaccination rates are above 95% (Eby, 2017). Herd immunity reduces the spread of disease to those who cannot be vaccinated, from the youngest infants to immunocompromised individuals of any age.

Childhood immunization has been so effective in preventing death and disease that many parents today have not encountered diseases that were common years ago. As a result, increasing numbers of parents believe that vaccine-preventable diseases (VPD) are mild or "natural," and that vaccines are no longer necessary (Navin, 2018). Decreasing vaccination rates, coupled with the ease of international travel and waning vaccine titers, has resulted in an increase in VPD outbreaks in the United States. Pertussis cases—which declined from over 100,000 per year to fewer than 10,000 per year between the 1940s and 1965, after the vaccine's introduction—rose to over 18,000

It was clear to me that the DHS bureaucrats facilitating this public hearing had no interest in what I had to say and it was appalling to me.

Is this typical behavior of government bureaucrats who hold public hearings? And if so, does this committee consider these actions to be an acceptable manor in which to conduct a public hearing?

While I was permitted my 2 minutes of public comment, there were several in attendance who were not – because at exactly 932am, the hearing was abruptly ended and several in attendance were denied the opportunity to speak. Moms and dads who secured childcare and drove upwards of 4 and 5 hours to speak were not heard as DHS bureaucrats chose to prioritize callers over those who had rearranged their schedules in order to attend in person to be allowed the opportunity to speak.

Wisconsin United For Freedom formally requested a meeting with DHS staff regarding the proposed rule changes to allow for our concerns to be adequately addressed; however this request was denied.

But honestly, given the demeanor of those in leadership within DHS, it is obvious that the manner by which a sit-down meeting would have been facilitated would likely have been pointless. DHS bureaucrats have no interest in hearing from concerned parents and they have made this very clear by their attitudes and actions throughout every step of the process.

They have even stated outside of this hearing that this should have been passive legislation that easily slid through, but there is a group of citizens creating some resistance. This further reiterates that they only care about this rule passing and do not care about those who would be impacted.

I am grateful to the committee on Constitution and Ethics for having this hearing today and allowing everyone's voices to be heard. Open government and transparency are the foundation of democracy – something that has been woefully absent throughout this entire process.

While I am here today to oppose rule 1, 2, 4, and 5 of clearinghouse rule 19-079, I will speak specifically to rule 1 and 2.

Per CR-19-079, rule 1 states *Varicella (chicken pox) and meningococcal disease are identified by the department as vaccine-preventable diseases. However, a substantial outbreak of these diseases is not currently defined in ch. DHS 144. The department proposes to amend the definition of a "substantial outbreak" to include Varicella (chicken pox) and meningococcal disease, and to ensure consistency with CDC recommendations.*[2]

I would like to know exactly what DHS is proposing to define as a *"substantial outbreak"* of both chickenpox and meningococcal disease because this information is absent from this rule.

From my research and knowledge of the CDC's *Manual for the Surveillance of Vaccine-Preventable Diseases, "substantial outbreak"* is not a term used by the CDC.[3] This is a term used in Wisconsin DHS 144.02 (12) and exclusive to Wisconsin.[4] The CDC uses the term *"outbreak",* and while it is very easy to assume that these terms are interchangeable, they are not – at least when comparing between what the CDC considers an outbreak and what Wisconsin DHS 144.02 (12) considers a *"substantial outbreak."*

If Wisconsin DHS is looking to ensure consistency with CDC recommendations, and looking to use what the CDC defines as an outbreak to be in line with what DHS 144.02 (12) defines as a *"substantial outbreak",* then they need to be consistent. Because if they are not, then it becomes obvious that they are choosing to use the CDC outbreak definitions only when it suits them – all while claiming they are simply following the CDC's recommendation.

For example – the CDC defines an outbreak of measles as more than 3 cases of measles linked by time and place and confirmed through laboratory testing.[5] But DHS 144.02 (12) considers one case of measles to be a substantial outbreak. Note the difference.

How about Rubella? Again, the CDC considers an outbreak of rubella to be 3 or more cases,[6] which is not aligned with DHS's 144.02 (12)'s definition – which considers one case to be a substantial outbreak.

A pertussis or whooping cough outbreak per the CDC is 2 cases that occur in 2 different households within a community, but the CDC also notes that some states define it as 3 cases.[7] However, DHS 144.02 (12) considers an outbreak of pertussis as 2 cases within a 30-day period. I'm not sure why this is the definition in use, but I can tell you that it is not consistent with the CDC's outbreak definition.

It took me a little bit of time to locate the information on what the CDC considers to be an outbreak of chickenpox because this is absent from the Chickenpox Chapter, Chapter 17, of the Manual for the Surveillance of Vaccine-Preventable Diseases. This is the CDC Manual that DHS is referencing for rule 2, as reason for changing the definition of a substantial mumps outbreak, or I should say outbreak, since, again, *"substantial outbreak"* is not a CDC term. However, I was able to locate this information on the instruction worksheet that the CDC makes available for use by health departments to report chickenpox to the CDC. According to this worksheet, an outbreak of chickenpox is defined as 5 or more epidemiologically-linked cases.[8]

Is this what DHS is planning to use when defining what a *"substantial outbreak"* of chickenpox is and why is this not clearly defined in Rule 1? Or will it be 1 case, 2 cases, or another number? There is no way to know for sure what DHS is planning to use because they are inconsistent with following what the CDC defines as an outbreak to define what Wisconsin DHS 144.02 (12) considers a substantial outbreak.

And while DHS has the right to decide on the number, they should not be claiming to be following the CDC's recommendations for substantial outbreaks when this is not a term used by the CDC.

I would like to know how this administrative rule change be permitted to pass through legislative review when the exact number is not specifically noted?

The same is true for the addition of meningococcal disease to the substantial outbreak list. Again, DHS has failed to provide the legislature with the number of meningococcal cases that will constitute a *"substantial outbreak"* of Meningococcal disease in Wisconsin. Per the CDC's manual entitled *"Guidance for the Evaluation and Public Health Management of Suspected Outbreaks of Meningococcal Disease"*[9] published on September 28, 2019, the CDC considers an outbreak of meningococcal to be 2 or 3 cases of meningococcal disease in an institutional setting. So why can't DHS tell us what number will be used to define a substantial outbreak in

Wisconsin, especially since Rule 1 states that they are updating the administrative code to *ensure consistency with CDC recommendations*?

Additionally, will it be accurately defined to indicate that an outbreak, whether it be 2 or 3 cases, must be confirmed as being of the same meningococcal strain, as there are 13 known meningococcal strains and not all are targeted in the vaccines available for use.

Further, the meningococcal vaccine that DHS is proposing to mandate, Men ACWY vaccine, is only routinely recommended to persons between 11 and 21 years of age. Will DHS be defining what the procedure will be should a substantial outbreak of meningococcal disease occur in children for which this vaccine is not recommended, such as 2nd or 3rd graders?

And will it still be considered a substantial outbreak of meningococcal disease should there be 2 or 3 cases of the disease from a strain not covered by the vaccine?

Why, after over 2 years of meetings and revisions on this rule change, has this not been clearly defined and included in the language of rule 1?

Just so this committee is clear, when a *"substantial outbreak"* of a disease listed under DHS 144.02 (12) occurs, DHS 144.07 (10) states that

> *If a substantial outbreak as defined in DHS 144.02 (12) occurs in a school or day care center, or in the municipality in which a school or day care center is located, the school or day care center shall exclude students who have not received all required immunizations against the disease, including students in all grades who have not had 2 doses of measles vaccine when it is an outbreak of measles that is occurring, when ordered to do so by the department. The exclusion shall last until the student is immunized or until the department determines that the outbreak has subsided.*[10]

I would also like to know why chickenpox has now become such a health threat that DHS feels the need to include it in the substantial outbreak list in Wisconsin. I'm a chickenpox survivor, as I am certain that many in this room are. I was 2 when I had chickenpox and my mother, a retired registered nurse, took me and my 3 sisters to the chickenpox party. I don't remember having it, but my mom said we were on vacation when we came down with it and she just let us run around at the beach all day.

I want this committee to know that while we vaccinate for chickenpox in the United States, this vaccine is not given in many high-income countries.

For example, the chickenpox vaccine is not routinely administered in the United Kingdom and they consider chickenpox a common childhood infection that is usually mild and report complications to be rare.[11]

The UK is not alone. Several European countries do not routinely vaccinate children with the chickenpox vaccine. These countries include Belgium, Bulgaria, Croatia, Denmark, Estonia, France, Ireland, Norway, The Netherlands, Portugal, and more.

Again, when did chickenpox become so serious in Wisconsin to warrant its addition to the substantial outbreak list?

This brings me to rule 2 – The rule change language states the following - *In recent years, mumps outbreaks have occurred in highly-vaccinated populations and in high transmission*

settings, including elementary, middle, and high schools, colleges, and camps. A substantial outbreak of mumps is currently defined as an incidence of the disease exceeding 2% of the unvaccinated population. In 2012, the CDC revised the Manual for the Surveillance of Vaccine-Preventable Diseases, to define a substantial outbreak of mumps as three or more cases linked by time and place. The department proposes to amend the definition of a "substantial outbreak" of mumps to be consistent with the CDC Manual for the Surveillance of Vaccine Preventable Diseases.[12]

Again, this is not accurate. While the Manual for the Surveillance of Vaccine-Preventable Diseases defines an outbreak of mumps as 3 or more cases linked by time and place, they do not use the term *"substantial outbreak"*.[13] And as I have previously mentioned, what the CDC defines as an outbreak is not what is currently being used to define *"substantial outbreak"* for other diseases, including measles, rubella, and pertussis per DHS 144.02 (12).

In the first sentence of this rule change, DHS admits that mumps outbreaks have occurred in highly-vaccinated populations. This is a fact that is evidenced by the numerous reports of mumps outbreaks that have occurred in recent years among fully-vaccinated individuals. The CDC has admitted to the fact that mumps vaccines do fail, and this is supported by Wisconsin DHS's own data which has consistently shown that fully vaccinated individuals are contracting mumps and spreading it to other fully vaccinated individuals.[14] [15] [16] [17] [18]

What is the point to this definition change, except to punitively exclude unvaccinated children from school? It is obvious that in the event of an outbreak, whether an outbreak be defined as 3 or more cases or 2 percent of the unvaccinated population, anyone without natural lifelong immunity as a result of having the actual illness, will be at risk for mumps.

In conclusion, I would respectfully request that this committee vote down rule 1, 2, 4, and 5 of CR 19-079. Specifically, I would like rule 1 voted down because DHS has not stated exactly what number will be used to define a substantial outbreak of chickenpox or meningococcal disease, and because chickenpox is a mild illness that does not need to be added to this list. I would also request that this committee vote down rule 2, as this definition will do nothing to stop the spread of mumps given the fact that mumps outbreaks are directly related to a failing mumps vaccine – not as a result of failure to vaccinate.

Further, given the lack of transparency, the exclusion of moms and dads- the demographic most impacted by this rule change - in any rule change discussions, coupled with the poor conduct shown by DHS bureaucrats towards concerned parents at the July 26th, 2019 hearing, I would respectfully ask that going forward, this committee insist that parents, the primary stakeholder, be given a seat at the table regarding any future revisions to DHS 144.

Thank you for your time, your respect, and for the opportunity to speak.

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[1] State of Wisconsin ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis – CR-19-079 May. 6, 2019

[2] State of Wisconsin RULEMAKING REPORT TO LEGISLATURE CLEARINGHOUSE RULE 19-079 Ch. DHS 144 Basis and Purpose of Proposed Rule Aug. 2017

[3] Centers for Disease Control and Prevention. Manual for the surveillance of vaccine-preventable diseases. Centers for Disease Control and Prevention, Atlanta, GA

[4] State of Wisconsin Administrative Code - Chapter DHS 144 IMMUNIZATION OF STUDENTS
[5] CDC Manual for the Surveillance of Vaccine-Preventable Diseases - Instructions for Completing the Measles Surveillance Worksheet No Date
[6] CDC Manual for the Surveillance of Vaccine-Preventable Diseases - Instructions for Completing the Rubella Surveillance Worksheet No Date
[7] CDC Manual for the surveillance of vaccine-preventable diseases - Instructions for Using the CDC Pertussis Surveillance Worksheet May 2015
[8] CDC Instructions for Completing the Varicella Outbreak Surveillance Reporting Worksheet April 2017
[9] CDC Guidance for the Evaluation and Public Health Management of Suspected Outbreaks of Meningococcal Disease Sept. 28, 2019
[10] State of Wisconsin Administrative Code - Chapter DHS 144 IMMUNIZATION OF STUDENTS
[11] NHS Chickenpox vaccine overview Jan 24, 2019
[12] State of Wisconsin RULEMAKING REPORT TO LEGISLATURE CLEARINGHOUSE RULE 19-079 Ch. DHS 144 Basis and Purpose of Proposed Rule Aug. 2017
[13] Centers for Disease Control and Prevention. Manual for the surveillance of vaccine-preventable diseases - Chapter 9 :Mumps Centers for Disease Control and Prevention, Atlanta, GA
[14] Vaccine-Preventable Diseases Surveillance Summary Wisconsin, 2018 Wisconsin Dept. of Health - P-02321 (April 9, 2019)
[15] Vaccine-Preventable Diseases Surveillance Summary Wisconsin, 2017 Wisconsin Dept. of Health – P-02321 (Dec. 19, 2018)
[16] Bonwitt J, Kawakami V, Wharton A, et al. Notes from the Field: Absence of Asymptomatic Mumps Virus Shedding Among Vaccinated College Students During a Mumps Outbreak — Washington, February–June 2017. *MMWR.* 2017;66:1307-1308.
[17] Donahue M, Schneider A, Ukegbu U, et al. Complications of Mumps During a University Outbreak Among Students Who Had Received 2 Doses of Measles-Mumps-Rubella Vaccine — Iowa, July 2015–May 2016. *MMWR.* 2017;66(14):390-391.
[18] Peltola H, Kulkarni PS, Kapre SV et al. Mumps outbreaks in Canada and the United States: time for new thinking on mumps vaccines. *Clin Infect Dis.* 2007 Aug 15;45(4):459-66

Reference

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
05/06/2019

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
DHS 144

4. Subject
Immunization of Students

5. Fund Sources Affected
☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
N/A

7. Fiscal Effect of Implementing the Rule
☒ No Fiscal Effect ☐ Increase Existing Revenues ☐ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☐ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
The department, through the Division of Public Health, is charged with carrying out a statewide immunization program. Essential to this charge of protecting individuals from vaccine preventable diseases is to identify and immunize those students who are still susceptible to measles, mumps, rubella, polio, hepatitis B, varicella, diphtheria, tetanus, pertussis, and meningococcal disease upon admission to an elementary, middle, junior or senior high school or a child care center, or Haemophilus influenzae b and pneumococcal infection upon admission to a child care center, in order to prevent transmission of these diseases.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The department formed an Advisory Committee consisting of representatives from the Wisconsin Department of Public Instruction, Wisconsin Chapter of the American Academy of Pediatrics, Wisconsin Department of Health Services Medicaid Program, Wisconsin Association of Local Health Departments and Boards, Wisconsin Academy of Family Physicians, Wisconsin Association of School Nurses, Wisconsin Medical Society, and Pharmacy Society of Wisconsin. Proposed rule revision language was drafted based on the recommendations of this committee. All advisory committee meetings were held as open meetings. They were inforemd via email when the proposed rule order was made available to the public.

The department also published a solicitation in the Administrative Register, requesting information and advice from businesses, associations representing businesses, local governmental units, and individuals who may be affected by the proposed rules. All comments received by the department, were used to analyze and determine the economic impact that the rules would have on businesses, individuals, public utility rate payers, local governmental units, and the state's economy as a whole.

The department also sent out a GovD email update informing immunization stakeholders of the proposed rule order and solitication for public comments. Immunization stakeholders include, but are not limited to, school districts, local health

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

departments, tribes, health care providers enrolled in the VFC program, and health care providers and staff who have self selelected to be on the immunization email list serv.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
See 12., above.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
There are no implementation or fiscal impacts on specific businesses, business sectors, public utility rate payers, local governmental units and the state's economy as a whole. There are no implemenation or compliance costs expected to be incurred from this rule change.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
No reasonable alternatives exist to the rulemaking. The current rule is outdated with national immunization guidance given by the Advisory Committee on Immunization Practices (ACIP). The proposed rule is meant to align with current ACIP recommendations.

16. Long Range Implications of Implementing the Rule
Proposed changes will decrease communicable diseases by ensuring children and students are identified and immunized against vaccine preventable diseases.

17. Compare With Approaches Being Used by Federal Government
There are no known federal approaches that address the activities to be regulated by the proposed rules.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Similar to the proposed rule, Illinois, Iowa, Michigan, and Minnesota all require at least one dose of meningococcal conjugate vaccine at either 6th or 7th grade. All states but Michigan require a booster dose either at the appropriate age of 16-18 years or grade 12, as is proposed in the proposed rule.

Similar to the proposed rule, Illinois, Iowa, Michigan, and Minnesota all require Tdap vaccine for students entering 7th grade.

Similar to the proposed rule, Illinois, Iowa, Michigan, and Minnesota all require a health care provider's documentation of varicella disease, instead of parental reporting.

Similar to the proposed rule, Illinois, Iowa, Michigan, and Minnesota refer to the Council of State and Territorial Epidemiologists case definitions and the Centers for Disease Control and Prevention guidance and recommendations in regards to disease outbreak definitions.

Similar to the proposed rule, Illinois, Iowa, Michigan, and Minnesota all have similar reporting requirements of vaccine preventable diseases.

19. Contact Name	20. Contact Phone Number
Stephanie Schauer	608-264-9884

This document can be made available in alternate formats to individuals with disabilities upon request.

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DEPARTMENT OF ADMINISTRATION
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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

Reference 2 & Reference 12

RULEMAKING REPORT TO LEGISLATURE

CLEARINGHOUSE RULE 19-079

Ch. DHS 144

Basis and Purpose of Proposed Rule

The department is required to carry out a statewide immunization program to eliminate mumps, measles, rubella (German measles), diphtheria, pertussis (whooping cough), poliomyelitis and other diseases that the department specifies by rule, and to protect against tetanus. Minimum immunization requirements for entry into Wisconsin schools and child care centers are established in ch. DHS 144. The department proposes to make the following revisions to the rule chapter:

1. Varicella (chicken pox) and meningococcal disease are identified by the department as vaccine-preventable diseases. However, a substantial outbreak of these diseases is not currently defined in ch. DHS 144. The department proposes to amend the definition of a "substantial outbreak" to include Varicella (chicken pox) and meningococcal disease, and to ensure consistency with CDC recommendations.

2. In recent years, mumps outbreaks have occurred in highly-vaccinated populations and in high-transmission settings, including elementary, middle, and high schools, colleges, and camps. A substantial outbreak of mumps is currently defined as an incidence of the disease exceeding 2% of the unvaccinated population. In 2012, the CDC revised the Manual for the Surveillance of Vaccine-Preventable Diseases, to define a substantial outbreak of mumps as three or more cases linked by time and place. The department proposes to amend the definition of a "substantial outbreak" of mumps to be consistent with the CDC Manual for the Surveillance of Vaccine-Preventable Diseases.

3. The department is proposing to move the current recommendation for Tdap from 6th grade to 7th grade to ensure that children are old enough to meet this age minimum (some children are 10 years old when starting 6th grade). This will reduce the number of children who enter 6th grade and are not vaccinated for Tdap, as some clinicians choose to wait until they are 11 years of age to vaccinate.

4. Neisseria meningitidis is a vaccine-preventable disease and a leading cause of bacterial meningitis and sepsis in the United States. The meningococcal vaccine is recommended by the Wisconsin Chapter of the American Academy of Pediatrics and the Wisconsin Academy of Family Physicians to reduce the incidence of bacterial meningitis and sepsis. Since 2005, the CDC Advisory Committee on Immunization Practices has recommended that the vaccine be administered at the 11-12 year old health care visit, along with other routine vaccinations such as Tdap. The department proposes to add the meningococcal vaccine to the list of vaccines required for students entering the 7th grade. This provision will ease the burden on families, providers, and schools by ensuring that both meningococcal and Tdap vaccines are receivedat the same visit and the same grade level. The department also proposes a booster dose for students entering 12th grade which is in accordance with ACIP recommendations. This will help to ensure students are fully vaccinated prior to leaving school.

5. Under the current rule, a parent or adult student may report a history of varicella disease as an acceptable exception to varicella vaccination. Recent studies have demonstrated that there is a high incidence of unvaccinated children who report a positive history of varicella that are not immune. The department proposes to allow the exception only when a history of varicella disease has been reported by a health care provider.

6. Chapter DHS 144 currently includes provisions relating to the 2008-2009 phase-in of Tdap and Varicella Vaccine coverage. The department proposes to eliminate these provisions because phase-ins are completed.

7. Curently, schools must only report compliance with program requirements and key indicators of vaccine-preventable disease and outbreaks to local health departments. The department proposes to add the state as a recipient of these reports which would be congruent with the current day care reporting requirements. This will improve the availability of important information and improve the department's reporting to the legislature, under s. 252.04 (11), Stats..

8. Chapter DHS 144 has not been substantially revised since 1981. The department proposes to update, correct, or clarify any outdated provisions in order to reflect current definitions, standards, and best practices.

Manual for the Surveillance of Vaccine-Preventable Diseases

Available on the internet at: www.cdc.gov/vaccines/pubs/surv-manual/

Suggested citation

Centers for Disease Control and Prevention. Manual for the surveillance of vaccine-preventable diseases. Centers for Disease Control and Prevention, Atlanta, GA.

This manual is not intended to be a therapeutic guide; therefore, while dosages of antimicrobials and immunobiologics are discussed in the context of prophylaxis and treatment for case-patients and contacts, physicians and other health-care professionals should review the package inserts prepared by the manufacturers to determine appropriate dosages.

This manual is designed to provide general guidance regarding surveillance activities for vaccine-preventable diseases. Because recommendations for use of vaccines may change, readers should consult their local or state health departments or CDC's Vaccines website at www.cdc.gov/vaccines/.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Public Health Service or the U.S. Department of Health and Human Services.

Acknowledgments

This manual was prepared by the Centers for Disease Control and Prevention (CDC), National Center for Immunization and Respiratory Diseases.

We thank colleagues in the National Center for Immunization and Respiratory Diseases, CDC, and others who offered advice, made specific recommendations on format and content, reviewed drafts, or assisted in other ways in the preparation of this manual.

We particularly wish to acknowledge the valuable assistance of the following:

Cathy Hogan
Curt Wommack

Table of Contents

Introduction

This manual was first developed in 1996 to provide general guidance to state and local health department personnel who are involved in surveillance activities for vaccine-preventable diseases. This manual answers commonly asked questions regarding the surveillance and reporting of vaccine-preventable diseases and provides information on enhancing existing surveillance systems.

Several reference documents, tables, and worksheets have been included in this manual for your convenience and information. The worksheets in this manual are in the public domain and may be copied and distributed for use in public health surveillance activities.

Please forward any suggestions and comments regarding this manual to:

Surveillance Officer
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS-A27
Atlanta, GA 30333
Phone: 404-639-8741

Acronyms

ACIP	Advisory Committee on Immunization Practices
APHL	Association of Public Health Laboratories
CDC	Centers for Disease Control and Prevention
CF	Complement fixation
CMV	Cytomegalovirus
CPHA	Commission on Professional and Hospital Activities
CRS	Congenital rubella syndrome
CSF	Cerebrospinal fluid
CSTE	Council of State and Territorial Epidemiologists
DAT	Diphtheria antitoxin
DFA	Direct fluorescent antibody
DHHS	Department of Health and Human Services
DRSP	Drug-resistant *Streptococcus pneumoniae*
DT	Diphtheria and tetanus toxoids
DTP	Diphtheria and tetanus toxoids and whole-cell pertussis vaccine
DTaP	Diphtheria and tetanus toxoids and acellular pertussis vaccine
EBV	Epstein-Barr virus
EIA	Enzyme-immunoassay
ELISA	Enzyme-linked immunosorbent assay
ELR	Electronic laboratory reporting
FAMA	Fluorescent antibody to membrane antigen
FDA	Food and Drug Administration
HA	Hemagglutinin
HAV	Hepatitis A virus
HBcAg	Hepatitis B core antigen
HBIG	Hepatitis B immune globulin
HBeAg	Hepatitis B e antigen
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HDV	Hepatitis D virus
HI	Hemagglutination inhibition
Hi	*Haemophilus influenzae*
Hib	*Haemophilus influenzae* type b
HMO	Health maintenance organization
IFA	Indirect fluorescent antibody
IG	Immune globulin
IOM	Institute of Medicine

IPV	Inactivated poliovirus vaccine
LA	Latex agglutination
MMR	Measles-mumps-rubella vaccine
MMWR	Morbidity and Mortality Weekly Report
MR	Measles-rubella vaccine
MSAEFI	Monitoring System for Adverse Events Following Immunization
NA	Neuraminidase
NCCLS	National Committee for Clinical Laboratory Standards
NCHS	National Center for Health Statistics
NCIRD	National Center for Immunization and Respiratory Diseases
NCRSR	National Congenital Rubella Syndrome Registry
NCVIA	National Childhood Vaccine Injury Act of 1986
NEDSS	National Electronic Disease Surveillance System
NETSS	National Electronic Telecommunications System for Surveillance
NHANES	National Health and Nutrition Examination Survey
NHIS	National Health Interview Survey
NNDSS	National Notifiable Diseases Surveillance System
NVICP	National Vaccine Injury Compensation Program
OPV	Oral poliovirus vaccine
P&I	Pneumonia and influenza
PCR	Polymerase chain reaction
PHA	Passive hemagglutination
RASH	Rapid Surveillance Helper
RET	Reportable Events Table
RIA	Radioimmunoassay
SIDS	Sudden Infant Death Syndrome
SHC	State health coordinator
SPSS	Supplementary Pertussis Surveillance System
TIG	Tetanus immune globulin
TT	Tetanus toxoid
VAE	Vaccine adverse event
VAERS	Vaccine Adverse Event Reporting System
VAPP	Vaccine-associated paralytic poliomyelitis
VHSP	Viral Hepatitis Surveillance Program
VPD	Vaccine-preventable disease
VZIG	Varicella-zoster immune globulin
VZV	Varicella-zoster virus
WBC	White blood-cell count
WHO	World Health Organization

Definitions of Terms

Attenuated virus	A strain of virus whose virulence has been lowered by physical or chemical processes or by repeated passage through the cells of another species.
Breakthrough	The appearance of clinical disease in an individual who has previously been vaccinated against the agent causing the disease.
Clinically compatible case	A case featuring a clinical syndrome generally compatible with the disease, but for which specific clinical criteria may not have been met unless they are noted in the case classification.
Confirmed case	A case that is classified as confirmed for reporting purposes.
Contraindication	A characteristic or attribute of an individual that may be temporary or permanent that prohibits the administration of a drug, vaccine, or other therapeutic intervention.
Encephalitis	An inflammatory condition of brain tissue caused by a variety of infectious and non-infectious diseases. In varicella, influenza, and measles, this is sometimes referred to as post-infectious encephalitis.
Epidemiologically linked case	A case in which the patient has or has had contact with one or more persons who have or have had the disease, and transmission of the agent by the usual modes of transmission is plausible. In general, a case may be considered epidemiologically linked to a laboratory-confirmed case if at least one case in the chain of transmission is laboratory confirmed.
Erythema	Redness (or inflammation) of the skin or mucous membranes that is the result of dilation and congestion of superficial capillaries.
Exanthem	A skin eruption or rash that may have specific diagnostic features of an infectious disease. Chickenpox, measles, roseola infantum, rubella, and smallpox are usually characterized by a particular type of exanthem.
Immunocompromised	A state in which an individual has either a decreased or absent ability to mount an antibody and/or cell-mediated immune response to infectious agents.
Incubation period	The period of time from exposure to an infecting agent to the onset of symptoms of disease.
Laboratory confirmed case	A case that is confirmed by one or more of the laboratory methods listed in the case definition under "Laboratory criteria." Although other laboratory methods may be used in clinical diagnosis, only those listed are accepted for laboratory confirmation for reporting purposes.
Line listing	A tool used during epidemiologic investigations to allow investigators to record case information and to review and follow up case reports or conduct data analysis.
Meets the clinical case definition	Meets precisely the clinical case definition. Although in clinical practice the diagnosis may be made with the use of other criteria, for reporting purposes the stated criteria must be met.
Primary vaccine failure	The absence of seroconversion after vaccination. This is manifest as the occurrence of disease in a vaccinated individual in which the disease occurrence closely resembles that found in natural infection with wild-type virus, i.e., more commonly moderate or severe disease.
Probable case	A case that is classified as probable for reporting purposes.
Secondary vaccine failure	Loss of immunity acquired after vaccination.
Sentinel event	A preventable disease, disability, or untimely death that serves as a warning signal of a possible underlying problem.

Sentinel surveillance	Activities focused on monitoring key health indicators in the general population or in special populations. The primary intent is to obtain timely information needed for public health or medical action in a relatively inexpensive manner rather than to derive precise estimates of prevalence or incidence in the general population.
Supportive laboratory results	Specified laboratory results consistent with the diagnosis but not meeting the criteria for laboratory confirmation.
Susceptible	Being sensitive to effects of an infectious disease, allergen, or other pathogenic agent; lacking immunity or resistance.
Thermolability	A characteristic of vaccines that cause them to lose potency when stored or held at temperatures other than that recommended by the manufacturer.
Vaccine coverage	The proportion or percentage of persons that have received a vaccine among all individuals in a particular group who are eligible to receive the vaccine.
Vaccine effectiveness	The ability of a vaccine to provide protection against disease when used under field conditions (e.g., use of the vaccine in routine practice).
Vaccine efficacy	The ability of a vaccine to provide protection against disease under ideal circumstances (e.g., during a clinical trial).

Unofficial Text (See Printed Volume). Current through date and Register shown on Title Page.

Reference 4 & Reference 10 (see p 22)

Chapter DHS 144

IMMUNIZATION OF STUDENTS

Note: Chapter H 44 as it existed on June 30, 1981, was repealed and a new chapter HSS 144 was created, effective July 1, 1981. Chapter HSS 144 was renumbered chapter HFS 144 under s. 13.93 (2m) (b) 1., Stats., and corrections made under s. 13.93 (2m) (b) 1., 6. and 7., Stats., Register, June, 1997, No. 498. **Chapter HFS 144 was renumbered chapter DHS 144 under s. 13.92 (4) (b) 1., Stats., and corrections made under s. 13.92 (4) (b) 7., Stats., Register January 2009 No. 637.**

DHS 144.01 Introduction. (1) PURPOSE AND AUTHORITY. The purpose of immunization is to prevent disease and suffering and any permanent disability resulting from the disease. These rules implement s. 252.04, Stats., which as public policy seeks to identify and immunize those students who are still susceptible to measles, mumps, rubella, polio, hepatitis B, varicella, diphtheria, tetanus and pertussis upon admission to an elementary, middle, junior or senior high school or a day care center, or Haemophilus influenzae b and pneumococcal infection upon admission to a day care center, in order to prevent transmission of these diseases.

(2) RELATIONSHIP TO INFANT AND PRESCHOOL IMMUNIZATION SCHEDULES. The emphasis placed in this chapter on meeting minimum immunization requirements upon entry to Wisconsin schools at any grade level or to a day care center complements efforts by the department to promote early immunization of infants and preschoolers according to accepted immunization schedules. Children immunized according to accepted immunization schedules will exceed the minimum requirements set forth herein for all ages and grades.

History: Cr. Register, June, 1981, No. 306, eff. 7-1-81; am. (1), Register, June, 1988, No. 390, eff. 7-1-88; correction in (1) made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476; am. (1), Register, June, 1997, No. 498, eff. 7-1-97; am. (1), Register, May, 2001, No. 545, eff. 6-1-01; CR 07-077: am. (1) Register February 2008 No. 626, eff. 3-1-08.

DHS 144.02 Definitions. (1) "Day care center" has the meaning prescribed in s. 48.65, Stats., and includes nursery schools that fit that definition.

(2) "Department" means the Wisconsin department of health services unless otherwise specified.

(3) "DTP/DTaP/DT/Td/Tdap" means any combination of diphtheria, tetanus, and pertussis vaccine; diphtheria, tetanus and acellular pertussis vaccine; pediatric type diphtheria and tetanus vaccine; adult type tetanus and diphtheria vaccine; or tetanus, reduced diphtheria and acellular pertussis vaccine.

(3g) "Hib" means Haemophilus influenzae type b vaccine.

(3m) "Hep B" means hepatitis B vaccine.

(3r) "Immunization" means the process of inducing immunity artificially by administering an immunobiologic.

(4) "Local health department" means any agency specified in s. 250.01 (4), Stats.

(4m) "MMR" means measles, mumps and rubella vaccine administered in combination or as separate vaccines.

(5) "Municipality" means any town, village, city or county.

(6) "Parent" means the parent, parents, guardian or legal custodian of any minor student.

(6m) "PCV" means pneumococcal conjugate vaccine.

(7) "Physician" means an individual possessing the degree of doctor of medicine or doctor of osteopathy or an equivalent degree as determined by the medical examining board under s. 448.05 (2), Stats., and holding a license granted by the medical examining board under s. 448.06, Stats.

(8) "School" means any public or private elementary, middle, junior or senior high school, which provides educational instruction to students in any grade kindergarten through 12, or in an ungraded educational setting, or to preschool children enrolled in early childhood programs.

(9) "School day" in reference to schools has the meaning prescribed in s. 115.01 (10), Stats. A school day for a day care center is any day that the center is open and caring for children.

(10) "Student" means any individual enrolled in a school or day care center or attending a school or day care center.

(11) "Subsided" in reference to substantial outbreak means passage of 2 incubation periods for the disease causing the outbreak without additional cases unless a shorter period of time is judged adequate by the department.

(12) "Substantial outbreak" means an occurrence of a vaccine-preventable disease covered by s. 252.04, Stats., in a given school, day care center or municipality with an incidence exceeding one of the following:

(a) For substantial outbreaks in a municipality, twice the incidence of that disease in the nation as a whole.

(b) For substantial outbreaks in a school or day care center population, the following absolute limits:

1. Measles, one case.
2. Mumps, 2% of the unvaccinated population.
3. Rubella, one case.
4. Polio, one case.
5. Pertussis, 2 cases in a 30-day period.
6. Diphtheria, one case.
7. Haemophilus influenzae b, one case in a day care center population.

(13) "Vaccine provider" means a health care facility, as defined in s. 155.01 (6), Stats., which administers vaccines, or a local health department or a physician's office which administers vaccines.

(13m) "Var" means varicella vaccine. Varicella is commonly known as chickenpox.

(14) "Written evidence of immunization" means a paper or an electronic record of at least the month and year that each required dose of vaccine was administered or the results of a laboratory test indicating immunity to the disease. Students who have not previously attended a Wisconsin school must provide the month, day and year for each required dose of vaccine.

History: Cr. Register, June, 1981, No. 306, eff. 7-1-81; r. and recr. (12) (b), Register, June, 1988, No. 390, eff. 7-1-88; correction in (12) made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476; am. (3), cr. (3g), (3m), (3r). (4m) and (13), r. and recr. (4), (6), (7) and (12), renum. (13) to be (14), Register, June, 1997, No. 498, eff. 7-1-97; cr. (13m), Register, May, 2001, No. 545, eff. 6-1-01; CR 07-077: am. (3) and (14), cr. (6m) Register February 2008 No. 626, eff. 3-1-08; **correction in (2) made under s. 13.92 (4) (b) 6., Stats., Register January 2009 No. 637.**

DHS 144.03 Minimum immunization requirements. (1) INDIVIDUALS INCLUDED. The minimum immunization requirements authorized by s. 252.04, Stats., apply to any student

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admitted to a Wisconsin elementary, middle, junior or senior high school or to a Wisconsin day care center.

(2) REQUIREMENTS FOR THE 2008–09 SCHOOL YEAR AND FOR SCHOOL YEARS FOLLOWING THE 2008–09 SCHOOL YEAR. (a) Table DHS 144.03–A as qualified by pars. (b) to (g) lists the number of doses of each required vaccine that each student in the 2008–09 school year and following school years shall have received since birth for the age or grade of the student. These comprise the minimum basic and booster immunizations required under s. 252.04 (2), Stats. They do not, however, represent all the recommended immunizations for those individuals who begin immunizations in infancy and follow currently accepted immunization schedules.

(b) Immunization against measles, mumps and rubella shall have been received on or after the date of the first birthday. A dose received 4 days or less before the first birthday is acceptable.

Table 144.03–A
Required Immunizations for the 2008–09 School Year and the Following School Years

Age/Grade	Required Immunizations (Number of Doses)							
5 months through 15 months	2 DTP/DTaP/DT		2 Polio			2 Hep B	2 Hib	2 PCV[5]
16 months through 23 months	3 DTP/DTaP/DT		2 Polio	1 MMR		2 Hep B	3 Hib[4]	3 PCV[5]
2 years through 4 years	4 DTP/DTaP/DT		3 Polio	1 MMR	1 Var	3 Hep B	3 Hib[4]	3 PCV[5]
Kindergarten through grade 5	4 DTP/DTaP/DT/Td[1]		4 Polio	2 MMR	2 Var[3]	3 Hep B		
Grade 6 through grade 8	4 DTP/DTaP/DT/Td	1 Tdap[2]	4 Polio	2 MMR	2 Var[3]	3 Hep B		
Grade 9 through grade 12	4 DTP/DTaP/DT/Td	1 Tdap[2]	4 Polio	2 MMR	2 Var[3]	3 Hep B		

[1] For kindergarten only, at least one dose to be received after 4 years of age unless medically contraindicated. A dose received 4 days or less before the fourth birthday is acceptable.

[2] A single dose, booster immunization against tetanus, diphtheria and pertussis is required on entrance to grades 6, 9 and 12, beginning with the 2008–09 school year. See sub. (3) for phase–in of other grades.

[3] Two doses of Var vaccine are required on entrance to grades K, 6 and 12, beginning with the 2008–09 school year. See sub. (3m) for phase–in of other grades.

[4] At least one dose to be received after 12 months of age unless medically contraindicated. A dose received 4 days or less before the first birthday is acceptable.

[5] Required on entrance to a day care center, beginning with the 2008–09 school year.

(c) Exceptions may be made in requirements for the fourth dose of DTP/DT/DTaP/Td vaccine and the fourth dose of polio vaccine. Students who receive the third dose of either of these vaccines after their fourth birthday are not required to receive a fourth dose of that vaccine. A dose received 4 days or less before the 4th birthday is acceptable.

(d) For students in ungraded schools or students age 5 or older in day care centers, the immunization requirements are those for the grade which would normally correspond to the individual's age. Immunization against measles, mumps and rubella is also required for all students age 19 or older.

(e) Exceptions may be made in requirements for Hib vaccine. Students who began the Hib series at 12 to 14 months are only required to receive 2 doses at least 2 months apart. Students who received one dose of Hib at 15 months of age or after are not required to obtain additional doses. A dose received 4 days or less before 15 months of age is acceptable.

(f) Exceptions may be made in requirements for Var vaccine. Students who have a reliable history of varicella disease are not required to receive Var vaccine. A parent of a minor student or an adult student may indicate a reliable history of varicella by signing a statement that the student has had varicella disease.

(g) Exceptions may be made in requirements for the third dose of Hep B vaccine. Students who receive two doses of a licensed two–dose formulation of Hep B vaccine are not required to receive a third dose of Hep B vaccine.

(h) Exceptions may be made in requirements for PCV. Students who begin the PCV series at 12 to 23 months of age are only required to receive 2 doses at least 2 months apart. Students who receive their first dose of PCV at 24 months of age or after are not required to obtain additional doses. A dose received 4 days or less before 24 months of age is acceptable.

(i) Exceptions may be made in requirements for Tdap vaccine. Students who received a dose of tetanus or diphtheria containing vaccine within 5 years of entering a grade for which Tdap is required are not required to receive Tdap vaccine.

(3) TDAP VACCINE COVERAGE PHASE–IN. (a) Beginning with the 2008–09 school year, students entering grades 6, 9 and 12 shall have received Tdap vaccine in addition to the other required vaccines listed in Table DHS 144.03–A as qualified by sub. (2) (b) to (i).

(b) For the 2009–10 school year, the requirements for Tdap vaccine listed in par. (a) that apply to students in grades 6, 9 and 12 shall apply to students in grades 6, 7, 9, 10 and 12; and to students in grades 6 through 12 in 2010–11 and thereafter.

(3m) VAR VACCINE COVERAGE PHASE–IN. (a) Beginning with the 2008–09 school year, students entering grades K, 6 and 12 shall have received two doses of Var vaccine in addition to the other required vaccines listed in Table DHS 144.03–A as qualified by sub. (2) (b) to (i).

(b) For the 2009–10 school year, the requirements for two doses of Var vaccine listed in par. (a) that apply to students in

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grades K, 6 and 12 shall apply to students in grades K, 1, 6, 7 and 12; to students in grades K through 2, 6 through 8 and 12 in 2010–11; to students in grades K through 3, 6 through 9 and 12 in 2011–12; to students in grades K through 4, 6 through 10 and 12 in 2012–13; and to students in grades K through 12 in 2013–14 and thereafter.

(4) FIRST DEADLINE. Within 30 school days after having been admitted to a school or day care center, each student who has not filed a waiver form shall submit written evidence of having completed at least the first dose of each vaccine required for that student's age or grade, as outlined in Table DHS 144.03–A.

(5) SECOND DEADLINE. Within 90 school days after having been admitted to a school or day care center, each student who has not filed a waiver form shall submit written evidence of having received the second dose of each vaccine required for that student's age or grade, as outlined in Table DHS 144.03–A.

(6) FINAL DEADLINE. Within 30 school days after having been admitted to a school or day care center for the following school year, each student who has not filed a waiver form shall submit written evidence of having received the third and, if required, the fourth dose of both DTP/DTaP/DT/Td and polio vaccines and the final dose of Hep B in grades required under sub. (3) and, for students in day care centers, the final dose of Hib vaccine, if a dose has not been received at or after 15 months of age.

(7) RECORDS OF VACCINATION. Any person who immunizes a student under s. 252.04, Stats., shall maintain records identifying the manufacturer and lot number of the vaccine used, the date of immunization and the name and title of the person who immunized the student.

(10) RELEASE OF IMMUNIZATION INFORMATION. (a) *Between vaccine providers and schools or day care centers.* Vaccine providers shall disclose a student's immunization information, including the student's name, date of birth and gender and the day, month, year and name of vaccine administered, to a school or day care center upon written or verbal request from the school or day care center. Written or verbal permission from a student or parent is not required to release this information to a school or day care center.

(b) *Among vaccine providers.* Immunization information, including the student's name, date of birth and gender and the day, month, year and name of vaccine administered, shall be provided by one vaccine provider to another without written or verbal permission from the student or the parent.

History: Cr. Register, June, 1981, No. 306, eff. 7–1–81; r. and recr. (2) and (3), am. (4) to (6), Register, June, 1988, No. 390, eff. 7–1–88; am. (2) (a) to (d), (3) (a) and (b), r. (2) (e), Register, January, 1989, No. 397, eff. 2–1–89; am. (2) (a), (4) and (5), r. and recr. (3), tables 144.03–A and B, Register, July, 1990, No. 415, eff. 8–1–90; corrections made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476; r. and recr. (2) (a), Table 144.03–A and (3), am. (2) (c) and (4) to (7), cr. (2) (e) and (10), r. Table 144.03–B, Register, June, 1997, No. 498, eff. 7–1–97; r. and recr. (2) (a) and Table 144.03–A, cr. (2) (f), (g) and (3m), am. (3) (a) and (6), Register, May, 2001, No. 545, eff. 6–1–01; CR 03–033: am. (2) (b), (c), (e) and Table 144.03–A Register December 2003 No. 576, eff. 1–1–04; CR 07–077: r. and recr. (2) (a), (f), (3), (3m) and Table–A, cr. (2) (h) and (i), am. (10) (a) and (b) Register February 2008 No. 626, eff. 3–1–08.

DHS 144.04 Waiver for health reasons. Upon certification by a licensed physician that an immunization required under s. 252.04, Stats., is or may be harmful to the health of a student, the requirements for that immunization shall be waived by the department. Written evidence of any required immunization which the student has previously received shall be submitted to the school or day care center with the waiver form.

History: Cr. Register, June, 1981, No. 306, eff. 7–1–81; correction made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476.

DHS 144.05 Waiver for reason of religious or personal conviction. Immunization requirements under s. 252.04, Stats., shall be waived by the department upon presentation of a signed statement by the parent of a minor student or by the adult student which declares an objection to immunization on religious or personal conviction grounds. Written evidence of any required immunization which the student has previously received shall be submitted to the school or day care center with the waiver form.

History: Cr. Register, June, 1981, No. 306, eff. 7–1–81; correction made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476; am. Register, June, 1997, No. 498, eff. 7–1–97.

DHS 144.06 Responsibilities of parents and adult students. The parent of any minor student or the student, if an adult, shall secure the immunizations required under s. 252.04, Stats., from available health care sources such as physicians' offices, hospitals or local health departments, or shall submit the waiver form.

History: Cr. Register, June, 1981, No. 306, eff. 7–1–81; correction made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476; am. Register, June, 1997, No. 498, eff. 7–1–97.

DHS 144.07 Responsibilities of schools and day care centers. (1) The responsibilities of schools under these rules shall be those of the local school board and the school administrator. The licensee for each day care center shall be responsible for compliance with these rules. The school or day care center shall assure compliance with s. 252.04 (2), Stats.

(1m) By the 15th school day after a child or adult is admitted to a school or day care center and again by the 25th school day after a child or adult is admitted to a school or day care center, the school or day care center shall notify the adult student or the parent of any minor student who has not submitted either written evidence of immunization or a waiver form. Notification shall include instructions for complying with the requirements of s. 252.04 (2), Stats., including a list of missing immunizations, the availability of waivers for reasons of health, religion or personal conviction, and an explanation of the penalty for noncompliance.

(2) For any student who has received the first dose of each immunization required for that student's age or grade under s. DHS 144.03, but who has not received all of the required doses, the school shall obtain written evidence that the student has received the required subsequent doses of immunization as they are administered, but no later than the deadlines described in s. DHS 144.03.

(3) If any minor student for whom a waiver form is not filed fails to comply with the immunization requirements described in s. DHS 144.03 by the date of admission to the school or day care center, the school or day care center shall, within 60 school days of that failure to comply, notify the district attorney in writing, with the notice to include the student's name and the name and address of the student's parent, and request the district attorney to seek a court order under s. 48.13 (13), Stats. The school or day care center shall keep the district attorney apprised of the subsequent compliance of a student initially reported to the district attorney.

(4) (a) The school shall report to the local health department and the day care center shall report to both the local health department and the department:

1. The degree of compliance with s. 252.04, Stats., and this chapter by students in that school or day care center.

2. The name and immunization history of any incompletely immunized student, including those students with waivers and those students in the process of being immunized.

(b) These reports shall be in a format prescribed by the department and shall be made by schools within 40 school days after the beginning of the term and by day care centers at intervals prescribed by the department. Updated reports shall be filed by the school on students who are in the process of being immunized. These updated reports shall be filed within 10 school days after the deadlines listed in s. DHS 144.03.

(5) The school and the day care center shall maintain on file the immunization history for each student and any waiver form submitted. Immunization histories shall be updated with information supplied by the local health department, parents or private physicians.

Unofficial Text (See Printed Volume). Current through date and Register shown on Title Page.

(6) The school or day care center shall maintain a current roster listing the name and immunization history of each student who does not meet all immunization requirements for that student's grade or age.

(7) The immunization record of any new student who transfers from one school or day care center to another shall be forwarded to the new school or day care center within 10 school days of the request for record transfer. The records of a day care student shall be transferred to a school if requested by either the admitting school or the parent.

(8) All suspected cases of diseases covered by s. 252.04 (2), Stats., or this chapter which occur among students or staff shall be reported immediately by telephone to the local health department.

(9) If one of the diseases covered by s. 252.04 (2), Stats., or this chapter occurs in a student or staff member, the school or day care center shall assist the local health department and the department in immediately identifying any unimmunized students, notifying their parents of the possible exposure and facilitating the disease control activities.

(10) If a substantial outbreak as defined in s. DHS 144.02 (12) occurs in a school or day care center, or in the municipality in which a school or day care center is located, the school or day care center shall exclude students who have not received all required immunizations against the disease, including students in all grades who have not had 2 doses of measles vaccine when it is an outbreak of measles that is occurring, when ordered to do so by the department. The exclusion shall last until the student is immunized or until the department determines that the outbreak has subsided.

History: Cr. Register, June, 1981, No. 306, eff. 7–1–81; am. (10), Register, July, 1990, No. 415, eff. 8–1–90; corrections made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476; renum. (intro.) and (1) to be (1) and (1m) and am. (1m), am. (3), (4) (intro.), (a), (5) and (7) to (9), Register, June, 1997, No. 498, eff. 7–1–97.

DHS 144.08 Responsibilities of local health departments. (1) Each local health department shall make available the immunizations required under s. 252.04 (2), Stats., insofar as the vaccine is available without charge from the department under ch. DHS 146. Vaccines made available free from the department under ch. DHS 146 shall be administered without charge for the cost of the biologic. By mutual agreement, responsibility for making the needed immunizations available may be transferred from the local health department to a school or day care center.

(2) By November 15 of each year, each local health department shall report to the department statistical information concerning the degree of compliance with s. 252.04, Stats., of students within its service area. These reports shall be on a form prescribed by the department.

(3) The local health department shall assist the department in informing schools and day care centers of the provisions of s. 252.04, Stats., and this chapter.

History: Cr. Register, June, 1981, No. 306, eff. 7–1–81; corrections made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476; am. Register, June, 1997, No. 498, eff. 7–1–97; **corrections in (1) made under s. 13.92 (4) (b) 7., Stats., Register January 2009 No. 637.**

DHS 144.09 Responsibilities of the department. (1) (a) The department, in cooperation with local boards of health and health officers, local school boards and school and day care center administrators and other agencies, as appropriate, shall provide guidance to parents, physicians, schools and day care centers and local health departments in understanding the minimum immunization requirements under s. 252.04, Stats., and this chapter, the reasons behind their establishment and the process for implementing them.

(b) The department shall undertake a public education campaign to inform parents of students about requirements and rights under s. 252.04, Stats., and this chapter.

(c) The department shall prepare the reporting and waiver forms required under this chapter, and shall make copies of those forms available without charge.

Note: For copies of required reporting and waiver forms, write Immunization Program, Division of Health, P.O. Box 309, Madison, WI 53707–0309.

(d) The department may temporarily suspend an immunization requirement if the department determines that the supply of a necessary vaccine is inadequate.

(2) The department shall maintain a surveillance system designed to detect occurrences of vaccine–preventable diseases listed in s. 252.04 (2), Stats., and this chapter and shall investigate outbreaks of these diseases to confirm the diagnosis, determine the source and probable pattern of spread of the infection and guide implementation of appropriate control measures.

History: Cr. Register, June, 1981, No. 306, eff. 7–1–81; corrections made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476; r. and recr. Register, June, 1997, No. 498, eff. 7–1–97; CR 07–077: cr. (1) (d) Register February 2008 No. 626, eff. 3–1–08.

Instructions for Completing the Measles Surveillance Worksheet

General

- If the month and year for any date is known but the exact day is unknown, enter a 15 for the day (i.e. the middle of the month).
- While "unknown" is an option for many questions, please make every effort to obtain the appropriate information.
- If information is obtained after the record has been submitted to the Centers for Disease Control and Prevention (CDC), please update the NETSS records with the new information and resend the record during the next scheduled transmission.
- If copies of the paper form are sent to CDC, either fold back the information above the dotted line or cut it off after photocopying and before sending the rest of the information to CDC to preserve confidentiality.

Zip Code: Requested (but not required) for vaccine-preventable diseases. Enter a 5-digit zip code.

Birth Date: If known, enter the birth date. If unknown or before the year 1900, leave blank and enter the age and age type.

Age and Age Type: If birth date is unknown and age is known, enter age of patient at rash onset in number of years, months, weeks, or days as indicated by the age type codes.

Event Date and Event Type: Enter the earliest known date associated with the incidence of the disease. The event type describes the date entered in the event date field. Types are listed in order of preference. For measles, please enter rash onset date.

Outbreak Associated: Enter 1 if the case is outbreak associated and the state does not assign numerical values to outbreaks; if the state assigns numerical values to outbreaks, enter the assigned value; if the case is known to be not associated with an outbreak, enter 0. If unknown, enter 999.

Reported: This field is used in various ways, such as to enter the date reported to the state, local or other health department. Check with the State Epidemiologist to determine what guidelines apply in your state.

Imported: Indicate where the patient acquired measles. This is a required field for measles reports.

Indigenous—In state; any case that cannot be proven to be imported

International—Out of U.S.; international importation from another country; onset of rash is within 18 days of entering the United States

Out of state—importation from another state; documentation that the person either had face-to-face contact with a case of measles outside the state or was out of the state for the entire period when he or she might have become infected (7–18 days before rash onset)

Complications

Death: If patient died from measles, verification with the physician is recommended.

Laboratory

IgG Result: This result is based on the interpretation of results from paired serum specimens. The criterion for positivity is a four-fold rise in specimen antibody titer between acute and convalescent phase serum specimens.

Epidemiologic Information

Date First Reported to a Health Department: Date reported is considered the earliest date the case was initially reported to a health department, either local, district, or state level health department.

Outbreak Related: An outbreak is defined as >3 cases (with at least one laboratory confirmed case) clustered in space and time.

Source of Exposure for Current Case: A source case must be either a confirmed or probable case and have had face-to-face contact with a subsequent case. Exposure must have occurred 7 to 18 days before rash onset of the subsequent case, and between 4 days before rash onset and 7 days after rash of the source case. Enter state ID if source was an in-state case (imported entry on core screen = 1), enter country name if source was out of USA (imported entry on core screen = 2), enter state name if source was out of state (imported entry on core screen =3).

Epi-Linked: An epi-linked case is either a source case or same generation case. Epi-linkage is characterized by direct face-to-face contact. For same generation cases that are epi-linked, a common exposure is likely.

Instructions for Completing the Rubella Surveillance Worksheet

General

- If the month and year for any date are known but the exact day is unknown, enter a 15 for the day (i.e. the middle of the month).
- While "unknown" is an option for many questions, please make every effort to obtain the appropriate information.
- If information is obtained after the record has been submitted to the Centers for Disease Control and Prevention (CDC), please update the NETSS record with the new information and resend the record during the next scheduled transmission.
- If copies of the paper form are sent to CDC, either fold back the information above the dotted line or cut it off after photocopying and before sending the rest of the information to CDC to preserve confidentiality.

Zip Code: Requested (but not required) for vaccine-preventable diseases. Enter a 5-digit zip code.

Birth Date: If known, enter the birth date. If unknown or before the year 1900, leave blank and enter the age and age type.

Age and Age Type: If birth date is unknown and age is known, enter age of patient at rash onset in number of years, months, weeks, or days as indicated by the age type codes.

Event Date and Event Type: Enter the earliest known date associated with the incidence of the disease. The event type describes the date entered in event date. The event types are listed in order of preference.

Outbreak Associated: Enter 1 if the case is outbreak associated and the state does not assign numerical values to outbreaks; if the state assigns numerical values to outbreaks, enter the assigned value; if the case is known to be not associated with an outbreak, enter 0. If unknown, enter 999.

Reported: This field is used in various ways, such as to enter the date reported to the state, a local or other health department. Check with the State Epidemiologist to determine what guidelines apply in your state.

Imported: Indicate where the patient acquired rubella. This is a required field for rubella reports.

Indigenous—In state; any case that cannot be proven to be imported

International—Out of U.S.; international importation from another country; onset of rash is within 18 days of entering the United States

Out of state—importation from another state; documentation that the person either had face-to-face contact with a case of rubella outside the state or was out of the state for the entire period when he or she might have become infected (12–23 days before rash onset)

Complications

Death: If patient died from rubella, verification with the physician is recommended.

Other Complications: Please indicate pregnancy complications (spontaneous abortion, fetal death) or termination if applicable.

Laboratory

Include laboratory results from specimens taken from the case. Serologic testing and virus detection can be used to confirm acute or recent rubella infection. A positive serologic test includes detection of rubella-specific IgM result and/or a four-fold rise in rubella-specific IgG antibody titers between acute and convalescent phase serum specimens, tested simultaneously. Rubella virus can be detected from nasal, throat, urine, blood, and cerebrospinal specimens using real-time RT-PCR, RT-PCR or viral culture.

IgM: Please indicate the date when the specimen was collected and the IgM test result.

IgG: Please indicate the dates when the acute and convalescent specimens were collected and the result. The result is based on the interpretation of results from the paired serum specimens. A four-fold rise in antibody titer between acute and convalescent serum specimens, tested at the same time, is considered a positive result.

Other Lab Result: Please indicate the test result(s) and type of test(s) used if other types of tests were performed, such as real-time RT-PCR, RT-PCR or viral culture.

Epidemiologic Information

Date First Reported to a Health Department: Date reported is considered the earliest date the case was initially reported to a health department, either local, district, or state level health department.

Outbreak Related: An outbreak is defined as 3 or more cases (with at least one laboratory-confirmed case) clustered in space and time.

Source of Exposure for Current Case: A source case must be either a confirmed or probable case and have had face-to-face contact with a subsequent case. Exposure must have occurred between 12 to 23 days before rash onset in the new case, and between 4 days before rash onset and 7 days after rash in the source case. Enter state ID if source was an in-state case (imported entry on core screen = 1), enter country name if source was out of USA (imported entry on core screen = 2), enter state name if source was out-of-state (imported entry on core screen = 3).

Epi-Linked to Another Confirmed or Probable Case? An epi-linked case is either a source case or same-generation case. Epi linkage is characterized by direct face-to-face contact. For same-generation cases that are epi-linked, a common exposure is likely.

Reference 7

Instructions for Using the CDC Pertussis Surveillance Worksheet

General

- Every effort should be made to reach both the medical provider and case-patient during a pertussis investigation.
- Every question should be answered, even if the information is unknown. Although "unknown" is an option for many questions, please make every effort to obtain the appropriate information.
- If the month and year for any date are known but the exact day is unknown, enter a 15 for the day (i.e. the middle of the month).
- If information is obtained after the record has been submitted to CDC, please update the record with the new information and resend the record during your next data transmission to CDC.

Demographics

1. **CDC NETSS ID:** Your state's unique alphanumeric identifier that will be reported to NNDSS for the pertussis case-patient under investigation.
2. **County:** County of case-patient's residence at time of cough onset.
3. **State:** State of case-patient's residence at time of cough onset.
4. **Zip:** Zip code corresponding with case-patient's residence at time of cough onset.
5. **Birth Date:** Birth date of the case-patient.
6. **Age:** Age of case-patient at time of cough onset.
7. **Age Type:** Indicate whether Age is reported in Days, Weeks, Months, or Years.
8. **Race:** Self-reported race of case-patient; more than one option may be reported.
9. **Ethnicity:** Self-reported ethnicity of case-patient.
10. **Sex:** Indicate whether case-patient is Male, Female, or Unknown.
11. **Date:** Date of event reported in Event Type field. Date may reflect (listed in order of preference) cough onset, diagnosis, lab test, case reported to county, or case reported to state/MMWR report date.
12. **Event Type:** Type of event reported; may be one of the following (listed in order of preference): cough onset, diagnosis, lab test, case reported to county, or case reported to state/MMWR report date.
13. **Report Status:** Classification status of an investigated case of pertussis based on the CSTE/CDC pertussis case definition.

Clinical Data

14. **Any Cough:** Indicate whether the case-patient ever experienced a cough of any duration during the course of illness.
15. **Cough Onset Date:** Date on which the case-patient experienced first cough during the course of illness.
16. **Paroxysmal Cough:** Indicate whether case-patient ever experienced sudden, uncontrollable bursts or spells of coughing where one cough follows the next without a break for breath.
17. **Whoop:** Indicate whether case-patient ever experienced a high-pitched noise heard on inhalation after paroxysms of cough.
18. **Posttussive Vomiting:** Indicate whether case-patient ever vomited immediately following a paroxysm.
19. **Apnea:** Indicate whether case-patient ever experienced prolonged failure to take a breath, possibly after a coughing spasm, or without prior coughing in an infant. Apnea may occur with or without cyanosis. *Patient or caregiver report is sufficient to confirm the presence of apnea.*
20. **Final Interview Date:** Date of the last interview conducted with the case-patient or medical provider to obtain case information.
21. **Cough at Final Interview:** Indicate whether case-patient still had cough at time of final interview.

22. **Duration of Cough at Final Interview:** The total number of days the case-patient coughed from the date of cough onset to the date of final interview. If a case-patient stopped coughing prior to final interview but cannot remember the date their cough stopped, duration of cough should be calculated using the date of the most recent interview during which case was actively coughing. For example, if a patient began coughing on January 1, was initially interviewed on January 12 (still coughing), and received a final call on January 30 (but was no longer coughing and could not remember when he/she had stopped), the cough duration at final interview should be recorded as 11 days (i.e., January 12–January 1.)
Note: *This variable is not intended to capture* full *cough duration and should not be used as such. If a case-patient has coughed <14 days on the first interview date, a follow-up interview should be conducted* no earlier *than 14 days after the date of cough onset. Every effort should be made to ensure confirmation of at least 14 days of cough.*

Complications

23. **Chest X-Ray for Pneumonia:** Provide x-ray results for case-patients tested for pneumonia. If no x-ray was performed, select option "Not Done". *Pneumonia only should be reported if diagnosed by a healthcare provider and should not be based on patient self-report.*
24. **Seizures Due to Pertussis:** Indicate whether case-patient ever experienced any seizures during course of illness not associated with another diagnosis. *Patient or caregiver report is sufficient to confirm the presence of seizures.*
25. **Acute Encephalopathy Due to Pertussis:** Indicate whether during the course of illness the case-patient experienced an acute illness of the brain manifesting as decreased level of consciousness (excluding altered consciousness following an unrelated seizure) and reduced level of nervous system functioning. Such patients are almost always hospitalized and have undergone extensive evaluation. *Acute encephalopathy should be reported only if diagnosed by a healthcare provider and should not be based on patient self-report.*
26. **Hospitalized:** Indicate whether the case-patient was hospitalized as a result of pertussis infection. Hospitalization typically refers to admission into an in-patient care facility; however, a case also would be considered hospitalized if admitted for 24 or more hours in an observation unit or ER. A case would not be considered hospitalized if admitted for a <24-hour observation period only.
27. **Days Hospitalized:** The number of days the case-patient was hospitalized for pertussis infection. The number of days should be calculated by subtracting the date of hospital discharge from the date of hospital admission. For instance, if a patient was admitted to the hospital on January 1st and was discharged on January 4th, the patient would have been hospitalized for 3 days.
28. **Died:** Indicate whether the case-patient died during the course of illness. If patient had pertussis at the time of death, even if the immediate or underlying cause of death was unknown or confirmed as something other than pertussis, enter 'yes'.

Treatment

29. **Were Antibiotics Given:** Indicate whether the case-patient was ever prescribed antibiotics during the course of their pertussis infection.
30. **1st Antibiotic Received:** Select the code that corresponds with the first antibiotic a case-patient was prescribed, specifically for treatment of pertussis.
31. **Date 1st Antibiotic Started:** Date the case-patient began taking initial dose of first antibiotic prescribed.
32. **Days 1st Antibiotic Actually Taken:** Based on case-patient self-report, the number of days the first prescribed antibiotic was taken.
33. **2nd Antibiotic Received:** Select the code that corresponds with the second antibiotic a case-patient was prescribed, specifically for treatment of pertussis.
34. **Date 2nd Antibiotic Started:** Date case-patient began taking initial dose of second antibiotic prescribed.
35. **Days 2nd Antibiotic Actually Taken:** Based on case-patient self-report, the number of days the second prescribed antibiotic was taken.

Laboratory

36. **Was laboratory testing for pertussis done?** Indicate whether any laboratory test for pertussis was conducted on the case-patient during course of illness.

37. **Laboratory Testing:**

    a. **Laboratory Test Results:** For each type of pertussis test result reported, select a single result code to indicate its outcome. The code for 'Pending' should not be transmitted to CDC for cases whose investigations have been completed.

    b. **Date Specimen Collected:** Although multiple tests may be performed on a single specimen, please indicate the date a specimen was collected from the case-patient for each test result reported (e.g. If a nasopharyngeal swab was collected for both PCR and culture, the same date of collection should be recorded for both test results.)

Vaccine History

General Instructions:

- While a complete vaccination history is preferred for all case-patients, regardless of age, a significant effort should be made to obtain complete vaccination histories for case-patients who are <21 years of age, including DTaP and Tdap (≥7 years) history. For adults 21 years and older, special emphasis should be placed on determination of Tdap and Td booster history. If Td or Tdap cannot be clearly distinguished based on medical records or case-patient report, do not assume the vaccine type. An unknown response is preferred.
- Vaccination histories should be obtained from a verifiable source and should be collected using the following source hierarchy:
    1. Medical records or state immunization registries
    2. Patient shot cards or school vaccine records
    3. Patient self-report (without shot card verification)
- When in doubt, do not simply select the most logical option for vaccine type. For example, DTaP should not be selected indiscriminately as the vaccine type for all doses administered to a case-patient prior to 10 years of age; an unknown response is preferable to a supposed one.
- Doses of vaccine should be entered chronologically with respect to their numbered fields (i.e. the Dose 1 field should contain the earliest administered dose of vaccine, Dose 2 field should contain the next known dose by date, etc.).
- If the vaccination history for a case-patient is incomplete, please enter all known doses of vaccine in chronological order by date of administration, regardless of whether age-specific doses are missing. For instance, if an adolescent case-patient has two doses administered at 2 and 4 months of age, and third dose administered at 5 years of age, please enter all three doses one after the other—even though the 6 month and 15–18 month doses of DTP/DTaP appear to be missing. Do not insert spaces for unknown or missing doses.
- If multiple doses are known but do not have corresponding dates, ensure that the vaccine type, manufacturer, and lot number are linked with the appropriate dose number.

38. **Vaccinated:** Indicate whether the case-patient has ever received a dose of tetanus, diphtheria, and/or pertussis-containing vaccine during his or her lifetime, prior to cough onset (this includes doses of Td and DT). *This variable should include undocumented vaccination history if documented information is unavailable.* ***For example:*** *a mother does not have a shot card for her child but knows that he/she was given the primary DTaP series when they were under the care of a previous pediatrician. The "Vaccinated" variable could then be submitted as "yes" for the child in this scenario.*

39. **Vaccination History**

    c. **Vaccination Date:** For each known dose of tetanus, diphtheria and/or pertussis-containing vaccine, please list the date of administration. If only month and year are available, fill in '15' for the day portion of the date.

d. **Vaccine Type:** For each known dose of tetanus, diphtheria and/or pertussis-containing vaccine, please select the appropriate vaccine type code from the list provided. Vaccine type should not be assumed based on case-patient's age at time of administration. For example, the code for DTaP should not be used if an actual vaccine type is not available for a case, solely because the case was 4 years of age when the dose was administered. If actual vaccine type is unlisted, select "Unknown".

e. **Vaccine Manufacturer:** For each known dose of tetanus, diphtheria and/or pertussis-containing vaccine, please select the appropriate vaccine manufacturer code from the list provided.

f. **Lot Number:** For each known dose of tetanus, diphtheria and/or pertussis-containing vaccine please fill in the corresponding lot number.

40. **Date of Last Pertussis-Containing Vaccine Prior to Illness Onset:** Record the last known date of pertussis-containing vaccine administration that occurred before the patient's pertussis illness began.
41. **Number of Doses of Pertussis-Containing Vaccine Prior to Illness Onset**: Based on the information recorded in the vaccination history section, record the number of doses of pertussis-containing vaccine the patient received prior to his/her pertussis illness onset.
42. **Reason Patient not Vaccinated with ≥3 Doses of Pertussis Vaccine:** Based on the information recorded in the vaccine history section, determine whether the case-patient was appropriately vaccinated at the time of cough onset. If not appropriately vaccinated, please indicate why.

Epidemiologic Information

43. **Date First Reported to a Health Department:** Date the first report of the case was received by either the local or state health department.
44. **Date Case Investigation Started:** Date on which the first contact was made with either a medical provider or the case-patient.
45. **Outbreak Related:** Indicate whether the case-patient was associated with a known pertussis outbreak. ***Note:*** *This variable is used differently across sites, as the definition of a pertussis outbreak varies. While an outbreak has been generically described as two or more cases occurring in separate households within a community, some states require a minimum of 3 cases before declaring an outbreak.*
46. **Epi-Linked:** Indicate whether the case-patient was epidemiologically-linked to another laboratory-confirmed case of pertussis, which was identified by either culture or PCR.
47. **Mother's Age at Infant Birth:** If case-patient <1 year of age, please indicate the 3-digit age of the mother, in years, at time of case-patient's birth.
48. **Weight of Infant at Birth:** If case-patient <1 year of age, please list his or her weight at birth in pounds and ounces, or kilograms and grams. ***Note:*** *Sites should select a* ***single*** *weight measurement unit (i.e. kg/g OR lbs/oz) for recording infant weights. Data should be recorded with NUMERIC,* non-decimal *values only.*
49. **Transmission Setting:** The setting in which the case-patient most likely acquired his or her pertussis infection.
50. **Setting of Further Documented Spread:** Any setting in which pertussis was documented as a result of contact with the case-patient. This should only be completed if additional pertussis cases are known to be epidemiologically-linked or outbreak-related to the case-patient. Further spread should be determined based on the patient's infectious period. Case-patients not treated with antibiotics prior to 21 days of cough should be considered infectious for the three weeks following cough onset. Patients treated with antibiotics prior to three weeks of cough should be considered infectious from cough onset until 5 days after consistently taking prescribed antibiotics.
51. **Number of Contacts Recommended Antibiotics:** The number of individuals the case-patient came into contact with during his or her illness that were recommended antibiotic treatment or prophylaxis.

Chapter 17: Varicella

Adriana Lopez, MHS; Jessica Leung, MPH; Scott Schmid, PhD; Mona Marin, MD

I. Disease Description

Varicella (chickenpox) is a febrile rash illness resulting from primary infection with the varicella-zoster virus (VZV). Humans are the only source of infection for this virus. Varicella is highly infectious, with secondary infection occurring in 61%–100% of susceptible household contacts.[1–5] Transmission occurs from person to person by direct contact with persons with either varicella or herpes zoster (shingles), inhalation of aerosols from vesicular fluid of skin lesions of persons with varicella or zoster, and through infected respiratory secretions that also may be aerosolized. The incubation period for varicella is 10–21 days, most commonly 14–16 days. Varicella is characterized by a pruritic, maculopapular, vesicular rash that evolves into noninfectious dried crusts over a 3- to 7-day period.[6]

Varicella severity and complications are increased among immunocompromised persons, pregnant women, children younger than 1 year of age, and adults.[7–10] However, healthy children may also develop serious complications and even die from varicella.[8–15] Severe complications include secondary bacterial infections (most notably those caused by group A beta-hemolytic *Streptococcus*, e.g., cellulitis, necrotizing fasciitis, septicemia, and toxic shock syndrome), pneumonia, encephalitis, cerebellar ataxia, Reye syndrome, and death.[7]

Congenital varicella syndrome, characterized by hypoplasia of an extremity, skin abnormalities, encephalitis, microcephaly, ocular abnormalities, mental retardation, and low birth weight, may occur among 0.4%–2.0% of infants born to women who develop varicella during the first or second trimester of pregnancy.[16–18] Infants born to women who develop varicella within the period of 5 days before delivery to 2 days after delivery are at high risk of severe neonatal varicella.

Immunity following varicella infection is considered to be long-lasting and second cases of varicella are thought to be rare. However, second cases may occur more commonly among immunocompetent persons than previously considered.[19,20]

VZV remains in a latent state in human nerve tissue and reactivates in approximately 1 in 3 infected persons during their lifetime, resulting in herpes zoster.[21–23] Herpes zoster usually presents as a vesicular rash with pain and itching in a dermatomal distribution. Herpes zoster incidence increases with age, especially after age 50, and is more common among immunocompromised persons and among children with a history of intrauterine varicella or varicella occurring within the first year of life; the latter have an increased risk of developing herpes zoster during childhood.[24–25] A decline or a relative absence of cell-mediated immunity is considered to be an important factor in development of herpes zoster in these groups. Two zoster vaccines (Zostavax™, Merck & Co., Inc.; and Shingrix, GlaxoSmithKline [GSK]) are licensed and recommended in the United States for adults 50 years of age and older (recombinant vaccine)[26] and 60 years of age and older (live attenuated vaccine).[27]

II. Background

Before the availability of varicella vaccine in the United States, almost everyone had varicella. Thus, the number of cases approximated the birth cohort over time, and in the early 1990s (the prevaccine era) this resulted in an average of 4 million cases of varicella, 10,500–13,000 hospitalizations (range: 8,000–18,000), and 100–150 deaths each year.[10,28–29] Varicella primarily affected children, with approximately 90% of cases occurring before the age of 15 years. In the 1970s and 1980s, the highest rates of disease were among children 5–9 years of age, followed closely by children 1–4 years of age.[8] In the 1990s, the highest rate of disease was reported in the preschool age group. This might have been due to increasing attendance at childcare centers and preschools.[8,30]

Varicella vaccine was licensed in the United States in 1995. Two doses are now recommended for routine use, with the first dose given to children 12–15 months of age and the second dose at 4–6 years of age.[31] Persons 13 years of age and older without evidence of immunity to varicella should routinely receive 2 doses of varicella vaccine 4–8 weeks apart.[31] Persons who previously received 1 dose of varicella vaccine should receive their second dose.

Since implementation of the varicella vaccination program in 1996, there have been substantial declines in varicella morbidity and mortality in the United States. One-dose varicella vaccination coverage among children 19–35 months of age was 91% in 2016,[32] and ≥2-dose varicella vaccination coverage among adolescents 13–17 years of age without history of varicella was 86% nationally in 2016.[33] Overall, from prevaccine years, varicella incidence declined an average of 97.4% (from 1993–1995 to 2013–2014) based on data from 4 states that have been continuously reporting varicella to the National Notifiable Disease Surveillance System (NNDSS)[34] since before the varicella vaccination program.The second dose of varicella vaccine was added to the national program in 2007.[31] During the 2-dose era, data from 40 states that reported varicella cases to NNDSS have shown an 85% decline in varicella incidence from 2005–06 to 2013–14, with the greatest declines among children 5–14 years of age (85%–89%).[34]

Medical claims data for varicella outpatient visits and hospitalizations demonstrated declines of 84% and 93%, respectively, by 2012 compared to the prevaccination period (1994–95).[35] Furthermore, in reports of varicella as the underlying cause of death to the National Vital Statistics System, national varicella mortality rates declined 87% for all ages, and 99% for persons <20 years of age in 2008–2011 as compared to pre-vaccine years (1990–1994).[36]

Although increased vaccination of children has lowered the overall burden of disease, a higher proportion of reported cases now occur among older children, adolescents, and adults who may have escaped varicella disease or vaccination, although age specific incidence remains significantly lower than during the prevaccine years for all age groups. As vaccination rates have increased, the majority of varicella cases now occur among vaccinated persons. Cases of varicella in vaccinated persons (i.e., breakthrough cases) are generally much milder, often with fewer than 50 lesions and fewer vesicles compared with 300 or more lesions and many vesicles typically seen in unvaccinated persons.[37] Persons with breakthrough cases are also less likely to have fever and more likely to have fewer days of illness.[38] Given its modified clinical presentation, breakthrough varicella illness can be challenging for practitioners and parents to recognize clinically.

III. Importance of Rapid Case Identification

Reporting of varicella cases in childcare centers, schools, other institutions, military barracks, and other group settings will facilitate public health action and outbreak control. In addition, in certain high-risk settings (e.g., hospitals and other healthcare settings, schools that may have students who are immunocompromised), rapid case identification and public health action are important to prevent infection of susceptible persons at high risk for serious complications of varicella, such as immunocompromised persons and pregnant women, for whom varicella vaccine is contraindicated.[31]

IV. Importance of Surveillance

Surveillance data are needed to

- document and monitor the impact of a vaccination program on disease incidence, morbidity, and mortality;
- evaluate the effectiveness of prevention strategies; and
- evaluate vaccine effectiveness under conditions of routine use.

With varicella vaccine coverage increasing and disease burden declining, varicella disease surveillance is especially important to monitor changes in varicella epidemiology. All states should establish or enhance varicella case-based surveillance to monitor these changes. Surveillance data will be used to assess progress towards *Healthy People 2020* disease reduction goals,[39] and determine whether any improvements to the vaccination policy are needed. *Healthy People 2020* goals for varicella include a greater than 80% reduction in the estimated number of varicella cases among children <18 years of age

compared to 2008; greater than 90% vaccine coverage among children 19–35 months of age; greater than 95% vaccination coverage with 2 doses of varicella vaccine among children in kindergarten; and greater than 90% 2-dose vaccine coverage among adolescents.[39]

V. Case Definition

The following case definitions were approved by the Council of State and Territorial Epidemiologists (CSTE) for varicella cases in June 1999 with an update in June 2009[40–41] and varicella deaths in 1998.[42]

Varicella clinical case definition

An illness with acute onset of diffuse (generalized) maculopapulovesicular rash without other apparent cause. In vaccinated persons, varicella that develops more than 42 days after vaccination (breakthrough disease) due to infection with wild-type VZV, is usually mild, with fewer than 50 skin lesions and of shorter duration of illness. The rash may also be atypical in appearance (maculopapular with few or no vesicles).

Laboratory criteria for diagnosis

- Demonstration of VZV DNA by polymerase chain reaction (PCR) tests from a clinical specimen, ideally scabs, vesicular fluid, or cells from the base of a lesion is the preferred method for varicella diagnosis. [See the varicella web site(https://www.cdc.gov/chickenpox/lab-testing/index.html) for more details.] PCR is also useful for confirming breakthrough disease (Table 1). Other methods, such as DFA and culture, are available for diagnosis but are less sensitive and specific than PCR.
- Positive serologic test for varicella-zoster IgM antibody when varicella-like symptoms are present
- Four-fold or greater rise in serum varicella IgG antibody titer by any standard serologic assay between acute and convalescent sera

For both unvaccinated and vaccinated persons, **PCR is the most reliable method for confirming infection**.

Data are limited regarding IgM antibody tests and the timing of the IgM response in unvaccinated persons. Even less information is available on serologic methods for laboratory confirmation for vaccinated persons. Therefore, a negative IgM result should not be used to rule out the diagnosis, and a positive IgM in the absence of rash should not be used to confirm a diagnosis. Furthermore, a 4-fold rise in IgG antibody may not occur in vaccinated persons. VZV IgG avidity testing is a method that can be used to distinguish between primary VZV infection and past infection but this method is not widely available. Therefore, DNA detection methods are the laboratory methods of choice for diagnosis.

Varicella case classification

Probable: A case that meets the clinical case definition, is not laboratory confirmed, and is not epidemiologically linked to another probable or confirmed case.

Confirmed: A case that is laboratory confirmed or that meets the clinical case definition and is epidemiologically linked to a confirmed or a probable case.

Note: Two probable cases that are epidemiologically linked are considered confirmed, even in the absence of laboratory confirmation.

Varicella deaths case classification

Probable: A probable case of varicella that contributes directly or indirectly to acute medical complications that result in death.

Confirmed: A confirmed case of varicella that contributes directly or indirectly to acute medical complications that result in death.

Other definitions

Varicella-like rash in vaccine recipients: A varicella-like rash in a recently vaccinated person may be caused by either wild- or vaccine-type virus or have other etiologies. Approximately 4% of children receiving varicella vaccine develop a generalized rash with a median of 5 lesions 5–26 days post-vaccination, and 4% develop a localized rash at the injection site with a median of 2 lesions 8–19 days postvaccination.[43] The rash may be atypical in appearance (maculopapular with no vesicles). Approximately

2% of children who received a placebo in the clinical trials also developed generalized rashes, some of which were varicella-like, indicating that not all rashes following vaccination are attributable to the vaccine.[44] Rashes occurring within 2 weeks of or more than 42 days after vaccination are more likely to be wild-type virus, and rashes occurring 15–42 days postvaccination are more likely to be vaccine-type virus.[45] Attribution of disease to vaccine strain VZV can only be confirmed by strain differential, real-time PCR, or by PCR combined with restriction fragment length polymorphism (RFLP) analysis.

Breakthrough disease: A case of wild-type varicella infection occurring more than 42 days after vaccination. Such disease is usually mild with a shorter duration of illness, fewer constitutional symptoms, and fewer than 50 skin lesions. Breakthrough cases with fewer than 50 lesions have been found to be one-third as contagious as varicella in unvaccinated persons, but breakthrough cases with 50 or more lesions can be just as contagious as cases in unvaccinated persons.[46] Though generally mild, about 25%–30% of breakthrough cases among 1-dose vaccinated children have clinical features more similar to those in unvaccinated children and rare, severe presentations with visceral dissemination have been reported.[47] Persons who received 2 doses of vaccine are less likely to have breakthrough disease than those who received 1 dose. Additionally, breakthrough varicella may be further attenuated among 2-dose vaccine recipients though the difference was not always statistically significant.[47] No cases of breakthrough varicella with visceral dissemination have been reported.

Secondary transmission of vaccine virus: A varicella-like rash due to Oka-VZV (i.e., the vaccine-strain variant of VZV) occurring in a non-vaccinated contact of a person who received varicella vaccine. Secondary transmission can occur within 10–21 days after exposure either to a person recently vaccinated or to a person who develops herpes zoster due to vaccine-strain virus. It is extremely rare; since 1995, only 11 secondary cases of transmission of vaccine virus from 9 healthy vaccinees have been documented with the varicella vaccine; 7 were acquired from vaccinees with varicella-like rashes soon after vaccination and 4 from children with HZ caused by Oka strain.[31,45,48–57] All secondary transmissions occurred from vaccine recipients who developed at least a limited rash illness. One additional report was of neonatal varicella with vaccine-strain VZV diagnosed after maternal postpartum vaccination; the mother did not have a rash but the newborn was in the room when she was vaccinated. It is considered more likely that transmission occurred by aerosolization when the syringe was cleared by flushing air bubbles rather than from the mother.[58] All laboratory-confirmed cases of Oka vaccine secondary transmission resolved without complications. Transmission of vaccine-strain VZV can only be confirmed by strain differential real-time PCR or by PCR combined with RFLP analysis.

VI. Evidence of Immunity to Varicella

Evidence of immunity to varicella includes any of the following:[31]

1. Documentation of age-appropriate vaccination
   - Preschool-aged children 12 months of age or older: 1 dose
   - School-aged children, adolescents, and adults: 2 doses
     - For children younger than 13 years of age, the minimum interval between the 2 doses is 3 months. However, if the child received the first dose before 13 years of age and the interval between the 2 doses was at least 28 days, the second dose is considered valid.
     - For persons 13 years of age or older the minimum interval between doses is 4 weeks (28 days).
2. Laboratory evidence of immunity or laboratory confirmation of disease
   - Commercial assays can be used to assess disease-induced immunity, but they lack sensitivity to always detect vaccine-induced immunity (i.e., they may yield false-negative results).
3. Born in the United States before 1980
   - For healthcare workers, pregnant women, and immunocompromised persons, birth before 1980 should not be considered evidence of immunity.
4. A healthcare provider diagnosis of varicella or verification of history of varicella disease
   - Verification of history or diagnosis of typical disease can be done by any healthcare provider (e.g., school or occupational clinic nurse, nurse practitioner, physician assistant, physician). For persons reporting a history of or presenting with atypical and/or mild cases, assessment by a

physician or designee is recommended and either one of the following should be sought: a) an epidemiologic link to a typical varicella case or laboratory-confirmed case, or b) evidence of laboratory confirmation, if testing was performed at the time of acute disease. When such documentation is lacking, persons should not be considered to have a valid history of disease, because other diseases may mimic mild, atypical varicella.

5. A healthcare provider diagnosis of herpes zoster or verification of history of herpes zoster

VII. Laboratory Testing

As varicella disease has declined with introduction of vaccine, the need for laboratory confirmation has concomitantly grown. This is because fewer physicians have direct experience with natural infection and breakthrough disease is often atypical in appearance, results in fewer lesions, and may lack characteristic vesicles. Varicella hospitalizations and deaths, as well as other severe or unusual disease, should routinely be laboratory confirmed. Postvaccination situations for which specimens should be tested include 1) rash occurring 7–42 days after vaccination; 2) suspected secondary transmission of the vaccine virus; 3) herpes zoster in a vaccinated person; or 4) any serious adverse event. In an outbreak, it is recommended that 3–5 cases be confirmed, regardless of vaccination status. The preferred diagnostic test to confirm varicella infection is detection of viral DNA. For additional information on laboratory support for vaccine-preventable disease surveillance, see Chapter 22, Laboratory Support for Surveillance of Vaccine-Preventable Diseases (https://www.cdc.gov/vaccines/pubs/surv-manual/chpt22-lab-support.html).

Skin lesions are the preferred sample for laboratory confirmation of varicella. Peripheral blood samples (serum or plasma) are preferred to test for varicella immunity. Samples from skin lesions should be collected by unroofing a vesicle, preferably a fresh fluid-filled vesicle, and then rubbing the base of a skin lesion with a polyester swab. If only macules or papules are present, suitable samples can often be obtained by scraping the lesion (e.g., with the edge of a glass microscope slide), swabbing the abraded lesion with a polyester swab, and then collecting any material that was accumulated on the object that was used to scrape the lesion on the same swab. Scabs from skin lesions are also excellent samples for PCR detection of VZV DNA. Other sources such as nasopharyngeal secretions, saliva, blood, urine, bronchial washings, and cerebrospinal fluid are less likely to provide an adequate sample than vesicular swabs and scabs from skin lesions, and can often lead to false negative results. Collecting skin lesion specimens from breakthrough cases can be challenging because the rash is often maculopapular with few or no vesicles. A video demonstrating the techniques for collecting various specimens for varicella confirmation, including specimens from breakthrough cases, can be found on the CDC varicella web site (https://www.cdc.gov/chickenpox/lab-testing/collecting-specimens.html). Additional information about collecting and submitting specimens for testing can also be found on the CDC varicella web site (https://www.cdc.gov/chickenpox/lab-testing/collecting-specimens.html) or by calling the National VZV laboratory at 404-639-0066, or emailing dds1@cdc.gov.

Virus isolation and identification

Table 1 provides a summary of the laboratory tests used for varicella, the types of specimens appropriate for each test, and comments about the tests. Further details about the most commonly used laboratory tests for varicella are provided below.

Rapid varicella zoster virus identification:

- **PCR.** PCR is the method of choice for rapid confirmation of a clinical diagnosis. This test is sensitive, specific, and widely available. Short turnaround times of several hours are possible. PCR is a powerful technique that permits the rapid amplification of specific sequences of viral DNA that would otherwise be present in clinical samples at concentrations well below detectable limits.
- **DFA.** If PCR is not available, the DFA test can be used, although it is only about 60% as sensitive as PCR and requires more meticulous specimen collection and handling. A vesicle should be unroofed and scrubbed with sufficient vigor to ensure that cellular matter is collected at the base. At the same time, care must be taken to avoid bleeding from the lesion as serum antibodies can interfere with the test and generate false-negative results. Crusts from lesions are not suitable for use with DFA.

Because viral DNA and viral particles persist after cessation of viral replication or after viral death, DFA or PCR may be positive when viral cultures are negative.

Virus strain identification: Methods are available in specialized laboratories to identify VZV strains and distinguish wild-type VZV from the vaccine (Oka/Merck) strain. Such testing is used in situations when it is important to distinguish wild-type from vaccine-type virus, e.g., in suspected vaccine adverse events. The National VZV Laboratory at CDC and the American Public Health Laboratory Association Vaccine Preventable Diseases Reference Centers (VPD-RCs, https://www.aphl.org/programs/infectious_disease/Documents/ID_VPDQuickReferenceGuide_updated62016.pdf) have the capacity to distinguish wild-type VZV from Oka strain using both strain differential real-time PCR or PCR combined with restriction fragment length polymorphism (RFLP) analysis. VPD-RCs are located in the state laboratories of Wisconsin, California, New York, and Minnesota, and each VPD-RC receives specimens from a designated group of states.

Virus culture: The diagnosis of VZV infection may be confirmed by culture (isolation) of VZV, but is generally not recommended because of the length of time for results and the insensitivity of the approach compared with PCR. Although newer, more sensitive and rapid culture techniques can provide results within 2–3 days, they are still substantially less sensitive than PCR, and may fail to confirm as many as 50% of varicella infections. Infectious VZV is usually recoverable from fluid from varicella lesions for 2–3 days and from zoster lesions for 7 days or longer. VZV may be cultured from other sites such as blood and cerebrospinal fluid, especially in immunocompromised patients. Viable VZV cannot be recovered from crusted lesions.

Serologic testing: IgM serology can provide evidence for a recent active VZV infection, but cannot discriminate between a primary infection and reinfection or reactivation from latency since specific IgM antibodies are transiently produced on each exposure to VZV. IgM tests are also inherently prone to poor specificity. Paired IgG acute- and convalescent-phase antibody tests are used in situations of mild or atypical presentation of disease when immediate therapy is not indicated and when, for clinical reasons, a confirmed diagnosis of the acute illness is important, e.g., a suspected second infection due to varicella. In addition, the laboratory at CDC has developed an IgG avidity assay, which can be used to identify recent primary VZV infection using a single VZV IgG-seropositive serum specimen. IgM detection does not confirm a primary infection, since specific IgM antibodies are transiently produced on each exposure to VZV, whether through reinfection or reactivation from latency.

Single serologic IgG tests may be used to determine the immune status of persons whose history of varicella is negative or uncertain and who may be candidates for varicella zoster immune globulin (VZIG) or vaccination. Commercial enzyme-linked immunosorbent assays (ELISAs) are recommended for the purpose of screening.[59] Routine testing for varicella immunity following vaccination is not recommended. Commercially available serologic IgG tests are not sufficiently sensitive to detect low levels of antibody following vaccination. There is evidence to suggest that the latex agglutination method, another method to test for serologic IgG, may result in false-positive results that could mistakenly categorize a susceptible person as immune.[60]

Table 1. Laboratory tests available for varicella confirmation

Test	Specimen	Comments
PCR	Vesicular swabs or scrapings; scrapings from maculopapular lesions; scabs from crusted lesions; biopsy tissue	Very sensitive and specific for detecting VZV. Results rapidly available (within 3 hours). Real-time methods (not widely available and require special equipment) have been designed that distinguish vaccine strain from wild-type.
DFA	Vesicle scraping; swab of lesion base (must include cells)	Identifies VZV. More rapid and sensitive than culture. Less sensitive than PCR.
Tissue culture	Vesicular fluid; biopsy specimens from sterile sites (e.g., CSF, joint fluid)	Used to detect the presence of viable VZV. Culture is considerably less sensitive than VZV PCR. Requires up to a week for results.
Tzanck smear	Vesicle scraping; swab of lesion base (must include cells)	Detects multinucleated giant cells with inclusions. Diagnostic of alpha herpes viruses (VZV, herpes simplex viruses). Less sensitive than DFA.
IgM	Acute or convalescent serum specimens for VZV IgM	IgM is inconsistently detected, even among patients with PCR-confirmed disease. Not a reliable method for routine confirmation, especially in vaccinated persons, but a positive result in presence of varicella-like symptoms indicates current/recent VZV infection. However, positive results in the absence of clinical disease would not be considered confirmation of active varicella disease due to limits in specificity.
EIA	Acute and convalescent serum specimens for IgG	Requires special equipment. Specific but may not be sensitive enough to identify vaccine-induced immunity.
LA	Acute and convalescent serum specimens for IgG	Rapid (15 min). No special equipment needed. More sensitive but less specific than EIA. Can produce false-positive results.
IFA	Acute and convalescent serum specimens for IgG	Requires special equipment. Good sensitivity and specificity; however, accurate interpretation requires an experienced operator.
gpELISA	Acute and convalescent serum specimens for IgG	Highly specific and sensitive but not widely or commercially available. Suitable for evaluation of vaccine-induced seroconversion.

Abbreviations: *CSF, cerebrospinal fluid; DFA, direct fluorescent antibody; EIA, enzyme immunoassay; gpELISA, glycoprotein-based enzyme-linked immunosorbent assay; IFA, indirect fluorescent antibody; LA, latex agglutination; PCR, polymerase chain reaction; VZV, varicella-zoster virus.*

Specimen collection

Specimen collection and shipping are important steps in obtaining laboratory diagnosis or confirmation for vaccine preventable diseases. Guidelines have been published for specimen collection and handling for microbiologic agents (https://stacks.cdc.gov/view/cdc/7590). Information is also available on using CDC laboratories as support for reference and disease surveillance (https://www.cdc.gov/ncezid/dsr/specimen-management-branch.html); this includes

- a central website (https://www.cdc.gov/laboratory/specimen-submission/index.html) for requesting lab testing;
- the form required for submitting specimens to CDC (See Appendix 23, Form # CDC 50.34);
- information on general requirements for shipment of etiologic agents (Appendix 24, https://www.cdc.gov/vaccines/pubs/surv-manual/appx/appendix24-etiologic-agent.pdf)—although written to guide specimen submission to CDC, this information may be applicable to submission of specimens to other laboratories; and
- the CDC Infectious Diseases Laboratories Test Directory (https://www.cdc.gov/laboratory/specimen-submission/list.html), which not only contains a list of orderable tests for that institution, but also detailed information on appropriate specimen types, collection methods, specimen volume, and points of contact.

The APHL/CDC Vaccine Preventable Disease Reference Centers (https://www.aphl.org/programs/infectious_disease/Documents/ID_VPDQuickReferenceGuide_updated62016.pdf} can perform RT-PCR to detect measles RNA and measles genotyping.

Specific instructions for specimen collection and shipping may be obtained from the CDC varicella website (https://www.cdc.gov/chickenpox/lab-testing/collecting-specimens.html) or by contacting the CDC Viral Vaccine Preventable Diseases Branch at 404-639-0066. Specimens for virus identification and genotyping should be sent to CDC as directed by the State Health Department.

For additional information on use of laboratory testing for surveillance of vaccine-preventable diseases, see Chapter 22, "Laboratory Support for the Surveillance of Vaccine-Preventable Diseases."

VIII. Reporting and Case Notification

Case reporting within a jurisdiction

Each state and territory has regulations or laws governing the reporting of diseases and conditions of public health importance.[61] These regulations and laws list the diseases to be reported and describe those persons or institutions responsible for reporting, including healthcare providers, hospitals, laboratories, schools, childcare facilities, and other institutions. Persons reporting should contact the state health department for state-specific reporting requirements.

In 2002, CSTE recommended that states establish case-based surveillance for varicella and that it be included in NNDSS. All states were encouraged to conduct ongoing varicella surveillance to monitor vaccine impact on morbidity.[62] States are encouraged to report varicella cases to NNDSS via the National Electronic Disease Surveillance System (NEDSS). As of 2017, 38 states are conducting case-based varicella surveillance. Persons reporting should contact the state health department for state-specific reporting requirements.

States not conducting case-based surveillance are encouraged to progressively implement individual case reporting. This can be done by establishing statewide or sentinel surveillance. Statewide surveillance involves adding varicella to the list of notifiable diseases that are reported to the state health department. Sentinel site surveillance involves identifying sites such as schools, childcare centers, physicians' practices, hospitals, colleges, and other institutions to perform surveillance for varicella. Sentinel sites can be limited to a geographic area, such as a county or city, or selected to be representative of the entire state population. States may also consider requesting reports from sites that already participate in other surveillance networks. Some states have initiated surveillance using sentinel or school-based surveillance even though statewide case reporting is not required. States can expand the number of sites as they develop their system with the intention of eventually having statewide surveillance.

Case notification to CDC

Notifications for cases with confirmed, probable, and unknown case status of varicella should be sent to CDC using event code 10030 in the NNDSS via NEDSS. Case notifications should not be delayed because of incomplete information or lack of confirmation. Data can be updated electronically as more information becomes available. The state in which the patient resides at the time of diagnosis should submit the case notification to CDC. The Varicella Surveillance Worksheet is included as Appendix 20 https://www.cdc.gov/vaccines/pubs/surv-manual/appx/appendix20-varicella-surv-wksht.pdf, to serve as a guide for data collection to be included in case investigations and case notification to CDC. Additional inquiries can be directed to the CDC National Center for Immunization and Respiratory Disease, Division of Viral Diseases, Viral Vaccine Preventable Diseases Branch (ncirddvdmmrhp@cdc.gov)

The Reporting Line List for Varicella Outbreak Surveillance at https://www.cdc.gov/vaccines/pubs/surv-manual/appx/appendix20-varicella-list.xlsx is included to serve as a guide for outbreak reporting.

The following data are epidemiologically important and should be collected in the course of a case investigation. Additional information may be collected at the direction of the state health department.

- Age—to monitor the impact of vaccination on disease reduction in specific age groups and any shift in disease to older persons.
- Varicella vaccination status—to determine the proportion of cases occurring in vaccinated persons and assess crude vaccine effectiveness.
    - Number of doses of varicella vaccine
    - Date(s) of vaccination

- Type and manufacturer of vaccine
- Vaccine lot number
- If not vaccinated, reason

- Severity of disease—to assess the severity of varicella (based on number of lesions) in vaccinated persons, to monitor the impact of vaccination on disease severity, and to determine if vaccine-induced immunity wanes over time.
  - Number of lesions
    - Mild: fewer than 50 lesions
    - Mild/moderate: 50–249 lesions
    - Moderate: 250–499 lesions
    - Severe: 500 or more lesions or any complications such as bacterial superinfection, varicella pneumonitis, encephalitis, hospitalization, or death
    - Hospitalization
      - » Reason for hospitalization, if known
- Laboratory information
  - Virus isolation test dates and results
  - PCR test dates and results
  - DFA test dates and results
  - Serologic test dates and results

Additional information to collect can include the following:

- Demographic information
  - Name
  - Address
  - Date of birth
  - Sex
  - Ethnicity
  - Race
  - Country of birth
- Reporting source
  - County
  - Earliest date reported
- Clinical data
  - Pre-existing medical conditions
  - History of varicella (to document reported second infections)
  - Medications
  - Dates of rash onset
  - Duration of rash
  - Symptoms and date of onset
  - Complications
- Outcome (patient survived or died)
  - Date of death
- Epidemiologic data
  - Transmission setting
  - Source of transmission
  - Vaccination status of source patient

Varicella deaths reporting

In 1998, CSTE recommended that varicella-related deaths be placed under national surveillance,[42] and varicella-related deaths became nationally notifiable on January 1, 1999.

Varicella deaths can be identified through death certificates, which may be available through state vital records systems and may be more readily available soon after death in states using electronic death certificates. State public health departments may also request that local health departments, healthcare practitioners, and hospitals report varicella deaths that occur in their community.

Because varicella is a vaccine-preventable disease, all deaths due to varicella should be investigated. Investigation may provide insight into risk factors for varicella mortality and may help identify missed opportunities for, and barriers to, vaccination. A worksheet is provided to guide varicella death investigations (see Appendix 19) at (https://www.cdc.gov/vaccines/pubs/surv-manual/appx/appendix19-2-varicella-wrsh.pdf). Deaths should be reported to the CDC National Center for Immunization and Respiratory Diseases, Division of Viral Diseases, Viral Vaccine Preventable Diseases Branch (ncirddvdmmrhp@cdc.gov), and to NNDSS via NEDSS.

The following data are epidemiologically important and should be collected in the course of a death investigation. Additional information may be collected at the direction of the state health department.

- Demographic information
  - Name
  - Address
  - Date of birth
  - Age
  - Sex
  - Ethnicity
  - Race
  - Country of birth
  - Date of death
- Medical history
  - Pre-existing medical conditions
  - History of varicella (to distinguish varicella from herpes zoster)
  - Medications
- Vaccination status
  - Number of doses of varicella vaccine
  - Date(s) of vaccination
  - Type and manufacturer of vaccine
  - If not vaccinated, reason
- Clinical data
  - Date of rash onset
  - Hospitalization, date of hospital admission, and discharge diagnoses
  - Postmortem examination results
  - Death certificate diagnoses
- Complications
  - Pneumonia
  - Infections (e.g., invasive group A beta-hemolytic streptococcal infection, cellulitis, sepsis, necrotizing fasciitis, other)
  - Encephalitis
  - Neurologic condition (specify)
  - Hemorrhagic condition (specify)
  - Reye syndrome

- Treatment
  - Medications given (e.g., antiviral drugs, VZIG, aspirin, nonsteroidal anti-inflammatory drugs)
  - Duration of therapy
- Laboratory information
  - Virus isolation test dates and results
  - PCR test dates and results
  - DFA test dates and results
  - Serology test dates and results
- Epidemiologic information
  - Transmission setting
  - Source of transmission (e.g., age, vaccination status, relationship to decedent)

IX. Vaccination

Two varicella vaccines are now available in the United States. The live attenuated single-antigen varicella vaccine (Varivax®, Merck & Co., Inc.) was licensed in March 1995 for use in persons 12 months of age and older. A combination vaccine, Measles, Mumps, Rubella, and Varicella (MMRV) (ProQuad®, Merck & Co., Inc.), was licensed in 2005 for use in children 12 months through 12 years of age. Because of the thermolability of the vaccines, the manufacturer's requirements for maintaining freezer storage for the vaccine must be followed strictly. Vaccine that is not properly stored before administration could have suboptimal potency.[31,63]

Prelicensure studies of 1 dose of varicella vaccine, using various vaccine formulations, showed vaccine efficacy ranging from 70% to 90% for all disease and greater than 95% for severe disease.[4,64,65] Post-licensure studies under conditions of community use in the United States have demonstrated 1-dose vaccine effectiveness of 82% (range of estimates, 44%–100%) for prevention of all disease and 100% effectiveness in preventing severe varicella.[66–74]

The efficacy of 2 doses of varicella vaccine was evaluated in a randomized clinical trial. Over a 10-year observation period, the estimated vaccine efficacy of 2 doses was 98.3% compared with 94.4% for 1 dose. The difference was statistically significant ($p<0.001$).[75] A second dose of vaccine reduced varicella attack rates by 3.3-fold.[75] Post-licensure studies in the United States found 2-dose vaccine effectiveness was 94%–98% though 2 studies found lower 2-dose vaccine effectiveness of 84% and 88%.[74,76–80]

Recommendations for the use of varicella vaccines[31]

Routine administration of 2 doses of live attenuated varicella vaccines

- All children should routinely receive their first dose at 12–15 months of age. The second dose is recommended routinely when children are 4–6 years of age (i.e., before a child enters kindergarten or first grade), but can be administered at an earlier age provided the interval between the first and second dose is at least 3 months.
  - Because MMRV vaccine is associated with a higher risk for fever and febrile seizures among young children, CDC recommends that MMR vaccine and varicella vaccine be administered for the first dose at 12-47 months old unless the parent or caregiver expresses a preference for MMRV vaccine.
- Persons 13 years of age or older without evidence of varicella immunity should receive 2 doses of single-antigen varicella vaccine administered 4–8 weeks apart. Serologic testing of adults with an uncertain or negative history of varicella may be cost-effective.
- Second-dose catch-up varicella vaccination is recommended for children, adolescents, and adults who previously received 1 dose.
- Healthcare workers without laboratory evidence of immunity to varicella, laboratory confirmation of disease, or provider-confirmed history of varicella or herpes zoster should receive 2 doses of varicella-containing vaccine. See Chickenpox for Healthcare Professionals (https://www.cdc.gov/chickenpox/hcp/index.html) for more guidance for healthcare workers.
- Evidence of immunity to varicella should be required for children and adults entering or working in childcare, school, college, other post-high school educational institutions, and healthcare settings.

- Prenatal assessment of women for evidence of varicella immunity is recommended. Upon completion or termination of their pregnancy, women without evidence of varicella immunity should receive a first dose of varicella vaccine before discharge from the hospital, birthing center, or healthcare facility. The second dose can be given 4 or more weeks after the first dose (e.g., at the postpartum visit). Postpartum vaccination need not be delayed because of breastfeeding.
- Vaccination should be considered for HIV-infected children with age-specific CD4+ T-lymphocyte counts of 15% or higher and without evidence of varicella immunity; eligible children should receive 2 doses of single-antigen varicella vaccine 3 months apart. Data on the use of varicella vaccine in older HIV-infected persons are lacking. However, based on expert opinion, vaccination for HIV-infected adults with similar immune function may be considered. Combination MMRV vaccine should not be administered as a substitute for the component vaccines when vaccinating HIV-infected children.
- A 2-dose vaccination policy is recommended for outbreak control. Persons without evidence of immunity or those who had received 1 dose of varicella vaccine should be offered vaccine.

Contraindications:[31]

- Allergy to vaccine components.
- Altered T-cell immunity from a malignant condition, including blood dyscrasias, leukemia, lymphomas of any type, other malignant neoplasms affecting the bone marrow or lymphatic systems, or HIV, except as discussed above.
- A family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents and siblings) unless the immune competence of the potential vaccine recipient has been demonstrated. Hypogammaglobulinemia and dysgammaglobulinemia are contraindications for MMRV administration.
- For children receiving high doses of systemic steroids (i.e., at least 2 mg/kg prednisone) for 2 weeks or longer, vaccination should be delayed until steroid therapy has been discontinued for at least 1 month, in accordance with the recommendations of ACIP for live virus vaccines.[81]
- Pregnancy. Varicella vaccination is contraindicated during pregnancy. Women should avoid pregnancy for 1 month after receiving a dose of varicella vaccine. To monitor pregnancy outcomes of women inadvertently vaccinated with VZV-containing vaccines immediately before or during pregnancy, Merck and CDC established the Merck/CDC Pregnancy Registry for VZV-Containing Vaccines in 1995. This registry was closed as of October 16, 2013.[82] During 1995 through March 2012, the pregnancy registry received 860 prospective and 68 retrospective reports and no cases of congenital varicella syndrome or other patterns of birth defects were reported, although a small risk cannot be excluded.[82,83] New cases of exposure immediately before or during pregnancy or other adverse events after vaccination with Varivax, ProQuad, or Zostavax, should be reported to Merck (telephone, 1-877-888-4231) and to the Vaccine Adverse Event Reporting System (https://vaers.hhs.gov/index).

Precautions:

- Severe illness. Vaccination of persons with severe illness should be postponed until recovery.
- Because of the potential inhibition of the response to varicella vaccination by passively transferred antibodies, varicella vaccine should not be administered for 3–11 months, depending on dosage, after administration of blood (except washed red blood cells), plasma, or immune globulin. In addition, varicella vaccine should not be administered for at least 5 months after administration of VZIG. Persons who have received varicella vaccine should not be given antibody-containing product for 2 weeks after vaccination unless the benefits exceed those of vaccination.
- Leukemic children who do not have evidence of immunity, are in remission, have restored immunocompetence and whose chemotherapy has been discontinued for at least 3 months can receive live virus vaccines. It is prudent that vaccination be undertaken with expert guidance and with the availability of antiviral therapy in case complications occur.
- The manufacturer recommends that salicylates (i.e., aspirin and related medications) should not be used for 6 weeks after receiving varicella vaccine because of the association between aspirin use and Reye syndrome following varicella disease. Vaccination with subsequent close monitoring should be considered for children who have rheumatoid arthritis or other conditions that require therapeutic aspirin.
- A personal or family (i.e., sibling or parent) history of seizures of any etiology is a precaution for MMRV administration.

X. Establishing or Enhancing Surveillance

Varicella surveillance is needed to facilitate public health action at the state and local level and to monitor the impact of the varicella immunization program. Several approaches may be used to monitor trends in varicella disease burden. States should consider their surveillance strengths and build varicella surveillance into an existing system where feasible.

Case investigation

Although investigation of all cases of varicella may not be feasible in all settings in all states, action may be required to prevent transmission to persons without evidence of immunity to varicella who are at high risk of serious complications of varicella.[31] In addition, investigation is warranted in some specific circumstances, including deaths associated with varicella, cases with severe complications such as invasive group-A streptococcal infections, outbreaks involving exposure of persons without evidence of immunity to varicella who are at high risk of serious complications of varicella, and outbreaks in populations with high 2-dose varicella vaccine coverage. For more information or for assistance with case, outbreak, and death investigations, the state health department should be contacted. Varicella postexposure prophylaxis of contacts should also be considered.[31]

Outbreak investigation

Although varicella vaccination coverage has increased and disease incidence has declined, outbreaks of varicella are still occurring. Institution of 2 doses routinely in the United States has substantially reduced the number of school outbreaks that were occurring among children who had received only 1 dose. Elementary schools are now the most common sites for varicella outbreaks, although outbreaks occur in middle and high schools. Because younger children are targeted for 2-dose vaccination, a higher proportion of older children and adolescents may have escaped exposure and vaccination at a younger age or did not receive a catch-up second dose and may thus be at risk for disease. Additionally, despite low susceptibility among adults (generally less than 5%), outbreaks have been reported from a variety of adult settings, including correctional facilities, hospitals, military training facilities, refugee centers, immigration detention facilities, homeless shelters, other residential institutions, and cruise ships. Outbreak response is particularly important in settings that present the greatest risk for severe disease (e.g., healthcare settings). Additionally, with implementation of the 2-dose varicella vaccine policy, investigations of outbreaks provide data to monitor the effectiveness of the varicella vaccination program.

Investigations of outbreaks of vaccine-preventable diseases help determine whether outbreaks are occurring because of failure of vaccine (lower than expected vaccine effectiveness) or failure to vaccinate (low vaccine coverage rates and therefore high susceptibility). Investigations of varicella outbreaks will:

- improve existing knowledge of the epidemiology of varicella;
- identify virus transmission patterns;
- describe disease burden;
- determine risk factors for severe varicella;
- provide additional estimates of varicella vaccine effectiveness; and
- describe risk factors for vaccine failure.

For more information about strategies for the investigation and control of varicella outbreaks view the varicella outbreak manual (https://www.cdc.gov/chickenpox/outbreaks/control-investigation.html). Reporting of varicella outbreaks is also important to help monitor impact of the 2-dose varicella vaccination recommendation. A worksheet for reporting varicella outbreaks is available in Appendix 20 (at https://www.cdc.gov/vaccines/pubs/surv-manual/appx/appendix20-varicella-surv-wksht.pdf).

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Reference 8

Instructions for Completing the Varicella Outbreak Surveillance Reporting Worksheet

GENERAL. Please complete the Varicella Outbreak Surveillance Reporting Worksheet to keep track of the number of cases associated with varicella clusters/outbreaks each year. Each case that is associated with a cluster (3-4 cases) or outbreak (5 or more cases) of varicella (epidemiologically linked), regardless of household status, should be listed in the line list on the 'Outbreak Sheet'. ***Please keep a running list of cases for the year. Add outbreak cases for each new quarter of report to the previous list and submit the entire list each quarter.*** Please complete as much information as possible for each case. Listing each case and their information will help provide the data needed to assess characteristics of cases associated with varicella clusters/outbreaks to help guide control and prevention strategies.

Reports should be submitted quarterly to CDC via email: alopez@cdc.gov or fax: 404-315-3398.

Cover Sheet

1. **SITE REPORTING.** Select Grantee site from drop down menu.
2. **NAME OF PERSON REPORTING**. Name of person completing worksheet.
3. **PHONE**. Phone number of person completing worksheet.
4. **EMAIL**. Email of person completing worksheet.
5. **QUARTER OF REPORT.** Select the current reporting quarter. Quarters are based on the calendar year (January to December).
6. **YEAR OF REPORT.** Enter the year of report.
7. **TOTAL NUMBER OF OUTBREAKS.** Enter the cumulative number of outbreaks identified through current period of report.

Outbreak Sheet

A. **CASE #.** This is to keep track of the total number of cases reported during the project year (August to July) and does NOT need to be changed.
B. **GRANTEE.** Select Grantee site from drop down menu.
C. **OUTBREAK NAME OR ID.** Name or ID given to the cluster/outbreak that the case is associated with. The outbreak name/ID is important because it will allow us to group together cases from the same cluster/outbreak, and will be used to generate information on cluster/outbreak size and duration.
D. **OUTBREAK SETTING.** Select a setting for the cluster/outbreak from the drop down menu. If "other" is selected, please specify the setting in the cell.
E. **CASE ID.** Grantee assigned ID for each case associated with cluster/outbreak.
F. **RASH ONSET DATE.** Case-patient's rash onset date.
G. **AGE.** Case-patient's age at time of illness.
H. **NUMBER OF LESIONS.** Enter range of lesions for case-patient. Valid values include: <50, 50-249, 50-500, 250-499, ≥500, Unknown. Select from drop down menu. **If case-patient has <50 lesions, please enter the number of lesions in the cell, if known. ***Please only enter 'unknown' if number of lesions truly unknown.
I. **VACCINATED WITH VARICELLA CONTAINING VACCINE.** Was case-patient vaccinated with varicella-containing vaccine? Select from drop down menu.

J. **IF VACCINATED, # OF DOSES.** If case-patient vaccinated with varicella-containing vaccine, how many doses were received? Select from drop down menu.

K. **DATE OF VACCINATION (DOSE 1).** Date of vaccination for dose 1 (***MM/DD/YYYY***), if known.

L. **DATE OF VACCINATION (DOSE 2).** Date of vaccination for dose 2 (***MM/DD/YYYY***), if known. If ≥3 doses given, please provide dates of vaccination for additional doses in COMMENTS (column R).

M. **HISTORY OF VARICELLA DISEASE.** Did the case-patient have varicella in the past, before this current episode? Select from drop down menu.

N. **HOW HISTORY OF DISEASE ASSESSED.** If case-patient had history of varicella disease in the past, how was it assessed? Select from drop down menu.

O. **WAS CASE LABORATORY CONFIRMED.** Was a specimen collected for laboratory confirmation and the case was laboratory-confirmed as having varicella? A case would be considered laboratory-confirmed if (1) VZV was detected by PCR from a skin lesion (ideally vesicles or crusts/scabs), (2) positive VZV IgM, or (3) 4-fold rise in IgG antibody from acute to convalescent sera. Select from drop down menu.

P. **WAS CASE HOSPITALIZED.** Was the case-patient hospitalized because of this illness? Select from drop down menu.

Q. **COMPLICATIONS.** Specify any complications that the case-patient experienced because of this illness.

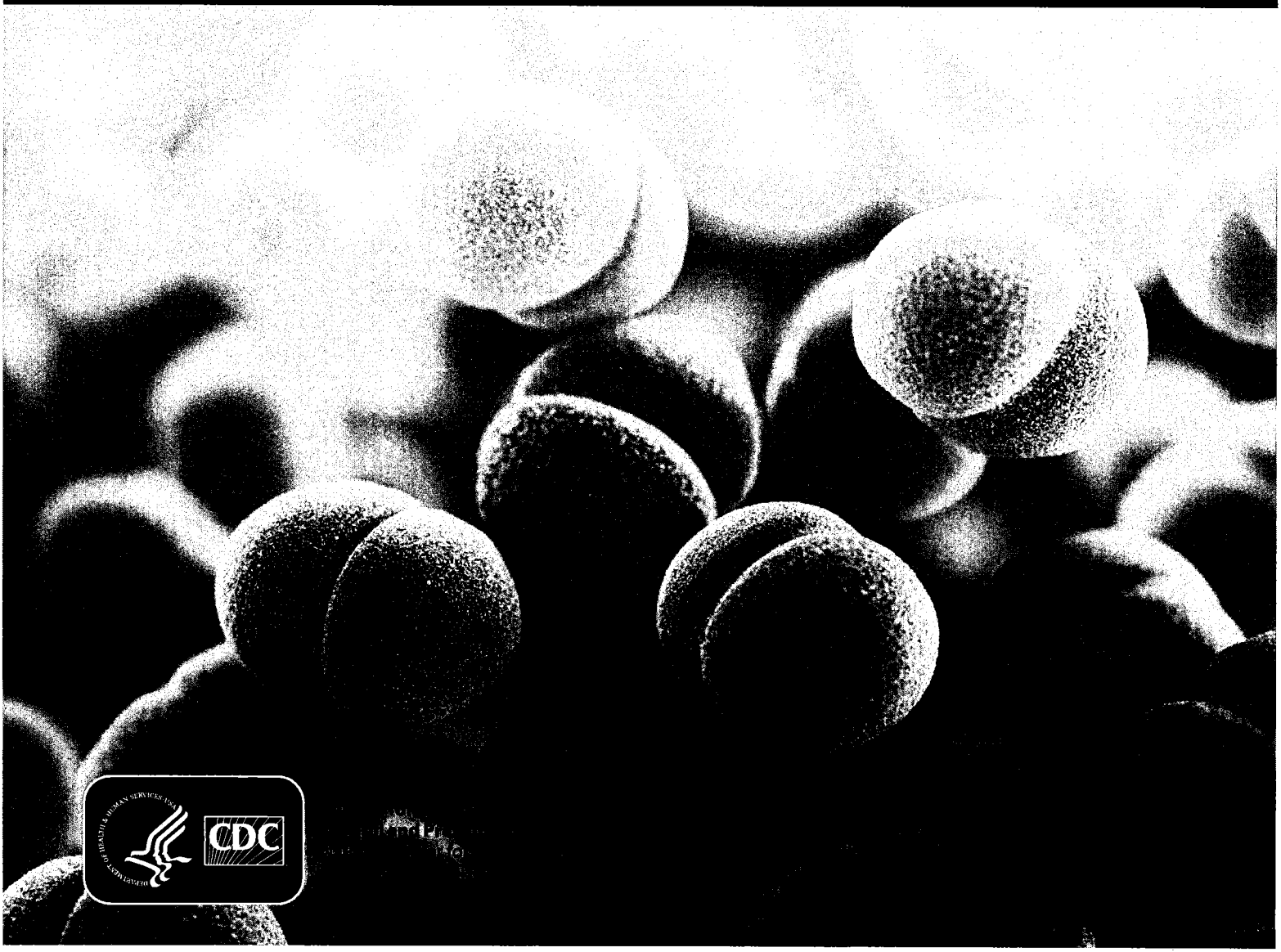
R. **COMMENTS.** List any other comments about this case-patient that are helpful, such as source of exposure, whether case-patient is in the same household as another case-patient that is part of the cluster/outbreak, immunocompromised status if known, did varicella illness result in death, other outbreak setting from those listed in drop down menu for OUTBREAK SETTING (column D), additional dates of vaccination if vaccinated with ≥3 doses, etc.

Reference 9 - All pg 45

Centers for Disease Control and Prevention

Guidance for the Evaluation and Public Health Management of Suspected Outbreaks of Meningococcal Disease

Version 2.0 September 28, 2019



ABBREVIATIONS

ACIP	Advisory Committee on Immunization Practices
CDC	Centers for Disease Control and Prevention
CSF	Cerebrospinal fluid
CSTE	Council of State and Territorial Epidemiologists
FDA	Food and Drug Administration
HIV	Human immunodeficiency virus
IHC	Immunohistochemistry
MenACWY vaccine	Quadrivalent (serogroups ACWY) meningococcal conjugate vaccine
MenB vaccine	Serogroup B meningococcal vaccine
MSM	Men who have sex with men
MLST	Multilocus sequence typing
NNDSS	National Notifiable Diseases Surveillance System
PCR	Polymerase chain reaction
PFGE	Pulsed field gel electrophoresis
SBA	Serum bactericidal antibody assay
WGS	Whole genome sequencing

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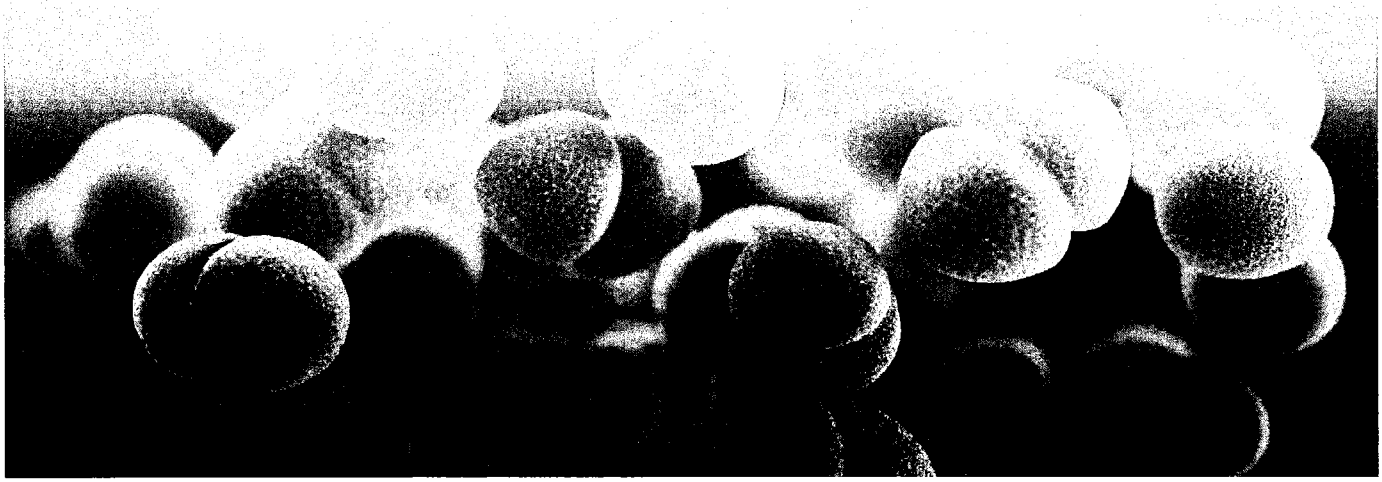

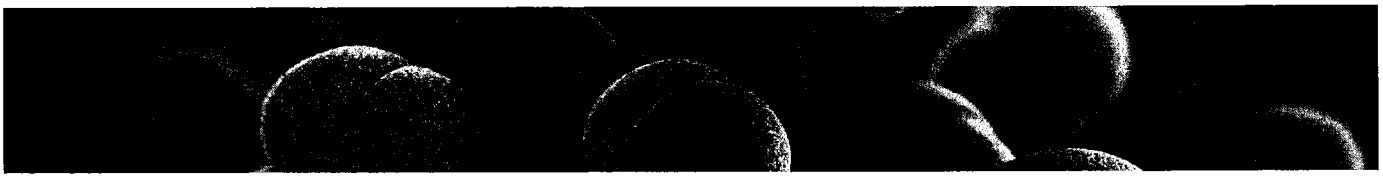

TABLE OF CONTENTS

SUMMARY OF GUIDANCE

Investigation of cases

All cases in a suspected outbreak of meningococcal disease should undergo thorough epidemiologic and laboratory investigation.

- ❒ Neisseria meningitidis is confirmed through culture and/or polymerase chain reaction (PCR) of fluid collected from a normally sterile site. Culture should always be attempted in order to obtain an isolate for molecular typing.
- ❒ Serogrouping should be performed on isolates or specimens from all confirmed cases.
- ❒ Whole genome sequencing (WGS) should be performed on all isolates.

Determination of a meningococcal disease outbreak

- ❒ All cases of meningococcal disease of the same serogroup should be included in the outbreak case count unless molecular typing indicates that the strain from a case is genetically different than the predominant outbreak strain. In outbreaks with well-defined risk groups, probable cases may be included as outbreak-associated even if they are unable to be confirmed or serogrouped.
- ❒ The outbreak threshold for vaccine decision-making should be determined on a case-by-case basis, using the following general guidance:
  - ❍ Organization-based outbreak: 2-3 outbreak-associated cases within an organization during a 3-month period.
  - ❍ Community-based outbreak: Multiple outbreak-associated cases with an incidence of meningococcal disease that is above the expected incidence in a community during a 3-month period.

Vaccination

- ❒ If vaccination is undertaken, vaccine should be selected based on outbreak serogroup:
  - ❍ A, C, W, or Y: quadrivalent meningococcal conjugate (MenACWY) vaccine in persons aged ≥2 months.
  - ❍ B: serogroup B meningococcal (MenB) vaccine in persons aged ≥10 years.
    - MenB-FHbp: 3-dose series (0, 1-2, 6 months)
    - MenB-4C: 2-dose series (0, ≥1 month)
- ❒ For serogroup B outbreaks, the identification of MenB vaccine antigens through WGS of outbreak isolates cannot be used to reliably infer strain coverage at this time; therefore these data should not drive the selection of MenB vaccine product (MenB-FHbp vs. MenB-4C).

Expanded antimicrobial chemoprophylaxis

- ❒ Expanded antimicrobial chemoprophylaxis (administration of antibiotics to a wider circle of individuals than those identified as close contacts of the case-patient) is typically not recommended as a standalone measure, but in some organization-based outbreaks, may be used in conjunction with vaccination or when vaccination is not possible.

Re-evaluation of outbreak status

- ❒ Meningococcal disease risk likely returns to expected levels:
  - ❍ Organization-based outbreak: One year after the last case.
  - ❍ Community-based outbreak: Re-assess one year after the last case to determine whether incidence remains above expected.

1. INTRODUCTION

This report summarizes updated CDC guidance for the evaluation and public health management of suspected outbreaks of meningococcal disease in the United States. Guidance was initially developed in 1997 and subsequently updated following the licensure of the quadrivalent meningococcal conjugate vaccine (MenACWY) and implementation of the routine MenACWY program [1-3]. In 2014, CDC issued interim guidance for the control of serogroup B meningococcal disease outbreaks in organizational settings prior to licensure of serogroup B meningococcal (MenB) vaccines in the United States [4].

This guidance document replaces both the recommendations in Appendix B of the 2013 Advisory Committee on Immunization Practices (ACIP) statement "Prevention and Control of Meningococcal Disease" and the 2014 CDC document "Interim Guidance for Control of Serogroup B Meningococcal Disease Outbreaks in Organizational Settings" [3, 4].

2. BACKGROUND

Since the late 1990s, a sustained decline in the incidence of meningococcal disease has been observed in the United States, decreasing from 1.3 cases per 100,000 population in 1996 to 0.12 cases per 100,000 population in 2015. This decline in incidence began prior to the introduction of MenACWY vaccine in adolescents in 2005 and the licensure of MenB vaccines in 2015. Incidence of serogroups B, C, and Y, the primary disease-causing serogroups in the United States, has declined and incidence of serogroup W has remained stably low.

Information on meningococcal disease cases, including outbreak-associated cases, is collected through the National Notifiable Diseases Surveillance System (NNDSS), though reporting on outbreak-association is likely incomplete. Thus, in 2014, CDC issued requests for this information through the Epidemic Information Exchange (Epi-X), CDC's system for rapid and secure exchange of public health information between CDC and state and local health departments. This call for cases was followed by a standardized questionnaire administered to each state health department, in order to identify and characterize clusters and outbreaks of meningococcal disease from 2009 through 2013. For the purposes of the review, CDC defined a cluster as 2 cases of the same serogroup within 3 months (not including secondary cases) within an organization or an increase in incidence of the same serogroup within a community, with an incidence of at least two times that observed during the same time period in recent years. An outbreak was defined according to the published threshold of ≥ 3 cases of the same serogroup and an attack rate of > 10 cases per 100,000 population during a 3-month period [3]. Of the 3,683 cases reported to NNDSS from 2009 through 2013, 195 (5.3%) primary cases were reported from 41 clusters/outbreaks that met the evaluation criteria.

Among these clusters/outbreaks, 22 were community-based, in which cases had no common affiliation other than a shared geographic space, and 19 were organization-based, in which cases had a common affiliation other than a shared geographic space. Community-based cluster/outbreak-associated cases were predominantly due to serogroup C, whereas organization-based cluster/outbreak-associated cases were predominantly due to serogroup B.

From January 1, 2008, through June 30, 2017, 11 clusters/outbreaks of serogroup B meningococcal disease were reported among university students and close contacts. These clusters/outbreaks ranged in duration from a few days to nearly three years, with a cluster/outbreak size ranging from 2 to 13 cases, and undergraduate population sizes ranging from approximately 4,000 to 35,000 students. MenB vaccines have been used in response to all 8 serogroup B university outbreaks from 2013, when MenB vaccines were first used for outbreak response prior to licensure in the United States, to March 2017.

From January 1, 2010 through June 30, 2017, 5 clusters/outbreaks of serogroup C meningococcal disease were reported among men who have sex with men (MSM) in the United States. These clusters/outbreaks have had duration of up to two and a half years, with 5 to 22 cases reported among MSM. MenACWY vaccination campaigns were implemented in 4 of 5 clusters/outbreaks during this period.

3. OBJECTIVE

The objective of this guidance is to assist state and local health departments in the evaluation and public health management of suspected outbreaks of meningococcal disease in the United States.

4. METHODS

This guidance was developed through a review of published and unpublished data on the epidemiologic and microbiologic features of meningococcal disease outbreaks, immunogenicity and impact of meningococcal vaccines on meningococcal disease and carriage, and use of mass or expanded antimicrobial chemoprophylaxis in outbreak settings, as well as through consultations with subject matter experts.

5. MENINGOCOCCAL DISEASE CASE DEFINITION

According to the 2015 Council of State and Territorial Epidemiologists (CSTE) case definition[5], meningococcal disease cases are classified as suspected, probable, or confirmed (Box 1).

Box 1. 2015 CSTE meningococcal disease case definition.

Case type	Case definition
Suspected	Clinical purpura fulminans in the absence of a positive blood culture; *or* Gram-negative diplococci, not yet identified, isolated from a normally sterile body site (e.g., blood or cerebrospinal fluid (CSF)).
Probable	Detection of *N. meningitidis* antigen in formalin-fixed tissue by immunohistochemistry (IHC) or CSF by latex agglutination.
Confirmed	Detection of *N. meningitidis*-specific nucleic acid in a specimen obtained from a normally sterile body site (e.g., blood or CSF), using a validated polymerase chain reaction (PCR) assay; *or* Isolation of *N. meningitidis* from a normally sterile body site or purpuric lesions.

6. INVESTIGATION OF SUSPECTED MENINGOCOCCAL DISEASE OUTBREAKS

6.1 Epidemiologic investigation

In addition to soliciting information to identify close contacts of the meningococcal disease patient, health department staff should collect information on each meningococcal disease case to identify epidemiologic linkages with other meningococcal disease patients, organizational affiliations such as university or school attendance, common social networks, or common geographic location. In addition, the sex of sex partners of men aged ≥16 years and behaviors such as illicit drug use, or underlying medical conditions such as human immunodeficiency virus (HIV), should be ascertained from all patients to characterize the population at risk.

6.2 Laboratory investigation

All persons with suspected meningococcal disease should undergo specimen collection from a normally sterile body site as indicated by presenting symptoms (e.g., cerebrospinal fluid [CSF], blood). Gram stain is useful for preliminary identification of likely *N. meningitidis* (Gram negative diplococci). However, it is not a confirmatory test, may be falsely negative or misidentified, and cannot distinguish among meningococcal serogroups. Culture is the preferred confirmatory test given the ability of public health laboratories to subsequently characterize the strain through whole genome sequencing (WGS), and should always be attempted whenever a specimen is obtained. Polymerase chain reaction (PCR) is a sensitive method for identifying *N. meningitidis*, particularly in situations where treatment with antibiotics was initiated prior to specimen collection. PCR should be performed on specimens from any patient with negative culture in whom meningococcal disease is suspected. When culture and PCR are unavailable or are negative despite strong suspicion of meningococcal disease, detection of *N. meningitidis* antigen may also be useful in CSF by latex agglutination or in formalin-fixed tissues by immunohistochemistry (IHC) of fatal cases in whom specimens were not obtained before death.

Once a diagnosis of meningococcal disease is confirmed, identifying the serogroup as quickly as possible is imperative for rapid detection of a suspected outbreak of meningococcal disease and implementation of outbreak response measures with the appropriate meningococcal vaccine. Serogrouping of isolates or clinical specimens (by slide agglutination or real-time PCR) should ideally be initiated within 24 hours of identification of *N. meningitidis*. Laboratories that cannot initiate serogrouping within this time frame should transfer the isolate or specimen to a reference laboratory that can perform this testing, such as

a state public health laboratory or an Association of Public Health Laboratories/CDC Vaccine Preventable Disease Reference Laboratory [6]. State public health laboratories may also send isolates or specimens to CDC's Bacterial Meningitis Laboratory for confirmation and further characterization [7].

Several new commercial multiplex PCR assays capable of simultaneously testing a single specimen for an array of pathogens have become available (e.g., FilmArray® Blood Culture Identification Panel and FilmArray® Meningitis/Encephalitis [ME] Panel from BioFire Diagnostics, Meningitis/Encephalitis Panel by PCR from ARUP Laboratories) [8, 9]. While these assays can rapidly identify *N. meningitidis* species, most do not determine serogroup. Thus, laboratories should continue to perform simultaneous culture and use validated, specific real-time PCR assays capable of detecting and differentiating all six disease-associated serogroups of *N. meningitidis* (A, B, C, W, X, and Y). Otherwise, additional steps need to be taken including performing a reflex culture or at a minimum retaining a clinical specimen for further testing at a public health laboratory [10].

6.2.1 Molecular typing

Molecular typing may provide useful information for determining whether a group of cases represent an outbreak. Isolates from all cases should undergo molecular typing when a suspected outbreak occurs. WGS provides the highest resolution in determining similarity of strains and should be performed on all isolates of confirmed cases. Isolates should be sent to CDC's Bacterial Meningitis Laboratory for WGS in order to facilitate comparison of the isolate against a national/global strain collection and for maintenance of a national strain collection. If WGS is performed elsewhere, sequences and isolates should be shared with CDC. Pulsed-field gel electrophoresis (PFGE), may also be used when WGS is not immediately available, though recent data suggests that it cannot definitively group strains within an outbreak or differentiate strains between outbreaks [11]. Multilocus sequence typing (MLST) may also be useful when only a clinical specimen (e.g., CSF, blood), and not an isolate, is available.

Molecular typing data revealing identical or closely related strains provides supportive evidence to the epidemiologic investigation of a suspected meningococcal disease outbreak. Because not all cases will have an available isolate for WGS, evidence of related strains by WGS is not required to determine that a group of cases represent an outbreak. However, if a case is found to be caused by a strain that is genetically distinct from others occurring as part of an outbreak, this case should not be included in the outbreak case count. Public health action, including vaccination campaigns, should not be delayed while awaiting molecular typing results.

6.3 Enhanced meningococcal disease surveillance during a suspected outbreak

When an outbreak of meningococcal disease is suspected, healthcare providers and laboratories should be alerted and encouraged to remain vigilant for patients with symptoms suggestive of meningococcal disease. In addition, they should be encouraged to ensure that all suspected cases of meningococcal disease have been reported to the local health department and that any subsequent suspected cases are promptly reported. Patients in whom meningococcal disease is suspected but whose laboratory results are negative should still be reported to the local health department to arrange for confirmatory or additional testing at a local or state public health laboratory. Clinical and commercial laboratories should be instructed to send all N. meningitidis isolates recovered from normally sterile body sites, or clinical specimens in the absence of an isolate, to a designated public health laboratory in order to facilitate rapid confirmation, serogrouping, and referral of the isolate or specimen for molecular typing. State health departments are also encouraged to notify CDC once an outbreak of meningococcal disease is suspected, in order to expedite confirmatory testing and/or WGS, as well as to detect and coordinate across outbreaks or outbreak-associated cases occurring in multiple states.

7. ANTIMICROBIAL CHEMOPROPHYLAXIS OF CLOSE CONTACTS

Antimicrobial chemoprophylaxis of close contacts of a patient with meningococcal disease is important to prevent secondary cases, regardless of whether a meningococcal outbreak is suspected. Guidance for antimicrobial chemoprophylaxis of close contacts can be found at bit.ly/meningprophylaxis. In the setting of a suspected meningococcal disease outbreak in which confirmed cases have occurred, it is not necessary to wait for confirmation of N. meningitidis in subsequent cases to initiate chemoprophylaxis of close contacts if meningococcal disease is strongly suspected based on identification of Gram negative diplococci, detection of N. meningitidis antigen from CSF by latex or from formalin-fixed tissue by IHC, or clinical signs such as purpura.

8. DETERMINATION OF A MENINGOCOCCAL DISEASE OUTBREAK

Determining whether a group of cases constitutes an outbreak of meningococcal disease can be challenging, although it is an important measure for public health action.

8.1 Define outbreak-associated cases

All cases of the same serogroup should be included in the outbreak case count unless molecular typing indicates that the strain from a case is genetically different than the predominant outbreak strain (Box 2). In outbreaks with well-defined risk groups, cases classified as probable by the CSTE definition may be included as outbreak-associated even if they are unable to be confirmed or serogrouped.

Box 2. Definition of meningococcal disease outbreak-associated cases

All cases of meningococcal disease of the same serogroup are to be included in the outbreak case count unless molecular typing indicates that the strain from a case is genetically different than the predominant outbreak strain. In outbreaks with well-defined risk groups, probable cases may be included as outbreak-associated even if they are unable to be confirmed or serogrouped.

8.2 Define the population at risk

Outbreaks are defined as either organization- or community-based, depending on the nature of the affiliation among cases (Box 3).

Box 3. Classification of meningococcal disease outbreaks

Outbreak type	Outbreak definition
Organization-based	Cases are linked by a common affiliation other than a shared, geographically defined community. Examples are those that occur in universities, schools, child-care centers, or correctional facilities.
Community-based	Cases have no common affiliations to an organization but are instead linked by a shared, geographically defined community, such as a neighborhood or town. Community outbreaks may include populations with shared characteristics, such as men who have sex with men, as long as no affiliation to a specific organization is identified.

The population at risk is the sub-population within the organization or community that includes most, if not all, of the cases and is the group that would be targeted to receive vaccination if a vaccination campaign were initiated in response to the outbreak. Because meningococcal disease outbreaks can be identified after only 2 to 3 cases have occurred, inferences on the population at risk are often made with incomplete information. Thus, each outbreak should be assessed on a case-by-case basis. The assessment should take into account previous experiences with outbreaks in a particular setting, to best estimate the population at risk, using the epidemiology of the cases and identifying potential common social networks.

8.3 Outbreak thresholds

The purpose of declaring an outbreak is to determine when public health interventions for outbreak response, such as mass vaccination, should be considered. In contrast to previous guidance in which a threshold of 3 cases of the same serogroup with an attack rate of > 10 cases per 100,000 population during a 3-month period was used to define both organization- and community-based outbreaks, the current guidance does not recommend the use of an absolute threshold. However, the following thresholds can be considered as guidance, with considerable flexibility to account for the unique nature of each meningococcal disease outbreak.

For organizations, 2-3 outbreak-associated cases within a 3-month period is considered to be an outbreak (Box 4). In most situations, 2 cases within an organization constitute an outbreak. However, in some situations, such as an outbreak within a large university (e.g., > 20,000 undergraduate students) where no identifiable subgroup at risk within the population can be identified, it may be reasonable to declare an outbreak after 3 cases.

For communities, an outbreak is defined as multiple outbreak-associated cases with an incidence of meningococcal disease that is above the expected incidence in a community during a 3-month period (Box 4). Several strategies may be considered to determine whether incidence is above expected in a community. For instance, incidence during the current 3-month period can be compared with the incidence during a similar time period in previous years, or in the setting of very low or unstable monthly incidence, annual incidence in the 3-5 years prior. If community incidence has historically been very low or zero, comparisons against state or national incidence can be made. Additional supportive evidence of an outbreak should be solicited, such as similarity of the strains by molecular typing and common epidemiologic or social characteristics of cases. Consultation with CDC is encouraged if an outbreak is suspected.

Box 4. Outbreak thresholds

Outbreak type	Outbreak threshold definition
Organization-based	2-3 outbreak-associated cases within an organization during a 3-month period.
Community-based	Multiple outbreak-associated cases with an incidence of meningococcal disease that is above the expected incidence in a community during a 3-month period.

Although an absolute outbreak threshold is no longer used, calculating an outbreak attack rate may still be useful in determining the magnitude of an outbreak and comparing against a historical baseline. An outbreak attack rate per 100,000 population is calculated as follows: [(Number of outbreak-associated meningococcal disease cases during a 3-month period) / (Population at risk)] x 100,000. The epidemiology of the cases should be used to determine the appropriate denominator for attack rate calculations and should include the population of the smallest geographic area that contains the cases and be limited to the sub-populations in which cases were reported (e.g., among certain age-groups or social networks). For some populations, such as MSM, determining the denominator can be very challenging. Results of local or statewide surveys (e.g., proportion of adult male population that is MSM, proportion of population with HIV) along with census data can be helpful in estimating population sizes.

Previous versions of the outbreak guidance do not define the term 'cluster' of meningococcal disease, though this term is used informally by public health officials. In this updated guidance, the term cluster can be used to describe a grouping of cases thought to be epidemiologically related that are still under investigation or that do not meet the definition of an outbreak.

9. VACCINATION

9.1 Decision to vaccinate

Vaccination is the preferred control measure for meningococcal disease outbreaks of all serogroups commonly seen in the United States (B, C, W, and Y). However, many factors should be taken into consideration when determining the need for vaccination. While the number of cases is important, other factors to consider include the population size, ability to define a target group for vaccination, whether ongoing transmission is likely, feasibility of a vaccination campaign, and timing of potential vaccination in relation to cases. In situations where ongoing transmission is unlikely (e.g., cases are limited to household members, roommates, or boyfriend/girlfriend), a vaccination campaign is not necessarily indicated as long as antimicrobial chemoprophylaxis of close contacts is implemented to prevent further transmission.

The guidance above suggests thresholds for considering vaccination, but decisions to vaccinate should be made on a case-by-case basis in consultation with the local/state health department and CDC taking into account all circumstances and epidemiology specific to the outbreak.

9.2 Vaccine choice

Four meningococcal vaccines are licensed and routinely available in the United States (Table 2). Approximately 2 weeks are required following vaccination for the development of protective antibody levels.

Table 2. Meningococcal vaccines licensed and available in the United States, 2017

Formulation	Type	Trade name	Manufacturer	Licensed age group	Serogroups
MenACWY-D	Conjugate	Menactra®	Sanofi Pasteur	9 m–55 y	A, C, W, Y
MenACWY-CRM	Conjugate	Menveo®	GlaxoSmithKline	2 m–55 y	A, C, W, Y
MenB-FHbp	Recombinant	Trumenba®	Pfizer	10–25 y	B
MenB-4C	Recombinant	Bexsero®	GlaxoSmithKline	10–25 y	B

9.2.1 MenACWY vaccination

Outbreaks of meningococcal disease due to serogroups A, C, W, and Y may be controlled using MenACWY in persons aged 2 months and older. ACIP recommends routine MenACWY vaccination for all adolescents aged 11 through 18 years of age and for persons at increased risk for meningococcal disease, including those at risk due to an outbreak of meningococcal disease [3]. Although there are currently no meningococcal vaccines licensed and available in the United States for adults aged ≥ 56 years, ACIP recommends that persons aged ≥ 56 years who are at increased risk for meningococcal disease receive conjugate MenACWY vaccine [12].

ACIP does not state a preference in brand of MenACWY vaccine for outbreak response. Persons who were previously vaccinated with MenACWY may require re-vaccination during a meningococcal disease outbreak depending on the interval since their last dose. For persons who received their last MenACWY dose at age ≥ 7 years, an additional dose should be administered if it has been 5 or more years since their last dose. For persons who received their last MenACWY dose at age < 7 years, an additional dose should be administered if it has been 3 or more years since their last dose [3].

9.2.2 MenB vaccination

ACIP recommends routine use of MenB vaccine for persons aged ≥10 years who are at increased risk for meningococcal disease [13]. In addition, ACIP recommends that adolescents and young adults aged 16 through 23 years may elect to be vaccinated with a MenB vaccine [14].

ACIP recommends MenB vaccines in response to outbreaks of serogroup B meningococcal disease among persons aged ≥ 10 years. Although MenB vaccines are only licensed in the United States for persons aged 10 through 25 years, there are no theoretical differences in safety for persons aged > 25 years; thus, ACIP recommends use of MenB vaccines in persons aged ≥10 years who are at increased risk during meningococcal outbreaks. MenB vaccines are not currently licensed or recommended by ACIP for children aged < 10 years who are at increased risk of meningococcal disease during an outbreak due to serogroup B [13].

MenB-4C is licensed as a 2-dose series, with the doses administered at least one month apart. MenB-FHbp is licensed as either a 2-dose series, with the doses administered 6 months apart, or as a 3-dose series, with doses administered 1-2 and 6 months following the first dose. However, if MenB-FHbp is utilized in response to a serogroup B meningococcal disease outbreak, ACIP recommends the 3-dose series in order to provide earlier protection and maximize the immune response [15]. The same vaccine product should be used for all doses in a series.

Persons who have initiated but not completed a MenB series when they become at increased risk for meningococcal disease during a serogroup B outbreak should complete the series using the same vaccine type at the recommended dosing intervals. For persons who received a single MenB-FHbp dose prior to outbreak exposure, the series should be completed using the recommended schedule for persons at increased risk for meningococcal disease (3-dose series at 0, 1, and 6 months). For persons who received two doses of MenB-FHbp, a third dose should be administered according to the recommended dosing schedule unless the second dose was administered at an interval of ≥6 months after the first dose, in which case no additional doses are needed [16]. For persons who received a single MenB-4C dose prior to outbreak exposure, the series should be completed with a second dose at an interval of ≥1 month since the first dose. If the vaccine type of any previous doses received is not known, the primary series should be restarted using any MenB vaccine.

Persons who previously completed a MenB primary series may require a booster dose during a meningococcal disease outbreak, depending on the interval since their last dose. The same vaccine type administered for the MenB primary series should be used for the booster dose.

In an outbreak setting, persons who previously completed a MenB series should receive a booster dose if it has been at least 1 year since their last dose. However, a booster dose interval of ≥6 months may be considered by public health officials depending on the outbreak circumstances, vaccination strategy, and projected duration of elevated risk. This flexibility may be useful to avoid missed opportunities for vaccination. For example, booster dose coverage may be optimized during a mass vaccination campaign conducted during a limited time period by allowing persons who completed the primary series 6 –11 months before the campaign to be vaccinated. For outbreaks lasting longer than a year, decisions regarding booster vaccination of persons who completed primary vaccination during the outbreak should be made on a case-by-case basis. Of note, whereas an initial booster dose is recommended if it has been at least 1 year since completion of the primary series, seroprotective antibody titers persist for at least 2–3 years following a booster dose. Thus, repeated booster doses are not indicated in most outbreak settings.

The recommendation to use the same vaccine type for the booster dose as was used for the MenB primary series could create additional challenges during outbreak response. Availability of both MenB vaccine types should be ensured for booster dose administration during an outbreak, even if the mass vaccination campaign is conducted using a single MenB vaccine type. If the primary series vaccine type is unknown for a given individual and cannot be quickly determined, an additional MenB vaccine of any type may be administered in order to avoid missed opportunities for booster vaccination during outbreak response-related vaccination campaigns. However, there are no data on efficacy of a single dose of one vaccine type following primary series vaccination with a different vaccine type. Thus, every effort should be made to determine vaccine type of the primary series for each individual. Ensuring the availability of complete immunization records for all individuals in the population at risk is an important part of outbreak preparedness for organization such as universities.

Unlike MenACWY vaccines, which induce an immune response to the meningococcal polysaccharide capsule, MenB vaccines induce an immune response to subcapsular proteins; the presence and expression of these proteins vary by strain. Identification of MenB vaccine antigens (PorA, NadA, NhbA, FHbp) through WGS may be helpful, though the presence of these antigens does not necessarily imply expression or expected coverage by one of the MenB vaccines. Currently, there are limited data to correlate the presence and expression of these subcapsular proteins with a protective immune response as measured by serum bactericidal antibody assay (SBA) [17,18]. Furthermore, operational challenges can preclude making this available in real-time during an outbreak. Thus, until additional data are available, the identification of vaccine antigens by WGS should not drive the selection of MenB vaccine product (MenB-FHbp or MenB-4C).

10. EXPANDED ANTIMICROBIAL CHEMOPROPHYLAXIS

Expanded antimicrobial chemoprophylaxis involves administering antibiotics to a wider circle of individuals than those identified as close contacts of a case. Because the impact of expanded chemoprophylaxis on the course of an outbreak has not been consistently demonstrated [19], expanded chemoprophylaxis is not usually recommended as a standalone measure to control outbreaks of meningococcal disease. However, it may be considered in some organization-based outbreaks, such as outbreaks involving limited populations or where persons/groups at increased risk can be clearly defined (e.g., jails, child-care centers, residential facilities, smaller primary or secondary schools, or defined social networks within a larger population, such as university fraternity, sorority, or sports team members). Expanded chemoprophylaxis can be used as an interim measure to temporarily reduce meningococcal carriage and transmission before potential protection from vaccination can be achieved, or when a vaccination campaign is indicated but not possible to implement.

If expanded chemoprophylaxis is undertaken, it should be initiated as soon as possible following determination that an outbreak exists. To maximize the potential impact on transmission, chemoprophylaxis should be administered to all targeted persons within the shortest time frame possible (ideally within 24 hours of each other). Expanded chemoprophylaxis should not delay or be used in place of vaccination when vaccination is feasible to provide potential longer term protection to the population at risk.

Antibiotics that are recommended as chemoprophylaxis for N. meningitidis may be considered for expanded chemoprophylaxis (Table 1), though the frequent development of antibiotic resistance following rifampin administration [20] make this antibiotic unsuitable for large-scale use. It may, however, be used in individuals with contraindications to other antibiotic options. Ciprofloxacin, a fluoroquinolone, is the preferred antibiotic for expanded chemoprophylaxis in persons without contraindications due to ease of oral administration as a single dose. Azithromycin is not routinely recommended for chemoprophylaxis due to limited data on effectiveness, but may be considered in the setting of ciprofloxacin resistance. Ceftriaxone, as an intramuscular injection, may not be feasible to rapidly implement on a larger scale, though may be used in pregnant or lactating women or in persons with contraindications to ciprofloxacin.

Potential recipients of ciprofloxacin should be assessed for contraindications or precautions and information should be provided on the potential risks and benefits of this antibiotic [21]. Because of the potential for disabling side effects of the tendons, muscles, joints, nerves, and central nervous system with fluoroquinolone use, the Food and Drug Administration (FDA) conducted a review of the risks and benefits of systemic fluoroquinolones [22]. While this review determined that the risks of fluoroquinolones outweighed the benefits for treatment of three specific conditions (acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections), the FDA advised that for some serious bacterial infections, the benefits of fluoroquinolones outweighs the risks, and fluoroquinolones should remain a treatment option in these situations [23, 24]. The serious nature of meningococcal disease and increased risk of meningococcal disease during outbreaks make ciprofloxacin an appropriate antibiotic choice in situations in which expanded chemoprophylaxis is deemed indicated.

The decision to implement expanded chemoprophylaxis should consider the challenges of identifying an appropriate target group, the feasibility of antibiotic administration to all persons in the target group within the shortest time frame possible (ideally within 24 hours of each other) and prolonged risk of exposure due to multiple sources of transmission within a population in an outbreak setting. Additional complexities of expanded chemoprophylaxis include cost of the drug and administration, drug side effects including idiosyncratic reactions, interactions with frequently used medications, and the emergence of drug-resistant organisms. If expanded chemoprophylaxis is offered prior to implementation of a vaccination campaign, it is critical to communicate the need for vaccination and continued reduction of behaviors that may increase risk of meningococcal transmission.

Each meningococcal disease outbreak is unique and public health authorities should carefully weigh the benefits and risks of expanded chemoprophylaxis on a case-by-case basis.

11. OTHER OUTBREAK RESPONSE MEASURES

Generally, CDC does not recommend restricting travel to an area with an outbreak, closing schools or universities, or canceling sporting or social events as part of meningococcal disease outbreak control, as these interventions are unlikely to alter the course of the outbreak.

Educating communities, physicians, and other health-care personnel about meningococcal disease to promote early care-seeking behaviors and case recognition is an important part of managing suspected meningococcal disease outbreaks. Education efforts should be initiated as soon as an outbreak of meningococcal disease is suspected. Information about the signs and symptoms of meningococcal disease is available at http://www.cdc.gov/meningococcal/about/symptoms.html.

12. RE-EVALUATION OF OUTBREAK STATUS

Following declaration of a meningococcal disease outbreak and implementation of public health measures, it is necessary to periodically reassess the status of the outbreak for continued public health decision-making. As meningococcal disease epidemiology is dynamic and unpredictable, with outbreak-associated cases sometimes reported months after the last known case, it is difficult to determine whether an outbreak has ended. Unlike with some pathogens, determination of the end of a meningococcal disease outbreak cannot be based on the passage of 2 incubation periods without a case because of transmission of the organism through asymptomatic carriers. Thus, based on expert opinion, a time frame of one year for reassessment is suggested for organization-based outbreaks. For the purposes of public health decision-making, the risk of meningococcal disease may be considered to have returned to expected levels one year following the last case in an organization-based outbreak. In community-based outbreaks, incidence should be re-assessed one year after the last case to determine whether the incidence remains above expected.

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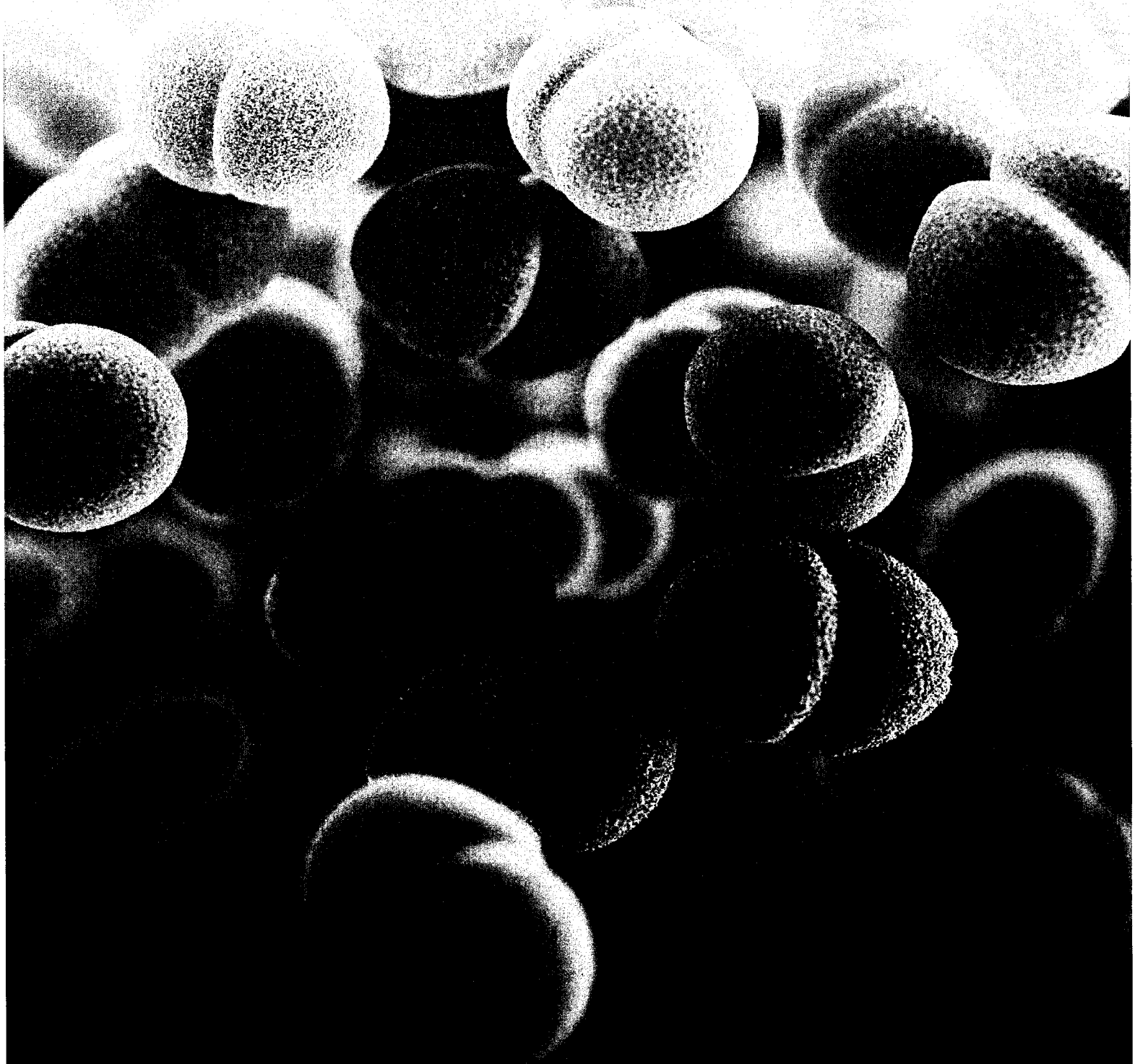
14. APPENDIX A: SUBJECT MATTER EXPERTS CONSULTED, 2015-2016

Last	First	Organization
Arwady	Allison	Chicago Department of Health
Baker	Carol	Baylor College of Medicine
Black	Stephanie	Chicago Department of Health
Campos-Outcalt	Doug	University of Arizona
Cieslak	Paul	Oregon Department of Health
Even	Susan	Missouri Department of Health
Ferris	Mary	University of California at Santa Barbara
Harriman	Kathleen	California Department of Public Health
Harrison	Lee	University of Pittsburgh
Healy	Mary	Baylor College of Medicine
Herlihy	Rachel	Colorado Department of Health
Johnson	Pete	Princeton University
Kemble	Sarah	Chicago Department of Health
Lee	Lucia	Food and Drug Administration
Luta	Martin	Delaware Department of Health
McKinney	Paul	University of Louisville
Meissner	Cody	Tufts University
Montana	Barbara	New Jersey Department of Health

Last	First	Organization
Moore	Jeffrey	Marshfield Clinic
Offit	Paul	Children's Hospital of Philadelphia
Peter	Georges	Brown University
Rastogi	Anuja	Food and Drug Administration
Rubin	Lorry	Steven and Alexandra Cohen Children's Medical Center of New York
Schaffner	William	Vanderbilt University
Stephens	David	Emory University
Tan	Tina	New Jersey Department of Health
Weiss	Don	New York City Department of Health
Yacovone	Margaret	Department of Defense
Zucker	Jane	New York City Department of Health
Albert	Alison	Centers for Disease Control and Prevention
Blain	Amy	Centers for Disease Control and Prevention
Bowen	Virginia	Centers for Disease Control and Prevention
Briere	Elizabeth	Centers for Disease Control and Prevention
Cohn	Amanda	Centers for Disease Control and Prevention
Duffy	Jonathan	Centers for Disease Control and Prevention
Folaranmi	Temitope	Centers for Disease Control and Prevention
Hadler	Stephen	Centers for Disease Control and Prevention
MacNeil	Jessica	Centers for Disease Control and Prevention
Martin	Stacey	Centers for Disease Control and Prevention
Mayer	Leonard	Centers for Disease Control and Prevention
McNamara	Lucy	Centers for Disease Control and Prevention
Meyer	Sarah	Centers for Disease Control and Prevention
Mootrey	Gina	Centers for Disease Control and Prevention
Ortega-Sanchez	Ismael	Centers for Disease Control and Prevention
Otshudiema	John	Centers for Disease Control and Prevention
Quinn	Conrad	Centers for Disease Control and Prevention
Soeters	Heidi	Centers for Disease Control and Prevention
Wang	Xin	Centers for Disease Control and Prevention



Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

NHS (Link: www.nhs.uk/)

Reference 11

Chickenpox vaccine overview

The chickenpox vaccine protects against the varicella zoster virus that causes chickenpox (Link: www.nhs.uk/conditions/chickenpox/).

The chickenpox vaccine is not part of the routine childhood vaccination schedule.

It is currently only offered on the NHS to people who are in close contact with someone who is particularly vulnerable to chickenpox or its complications.

There are 2 chickenpox vaccines currently available. The brand names of the chickenpox vaccine are VARIVAX and VARILRIX.

Read the patient information leaflet (PIL) for VARIVAX (Link: http://www.medicines.org.uk/emc/PIL.17494.latest.pdf).

Read the patient information leaflet (PIL) for VARILRIX (Link: https://www.medicines.org.uk/emc/PIL.9453.latest.pdf).

Who is at risk from chickenpox?

Chickenpox is a common childhood infection. Usually, it's mild and complications are rare. Almost all children develop immunity to chickenpox after infection, so most only catch it once. The disease can be more severe in adults.

Certain groups of people, however, are at greater risk of serious complications from chickenpox. These include:

- people who have weakened immune systems through illnesses such as HIV (Link: www.nhs.uk/conditions/hiv-and-aids/), or treatments like chemotherapy (Link: www.nhs.uk/conditions/chemotherapy/)
- pregnant women – chickenpox can be very serious for an unborn baby when a pregnant woman catches the infection. It can cause a range of serious birth defects, as well as severe disease in the baby when it is born. Read more about what to do if you catch or are exposed to chickenpox in pregnancy (Link: www.nhs.uk/conditions/chickenpox/complications/)

Who should have the chickenpox vaccine?

It is recommended for certain individuals, such as:

- non-immune healthcare workers
- people who come into close contact with someone who has a weakened immune system

This is to lower the chances of infecting people at risk. For example, if you're having chemotherapy treatment, it's advisable that non-immune children close to you are given the chickenpox vaccine.

The vaccine would also be recommended if you were about to start work in a radiotherapy department and had not had chickenpox before.

How the chickenpox vaccine works

The chickenpox vaccine is a live vaccine and contains a small amount of weakened chickenpox-causing virus.

The vaccine stimulates your immune system to produce antibodies that will help protect against chickenpox.

Read more about live vaccines (Link: www.nhs.uk/conditions/vaccinations/vaccine-ingredients/).

Read more about chickenpox vaccine side effects (Link: www.nhs.uk/conditions/vaccinations/chickenpox-vaccine-side-effects/).

Read more about who should have the chickenpox vaccine (Link: www.nhs.uk/conditions/vaccinations/when-is-chickenpox-vaccine-needed/).

How is the chickenpox vaccine given?

The vaccine is given as 2 separate injections, usually into the upper arm, 4 to 8 weeks apart.

How effective is the chickenpox vaccine?

It's been shown that 9 out of 10 children vaccinated with a single dose will develop immunity against chickenpox. Having 2 doses is recommended, as this gives an even better immune response.

The vaccination is not quite as effective after childhood. It's estimated that three-quarters of teenagers and adults who are vaccinated will become immune to chickenpox.

Read answers to common questions about the chickenpox vaccine (Link: www.nhs.uk/conditions/vaccinations/chickenpox-vaccine-questions-answers/).

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Next review due: 24 January 2022

Reference 13

Chapter 9: Mumps

Nakia Clemmons, MPH; Carole Hickman, PhD; Adria Lee, MSPH; Mona Marin, MD; Manisha Patel, MD, MS

I. Disease Description

Mumps is an acute viral illness caused by a paramyxovirus. The classic symptom of mumps is parotitis (i.e., acute onset of unilateral or bilateral tender, self-limited swelling of the parotid or other salivary gland[s]), lasting at least 2 days, but may persist longer than 10 days.[1] The mumps incubation period ranges from 12–25 days, but parotitis typically develops 16 to 18 days after exposure to mumps virus.[2] Nonspecific prodromal symptoms may precede parotitis by several days, including low-grade fever which may last 3–4 days, myalgia, anorexia, malaise, and headache. However, mumps infection may present only with nonspecific or primarily respiratory symptoms or may be a subclinical infection.[3]

Clinical manifestations

In the prevaccine era, rates of classical parotitis among all age groups typically ranged from 31% to 65%, but in specific age groups could be as low as 9% or as high as 94% depending on the age and immunity of the group.[4–7] Several articles discuss mumps symptoms as nonspecific or primarily respiratory; however, findings in these articles were based on results of serologic specimens once every 6 months or once per year, so it is difficult to prove that the respiratory symptoms resulted from mumps or that the symptoms occurred at the same time as the mumps infection.[6,7] In the prevaccine era, 15%–27% of infections were asymptomatic.[4–6] In the postvaccine era, it is difficult to estimate the number of asymptomatic infections, because it is unclear how vaccine modifies clinical presentation. Serious complications can occur in the absence of parotitis.[8,9]

Prevaccine era complications

In the prevaccine era, mumps gained notoriety as an illness that substantially affected armies during mobilization.[1] The average annual rate of hospitalization resulting from mumps during World War I was 55.8 per 1,000, which was exceeded only by the rates for influenza and gonorrhea.[1] Mumps caused transient deafness in 4.1% of infected adult males in a military population.[10] Permanent unilateral deafness caused by mumps occurred in 1 of 20,000 infected persons;[11] bilateral, severe hearing loss was very rare.[11] Before the introduction of the live attenuated mumps vaccine in 1967, mumps accounted for approximately 10% of cases of aseptic meningitis in the United States with men afflicted 3 times as often as women.[12] Mumps encephalitis accounted for 35.9% of all reported encephalitis cases in the United States in 1967.[13] The incidence of mumps encephalitis is reported to range from 1 in 6,000 mumps cases (0.02%)[14] to 1 in 300 mumps cases (0.3%).[13] Orchitis has been reported in 11.6% to 66% of postpubertal males infected with mumps.[15,16] In 60% to 83% of males with mumps orchitis, only one testis was affected.[4,9] Sterility from mumps orchitis, even bilateral orchitis, has rarely been reported.[15] Oophoritis was reported in approximately 5% of postpubertal females affected with mumps.[17,18] Mastitis, which had been reported in a few case reports[19,20] was described in an outbreak in 1956–1957 as affecting 31% of postpubertal females.[4] Pancreatitis was reported in 3.5% of persons infected with mumps in 1 community during a 2-year period[6] and was described in case reports.[21,22] Permanent sequelae such as paralysis, seizures, cranial nerve palsies, and hydrocephalus occurred very rarely.[23] Death due to mumps is exceedingly rare, and is primarily caused by mumps-associated encephalitis.[13] In the United States during 1966–1971, there were 2 deaths per 10,000 reported mumps cases.[13]

Postvaccine era complications

Results from several outbreak investigations showed that hospitalizations and overall complications are lower in 2-dose vaccinated case-patients compared with unvaccinated individuals.[24–27] Among vaccinated persons, severe complications of mumps are uncommon but occur more frequently among adults than children. In recent U.S. outbreaks in 2006 and 2009–2010, rates of orchitis among postpubertal males have

ranged from 3.3% to 10%;[25–27] among postpubertal females, mastitis and oophoritis rates have both ranged from <1% to 1%.[25–27] Among all persons infected with mumps, reported rates of pancreatitis, deafness, meningitis, and encephalitis were all <1%.[25–27] No mumps-related deaths have been reported in recent U.S. outbreaks.

Mumps during pregnancy

An association between maternal mumps infection during the first trimester of pregnancy and an increase in the rate of spontaneous abortion or intrauterine fetal death has been reported in a large prospective controlled cohort study,[28] but this association was not found in another study.[29] One study with methodological limitations showed that congenital malformations may occur from mumps during pregnancy, but because the author did not compare rates with infants born to women not affected with mumps, these findings must be interpreted with caution;[30] other papers have not reported similar findings.[4, 31]

Infectious period

Mumps virus is transmitted person to person through direct contact with saliva or respiratory droplets of a person infected with mumps. Although mumps virus has been isolated from 7 days before through 11–14 days after parotitis onset,[7, 32, 33] the highest percentage of positive isolations and the highest virus loads occur closest to parotitis onset and decrease rapidly thereafter. Mumps is therefore most infectious in the several days before and after parotitis onset. Most transmission likely occurs before and within 5 days of parotitis onset.[32] Transmission also likely occurs from persons with asymptomatic infections and from persons with prodromal symptoms.[34] In 2008, the period of isolation for mumps patients was changed from 9 days to 5 days.[32, 33] The recommended period for contact tracing for mumps is 2 days before through 5 days after parotitis onset.

Other parotitis etiologies

Not all cases of parotitis—especially sporadic ones—are due to mumps infection. Parotitis can be caused by parainfluenza virus types 1 and 3, Epstein Barr virus, influenza A virus, Coxsackie A virus, echovirus, lymphocytic choriomeningitis virus, human immunodeficiency virus, and noninfectious causes such as drugs, tumors, immunologic diseases, and obstruction of the salivary duct. However, other causes do not produce parotitis on an epidemic scale.[35, 36]

II. Background

Mumps vaccine was licensed in the United States in 1967. The Advisory Committee on Immunization Practices (ACIP) made a recommendation in 1977 for 1 dose of mumps vaccine for all children at any age after 12 months.[37] In 1989, children began receiving 2 doses of mumps vaccine because of implementation of a 2-dose measles vaccination policy using the combined measles, mumps, and rubella vaccine (MMR).[38] In 2006, a 2-dose mumps vaccine policy was recommended routinely for school-aged children, students at post high school educational institutions, healthcare personnel, and international travelers; 2 doses should be considered in outbreak settings for children 1–4 years of age and for adults previously vaccinated with 1 dose.[39]

Following mumps vaccine licensure, reported cases of mumps steadily decreased from more than 152,000 reported cases in 1968 to 2,982 in 1985.[40] During 1986–1987, a resurgence occurred with more than 20,000 reported mumps cases. The primary cause of this resurgence was low vaccination levels among adolescents and young adults.[40] In the late 1980s and early 1990s, outbreaks were reported among primary and secondary school children who had previously received 1 dose of mumps-containing vaccine.[41, 42] By 2003, only 231 mumps cases were reported, the lowest annual number since reporting began. However, in 2006, another resurgence occurred, with 6,584 reported cases.[25] The incidence was highest among persons 18–24 years of age, many of whom were college students. Approximately 63% of all case-patients with known vaccination status in the main outbreak states had received 2 doses of MMR vaccine.[25] In 2007 and 2008, the number of annual cases declined to 800 and 454 cases, respectively.

Between June 28, 2009, and June 27, 2010, another large outbreak (3,502 mumps cases) occurred in Orthodox Jewish communities in the Northeast. The median age of persons with mumps was 15 years (range: 3 months to 90 years); 2,479 (71%) were male; and of the 2,519 (72%) for whom vaccination status was reported, 76% had received 2 doses.[26]

From December 9, 2009, through December 31, 2010, the U.S. Territory of Guam also experienced an outbreak, with 505 mumps cases reported; the median age was 12 years with a range of 2 months to 79 years.[27] Of the 287 school-aged children 6–18 years of age with reported mumps, 270 (94%) had received at least 2 doses of MMR vaccine. Two-dose MMR vaccine coverage in the most highly affected schools ranged from 99.3% to 100%.[27]

In the Northeast and Guam mumps outbreaks, third doses of MMR vaccine, under Institutional Review Board protocols, were administered to the most affected populations.[27,43] In both studies, the attack rates among those vaccinated with 3 doses of MMR were lower than among those vaccinated with 2 doses; statistical significance was not established. One study that assessed community attack rates found declines in attack rates that were more pronounced in the age groups targeted for the intervention; however, due to late timing of the intervention and other factors, the results are inconclusive as to whether the decrease was due to the intervention. Other locations experiencing mumps outbreaks during the same time frame among similar populations also showed a decline in attack rates without the third dose intervention (New York City, unpublished data).

Between July 2010 and December 2015, at least 23 large outbreaks (defined as ≥20 cases), consisting of 20–485 cases per outbreak were reported in 18 states. Eighteen of these outbreaks involved universities; 16 were primarily among young adults with a median age of 18 to 24 years. Of the 23 outbreaks, 9 occurred in highly vaccinated populations where 85% or more of the people affected had documentation of 2 doses of MMR vaccine. Standard intervention measures (isolation of infected individuals and age appropriate catch-up vaccinations) were instituted.[44]

In 2016, a third resurgence began with 6,366 mumps cases reported, the highest number of cases since 2006; more than two-thirds of cases were outbreak-associated with outbreaks occurring in 32 jurisdictions. To better characterize the burden of outbreaks nationally, CDC invited jurisdictions to submit aggregate-level outbreak data from January 1, 2016, through June 30, 2017. This data call captured 150 outbreaks in 39 jurisdictions, consisting of 3–2,942 cases per outbreak. Seventy-five (50%) of these outbreaks occurred in universities. Fifty percent of outbreaks consisted of less than 10 cases but 20 (13%) outbreaks had 50 or more cases and accounted for 83% of the total case count. Fifty-five percent of all case-patients (n=9,200) and 70% of case-patients with known vaccination history (n=7,187) had 2 doses of MMR vaccine prior to infection. Similar to other outbreaks in the postvaccine era, the proportion of complications was low, with 270 complications occurring among 9,200 case-patients.[45]

A third study, in which a third dose of MMR vaccine was administered to highly vaccinated college students during a mumps outbreak in 2015–2016, found a lower attack rate for mumps in students who received a third dose of MMR compared with students who had two doses and an increased risk for mumps with increased time since the second dose of MMR. Receipt of a third dose of MMR was associated with a 78% lower risk for mumps than receipt of two doses of MMR (95% confidence interval: 61%–88%).[46]

In October 2017, ACIP recommended a third dose of a mumps-containing vaccine for persons previously vaccinated with 2 doses of a mumps-containing vaccine who are identified by public health as at increased risk for mumps because of an outbreak to improve protection against mumps and its complications (see Section XI. Outbreak Control). Worldwide, mumps is not as well controlled as measles and rubella; mumps vaccine is only routinely used in 62% of countries in the world.[47] Mumps outbreaks have also been reported among populations with high 2-dose MMR coverage in other countries.

III. Disease Reduction Goals

The 338 reported cases of mumps in 2000 met the *Healthy People 2000* reduction goal of fewer than 500 cases. Subsequently, a goal of elimination of indigenous mumps by the year 2010 was made.[48] However, major resurgences in mumps during 2006, 2009, and 2010 highlighted the challenges of obtaining this goal with currently available vaccines and the existing vaccination policy, resulting in re-evaluation of the mumps program goal in the United States. Mumps is endemic throughout the world, and achieving elimination was considered difficult in the context of potential for ongoing mumps virus importations and the current 2-dose vaccination program. Subsequently, the *Healthy People 2020* target for mumps is a disease reduction goal (i.e., to have fewer than 500 reported cases of mumps annually), rather than an

elimination goal.[49] The *Healthy People 2020* target has not been met since 2013; during this time more than half of the reported mumps cases were associated with outbreaks.

Vaccination

Live attenuated mumps virus vaccine is incorporated into combined MMR vaccine. Monovalent mumps vaccine is no longer available in the United States. For prevention of mumps, 2 doses of MMR vaccine are recommended routinely for children with the first dose at 12–15 months of age and the second dose at 4–6 years of age (school entry).[39,50]

Two doses of MMR vaccine are also recommended for prevention of mumps in adults at high risk, including international travelers, college and other post high school students, and healthcare personnel born during or after 1957.[39] All other adults born during or after 1957 without other evidence of mumps immunity should be vaccinated with 1 dose of MMR vaccine.[39] Vaccination recommendations for an outbreak setting, including use of a third dose of MMR vaccine, are discussed in the "Outbreak Control" section later in this chapter.

The mumps vaccine component of the MMR vaccine has a lower effectiveness compared to the measles and rubella components. Mumps vaccine effectiveness has been estimated at a median of 78% (range: 49%–91%) for 1 dose1.[1,42,51–53] and a median of 88% (range: 66%–95%) for 2 doses.[34,53]

Mumps vaccine can also be administered as a combined vaccine with measles, rubella, and varicella vaccines (MMRV);[54] MMRV vaccine can be used for children 12 months through 12 years of age who need either the first or the second dose of MMR vaccine.[54] For the first dose of measles, mumps, rubella, and varicella vaccines at 12–47 months of age, either MMR vaccine and varicella vaccine or MMRV vaccine may be used. Providers who are considering administering MMRV vaccine should discuss the benefits and risks of both vaccination options with the parents or caregivers. Use of the combined MMRV vaccine entails 1 fewer injection than when MMR and varicella vaccinations are given separately. However, MMRV is associated with a higher risk for fever and febrile seizures 5–12 days after the first dose among children 12 through 23 months of age (about 1 extra febrile seizure for every 2,300–2,600 MMRV vaccine doses). Unless the parent or caregiver expresses a preference for MMRV vaccine, CDC recommends that MMR vaccine and varicella vaccine be administered for the first dose in this age group.[54] For the first dose of measles, mumps, rubella, and varicella vaccines at ages 48 months and older and for dose 2 at any age (15 months through 12 years of age), use of MMRV vaccine generally is preferred over separate injections of its equivalent component vaccines (i.e., MMR and varicella vaccines).

IV. Presumptive Evidence of Mumps Immunity

According to ACIP recommendations published in 2013,[39] acceptable presumptive evidence of mumps immunity includes at least 1 of the following:

- written documentation of receipt of 1 dose of a mumps-containing vaccine administered on or after the first birthday for preschool-aged children and adults not at high risk, and 2 doses of mumps-containing vaccine for school-aged children and adults at high risk (i.e., healthcare personnel, international travelers, and students at post high school educational institutions);
- laboratory evidence of immunity;
- laboratory confirmation of disease; or
- birth before 1957.

Persons who do not meet the above criteria are considered susceptible.[39] Healthcare settings have slightly different criteria for acceptable presumptive evidence of immunity, and these criteria are detailed in the "Healthcare personnel: presumptive evidence of immunity" section below.

V. Case Definition

The following case definition for mumps was updated and approved by the Council of State and Territorial Epidemiologists in 2011.[55]

Disease-specific data elements:

Disease-specific data elements to be included in the initial report are listed below.

Clinical presentation

- Parotitis or swelling of sublingual or submandibular salivary glands for 2 or more days
- Onset date of symptoms
- Mumps-associated complications

Epidemiological evidence

- Contact (or in a chain of contacts) of a laboratory-confirmed mumps case
- Contact of a person with parotitis
- Contact of a person with a mumps-associated complication
- Member of a risk group defined by public health authorities during an outbreak
- Return from domestic or international travel within 25 days of symptom onset
- Travel location
- Date of return to state or U.S.

Immunization history

- Number of doses of mumps-containing vaccine received
- Date of all doses of mumps-containing vaccine received

Case definition for case classification

Suspect:

- Parotitis, acute salivary gland swelling, orchitis, or oophoritis unexplained by another more likely diagnosis,
  or
- A positive lab result with no mumps clinical symptoms (with or without epidemiological linkage to a confirmed or probable case).

Probable:

- Acute parotitis or other salivary gland swelling lasting at least 2 days,
  or orchitis or oophoritis unexplained by another more likely diagnosis, in:
  - a person with a positive test for serum anti-mumps IgM antibody, or
  - a person with epidemiologic linkage to another probable or confirmed case or linkage to a group/community defined by public health during an outbreak of mumps.

Confirmed:

- A positive mumps laboratory confirmation for mumps virus with RT-PCR or culture in a patient with an acute illness characterized by any of the following:
  - acute parotitis or other salivary gland swelling, lasting at least 2 days
  - aseptic meningitis
  - encephalitis
  - hearing loss
  - orchitis
  - oophoritis

- mastitis
- pancreatitis

Case classification for import status

Internationally imported case: An internationally imported case is defined as a case in which mumps results from exposure to mumps virus outside the United States as evidenced by at least some of the exposure period (12–25 days before onset of parotitis or other mumps-associated complications) occurring outside the United States and the onset of parotitis or other mumps-associated complications within 25 days of entering the United States and no known exposure to mumps in the U.S. during that time. All other cases are considered US-acquired cases.

US-acquired case: A US-acquired case is defined as a case in which the patient had not been outside the United States during the 25 days before onset of parotitis or other mumps-associated complications or was known to have been exposed to mumps within the United States.

States may also choose to classify cases as "out-of-state-imported" when imported from another state in the United States. For national reporting, however, cases will be classified as either internationally imported or US-acquired.

VI. Laboratory Testing

If mumps is suspected, laboratory testing should be performed. Acute mumps infection can be confirmed by detection of virus by real-time RT-PCR (rRT-PCR) or by positive mumps virus culture. The presence of serum mumps immunoglobulin M (IgM), a significant rise in immunoglobulin G (IgG) antibody titer in acute- and convalescent-phase serum specimens, and IgG seroconversion, can also be used to aid in the diagnosis of mumps infection. However, in both unvaccinated and previously vaccinated persons, false-positive serologic results can occur because assays may be affected by other diagnostic entities that cause parotitis. Furthermore, laboratory confirmation of mumps in highly vaccinated populations may be challenging, and serologic tests should be interpreted with caution because false-negative results in vaccinated persons (i.e., a negative serologic test in a person with true mumps) are common. With previous contact with mumps virus either through vaccination (particularly with 2 doses) or natural infection, serum mumps IgM test results may be negative; IgG test results may be positive and elevated at the initial blood draw, making detection of a 4-fold rise unlikely; and, viral detection in RT-PCR or culture may have low yield if the buccal swab is collected more than 3 days after parotitis onset. Therefore, mumps cases should not be ruled out by negative laboratory results. These challenges are discussed in more detail below.

Virus detection (rRT-PCR and culture)

Mumps virus can be detected from fluid collected from the parotid duct (Stensen's duct), other affected salivary gland ducts, the throat, from urine, and from cerebrospinal fluid (CSF). Parotid duct swabs yield the best viral sample, when parotitis is present. This is particularly true when the salivary gland area is massaged approximately 30 seconds prior to swabbing the buccal mucosa/parotid duct, so that the specimen contains the secretions from the parotid or other salivary duct glands. Efforts should be made to obtain the specimen as soon as possible after onset of parotitis or meningitis. Ideally, clinical specimens should be obtained within 3 days and not more than 8 days after parotitis onset.

Urine samples are less likely than oral specimens to contain sufficient virus copies or virus-infected cells for culture or detection by molecular methods, and therefore are not preferred as specimens from cases with parotitis. However, in patients presenting with mumps complications, such as orchitis or meningitis, specimens such as urine or CSF may be useful for diagnosis in addition to oral specimens.

Successful virus isolation should always be confirmed by immunofluorescence with a mumps-specific monoclonal antibody or by molecular techniques. Molecular techniques such as rRT-PCR can also be used to detect mumps RNA directly for mumps confirmation in appropriately collected specimens.

Molecular typing is recommended because it provides important epidemiologic information. Molecular

epidemiologic surveillance (i.e., virus genotyping) allows the building of a sequence database that will help track transmission pathways of mumps strains circulating in the United States. In addition, genotyping methods are available to distinguish wild-type mumps virus from vaccine virus.

- **Unvaccinated persons:** Virus may be isolated from the parotid duct/buccal mucosa until 11–14 days after salivary enlargement; however, viral isolation is most likely to be successful just prior to and within the first 3 days of parotitis onset.
- **Vaccinated persons:** In order to optimize virus yield, emphasis should be placed on obtaining mumps clinical specimens from buccal mucosa within 1 to 3 days after onset of symptoms (usually parotitis).

For specimens being submitted for virus culture or RT-PCR assay, immediately place specimens in a cold storage container and transport to the laboratory.

Serologic testing

The serologic tests available to aid in the diagnosis of acute mumps infection and confirmation of previous exposure to mumps vary among laboratories. The state health department can provide guidance regarding available laboratory services. At the direction of the state health department, healthcare providers and state and local health departments may send serum specimens from suspected mumps cases to CDC's Measles, Mumps, Rubella, and Herpes Laboratory Branch for IgM detection using a capture IgM enzyme immunoassay (EIA; non-quantitative) that incorporates a recombinant mumps nucleocapsid protein as the antigen. See the "Specimen collection and management" section below.

Tests for IgM antibody

- **EIA:** a highly specific test for diagnosing acute mumps infection. The use of the IgM capture EIA is preferred over the immunofluorescence assay (IFA).
- **IFA:** a test that is relatively inexpensive and simple, but the IFA format is particularly susceptible to interference by high levels of mumps-specific IgG. Reading the test requires considerable skill and experience since this nonspecific staining may cause false-positive readings if the serum is not treated with an agent to remove human IgG antibody.

Note: *Commercially available EIA kits and IFA antibody assays for detection of mumps IgM are currently not approved by the Food and Drug Administration for this use. Therefore, each laboratory must validate these tests independently.*

Serum collection and timing of the mumps IgM response

- **Unvaccinated persons:** IgM antibody is detectable within 5 days after onset of symptoms, reaches a maximum level about a week after onset, and remains elevated for several weeks or months.[56,57] If an acute-phase serum sample collected ≤3 days after parotitis onset is negative for IgM, testing a second sample collected 5–7 days after symptom onset is recommended as the IgM response may require more time to develop.
- **Vaccinated persons:** Patients that mount a secondary immune response to mumps, as seen in most previously vaccinated persons, may not have an IgM response, or it may be transient and not detected depending on the timing of specimen collection.[56] Because of this, a high number of false-negative results may occur in previously vaccinated individuals. False-positive IgM results may also occur and appear to be more prevalent with certain IgM test formats, such as the IFA. Collecting specimens >3 days after parotitis onset improves the ability to detect IgM among persons that were previously vaccinated. Of serum samples collected from outbreaks less than 3 days after symptom onset 13–46% were positive compared to 71% of serum samples collected >3 days.[58–61] However, persons with a history of mumps vaccination may not have detectable mumps IgM antibody regardless of the timing of specimen collection.

Tests for IgG antibody

Tests for IgG antibody: may be used for mumps diagnosis or for determining prior exposure to mumps vaccine or mumps virus. A variety of tests for IgG antibodies to mumps are available and include EIA, IFA, and plaque reduction neutralization. The specific criteria for documenting the presence of antibody or an increase in titer depends on the test. Older persons or persons with no history of mumps illness or vaccination may have detectable mumps IgG due to a previous subclinical infection.

Diagnosis of mumps with IgG: a single serum sample tested for mumps-specific IgG is not useful for diagnosing acute mumps infection. Documentation of seroconversion from negative to positive or a 4-fold rise in IgG titer using paired specimens as measured in plaque-reduction neutralization assays or similar quantitative assays can be used to aid in the diagnosis of mumps. Tests for IgG antibody should be conducted on both acute- and convalescent-phase specimens at the same time, and the same type of test should be used on both specimens. EIA values are not titers, and increases in EIA values do not directly correspond to rises in titer results.

- **Unvaccinated persons:** In unvaccinated persons, IgG antibody increases rapidly after onset of symptoms and is long lasting.
- **Vaccinated persons:** In vaccinated persons, the IgG may already be quite elevated in the acute-phase blood sample, which frequently prevents detection of a 4-fold rise in IgG titer in the convalescent serum specimen. For this reason, detection of a 4-fold rise in IgG is not recommended for use among previously vaccinated persons.

Presumptive laboratory evidence of immunity

The presence of mumps-specific IgG, as detected using a serologic assay (EIA or IFA), is considered evidence of prior exposure to mumps vaccine or mumps virus but does not necessarily predict the presence of neutralizing antibodies or protection from mumps disease.

Specimen collection and management

Specimen collection and shipping are important steps in obtaining laboratory diagnosis or disease confirmation. Guidelines have been published for specimen collection and handling for viral and microbiologic agents. Information is also available on using CDC laboratories as support for reference and disease surveillance; this includes

- a central website (https://www.cdc.gov/laboratory/specimen-submission/index.html) for requesting lab testing;
- the form (https://www.cdc.gov/laboratory/specimen-submission/pdf/form-50-34.pdf) required for submitting specimens to CDC (See Appendix 23, Form # CDC 0.5034);
- information on general requirements for shipment of etiologic agents (Appendix 24, https://www.cdc.gov/vaccines/pubs/surv-manual/appx/appendix24-etiologic-agent.pdf)—although written to guide specimen submission to CDC, this information may be applicable to submission of specimens to other laboratories; and
- the CDC Infectious Diseases Laboratories Test Directory (https://www.cdc.gov/laboratory/specimen-submission/list.html), which contains not only a list of orderable tests for that institution, but also detailed information on appropriate specimen types, collection methods, specimen volume, and points of contact.

Specific instructions for specimen collection and shipping may be obtained from the CDC mumps website (https://www.cdc.gov/mumps/lab/specimen-collect.html) or by contacting the CDC Viral Vaccine Preventable Diseases Branch at 404-639-3339. Specimens for RT-PCR, virus isolation, and genotyping should be sent to CDC as directed by the State Health Department.

For additional information on use of laboratory testing for surveillance of vaccine-preventable diseases, see Chapter 22, "Laboratory Support for the Surveillance of Vaccine-Preventable Diseases."

VII. Reporting and Case Notification

Case reporting within a jurisdiction

Each state and U.S. territory has regulations or laws governing the reporting of diseases and conditions of public health importance.[62] These regulations and laws list the diseases that are to be reported and describe those persons or groups responsible for reporting, such as healthcare providers, hospitals, schools, laboratories, daycare and childcare facilities, and other institutions. Persons reporting these conditions should contact their State Health Department for state-specific reporting requirements.

Case notification to CDC

Provisional notifications of all probable and confirmed mumps cases should be sent by the State Health Department to CDC using eventcode 10180 via the National Notifiable Diseases Surveillance System (NNDSS). Electronic reporting of case records should not be delayed because of incomplete information or lack of confirmation. Following completion of case investigations, case records should be updated with any new information and resubmitted to CDC. Final laboratory results may not be available for the initial report but should be submitted via NNDSS when available. The state in which the patient resides at the time of diagnosis should submit the case notification to CDC. For further inquiries, please email: ncirddvdmmrhp@cdc.gov

Information to collect

The following data should be collected in the course of the case investigation. Additional information may be collected at the direction of the State Health Department.

- **Demographic information**
  - Name
  - Address
  - Date of birth
  - Age
  - Sex
  - Ethnicity
  - Race
  - Country of birth
  - Length of time in United States
  - Reporting source
  - County
  - Earliest date reported
- **Clinical information**
  - Date of illness onset (note: this may be earlier than parotitis onset due to prodromal symptoms)
  - Parotitis or other salivary gland involvement (pain, tenderness, swelling)
  - Date of parotitis (or other salivary gland swelling) onset
  - Duration of parotitis (or other salivary gland swelling)
  - Other symptoms (e.g., headache, anorexia, fatigue, fever, body aches, stiff neck, difficulty in swallowing, nasal congestion, cough, earache, sore throat, nausea, abdominal pain)
- **Complications**
  - Deafness (transient or permanent; unilateral or bilateral)
  - Encephalitis
  - Mastitis
  - Meningitis
  - Oophoritis
  - Orchitis (unilateral or bilateral)
  - Pancreatitis
  - Other

- **Hospitalization**
  - Outcome (patient survived or died)
  - Date of death
  - Postmortem examination results
  - Death certificate diagnoses
  - Reason/association to mumps
  - Duration of stay
- **Treatment**
  - Medications given
  - Duration person was on each medication
- **Laboratory**
  - Serology (IgM, IgG)
  - Virus detection (PCR, culture)
  - Specimen collection date(s)
- **Vaccine information**
  - Number of doses of vaccine given
  - Type of vaccine administered (i.e., MMR, MMRV, or single antigen mumps vaccine)
  - Dates of mumps vaccination for each dose
  - Manufacturer of vaccine
  - Vaccine lot number
  - If not vaccinated, reason
- **Epidemiologic**
  - Epidemiologic linkages
  - Transmission setting (e.g., college, school, doctor's office)
  - Import status (e.g., internationally imported or US-acquired). See Case Classification section above.
  - Location of exposure (country, if international import; state, if out-of-state import)
  - Travel history

VIII. Case Investigation

The Mumps Surveillance Worksheet (Appendix 10) may be used as a guideline to collect case information during a case investigation; the details are discussed below.

Case identification

Identification of suspected or confirmed cases of mumps is important in the initiation of control measures to prevent the spread of the disease among persons who do not have presumptive evidence of immunity. Once a sporadic case has been identified, several factors should be considered before initiating a public health response, such as epidemiological risk factors, vaccination status, and other etiologies. However, in transmission settings with high risk, such as households, schools, and camps, health departments may want to be more proactive. In these settings, health departments should consider conducting case investigations and assessing immune status of close contacts before laboratory results are known or before additional cases are identified. Implementation of control measures may be contingent on setting, likelihood of ongoing transmission, and available resources.

Establishing a diagnosis of mumps

Clinical diagnosis of mumps may be unreliable. Cases of suspected mumps should be laboratory confirmed; however, negative laboratory results among vaccinated persons do not necessarily rule out the diagnosis of mumps, particularly if there is an outbreak of parotitis. Efforts should be made to obtain clinical specimens (buccal cavity/parotid duct fluids, throat swabs, or serum; urine can be collected for cases of orchitis or CSF collected for meningitis or encephalitis) for molecular detection and/or serologic testing from all sporadic cases and at least some cases in each outbreak at the time of the initial investigation. For sporadic cases that have negative laboratory results for mumps, consider testing for other etiologies such as influenza virus, Epstein Barr virus, adenovirus, parainfluenza viruses types 1, 2, and 3.

Obtaining accurate, complete immunization histories

Mumps case investigations should include complete immunization histories verified by documentation of administration of all doses. Verbal history of receipt of mumps vaccine is not considered adequate proof of vaccination. Some case-patients or their caregivers may have personal copies of immunization records available that include dates of administration—these are acceptable for reporting purposes.

Identifying the source of infection

Efforts should be made to identify the source of infection for every confirmed case of mumps (i.e., case-patients should be asked about contact with other known patients). However, this is not always possible, especially with sporadic cases, and this should not occur at the expense of higher public health priorities. If it can be determined when and where transmission likely occurred, investigative efforts should be directed to these locations.

Assessing potential transmission and identifying contacts

The potential for further transmission should be assessed. Contacts of the case-patient during the 2 days prior through 5 days after onset of parotitis should be identified, assessed for immunity, offered vaccine as appropriate, and educated about signs and symptoms.

CDC recommends a 5-day period after onset of parotitis for: 1) isolation of persons with mumps in the community and for 2) use of droplet precautions, in addition to standard precautions in healthcare settings.[32]

IX. Enhancing Surveillance

Importance of surveillance

Information obtained through surveillance is used to follow disease trends in the population, to assess progress towards disease reduction goals, and to characterize populations requiring additional disease control measures.

Monitoring surveillance indicators

Regular monitoring of surveillance indicators can help identify specific areas of the surveillance and reporting system that need improvement. The following indicators should be monitored.

- The proportion of confirmed cases reported to NNDSS with complete information (e.g., date of birth, onset date, clinical case definition, hospitalization, laboratory testing, vaccine history, date reported to health department, transmission setting, outbreak-related, and epidemiologic linkage)
- The interval between date of symptom onset and date of public health notification
- The proportion of cases that are laboratory confirmed
- The proportion of cases that have an imported source

The activities listed below can help increase the number of suspected mumps cases that are reported and improve the comprehensiveness and quality of reports that are received. Additional guidelines for enhancing surveillance are given in Chapter 19, "Enhancing Surveillance."

Promoting awareness

In the event of an outbreak, surveillance should be enhanced by promoting awareness in the community affected by the outbreak and among healthcare personnel. Healthcare personnel should be aware that mumps outbreaks have occurred in highly vaccinated populations in high transmission settings, including

school settings (e.g., elementary school, middle school, high school, and college students). Therefore, mumps should not be ruled out on the assumption that individuals have evidence of mumps immunity because of vaccination.

X. Outbreak Investigation

A mumps outbreak is defined as 3 or more cases linked by time and place. In recent years, mumps outbreaks have occurred in highly vaccinated populations in high transmission settings, including elementary, middle, and high schools, colleges, and camps. Especially in these settings, rapid detection and investigation of cases, and implementation of control measures may reduce the magnitude of outbreaks.[53] The following are general guidelines for an outbreak investigation.

Collecting tracking information

During an outbreak, a line listing of cases on a spreadsheet allows for quick identification of known and unknown data and ensures for complete case investigations.

Identifying the population affected by the outbreak

During an outbreak, every suspected case should be investigated, as described above. In very large outbreaks, it may not be possible to thoroughly investigate each reported case.

Based on the findings of individual case investigations, the population affected by the outbreak should be characterized in terms of:

- person (who is becoming infected with mumps, what is their vaccination status),
- place (where are the cases), and
- time (when did the outbreak start, and is it still going on).

These essential data elements allow public health officials to determine the population at risk of infection (e.g., unvaccinated persons, students who have only received 1 dose of mumps vaccine, persons who visited the emergency department of Hospital A on a certain day, highly vaccinated populations in high transmission settings); to determine where transmission is occurring (e.g., schools, colleges, healthcare settings); and to identify individuals who are at potential risk of infection (e.g., other unvaccinated persons, students attending other schools).

Obtaining accurate and complete immunization histories

Vaccination histories may be obtained from schools (generally available for children attending licensed childcare centers or kindergarten through high school, as well as many universities), medical providers, or immunization records provided by the case-patient. Immunization registries, if available, can also readily provide vaccination histories.

Investigating contacts

Identifying contacts (e.g., household, school/college, and other close contacts) and following up with persons without evidence of mumps immunity may reveal previously undiagnosed and unreported cases.

Enhancing surveillance for mumps

Local or state health departments should contact healthcare providers in outbreak areas to inform them of the outbreak and request reporting of any suspected cases. During outbreaks, active surveillance for mumps should be conducted for every confirmed and probable mumps case. Active surveillance should be maintained for at least 2 incubation periods (50 days) following parotitis onset in the last case. Two incubation periods allow for the identification of transmission from subclinical infections or unrecognized cases. Previously unreported cases may be identified by reviewing laboratory records.

XI. Outbreak Control

Initial preparation for control activities may need to start before laboratory results are known.

The main strategy for controlling a mumps outbreak is to define the population(s) at risk and transmission setting(s), and to rapidly identify and vaccinate persons without presumptive evidence of immunity; or, if a

contraindication exists, to consider excluding persons without presumptive evidence of immunity from the setting to prevent exposure and transmission. The ACIP reviewed the available evidence and determined that a third dose of MMR was safe and effective at preventing mumps and its complications in persons at increased risk because of an outbreak and recommended for its use in October 2017.

Mumps-containing vaccine should be administered to persons without evidence of immunity and everyone should be brought up to date with age appropriate vaccination (1 or 2 doses). In an outbreak setting, persons previously vaccinated with 1 or 2 doses of a mumps-containing vaccine and who are identified by public health as at increased risk for mumps because of the outbreak should receive a dose of a mumps-containing vaccine (second dose for persons previously vaccinated with 1 dose or a third dose for persons previously vaccinated with 2 doses) to improve protection against mumps and its complications. Although mumps-containing vaccination has not been shown to be effective in preventing mumps in persons already infected, it will prevent infection in those persons who are not yet exposed or infected. If persons without evidence of immunity can be vaccinated early in the course of an outbreak, they can be protected prior to exposure. However, because of the long incubation period for mumps, cases are expected to continue to occur for at least 25 days among newly vaccinated persons who may have been infected before vaccination.[63] As with all vaccines, some individuals will not develop protective immunity after receipt of mumps vaccine.

Exclusion of susceptible persons during outbreaks in schools and colleges until the 26th day after parotitis onset in the last person with mumps at the affected school may decrease risk of infection in these individuals; complications may also be decreased by decreasing risk of disease. Exclusion from schools/ colleges affected by a mumps outbreak or other schools that are unaffected but deemed by local public health authorities to be at risk for transmission of disease should be considered for students with zero doses of MMR vaccine and with no other evidence of mumps immunity, including students with exemptions for medical, religious, or other reasons.Considerations for recommending exclusion include increased risk of complications in susceptible persons or contribution of unvaccinated persons to ongoing transmission. Excluded students can be readmitted immediately after they are vaccinated. Students who have a history of 1 dose of MMR vaccination should be allowed to remain in school and recommended to receive their second vaccine dose.

Evidence is limited and insufficient at this time to fully characterize the impact of a third dose of a mumps-containing vaccine on reducing the size and duration of mumps outbreaks; studies are ongoing to address this question. CDC is currently updating guidance for use of a third dose of a mumps-containing vaccine during mumps outbreaks. Persons at increased risk for mumps are those who are more likely to be exposed to respiratory droplets or saliva of a mumps case-patient, such as through close contact with infected persons or sharing of drinks or utensils. Public health should consider several factors in identifying defined groups at increased risk for mumps during an outbreak, including:

1. number and distribution of cases
2. intense exposure settings likely to facilitate transmission
   (e.g., schools, colleges, correctional facilities, congregate living facilities)
3. site(s) of ongoing transmission
4. place of residence during the outbreak
5. intensity and duration of close contact
6. social networks.

Once groups at increased risk are identified, persons in these groups may be advised to seek vaccine through routine channels or through designated clinics; the recommendation of a third dose by public health does not obligate the use of publicly financed vaccine or a vaccination campaign.

Catch-up vaccination efforts to ensure that populations at risk are up to date with the recommended number of vaccine doses, including a third dose for persons identified by public health as at increased risk because of a mumps outbreak, as well as reducing opportunities for close contact, are recommended strategies during mumps outbreaks.

XII. Healthcare Settings

Prevention and control strategies in healthcare settings

Prevention and control strategies should be applied in all healthcare settings, including outpatient and long-term care facilities. These measures include:

- assessment of presumptive evidence of immunity of healthcare personnel, including documented administration of 2 doses of live mumps virus vaccine, laboratory evidence of immunity or laboratory confirmation of disease, or birth before 1957 (refer to next section, "Healthcare personnel: presumptive evidence of immunity" for footnotes);
- vaccination of those without evidence of immunity;
- exclusion of healthcare personnel with active mumps illness, as well as healthcare personnel who do not have presumptive evidence of immunity who are exposed to persons with mumps;
- isolation of patients in whom mumps is suspected; and
- implementation of droplet precautions, in addition to standard precautions.

An effective vaccination program is the best approach to prevent healthcare-associated mumps transmission. Healthcare Infection Control Practices Advisory Committee (HICPAC) and CDC have recommended that secure, preferably computerized, systems should be used to manage vaccination records for healthcare personnel so records can be easily retrieved as needed.[64] Facilities are also encouraged to review employee evidence of immunity status for mumps and other vaccine preventable infections. Healthcare facilities should provide MMR vaccine to all personnel without evidence of mumps immunity at no charge.

Healthcare personnel: presumptive evidence of immunity

The presumptive evidence of immunity criteria for healthcare personnel differs slightly from the criteria for community settings. The following criteria should be followed to assess presumptive evidence of immunity among healthcare personnel.[65]

- Written documentation of vaccination with 2 doses of live mumps or MMR vaccine administered at least 28 days apart*
- Laboratory evidence of immunity†
- Laboratory confirmation of disease
- Birth before 1957‡§¶

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* *The first dose of mumps-containing vaccine should be administered on or after the first birthday; the second dose should be administered no earlier than 28 days after the first dose.*

† *Mumps immunoglobulin (IgG) in the serum; equivocal results should be considered negative.*

‡ *May vary depending on current state or local requirements.*

§ *For unvaccinated personnel born before 1957 who lack laboratory evidence of mumps immunity or laboratory confirmation of disease, healthcare facilities should consider vaccinating personnel with two doses of MMR vaccine at the appropriate interval.*

¶ *For unvaccinated personnel born before 1957 who lack laboratory evidence of mumps immunity or laboratory confirmation of disease, healthcare facilities should recommend two doses of MMR vaccine during an outbreak of mumps.*

Mumps outbreaks among vaccinated healthcare personnel are rare and when they do occur, are usually quickly contained. In the event that a nosocomial outbreak occurs, healthcare facilities should have a plan in place for the implementation of the 2-dose recommendation for all healthcare personnel, including those who were born before 1957 and lack laboratory evidence of immunity or laboratory confirmation of disease. Healthcare facilities may choose to proceed with appropriate assessment and vaccination of personnel born before 1957 before an outbreak occurs.

Although there are no data that correlate levels of serum antibody with protection from disease, presence of mumps-specific IgG antibodies is considered evidence of mumps immunity. For healthcare personnel who do not have adequate presumptive evidence of mumps immunity, prevaccination antibody screening before MMR vaccination is not necessary.

Results of serum antibody tests in vaccinated persons are difficult to interpret. In vaccinated persons, antibody levels are often lower than following natural infection, and commercially available tests may not detect such low levels of antibody. As a result, postvaccination serologic testing to verify an immune response to MMR or its component vaccines is not recommended.

Management of healthcare personnel with illness due to mumps

A diagnosis of mumps should be considered in exposed healthcare personnel who develop non-specific respiratory infection symptoms during the incubation period after unprotected exposures to mumps, even in the absence of parotitis.

Healthcare personnel with mumps illness should be excluded for 5 days after the onset of parotitis.

Management of healthcare personnel who are exposed to persons with mumps

Unprotected exposures are defined as being within 3 feet of a patient with a diagnosis of mumps without the use of proper personal protective equipment. Irrespective of their immune status, all exposed healthcare personnel should report any signs or symptoms of illness during the incubation period, from 12 through 25 days after exposure.

For healthcare personnel who do not have acceptable presumptive evidence of immunity: Healthcare personnel without evidence of immunity should be excluded from the 12th day after the first unprotected exposure to mumps through the 25th day after the last exposure. Previously unvaccinated healthcare personnel who receive a first dose of vaccine after an exposure are considered non-immune and should be excluded from the 12th day after the first exposure to mumps through the 25th day after the last exposure. The mumps vaccine cannot be used to prevent the development of mumps after exposure.

For healthcare personnel with partial vaccination: Healthcare personnel who had been previously vaccinated for mumps, but received only 1 dose of mumps vaccine may continue working following an unprotected exposure to mumps. Such personnel should receive a second dose as soon as possible, but no sooner than 28 days after the first dose. They should be educated about symptoms of mumps, including nonspecific presentations, and should notify occupational health if they develop these symptoms.

For healthcare personnel who have presumptive evidence of immunity: Healthcare personnel with evidence of immunity do not need to be excluded from work following an unprotected exposure. However, 2 doses of MMR vaccine do not provide 100% protection from mumps. Some vaccinated personnel may remain at risk for mumps and steps should be taken to reduce the risk of infection. Therefore, healthcare personnel should be educated about symptoms of mumps, including nonspecific presentations, and should notify occupational health if they develop these symptoms.

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Reference 14

Vaccine-Preventable Diseases Surveillance Summary (p 2)
Wisconsin, 2018

This report summarizes information on vaccine-preventable diseases among Wisconsin residents reported to the Wisconsin Department of Health Services through the Wisconsin Electronic Disease Surveillance System.

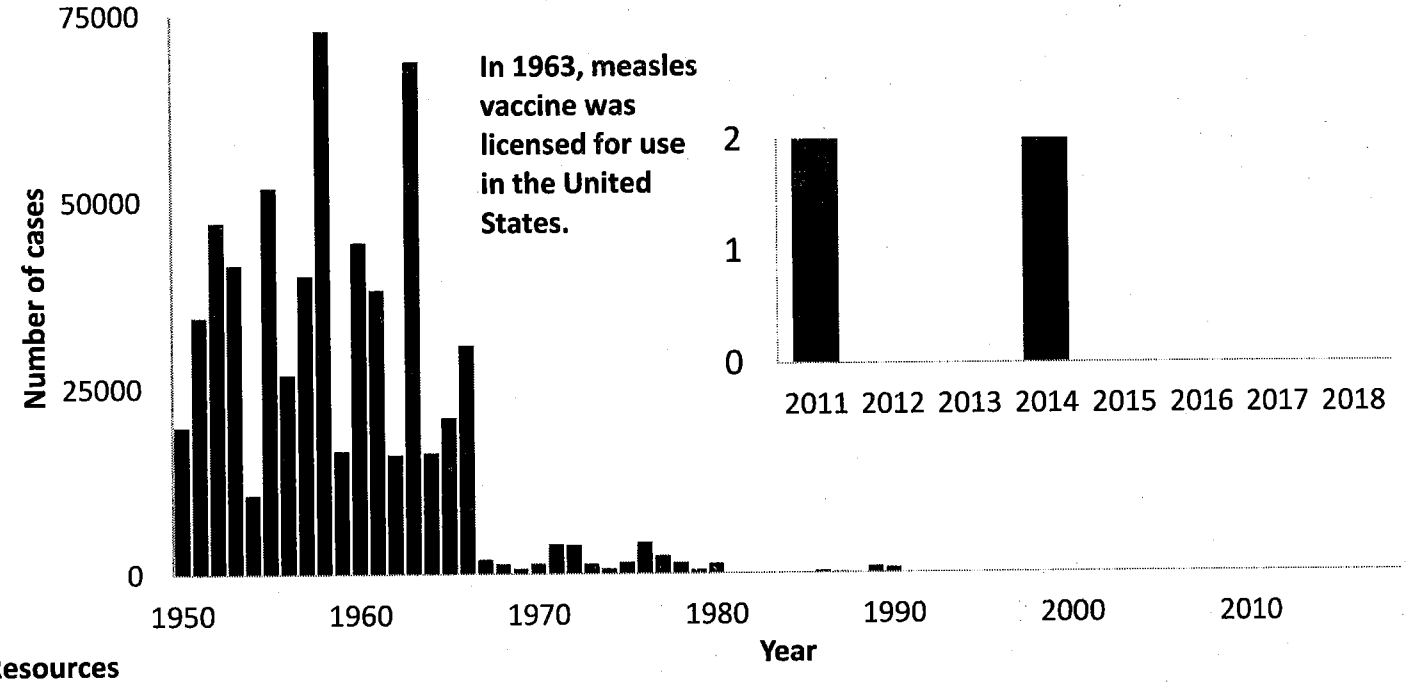
Measles

Trends
After measles vaccine was introduced in 1963, the number of measles cases decreased significantly in Wisconsin (Figure 1) and in the United States.

2018
During 2018, no measles cases were reported among Wisconsin residents.

Summary
Although measles is now rare in Wisconsin, measles is still common in many parts of the world, including some countries in Europe, Asia, and Africa. Travelers continue to bring measles to the United States and to Wisconsin. In 2018, the US experienced 17 outbreaks of measles and 372 confirmed cases. In 2014, two Wisconsin residents were infected with measles. One was believed to be infected at a U.S. airport while waiting for a domestic flight, and the other had travelled internationally. It is important to prevent measles because measles spreads quickly among unvaccinated people and can cause serious illness and complications, especially for children. The measles vaccine is the most effective method for preventing measles.

Figure 1. Number of reported confirmed measles cases, by year, Wisconsin, 1950–2018



Resources
DHS measles page: https://www.dhs.wisconsin.gov/immunization/measles.htm
United States cases and outbreaks: https://www.cdc.gov/measles/cases-outbreaks.html
Measles vaccine: https://www.cdc.gov/measles/vaccination.html

Mumps

Trends

After the live attenuated mumps vaccine was introduced in 1967, the number of mumps cases decreased significantly in Wisconsin (Figure 2) and in the United States. However, cases and outbreaks still occur.

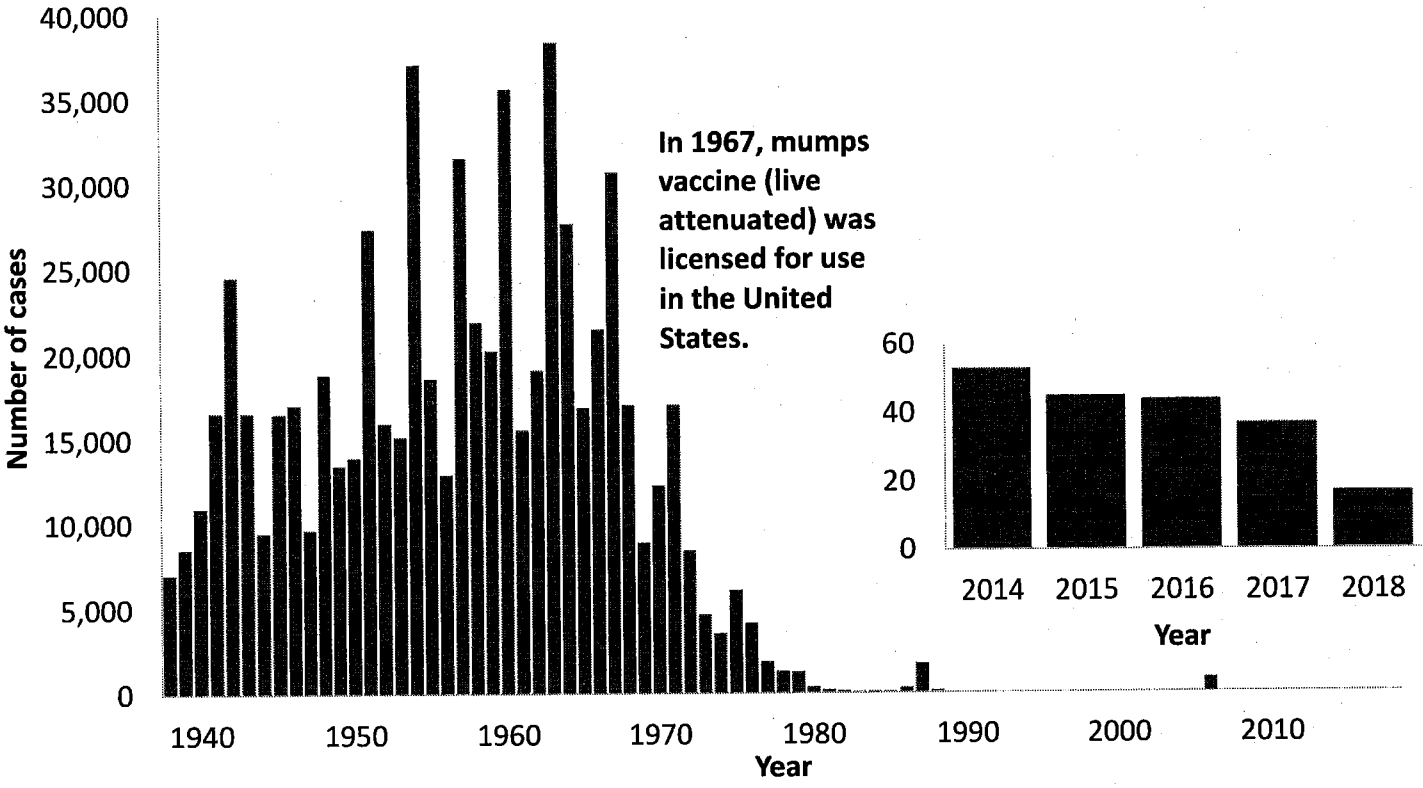
2018

- During 2018, 17 confirmed mumps cases were reported among Wisconsin residents of 6 counties.
- Ages ranged from 10 to 59 years (median age: 31 years) with 35% female and 65% male.
- Vaccination status was known for 10 (59%) cases. Of cases with known vaccination status, 90% had received two doses and 10% had received one dose.
- Three cases (18%) were associated with two outbreaks.
- Two (12%) cases were known to have had contact with another mumps case.
- One (6%) had a recent history of travel outside of Wisconsin. None travelled internationally.

Summary

Cases and outbreaks of mumps continue to occur in Wisconsin and the United States, often among young adults in close-contact settings. It is important to prevent mumps because mumps can cause serious complications, especially among adults. The mumps vaccine prevents most mumps cases and complications.

Figure 2. Number of reported confirmed mumps cases, by year, Wisconsin, 1950–2018



Resources

Update on recent Wisconsin mumps cases: https://www.dhs.wisconsin.gov/immunization/mumps-report.pdf
DHS mumps page: https://www.dhs.wisconsin.gov/immunization/mumps.htm
United States cases and outbreaks: https://www.cdc.gov/mumps/outbreaks.html
Mumps vaccine: https://www.cdc.gov/mumps/vaccination.html

Pertussis (Whooping Cough)

Trends

After whole cell pertussis vaccine was introduced during the 1940s, the number of pertussis cases decreased significantly in Wisconsin (Figure 3) and in the United States. During the 1990s a new diagnostic test (PCR) was introduced that allowed for more pertussis cases to be detected and reported. Additionally, during the 1990s whole cell vaccine was replaced by acellular pertussis vaccine (DTaP) and recent studies indicate it provides a shorter duration of protection from pertussis than whole cell vaccine. A booster vaccine, Tdap, was introduced in 2006. Recent studies indicate the protection from Tdap vaccination wanes in 3-4 years.

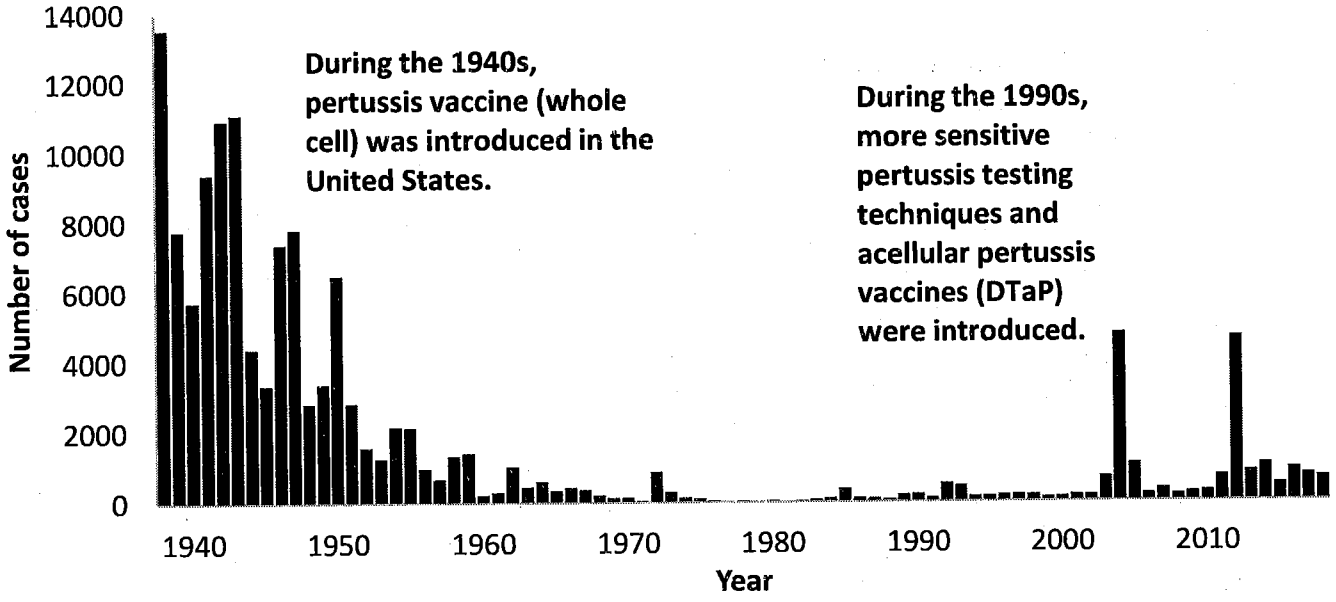
2018

- During 2018, 388 confirmed and 312 probable pertussis cases were reported among Wisconsin residents in 60 counties. Persons with pertussis ranged in age from <1 month to 88 years (median age: 1 year).
- Thirty-five (5%) cases were hospitalized.
- Among cases aged 2 months through 10 years, 55% were up to date with pertussis vaccinations, and 79% of cases aged 11–18 years had previously received the Tdap booster dose.
- For the full 2018 annual summary: https://www.dhs.wisconsin.gov/publications/p01263-18.pdf

Summary

Pertussis continues to affect people of all ages in Wisconsin and the United States. Large and small outbreaks continue to occur. Infants too young to be fully vaccinated are at highest risk of pertussis and its serious complications, including death. Routine vaccination with pertussis vaccine is the most effective method for preventing pertussis. Newborn infants are best protected from pertussis when their mothers are vaccinated with Tdap vaccine during the third trimester of pregnancy. These infants are born with passive protection from pertussis.

Figure 3. Number of reported confirmed pertussis cases, by year, Wisconsin, 1938–2018



Resources

Update on recent Wisconsin pertussis cases: https://www.dhs.wisconsin.gov/immunization/pert-report.pdf
DHS annual surveillance summaries: pertussis page | 2017| 2016 | 2015 | 2014 | 2013 | 2012
National pertussis trends: https://www.cdc.gov/pertussis/surv-reporting.html
Pertussis vaccine: https://www.cdc.gov/vaccines/vpd/pertussis/index.html

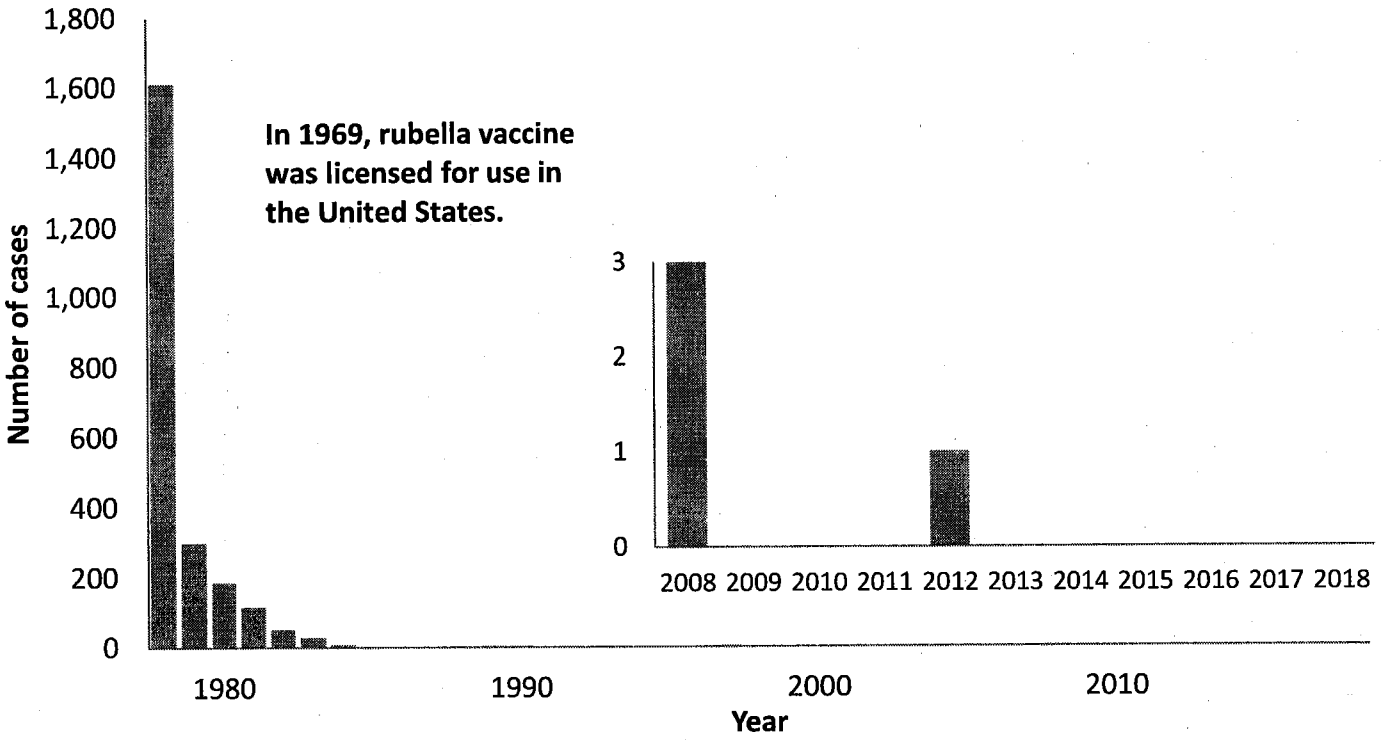
Rubella

Trends
After rubella vaccine was introduced in 1969, the number of rubella cases decreased significantly in Wisconsin (Figure 4) and in the United States.

2018
During 2018, no rubella cases were reported among Wisconsin residents.

Summary
Rubella is no longer constantly present in the United States. However, because rubella is still common in many parts of the world, including Southeast Asia, Africa, and the Eastern Mediterranean region, travelers to affected areas can bring rubella to the United States and Wisconsin. For example, in 2012 a Wisconsin resident developed rubella after having contact with family members who recently arrived from an affected country. It is important to prevent rubella because rubella can cause serious complications, and women who are infected with rubella during pregnancy are at risk for miscarriage, stillbirth, and of having a baby with severe birth defects, a condition known as congenital rubella syndrome. Vaccination with rubella vaccine is the most effective method for preventing rubella. To prevent congenital rubella syndrome, before women become pregnant, they should be vaccinated with rubella vaccine.

Figure 4. Number of reported confirmed rubella cases, by year, Wisconsin, 1978–2018



Resources
DHS rubella page: https://www.dhs.wisconsin.gov/immunization/rubella.htm
CDC rubella page: https://www.cdc.gov/rubella/about/index.html
Congenital rubella syndrome: https://www.cdc.gov/rubella/pregnancy.html
Information for travelers: https://wwwnc.cdc.gov/travel/diseases/rubella
Rubella vaccine: https://www.cdc.gov/vaccines/vpd/mmr/public/index.html

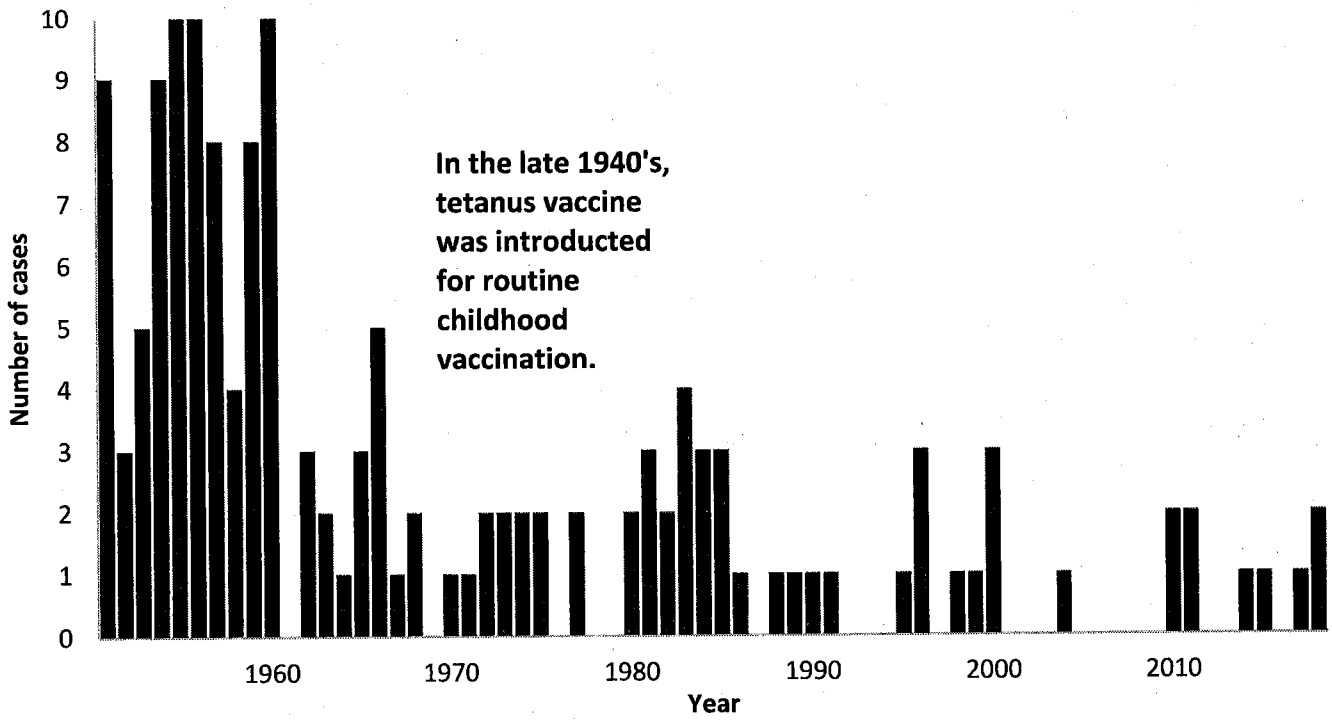
Tetanus

Trends
After tetanus vaccine was introduced for routine childhood vaccination during the late 1940s, the number of tetanus cases decreased steadily in Wisconsin (Figure 5) and in the United States.

2017
During 2018, there were two tetanus cases reported among Wisconsin residents.

Summary
Because the bacteria that cause tetanus live in soil, unvaccinated people and people overdue for a tetanus booster shot are at risk for tetanus when they have a contaminated wound or other breaks in the skin. Tetanus cases continue to occur among Wisconsin residents. For example, in 2015 an unvaccinated Wisconsin child was diagnosed with tetanus requiring hospitalization for 33 days (including 15 days in intensive care). Preventing tetanus is important because tetanus can cause severe symptoms and complications, including breathing difficulty that can lead to death. Vaccination with tetanus vaccine is the most effective method for preventing tetanus.

Figure 5. Number of reported tetanus cases, by year, Wisconsin, 1951–2018



Resources
DHS tetanus page: https://www.dhs.wisconsin.gov/immunization/tetanus.htm
CDC tetanus page: https://www.cdc.gov/tetanus/about/index.html
Tetanus vaccine: https://www.cdc.gov/tetanus/vaccination.html

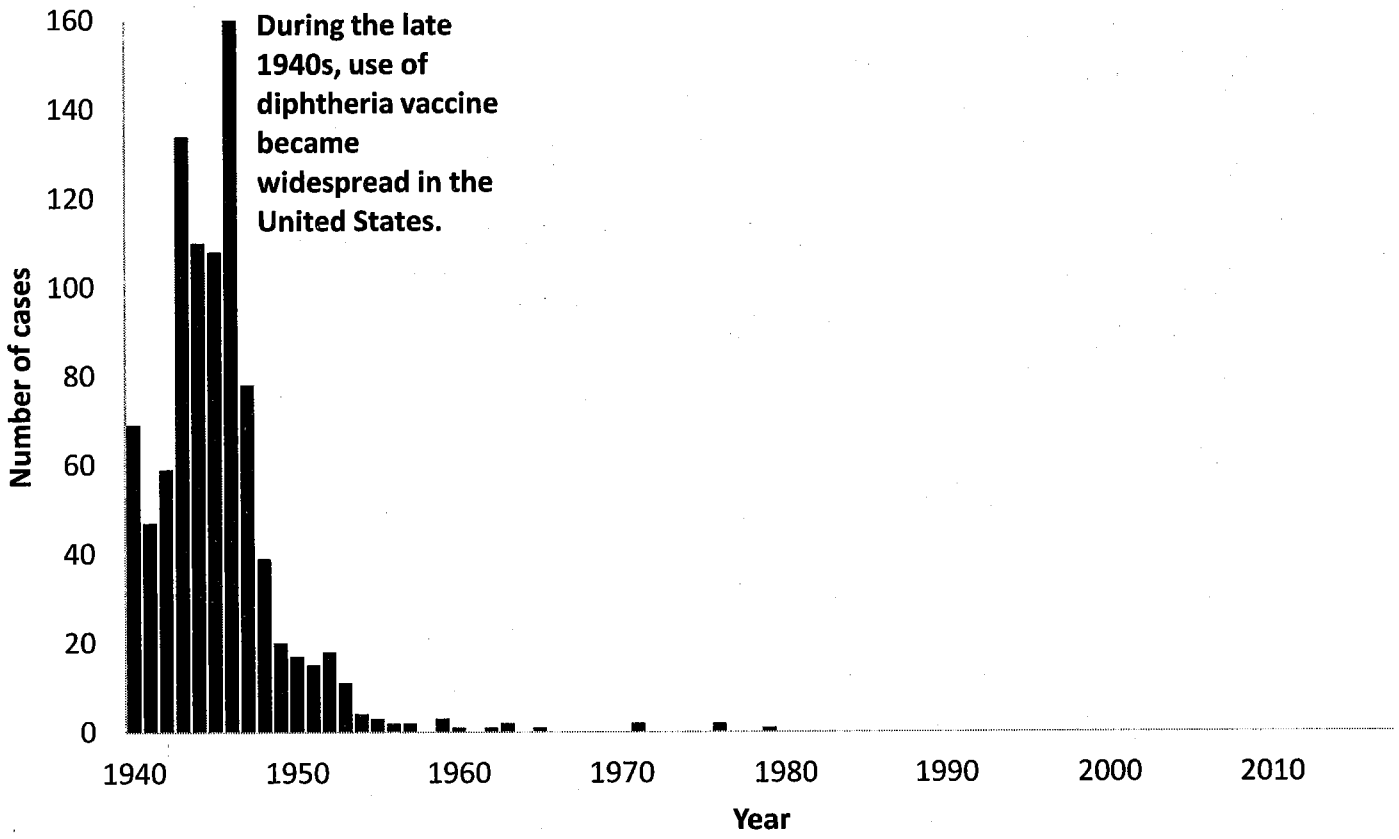
Diphtheria

Trends
After use of diphtheria vaccine became routine and widespread during the late 1940s, the number of diphtheria cases decreased significantly in Wisconsin (Figure 6) and in the United States.

2018
During 2018, no diphtheria cases were reported among Wisconsin residents.

Summary
Diphtheria infection is rare in the United States, but continues to occur in many developing countries in Asia, the Middle East, Eastern Europe, Haiti, and the Dominican Republic. Travelers to these areas are at risk of diphtheria infection. It is important to prevent diphtheria because diphtheria can cause serious complications, including death. Vaccination with diphtheria vaccine is the most effective method for preventing diphtheria.

Figure 6. Number of reported confirmed diphtheria cases, by year, Wisconsin, 1943–2018



Resources
DHS diphtheria page: https://www.dhs.wisconsin.gov/immunization/diphtheria.htm
CDC diphtheria page: https://www.cdc.gov/diphtheria/index.html
Information for travelers: https://wwwnc.cdc.gov/travel/diseases/diphtheria
Diphtheria vaccine: https://www.cdc.gov/diphtheria/vaccination.html

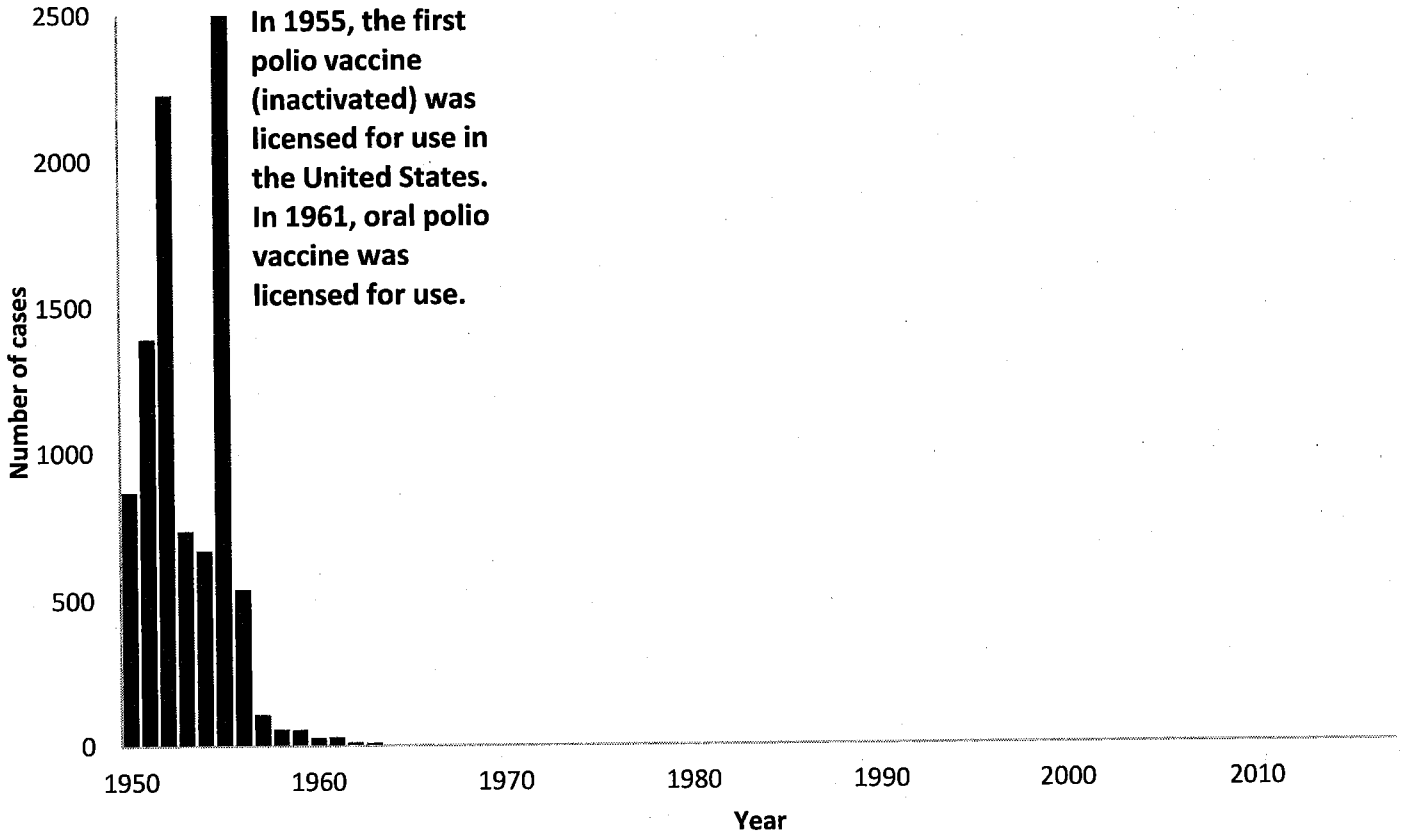
Polio

Trends
After the first polio vaccine was introduced in 1955, the number of polio cases decreased significantly in Wisconsin (Figure 7) and in the United States.

2018
During 2018, no polio cases were reported among Wisconsin residents.

Summary
Health officials from around the globe have been working intently to eradicate polio. Only a few countries remain where polio cases continue to occur, but travelers can and have spread polio to other previously polio-free countries. Travelers to affected areas, including some parts of Africa and Asia, are at risk for polio. Vaccination with polio vaccine prevents polio, its serious complications, and reduces polio transmission to other countries.

Figure 7. Number of reported confirmed polio cases, by year, Wisconsin, 1950–2018



Resources
DHS polio page: https://www.dhs.wisconsin.gov/immunization/polio.htm
CDC polio page: https://www.cdc.gov/polio/about/index.htm
Information for travelers: https://wwwnc.cdc.gov/travel/diseases/poliomyelitis
Polio vaccine: https://www.cdc.gov/vaccines/vpd/polio/index.html

Varicella (Chickenpox)

Trends

After varicella vaccine was introduced in 1995, the number of varicella cases decreased significantly in Wisconsin (Figure 8) and in the United States. In response to outbreaks among vaccinated children, in 2006 a second dose of varicella vaccine was routinely recommended. Varicella cases and outbreaks continue to occur. Surveillance for varicella is challenging because most cases are not laboratory confirmed and the clinical presentation of varicella can be confused with other rash illnesses.

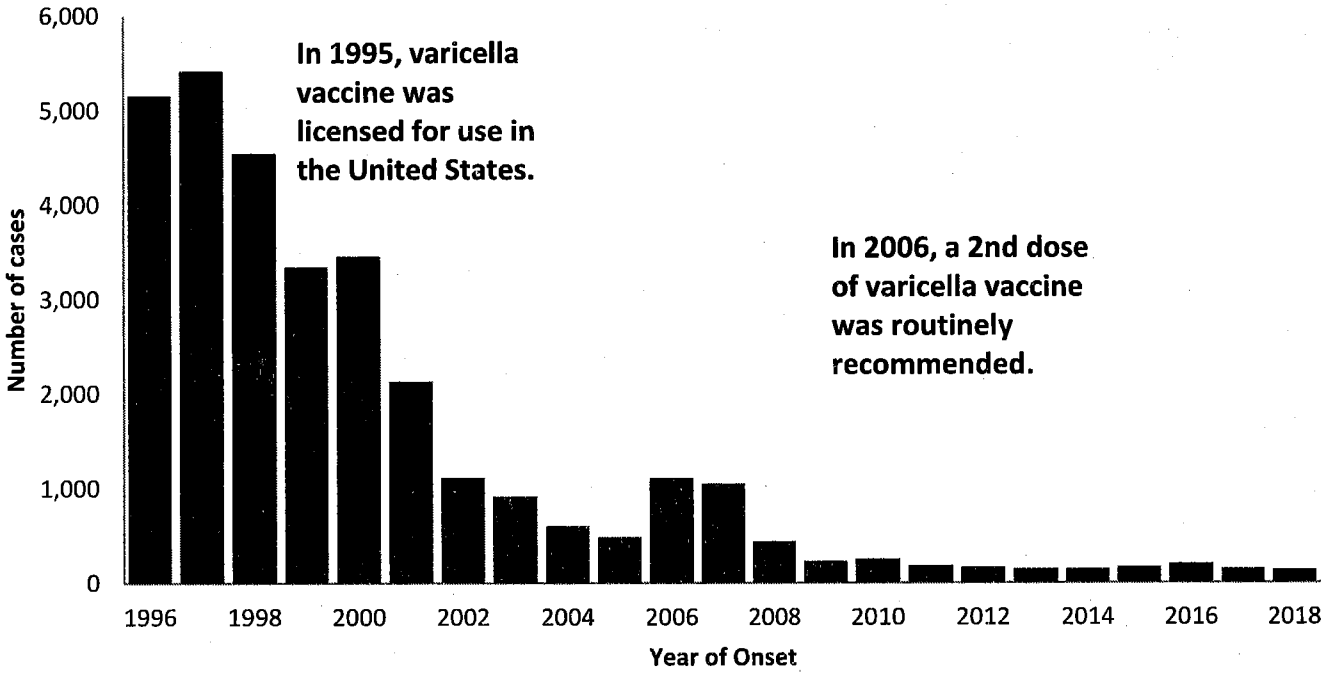
2018

- During 2018, 136 confirmed and 154 probable varicella cases were reported among Wisconsin residents.
- Cases of varicella were reported from 56 of Wisconsin's 72 counties.
- Persons with varicella ranged in age from 2 months to 90 years (median age: 6 years).
- Seven (2%) persons with varicella were hospitalized, including one infant.
- Among persons with varicella aged 1–3 years, 65% were up to date for age and had received one dose of varicella vaccine. Among persons with varicella aged 4–18 years, 56% were up to date for age and had received two doses of varicella vaccine, 10% had received one dose of varicella vaccine, and 32% had not been vaccinated with varicella vaccine.

Summary

Varicella continues to affect persons of all ages in Wisconsin and the United States. It is important to prevent varicella because varicella can result in serious complications, especially for infants, adolescents, adults, pregnant women, and immunocompromised persons. Vaccination with varicella vaccine prevents most varicella cases and complications.

Figure 8. Number of reported confirmed varicella cases, by year, Wisconsin, 1996–2018



Resources

DHS varicella page: https://www.dhs.wisconsin.gov/immunization/varicella.htm
CDC varicella page: https://www.cdc.gov/chickenpox/index.html
Varicella vaccine: https://www.cdc.gov/chickenpox/vaccination.html

Notes

Additional Resources

Vaccination rates for Wisconsin: https://www.dhs.wisconsin.gov/immunization/data.htm
Vaccine-preventable diseases by year: https://www.dhs.wisconsin.gov/immunization/vpdsbyyear.pdf
Recommended vaccination schedules
Children: https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html
Adults: https://www.cdc.gov/vaccines/schedules/hcp/adult.html

References

Epidemiology and Prevention of Vaccine-Preventable Diseases: The Pink Book:
https://www.cdc.gov/vaccines/pubs/pinkbook/index.html
Measles transmission at a domestic terminal gate in an international airport – United States, January 2014:
https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6350a9.htm

Data Source

The diseases included in this report have significant public health impact and are required by law to be reported to the local health officer when suspected in a Wisconsin resident. This information is collected and reported to DHS through the Wisconsin Electronic Disease Surveillance System:
https://www.dhs.wisconsin.gov/wiphin/wedss.htm
More information on disease reporting: https://www.dhs.wisconsin.gov/disease/diseasereporting.htm

Limitations

Monitoring trends in disease occurrence depends on complete and consistent reporting of diseases to DHS through the Wisconsin Electronic Disease Surveillance System. This report only includes information on the cases that were reported to WDPH. Therefore, to the extent that diseases are underreported or misreported to WDPH, the results depicted in this report might differ from the true burden of these diseases in Wisconsin.

Abbreviations

CDC: Centers for Disease Control and Prevention
DTaP: diphtheria, tetanus, acellular pertussis vaccine
Tdap: tetanus, diphtheria, acellular pertussis vaccine
DHS: Wisconsin Division of Public Health

Wisconsin Immunization Program, Division of Public Health
Wisconsin Department of Health Services
P-02321 (April 2019)

Reference 15 (p. 2)

Vaccine-Preventable Diseases Surveillance Summary Wisconsin, 2017

This report summarizes information on vaccine-preventable diseases among Wisconsin residents reported to the Wisconsin Department of Health Services through the Wisconsin Electronic Disease Surveillance System.

Measles

Trends

After measles vaccine was introduced in 1963, the number of measles cases decreased significantly in Wisconsin (Figure 1) and in the United States.

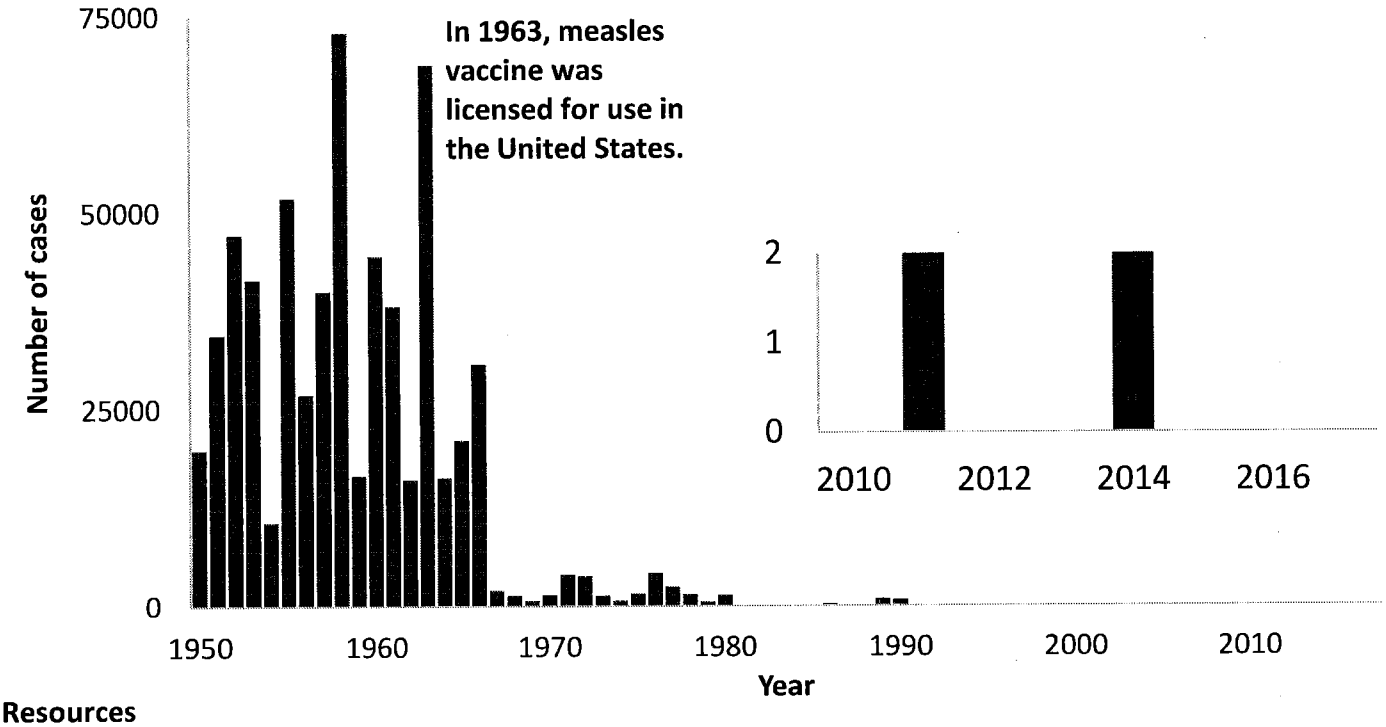
2017

During 2017, no measles cases were reported among Wisconsin residents.

Summary

Although measles is now rare in Wisconsin, measles is still common in many parts of the world, including some countries in Europe, Asia, and Africa. Travelers continue to bring measles to the United States and to Wisconsin. In 2014, two Wisconsin residents were infected with measles. One was believed to be infected at a U.S. airport while waiting for a domestic flight, and the other had travelled internationally. It is important to prevent measles because measles spreads quickly among unvaccinated people and can cause serious illness and complications, especially for children. The measles vaccine is the most effective method for preventing measles.

Figure 1. Number of reported confirmed measles cases, by year, Wisconsin, 1950–2017



Resources

DHS measles page: https://www.dhs.wisconsin.gov/immunization/measles.htm
United States cases and outbreaks: https://www.cdc.gov/measles/cases-outbreaks.html
Measles vaccine: https://www.cdc.gov/measles/vaccination.html

Mumps

Trends

After the live attenuated mumps vaccine was introduced in 1967, the number of mumps cases decreased significantly in Wisconsin (Figure 2) and in the United States. However, cases and outbreaks still occur.

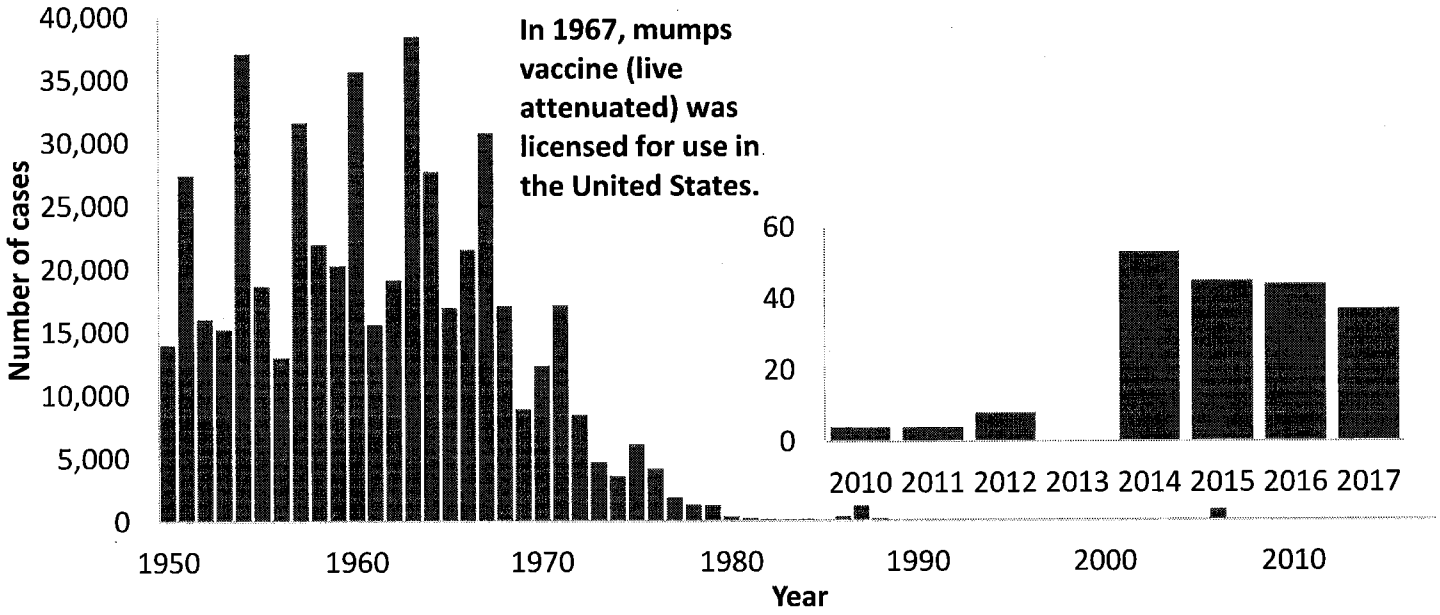
2017

- During 2016, 37 confirmed mumps cases were reported among Wisconsin residents of 11 counties.
- Ages ranged from 15 to 37 years (median age: 21 years) with 27% female and 73% male.
- Vaccination status was known for 29 (78%) cases. Of cases with known vaccination status, 96% had received two doses and 3% had received one dose.
- Twenty-five cases (68%) were associated with two outbreaks. An outbreak among University of Wisconsin-Platteville students and others in the community had nine cases (with an additional 14 in 2016). Another outbreak in the Milwaukee area included 7 cases and an outbreak among University of Wisconsin-La Crosse students and others in the community included 9 cases.
- Thirteen (35%) cases were known to have had contact with another mumps case.
- Seven (19%) had a recent history of travel outside of Wisconsin. Of these, two travelled internationally.

Summary

Cases and outbreaks of mumps continue to occur in Wisconsin and the United States, often among young adults in close-contact settings. It is important to prevent mumps because mumps can cause serious complications, especially among adults. The mumps vaccine prevents most mumps cases and complications.

Figure 2. Number of reported confirmed mumps cases, by year, Wisconsin, 1950–2017



Resources

Update on recent Wisconsin mumps cases: https://www.dhs.wisconsin.gov/immunization/mumps-report.pdf
DHS mumps page: https://www.dhs.wisconsin.gov/immunization/mumps.htm
United States cases and outbreaks: https://www.cdc.gov/mumps/outbreaks.html
Mumps vaccine: https://www.cdc.gov/mumps/vaccination.html

Pertussis (Whooping Cough)

Trends

After whole cell pertussis vaccine was introduced during the 1940s, the number of pertussis cases decreased significantly in Wisconsin (Figure 3) and in the United States. During the 1990s a new diagnostic test (PCR) was introduced that allowed for more pertussis cases to be detected and reported. Additionally, during the 1990s whole cell vaccine was replaced by acellular pertussis vaccine (DTaP) and recent studies indicate it provides a shorter duration of protection from pertussis than whole cell vaccine. A booster vaccine, Tdap, was introduced in 2006. Recent studies indicate the protection from Tdap vaccination wanes in 3-4 years.

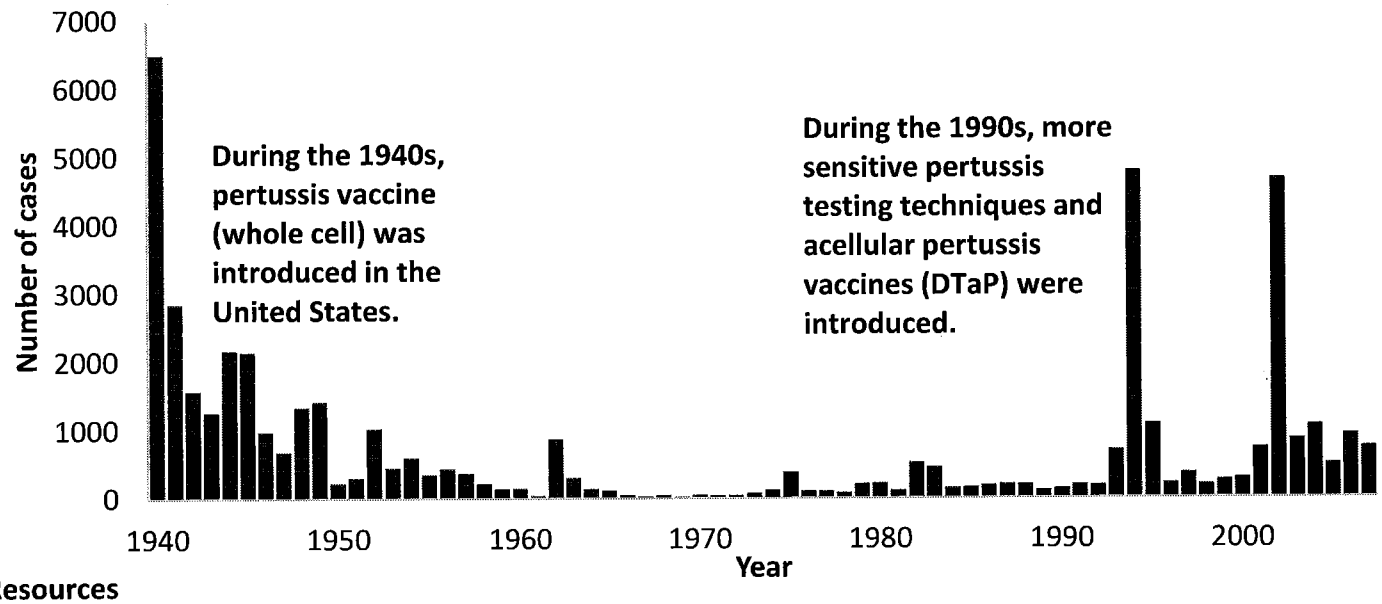
2017

- During 2017, 529 confirmed and 247 probable pertussis cases were reported among Wisconsin residents in 61 counties. Persons with pertussis ranged in age from <1 month to 89 years (median age: 13 years).
- Three percent (n=25) of cases were hospitalized.
- Among cases aged 2 months through 10 years, 66% were up to date with pertussis vaccinations, and 85% of cases aged 11–18 years had previously received the Tdap booster dose.
- For the full 2017 annual summary: https://www.dhs.wisconsin.gov/immunization/pertussis.htm

Summary

Pertussis continues to affect people of all ages in Wisconsin and the United States. Large and small outbreaks continue to occur. Infants too young to be fully vaccinated are at highest risk of pertussis and its serious complications, including death. Routine vaccination with pertussis vaccine is the most effective method for preventing pertussis. Newborn infants are best protected from pertussis when their mothers are vaccinated with Tdap vaccine during the third trimester of pregnancy. These infants are born with passive protection from pertussis.

Figure 3. Number of reported confirmed pertussis cases, by year, Wisconsin, 1938–2017



Resources

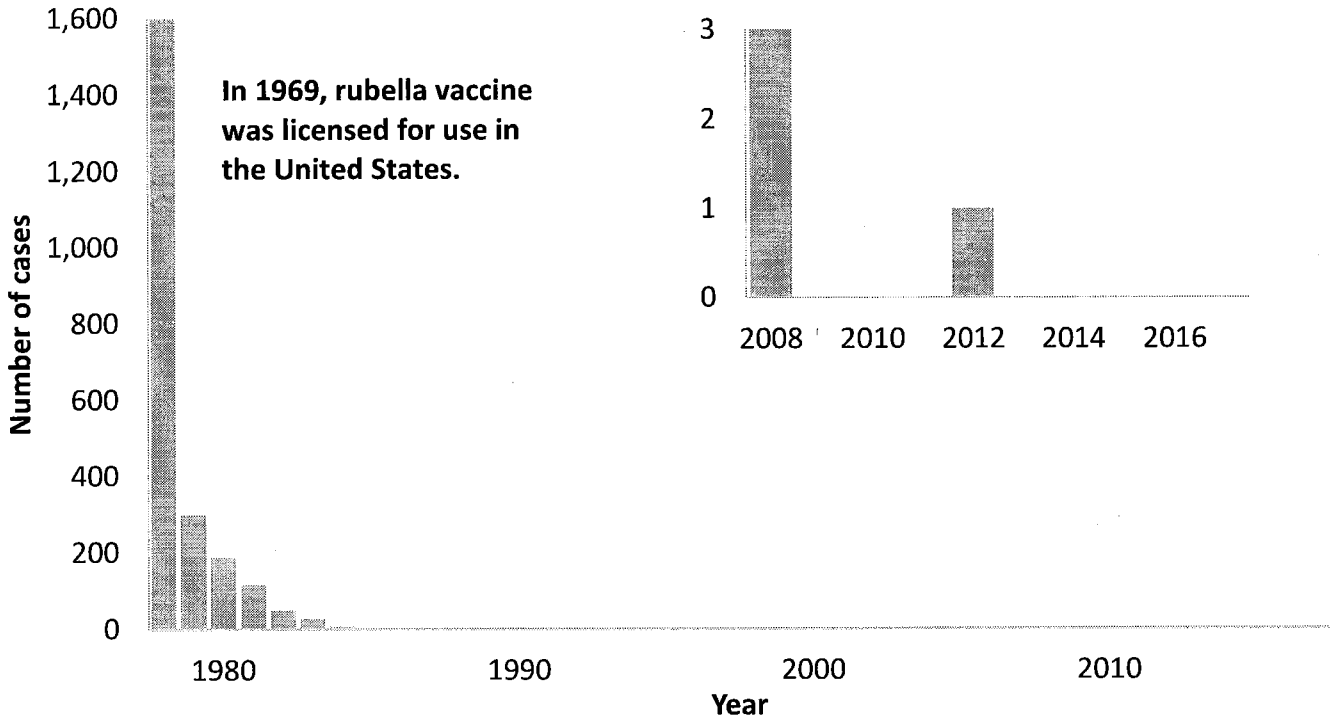
Update on recent Wisconsin pertussis cases: https://www.dhs.wisconsin.gov/immunization/pert-report.pdf
DHS annual surveillance summaries: pertussis page | 2017| 2016 | 2015 | 2014 | 2013 | 2012
National pertussis trends: https://www.cdc.gov/pertussis/surv-reporting.html
Pertussis vaccine: https://www.cdc.gov/vaccines/vpd/pertussis/index.html

Trends
After rubella vaccine was introduced in 1969, the number of rubella cases decreased significantly in Wisconsin (Figure 4) and in the United States.

2017
During 2017, no rubella cases were reported among Wisconsin residents.

Summary
Rubella is no longer constantly present in the United States. However, because rubella is still common in many parts of the world, including Southeast Asia, Africa, and the Eastern Mediterranean region, travelers to affected areas can bring rubella to the United States and Wisconsin. For example, in 2012 a Wisconsin resident developed rubella after having contact with family members who recently arrived from an affected country. It is important to prevent rubella because rubella can cause serious complications, and women who are infected with rubella during pregnancy are at risk for miscarriage, stillbirth, and of having a baby with severe birth defects, a condition known as congenital rubella syndrome. Vaccination with rubella vaccine is the most effective method for preventing rubella. To prevent congenital rubella syndrome, before women become pregnant, they should be vaccinated with rubella vaccine.

Figure 4. Number of reported confirmed rubella cases, by year, Wisconsin, 1978–2017



Resources
DHS rubella page: https://www.dhs.wisconsin.gov/immunization/rubella.htm
CDC rubella page: https://www.cdc.gov/rubella/about/index.html
Congenital rubella syndrome: https://www.cdc.gov/rubella/pregnancy.html
Information for travelers: https://wwwnc.cdc.gov/travel/diseases/rubella
Rubella vaccine: https://www.cdc.gov/vaccines/vpd/mmr/public/index.html

Tetanus

Trends

After tetanus vaccine was introduced for routine childhood vaccination during the late 1940s, the number of tetanus cases decreased steadily in Wisconsin (Figure 5) and in the United States.

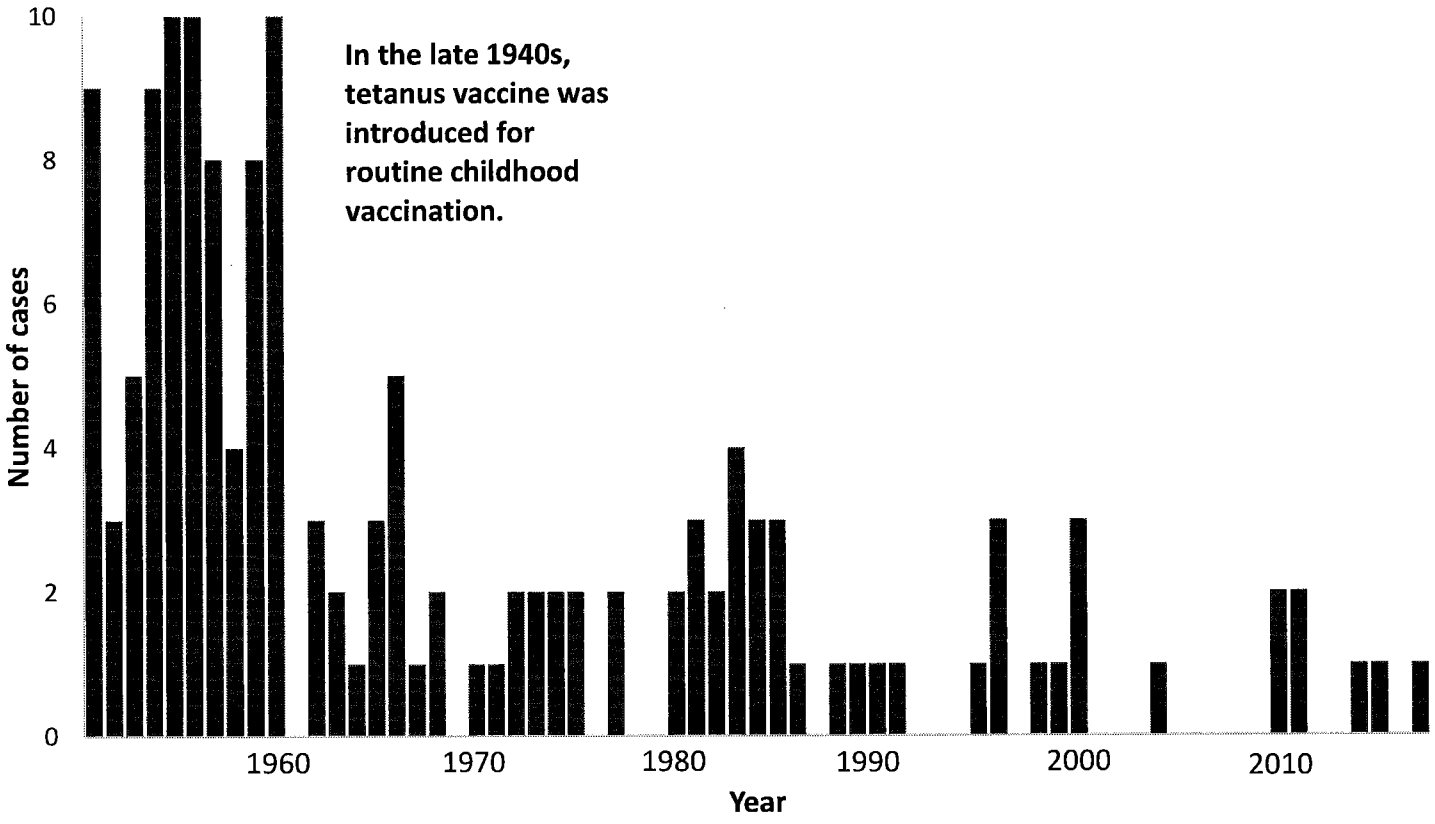
2017

During 2017, there was one tetanus case reported among Wisconsin residents.

Summary

Because the bacteria that cause tetanus live in soil, unvaccinated people and people overdue for a tetanus booster shot are at risk for tetanus when they have a contaminated wound or other breaks in the skin. Tetanus cases continue to occur among Wisconsin residents. For example, in 2015 an unvaccinated Wisconsin child was diagnosed with tetanus requiring hospitalization for 33 days (including 15 days in intensive care). Preventing tetanus is important because tetanus can cause severe symptoms and complications, including breathing difficulty that can lead to death. Vaccination with tetanus vaccine is the most effective method for preventing tetanus.

Figure 5. Number of reported tetanus cases, by year, Wisconsin, 1951–2017



Resources

DHS tetanus page: https://www.dhs.wisconsin.gov/immunization/tetanus.htm
CDC tetanus page: https://www.cdc.gov/tetanus/about/index.html
Tetanus vaccine: https://www.cdc.gov/tetanus/vaccination.html

Diphtheria

Trends

After use of diphtheria vaccine became routine and widespread during the late 1940s, the number of diphtheria cases decreased significantly in Wisconsin (Figure 6) and in the United States.

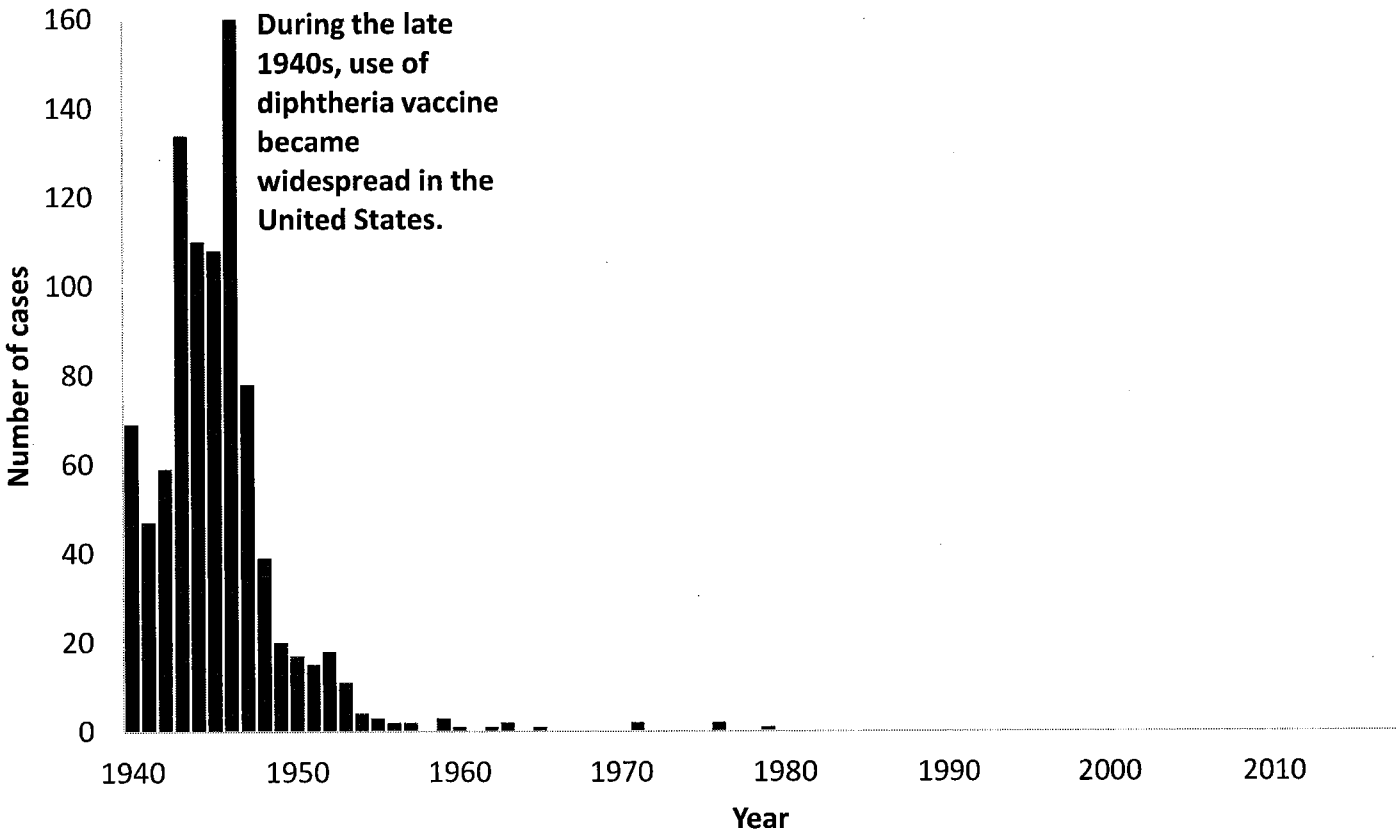
2017

During 2017, no diphtheria cases were reported among Wisconsin residents.

Summary

Diphtheria infection is rare in the United States, but continues to occur in many developing countries in Asia, the middle east, eastern Europe, Haiti, and the Dominican Republic. Travelers to these areas are at risk of diphtheria infection. It is important to prevent diphtheria because diphtheria can cause serious complications, including death. Vaccination with diphtheria vaccine is the most effective method for preventing diphtheria.

Figure 6. Number of reported confirmed diphtheria cases, by year, Wisconsin, 1943–2017



Resources

DHS diphtheria page: https://www.dhs.wisconsin.gov/immunization/diphtheria.htm
CDC diphtheria page: https://www.cdc.gov/diphtheria/index.html
Information for travelers: https://wwwnc.cdc.gov/travel/diseases/diphtheria
Diphtheria vaccine: https://www.cdc.gov/diphtheria/vaccination.html

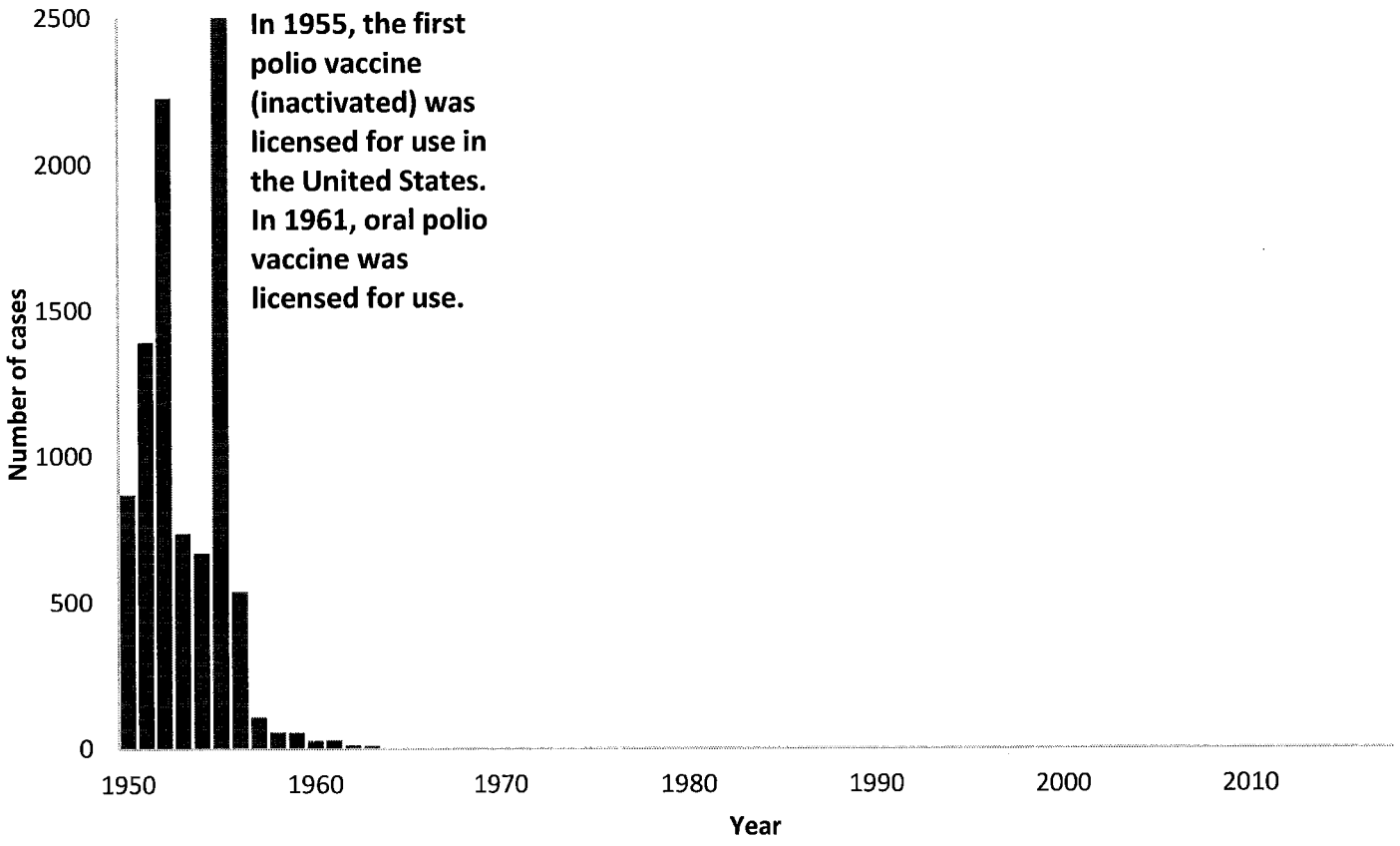
Polio

Trends
After the first polio vaccine was introduced in 1955, the number of polio cases decreased significantly in Wisconsin (Figure 7) and in the United States.

2017
During 2017, no polio cases were reported among Wisconsin residents.

Summary
Health officials from around the globe have been working intently to eradicate polio. Only a few countries remain where polio cases continue to occur, but travelers can and have spread polio to other previously polio-free countries. Travelers to affected areas, including some parts of Africa and Asia, are at risk for polio. Vaccination with polio vaccine prevents polio, its serious complications, and reduces polio transmission to other countries.

Figure 7. Number of reported confirmed polio cases, by year, Wisconsin, 1950–2017



Resources
DHS polio page: https://www.dhs.wisconsin.gov/immunization/polio.htm
CDC polio page: https://www.cdc.gov/polio/about/index.htm
Information for travelers: https://wwwnc.cdc.gov/travel/diseases/poliomyelitits
Polio vaccine: https://www.cdc.gov/vaccines/vpd/polio/index.html

Varicella (Chickenpox)

Trends

After varicella vaccine was introduced in 1995, the number of varicella cases decreased significantly in Wisconsin (Figure 8) and in the United States. In response to outbreaks among vaccinated children, in 2006 a second dose of varicella vaccine was routinely recommended. Varicella cases and outbreaks continue to occur. Surveillance for varicella is challenging because most cases are not laboratory confirmed and the clinical presentation of varicella can be confused with other rash illnesses.

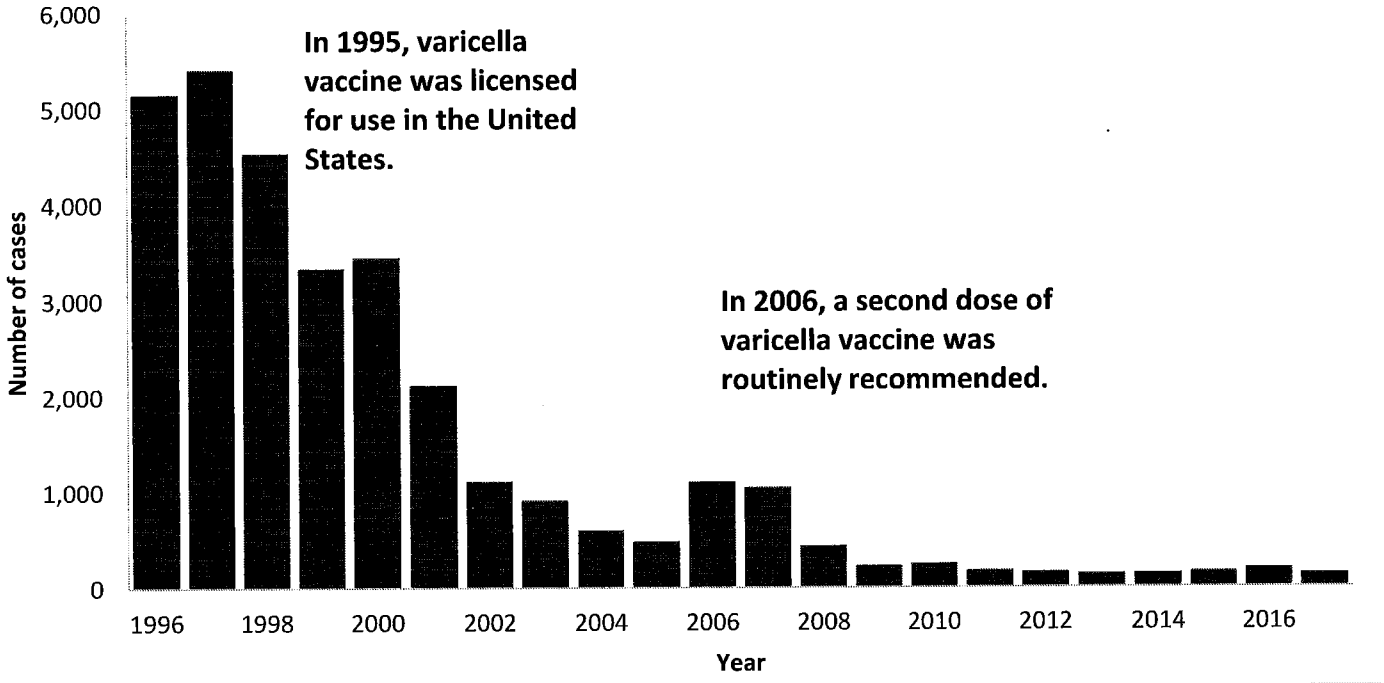
2016

- During 2017, 145 confirmed and 142 probable varicella cases were reported among Wisconsin residents.
- Cases of varicella were reported from 52 of Wisconsin's 72 counties.
- Persons with varicella ranged in age from <1 month to 82 years (median age: 7 years).
- Twelve (4%) persons with varicella were hospitalized, including one infant.
- Among persons with varicella aged 1–3 years, 52% were up to date for age and had received one dose of varicella vaccine. Among persons with varicella aged 4–18 years, 54% were up to date for age and had received two doses of varicella vaccine, 12% had received one dose of varicella vaccine, and 32% had not been vaccinated with varicella vaccine.

Summary

Varicella continues to affect persons of all ages in Wisconsin and the United States. It is important to prevent varicella because varicella can result in serious complications, especially for infants, adolescents, adults, pregnant women, and immunocompromised persons. Vaccination with varicella vaccine prevents most varicella cases and complications.

Figure 8. Number of reported confirmed varicella cases, by year, Wisconsin, 1996–2017



Resources

DHS varicella page: https://www.dhs.wisconsin.gov/immunization/varicella.htm
CDC varicella page: https://www.cdc.gov/chickenpox/index.html
Varicella vaccine: https://www.cdc.gov/chickenpox/vaccination.html

Notes

Additional Resources

Vaccination rates for Wisconsin: https://www.dhs.wisconsin.gov/immunization/data.htm
Vaccine-preventable diseases by year: https://www.dhs.wisconsin.gov/immunization/vpdsbyyear.pdf
Recommended vaccination schedules
Children: https://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html
Adults: https://www.cdc.gov/vaccines/schedules/hcp/adult.html

References

Epidemiology and Prevention of Vaccine-Preventable Diseases: The Pink Book:
https://www.cdc.gov/vaccines/pubs/pinkbook/index.html
Measles transmission at a domestic terminal gate in an international airport – United States, January 2014:
https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6350a9.htm

Data Source

The diseases included in this report have significant public health impact and are required by law to be reported to the local health officer when suspected in a Wisconsin resident. This information is collected and reported to DHS through the Wisconsin Electronic Disease Surveillance System:
https://www.dhs.wisconsin.gov/wiphin/wedss.htm
More information on disease reporting: https://www.dhs.wisconsin.gov/disease/diseasereporting.htm

Limitations

Monitoring trends in disease occurrence depends on complete and consistent reporting of diseases to DHS through the Wisconsin Electronic Disease Surveillance System. This report only includes information on the cases that were reported to WDPH. Therefore, to the extent that diseases are underreported or misreported to WDPH, the results depicted in this report might differ from the true burden of these diseases in Wisconsin.

Abbreviations

CDC: Centers for Disease Control and Prevention
DTaP: diphtheria, tetanus, acellular pertussis vaccine
Tdap: tetanus, diphtheria, acellular pertussis vaccine
DHS: Wisconsin Division of Public Health

Wisconsin Immunization Program, Division of Public Health
Wisconsin Department of Health Services
P-02321 (December 2018)

Reference 16

Notes from the Field

Absence of Asymptomatic Mumps Virus Shedding Among Vaccinated College Students During a Mumps Outbreak — Washington, February–June 2017

Jesse Bonwitt, BVSc[1,2]; Vance Kawakami, DVM,[3]; Adam Wharton, MS[4]; Rachel M. Burke, PhD[1,4]; Neil Murthy, MD[1,4]; Adria Lee, MSPH[4]; BreeAnna Dell, DVM[5]; Meagan Kay, DVM[3]; Jeff Duchin, MD[3,6]; Carole Hickman, PhD[4]; Rebecca J. McNall, PhD[4]; Paul A. Rota, PhD[4]; Manisha Patel, MD[4]; Scott Lindquist, MD[2]; Chas DeBolt, MPH[2]; Janell Routh, MD[4]

On February 8, 2017, a suspected case of mumps in a member of a fraternity or sorority at the University of Washington, Seattle campus (UW) was reported to Public Health—Seattle & King County (PHSKC). Additional confirmed and probable mumps cases were subsequently identified among UW students and staff members according to the national case definition.* By July 19, 2017, a total of 42 (16 confirmed and 26 probable) mumps cases were reported among UW students and associated community members, with symptom onset February 6–June 4 (Figure).

Among the 42 cases, 32 (76%) occurred in UW fraternity and sorority members. Of these, 12 (37.5%) were confirmed cases, and 20 (62.5%) were probable cases. Cases occurred in residents in 20 (38.5%) of 52 fraternity and sorority houses that lodged 2,259 (48.6%) of 4,646 total fraternity and sorority members on the UW campus (42,000 students). All mumps patients had received ≥2 documented doses of measles-mumps-rubella (MMR) vaccine, as is currently recommended (*1*); 2-dose MMR coverage among all UW students exceeded 99%. Genotyping of viral isolates from four patients with confirmed mumps identified genotype G in all four, and molecular sequencing demonstrated differences between circulating strains at UW and a concurrent community outbreak in Washington.

On the basis of CDC guidance, PHSKC recommended an additional dose of MMR vaccine to protect fraternity and sorority members who were subject to potential mumps exposure (*2*). During March 6–9, the week before spring break, PHSKC administered 235 doses of MMR vaccine to members of the eight fraternity and sorority houses reporting the highest number of cases (Figure); the vaccination clinics were open to members of other fraternity and sorority houses.

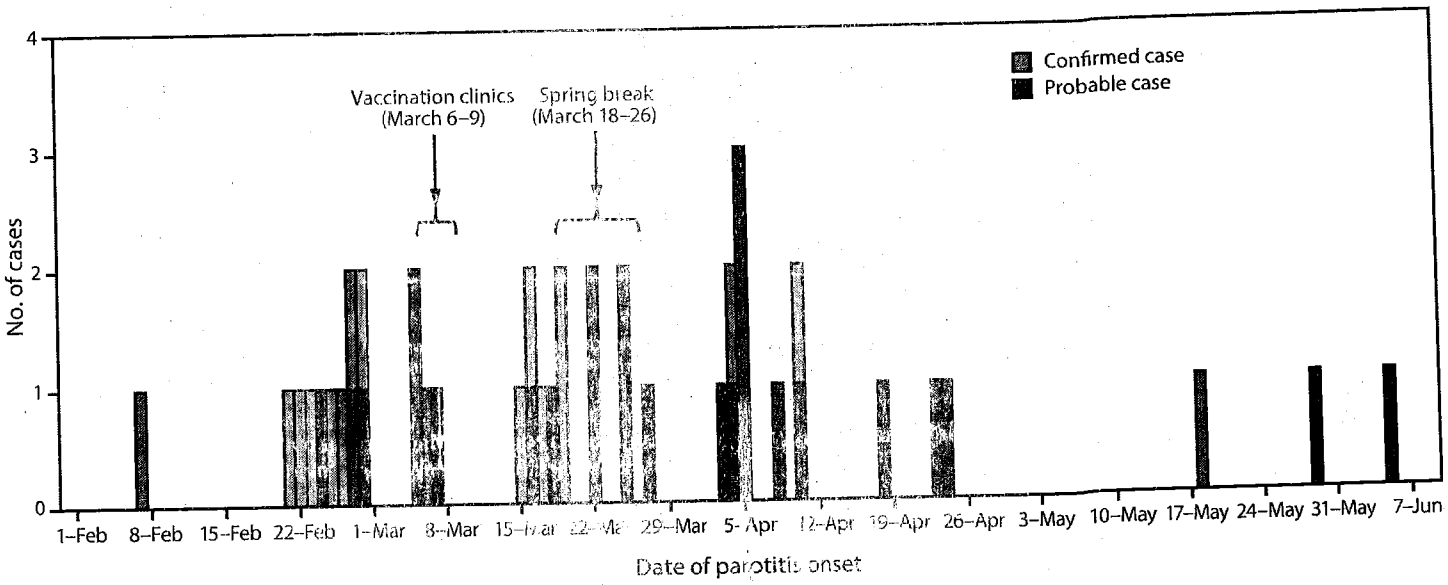
Previous studies have suggested that mumps might be propagated by vaccinated persons with nonspecific symptoms or asymptomatic infection (*3*). Before licensure of mumps vaccine in 1967, 15%–27% of mumps infections were asymptomatic (*2*). How vaccination modifies clinical signs and symptoms of mumps is unknown (*2*). The prevalence of asymptomatic infection has not been assessed in the postvaccination era.

To assess the presence, prevalence, symptoms, and associated risk factors of asymptomatic mumps virus shedding in vaccinated persons, PHSKC, Washington State Department of Health, and CDC recruited a convenience sample of students at each MMR vaccination clinic. Participants provided written consent, completed a symptom and risk factor questionnaire, and provided a bilateral buccal swab immediately before or after vaccination. The Washington State Institutional Review Board determined this project to be nonresearch and exempt from review. Buccal swabs were collected from 160 of the 161 student participants, who represented at least eight fraternities and sororities; 80 (49.7%) were male. Participants reported the following symptoms during the preceding month, none of which required hospitalization: fever (10, 6%), cough (55, 34%), sore throat (37, 23%), and swelling or pain of the parotid gland or jaw not attributable to dental problems (eight, 5%). Specimens were processed at CDC. All 160 buccal swabs were mumps-virus negative by real-time reverse transcription–polymerase chain reaction; positive control testing in the laboratory indicated >99% successful specimen collection and processing.

The majority of mumps cases in this outbreak occurred among fraternity and sorority members; other studies have demonstrated that close contact is required for mumps transmission to occur in a population with high mumps vaccination coverage (*4*,*5*). This evaluation found no laboratory evidence of asymptomatic mumps virus shedding. Limitations include timing of sample collection, which might have missed the period when viral shedding was highest among infected persons, and the lack of serologic testing to identify infected participants. Serial sampling of exposed persons might yield different results. Mumps outbreaks have increased in recent years in the United States; from 2015 through 2016, the proportion of outbreak-related cases increased from 63% to 78% (*6*). Further evaluations to better understand the prevalence of mumps virus shedding among vaccinated populations are needed to guide outbreak surveillance and control.

*https://wwwn.cdc.gov/nndss/conditions/mumps/case-definition/2012/.

FIGURE. Number of confirmed and probable mumps cases among fraternity and sorority members and associated community members, by date of parotitis onset — University of Washington, February–June 2017.



Acknowledgments

Mumps Laboratory Team, Viral Vaccine Preventable Diseases Branch, Division of Viral Diseases, National Center for Immunization and Respiratory Diseases, CDC; Washington State Public Health Laboratories and Office of Communicable Disease Epidemiology; Washington State Department of Health; Public Health—Seattle & King County, Washington; University of Washington, Seattle.

Conflict of interest

No conflicts of interest were reported.

[1]Epidemic Intelligence Service, Division of Scientific Education and Professional Development, CDC; [2]Office of Communicable Disease Epidemiology, Washington State Department of Health; [3]Public Health—Seattle & King County, Washington; [4]National Center for Immunization and Respiratory Diseases, CDC; [5]Department of Biomedical and Diagnostic Sciences, University of Tennessee, Knoxville; [6]University of Washington, Seattle.

Corresponding author: Jesse Bonwitt, jbonwitt@cdc.gov, 206-418-5500.

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Reference 17

Notes from the Field

Complications of Mumps During a University Outbreak Among Students Who Had Received 2 Doses of Measles-Mumps-Rubella Vaccine — Iowa, July 2015–May 2016

Matthew Donahue, MD[1]; Allison Schneider, MD[1]; Ugochi Ukegbu, MPH[2]; Minesh Shah, MD[3]; Jacob Riley, MS[4]; Andrew Weigel, MSW[4]; Lisa James, MSN[5]; Kathleen Wittich, MD[5]; Patricia Quinlisk, MD[6]; Cristina Cardemil, MD[7]

During July 2015–May 2016, a mumps outbreak occurred at the University of Iowa, which is located in Johnson County (*1*). A total of 301 cases of mumps were diagnosed among students. To characterize the outbreak, the Johnson County Public Health Department, the Iowa Department of Public Health, and the University of Iowa, with assistance from CDC, conducted an investigation through telephone interviews, medical chart abstractions, and review of immunization records. Among 287 (95%) students with mumps for whom clinical information was available, 20 (7%) patients with complications were identified (16 self-reported and four clinician-diagnosed). The 20 cases included 15 (5%) cases of orchitis, three (1%) of transient hearing loss, two of mastitis, and one of meningitis (one patient had both orchitis and transient hearing loss). All 20 patients had documentation of receipt of at least 2 doses of measles-mumps-rubella vaccine. Because data are limited regarding the presentation and clinical course of mumps complications in persons who have received 2 doses of mumps-containing vaccine, three illustrative cases of complications (orchitis, transient hearing loss, and meningitis) in students with mumps are presented.

Patient A

On November 17, 2015, a man aged 21 years developed right jaw pain and swelling and received a clinical diagnosis of mumps parotitis; the diagnosis occurred 2 weeks after his roommate had received a mumps diagnosis. By the ninth day after symptom onset, the patient's parotitis had resolved, but he reported a fever of 101.0°F (38.8°C), and 2 days later, he developed left testicular pain and swelling. Orchitis was diagnosed and he was prescribed nonsteroidal anti-inflammatory drugs and ice packs and had no further follow-up care.

Patient B

On October 13, 2015, a woman aged 21 years developed progressive right ear pain, cough, and shortness of breath. Two days later, she was treated in a hospital emergency department where she received a diagnosis of right otitis externa and left otitis media, for which she was prescribed amoxicillin and analgesics. Later that day, she went to the University of Iowa Student Health Center because of worsening respiratory symptoms. During that encounter, she was also noted to have right bullous myringitis (purulent inflammation of the tympanic membrane), right parotitis suspected to be mumps, and suspected pneumonia. Azithromycin was prescribed empirically to treat both the bullous myringitis and atypical pulmonary pathogens. A polymerase chain reaction (PCR) test for mumps was performed on a buccal swab specimen and was negative. However, her symptoms and epidemiologic link to the outbreak met the Council of State and Territorial Epidemiologists case definition for a probable case of mumps. One day later, she noticed tinnitus and diminished hearing in her right ear; on day 8, she had audiology testing and was evaluated by an otolaryngologist, at which time she received a diagnosis of moderate right sensorineural hearing loss, attributed to mumps, and conductive hearing loss, attributed to otitis media and myringitis. She was treated for 1 week with prednisone, and all her symptoms resolved by the thirteenth day after onset of parotitis. No repeat audiology testing was performed.

Patient C

On November 2, 2015, a man aged 21 years developed left facial pain and swelling and tested positive for mumps by PCR on a buccal swab specimen. Twenty-two days after onset of symptoms, he was treated at an emergency department for neck stiffness, fever, and tachycardia. A lumbar puncture was performed, and he was empirically treated for meningitis with acyclovir and ceftriaxone. Volume of cerebrospinal fluid was inadequate for performing PCR testing for mumps, but Gram stain and bacterial culture were negative, and analysis was consistent with viral meningitis (40 lymphocytes/mm^3, 60 mg/dL of protein, and 67 mg/dL of glucose). Because the onset of mumps-related meningitis has been described as ranging from 4 days before the onset of parotitis until 3 weeks after (*2*), the patient's viral meningitis diagnosis was attributed to mumps. He was discharged with recommendations for symptomatic care, and meningeal symptoms resolved within 1 week.

Complications of mumps have been reported less frequently since licensure and widespread use of mumps-containing vaccines. However, this case series demonstrates that complications still occur, even in persons who have received the recommended 2 doses of measles-mumps-rubella vaccine. In

addition, complications can occur at varying times throughout the course of the illness and in the absence of parotitis (*2*,*3*). Health officials should remain vigilant for these complications and their relation to mumps, and when mumps is suspected, conduct PCR testing on a buccal swab specimen and serology on a serum specimen (*4*,*5*).

[1]University of Iowa Carver College of Medicine; [2]Duke University School of Medicine, Durham, North Carolina; [3]Epidemic Intelligence Service, CDC; [4]Johnson County Public Health Department, Iowa; [5]University of Iowa Student Health & Wellness; [6]Iowa Department of Public Health; [7]Division of Viral Diseases, National Center for Immunization and Respiratory Diseases, CDC.

Corresponding author: Patricia Quinlisk, patricia.quinlisk@idph.iowa.gov, 515-281-4941.

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Reference 18

REVIEW ARTICLE

Mumps Outbreaks in Canada and the United States: Time for New Thinking on Mumps Vaccines

Heikki Peltola,[1] Prasad S. Kulkarni,[2] Subhash V. Kapre,[2] Mikko Paunio,[3] Suresh S. Jadhav,[2] and Rajeev M. Dhere[2]

[1]HUCH Hospital, Hospital for Children and Adolescents, University of Helsinki, Finland; [2]Serum Institute of India, Pune, India; and [3]World Bank, Washington DC

(See the editorial commentary by Brunell on pages 467–9)

Mumps epidemics in Canada and the United States prompted us to review evidence for the effectiveness of 5 different vaccine strains. Early trials with the Jeryl Lynn vaccine strain demonstrated an efficacy of ~95%, but in epidemic conditions, the effectiveness has been as low as 62%; this is still considerably better than the effectiveness of another safe strain, Rubini (which has an effectiveness of close to 0% in epidemic conditions). The Urabe vaccine strain has an effectiveness of 54%–87% but is prone to cause aseptic meningitis. Little epidemiological information is available for other vaccines. The Leningrad-Zagreb vaccine strain, which is widely used in developing countries and costs a fraction of what vaccines cost in the developed world, seems to have encouraging results; in 1 study, the effectiveness of this vaccine exceeded 95%. Aseptic meningitis has also been reported in association with this vaccine, but the benign nature of the associated meningitis was shown recently in Croatia. Also, the Leningrad-3 strain seems to be effective but causes less-benign meningitis. No mumps vaccine equals the best vaccines in quality, but the virtually complete safety of some strains may not offset their low effectiveness. Epidemiological data are pivotal in mumps, because serological testing is subject to many interpretation problems.

An outbreak of mumps occurred unexpectedly in May 2005 in Nova Scotia, Canada, followed later by an outbreak in Quebec, Canada [1] and, in September 2005, by an outbreak in Iowa [2]. Soon, other US states were affected, with commercial flights being an effective means of dispersing infection quickly. To date, at least 45 US states have reported a total of >10,000 cases associated with this outbreak [3–5]. The fact that the isolates have all been identified as genotype G strongly suggests that the epidemic is caused by only a single strain [5, 6].

The age of affected patients has ranged from 1 year to 96 years, with the majority of patients being aged 18–24 years. In many patients, complications have developed. Among 363 male patients in Iowa, 27 (8%) had cases of orchitis, and of 1254 patients involved in the epidemic, 4 (0.3%) developed encephalitis [4]. Several cases of meningitis, deafness, oophoritis, mastitis, and pancreatitis have been diagnosed in patients involved in the outbreaks. Because the manifestations and severity of disease in vaccinees do not much differ from those found in nonvaccinated populations [7, 8], vaccinees with disease have not gained much from vaccination. Among 1798 patients in the United States, only 123 (7%) were unvaccinated, 245 (14%) had received 1 dose of measles-mumps-rubella (MMR) vaccine, and 884 (49%) were vaccinated twice [3]. In the first outbreak in Canada, 9 (69%) of 13 teenagers had received 2 doses of MMR vaccine [1]. There remains little room for discussion as to whether most cases involve vaccine failure; they do.

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Reprints or correspondence: Dr. H. Peltola, HUCH Hospital, Hospital for Children and Adolescents, PO Box 281 (11 Stenbäck St.), 00029 HUS Helsinki, Finland (heikki.peltola@hus.fi).

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The epidemic likely originates from the United Kingdom [9], where mumps has been a growing problem, with 56,000 reported cases in 2004–2005 [10]. The question now raised is why North America is experiencing the largest epidemic since 1991, when 4264 cases were reported in the United States [11]. The vaccination coverage in the United States exceeds 95% [12], and the decrease in the number of cases to <300 cases per year prompted the declaration of a national health objective to eliminate indigenous mumps by 2010 [13]. The epidemic likely postpones that goal.

MUMPS IMMUNOLOGY: A COMPLEX ISSUE

A vaccinee may remain unprotected if the primary response is insufficient (primary vaccine failure) or if immunity wanes (secondary vaccine failure). The prevailing view [14, 15] is that most mumps vaccine failures are attributable to primary vaccine failure. This view is challenged, and with good reasoning [16–19].

A statistically significant difference has not always been demonstrated [20, 21], but receiving >1 dose of vaccine seems to be beneficial in mumps [22]; in fact, receipt of 2 doses may confer up to 5 times the protection of a single dose [23]. Realizing all of the advantages of multiple dosing (such as better tracing of individuals), Finland and Sweden adopted a 2-dose policy for MMR vaccination in 1982 [24]. As a consequence, indigenous mumps was eliminated from Finland in 1996 [25]. The United States added a second MMR vaccination dose in the schedule in 1989, and Canada and the United Kingdom added a second dose in 1996 [1, 26]. The virtual disappearance of mumps in Scandinavia and elsewhere implies that many children and young adults there are protected solely by vaccination. The receipt of only 1 dose leaves the vaccinees in danger [27], because chances to receive natural boosters are continuously lessening. But why did many individuals in North America who received 2 doses of vaccine develop mumps?

Here, we arrive at a complex issue—the differences between different mumps vaccine strains (or, preferably, substrains) [19, 28]. The main practical problem is that, although several tests are used, no serological test reliably predicts who is at risk and who is not [22]; association between positive ELISA or other serological test results and clinical protection is especially poor in mumps vaccination. Virus neutralization is the best test available [19], but it is too laborious for routine use. The only way to try to evaluate vaccines is to scrutinize the epidemiological data obtained from "real-life" conditions. Fair judgment is difficult, because only 1 strain has undergone stringent efficacy trials in the sense that we currently require. On the other hand, useful data are available from various environments, including historical data and, in particular, data from epidemic conditions. Although prone to confounding factors, those data are likely to be informative enough to give a rather reliable overview of the current situation.

METHODS

Because we have worked in the field for many years, much data existed in our own files; however, to update the information, we searched the electronic databases from 1 July 2006 through 15 January 2007. Epidemiological and reactogenicity data on different mumps vaccines were collected, and additional information was obtained by cross references. All valuable information deriving from prospective or retrospective studies, controlled trials, or observational studies was used.

Information was retrieved regarding 5 vaccine strains: Jeryl Lynn, Urabe, Rubini, Leningrad-Zagreb (L-Zagreb), and Leningrad-3. References in the articles dealing with these vaccines offered an additional way to obtain more information. We could not trace impact data on RIT 4385, which was developed from Jeryl Lynn and is used widely as a component of 1 type of MMR vaccine.

RESULTS

Jeryl Lynn. Jeryl Lynn, the only mumps vaccine strain used in the United States, is derived from a patient's throat isolate [29]. It contains 2 viral populations, which is probably an advantage. The strain is very safe, as shown in extensive reactogenicity studies using monovalent mumps [30] or combined MMR vaccine [31]. Aseptic meningitis, the Achilles' heel of mumps vaccines (vide infra), has never been documented to be caused by Jeryl Lynn [32] (albeit, in 1 case in Germany, it was claimed to have done so [33, 34]). Long-term follow-up studies with Jeryl Lynn–containing MMR vaccine [35–37] confirm the general safety of that vaccine.

Developed in 1967, Jeryl Lynn had the privilege of being the first mumps vaccine available to the international market. A randomized trial, conducted in Philadelphia, Pennsylvania, from 1965 through 1967, involved nursery school or kindergarten attendees [38]. A 20-month follow-up of seronegative children showed a 95% effectiveness (95% CI, 88%–98%), with the point estimates varying from 92% to 96%, depending on the subgroup (families vs. classrooms) or the interval from vaccination to exposure (0–10 months vs. 11–20 months). In a subsequent double-blind, placebo-controlled study among first- and second-graders in North Carolina, 5 cases were identified among 2965 vaccinees, compared with 13 cases identified among 316 control subjects, during the 180 days after vaccination [39]. The vaccine efficacy was 96% (95% CI, 88%–99%).

These encouraging results predicted good effectiveness in routine use, as well. However, vaccine failures soon occurred [40], although they were rare. A 99% reduction in reported cases occurred in the United States by 1993 [41], and the impact has been spectacular elsewhere, as well [42]. By using Jeryl

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Lynn–containing MMR vaccine almost exclusively, Finland eliminated indigenous mumps in 1996 [25].

Outbreak conditions, in which the time interval from vaccination to the outbreak has varied, have brought less favorable information (figure 1). The highest efficacy, 91% (95% CI, 77%–93%), was reported from New Jersey in 1983 [52], whereas, in Geneva, Switzerland, during the period 1993–1996, it was no greater than 62% (95% CI, 0%–85%) [47]. A case-control study from British Columbia, Canada, in 1997 estimated an 80% effectiveness (95% CI, 29%–96%) [43]. Although acknowledging problems in methodology in these observational studies, one may fairly conclude that protection has not been perfect.

Rubini. Another very safe mumps vaccine derived its name, Rubini, from the Swiss child whose urine was used as the source of virus isolation [53]. The problem with this human diploid cell strain is that it has very low or no clinical effectiveness, the lower extreme being −55% (95% CI ,−122 to −9), reported in Singapore (figure 1) [46]. This is surprising, because Rubini-containing MMR causes seroconversion against mumps in 95% of children aged 14–24 months [55]. Portugal began to use this vaccine exclusively in 1992, and the country was soon swept by a large mumps epidemic [56]. Similar experiences, reported in countries such as Switzerland [57], Italy [58], and Singapore [46], have led to the abandonment of the Rubini strain [46, 57].

Urabe. The Urabe strain derives from a patient's saliva isolate. The vaccine was developed in Japan, but large quantities have been also been produced in Europe. The strain is highly immunogenic, with 95% of children aged 14–20 months experiencing seroconversion [59]. Compared with the Jeryl Lynn vaccine, the immunogenicity of the Urabe vaccine, measured by ELISA (whatever that might mean in terms of protection), is at least equivalent. More importantly, 88% of children aged 13–15 months who receive the vaccine develop neutralizing antibodies [60].

The problem with the Urabe vaccine is that it is prone to cause aseptic meningitis [61]. The reason for this is not entirely clear, but the vaccine contains 2 distinct strains, 1 of which seems to be more neurovirulent [62]. Meningitis occurring after administration of mumps vaccine is clinically very mild, but understandably, any vaccine-induced inflammation of the CNS is a matter of concern. The incidence rates vary from as high as 1 case per 900 doses in 1 prefecture of Japan [63] to 1 case per 62,000 doses in Canada [64] and 1 case per 120,000 doses in France [65]. Such great differences in incidence are partly dependent on the manufacturer of the vaccine.

In clinical effectiveness, the Urabe vaccine competes with the

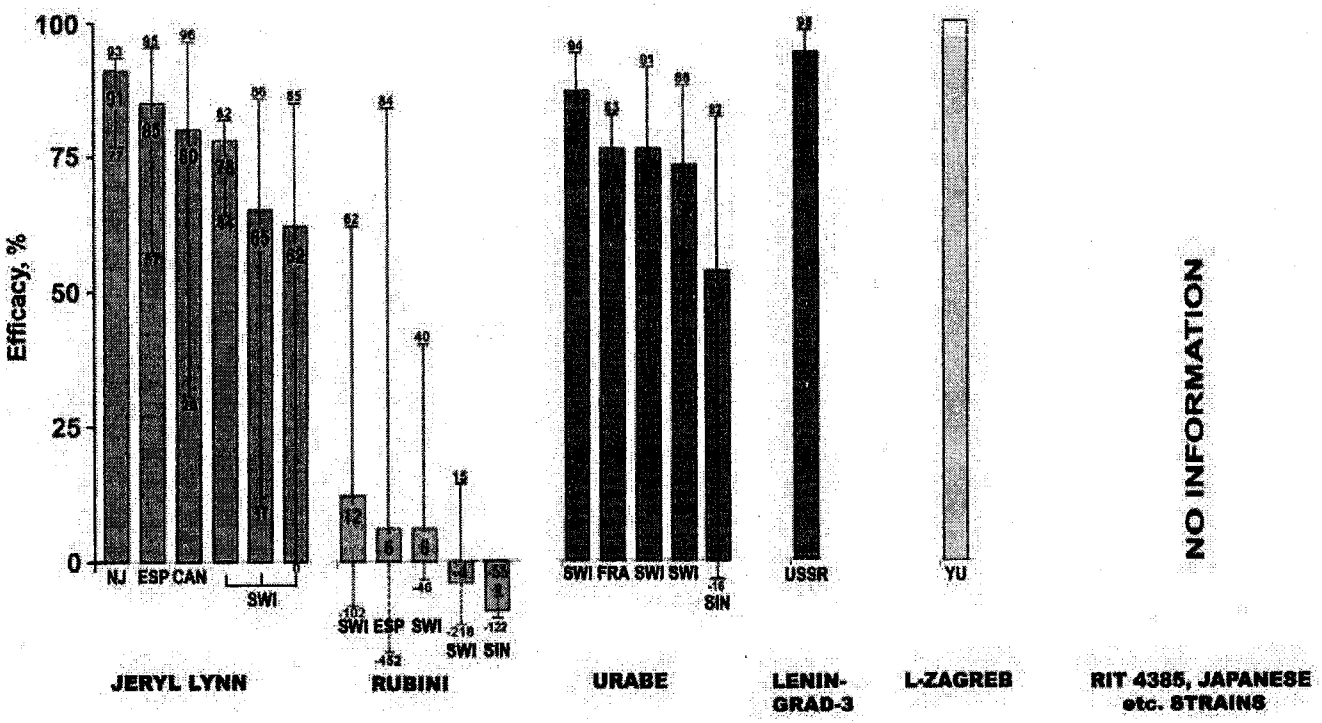

Figure 1. Clinical efficacy in outbreak conditions of 5 mumps vaccine strains reported in representative studies. Brackets indicate 95% CIs. CAN, Canada [43]; ESP, Spain [44]; FRA, France [45]; NJ, New Jersey [40]; SIN, Singapore [46]; SWI, Switzerland [21, 47]; USSR, former Union of Soviet Socialist Republics [48]; YU, former Yugoslavia [49–51].

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Jeryl Lynn vaccine. In outbreak conditions, an effectiveness of ~75% [21, 47, 45] has been observed (figure 1), the extremes being a high of 87% (95% CI, 76%–94%) in a Swiss study [54] and a low of 54% (95% CI, −16% to 82%) in Singapore [46].

Leningrad-3. Researchers of the former Soviet Union developed the Leningrad-3 vaccine in the 1960s, and Russia has used it since 1981 [66]. The vaccine was prepared in a guinea pig kidney cell culture and passaged in Japanese quail embryo cultures [49]. It was tested in a small series of children aged 3–6 years [48]. Because mumps developed in 2 (2%) of 85 vaccinees, compared with 42 (39%) of 108 nonvaccinees, the effectiveness was calculated as 94% (95% CI, 76%–98%). Subsequent studies have suggested a protection of 91%–99% [67].

Unfortunately, aseptic meningitis is a particularly common event among recipients of the Leningrad-3 strain vaccine, and clinical trials were cancelled because of this problem in the former German Democratic Republic [68]. As was shown recently in Novosibirsk, Siberia [69], the Leningrad-3 strain may also transmit horizontally and cause symptomatic disease in vaccinees. For these reasons, Leningrad-3 vaccine has not gained much attention outside of the countries of the former Communist bloc.

L-Zagreb. Brought to Zagreb, Croatia (in the former Yugoslavia), the Leningrad-3 vaccine was further attenuated and was renamed L-Zagreb. It meets the World Health Organization requirements and has been sold in tens of millions of doses, especially in the developing world. Early immunogenicity studies involving 6800 preschool children, conducted in 1971, showed a rate of seroconversion by hemagglutination inhibition of 88%–94% [66]. The rate of adverse reactions did not differ from that found in the control group.

From the Balkan peninsula, data has been reported on the impact of the L-Zagreb vaccine in nonepidemic conditions. L-Zagreb–containing MMR vaccination became compulsory in Croatia in 1976, and reported mumps cases decreased by >90% [50]. In Slovenia, a 2-dose program has maintained a coverage rate of >90% since 1990, and the incidence of mumps has remained at 2 cases per 100,000 vaccine doses [42]. Because the reporting of infectious diseases in the former Communist block used to be fairly reliable, there should be few flaws in this information.

For the vaccine's performance under epidemic conditions, we have more-solid data. In an outbreak that occurred in Yugoslavia in 1976, a total of 164 (7%) of 2434 nonvaccinated first-graders developed mumps, whereas no cases were found among 696 individuals who had received L-Zagreb–containing MMR vaccine. Assuming a case in 1 (0.1%) of these 696 children and similar exposure in these 2 populations, the effectiveness might have been ⩾97% [49]. Effectiveness of 97%–100% was also reported among preschool children [50]. In a kindergarten setting, no cases of mumps were detected among 40 vaccinees, compared with cases in 74 (38%) of 197 nonvaccinees [51]. Compulsory vaccination with obligatory reporting began in the Rijeka region of Croatia in 1976 [70]. Epidemics with a peak incidence of 552 cases per 100,000 doses per year occurred in 1977 and during 1981–1982; thereafter, the incidence of mumps remained at 31–78 cases per 100,000 doses for at least 8 years [70]. Simultaneously, a shift in age distribution occurred from children aged 5–9 years to adolescents. Both observations speak for the effectiveness of vaccination.

Five municipalities of Brazil performed a large-scale mumps vaccination campaign with L-Zagreb–containing MMR vaccine in 1997. A total of 105,098 doses were administered to children aged 1–11 years, and the vaccine coverage was 95% [71]. Comparing the 2.5 years before the campaign with the 3 years after the campaign, the number of reported cases of mumps-related meningitis decreased from 16 cases to 0 cases. The crude annual rate of mumps decreased by 93% (95% CI, 86%–96%).

An association with aseptic meningitis has also been a matter of concern with the L-Zagreb strain. The discussion began in Brazil, where, in 1998, an observation was made that, following 2 mass campaigns using MMR vaccine, a high incidence of aseptic meningitis was found [71, 72]. The estimates varied, but within 3 weeks after vaccination, the rate of aseptic meningitis ranged from 1 case per 6199 doses (95% CI, 4854–8058 doses) to 1 case per 19,247 doses (95% CI, 12,648–29,513 doses), depending on the diagnostic criteria used and the state of Brazil that the data were from.

The interpretation of the Brazilian data has been challenged [73]. A retrospective study from India found only 1 case of aseptic meningitis per 95,361 doses (95% CI, 0.5–1.6 cases per 100,000 doses) [74], and an incidence of 0.96 cases per 100,000 doses was estimated in the Bahamas [75]. No mumps or mumps vaccine viruses were identified in these surveys. Instead, viruses were searched for using samples of CSF from 50 patients with cases of meningitis following L-Zagreb vaccination in Croatia during the period 1988–1992 [76]. All cultures showed no growth, except 1 case in which Coxsackie virus B4 was detected. In a similar setting in Brazil, 8 patients with cases of meningitis were checked for the presence of virus in 1998 [77]; all patients had negative results. A recent study from Croatia [78] suggests that primary L-Zagreb vaccination may cause aseptic meningitis at the rate of 1 case per 2020 vaccinees, but methodological problems [79] might have led to a gross overestimation of this rate. Of special note, the clinical disease was benign, all patients were discharged from the hospital in good condition, and no neurological symptoms were detected during a 36-month follow-up period [78].

To disclose the true incidence of aseptic meningitis following vaccination with the L-Zagreb strain, a massive prospective study was undertaken among >300,000 children in Egypt. The

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study was funded by the Indian manufacturer of the vaccine (Serum Institute of India) [80]. Results are yet to be published, but not a single case of aseptic meningitis was detected (Saeed Aly Oun, personal communication). This information adds to the view that aseptic meningitis is not a major issue with respect to vaccination with the L-Zagreb strain, especially if weighed against the good protection provided by the vaccine against overt mumps and its associated complications.

Other strains. Several other strains have been used for mumps vaccination, but mostly in only a single country or area. In Japan, strains such as Hoshino, Miyahara, Torii, and NK M-46 have been produced. Iran has its own strain, called S-12, which is produced on human diploid cells (as is the case with Rubini) [81]. Common to all of these vaccines is the fact that little information is available on their clinical effectiveness (which may be good). Bulgaria produced a strain named Sofia-6 in guinea pig kidney cell culture. The vaccine was introduced into the Bulgarian national vaccination program in 1977, and targeted vaccination for children aged 4–12 years was executed in 1982. The effectiveness was reported to be good [82], but the vaccine was prone to cause adverse events, including aseptic meningitis, which led to its abandonment.

The predecessor of the European consortium GlaxoSmithKline developed a vaccine strain called RIT 4385 from the Jeryl Lynn strain by leaving out 1 of the 2 virus populations and adding further passages. The clinical effectiveness of this vaccine strain has not, thus far, been determined. Safety is not a problem, as shown by a large passive surveillance study of RIT 4385–containing MMR vaccine in Germany [83].

DISCUSSION

Where are we now with respect to mumps vaccines? To unwind the tangled skein of the data on mumps vaccination is a challenge. Which vaccine to recommend? Although the World Health Organization deems all vaccine strains except Rubini to be acceptable [84], there is more than a single answer. Experience obtained from outbreaks (figure 1) suggests that vaccine effectiveness is lower than one would expect from the findings of serological studies (which are unreliable) or controlled efficacy trials (of which there are only a few). Waning immunity has not been deemed to be important [14, 15, 85, 86], but outbreaks in highly vaccinated populations [1, 2, 14–16, 18–20] warrant some rethinking. Also, modeling of the serological information [19, 27] supports the view that waning immunity is an issue. We recommend that IgG avidity measurement, which works so well in the context of measles vaccination [87–89], be used as an important tool when addressing the difficult question of whether a mumps vaccine failure is primary or secondary. With avidity testing, Japanese investigators found that secondary vaccine failures occurred even in school children, whose exposure to wild mumps was likely to be high (a population with low vaccine coverage) [90]. Obviously, avidity testing has the potential to increase our understanding of the true role of waning immunity after mumps vaccination.

Immunological data on mumps vaccination are abundant, but as vaccine trials indicate [55, 59], the interpretation problems are immense. The immunogenicity of the Jeryl Lynn– and RIT 4385–containing MMR vaccines was examined in a double-blind study involving German children [91] that used neutralizing antibodies as a yardstick (the best method available) [19]. Seroconversion against the vaccine strains occurred in 96% and 91% of the children, respectively, but seroconversion against wild mumps virus occurred in only 75% and 68%, respectively. Because usually only antibodies against the vaccine strain are measured, good results can be obtained that do not reflect the actual ability of the vaccine to provide protection from disease. A vaccine failure is investigated properly only if, in addition to avidity testing [87–90], the ability of antibodies to neutralize wild mumps virus has been checked.

A mathematical model assessing the potential of vaccination using the Urabe or Jeryl Lynn strains [92] suggested that, in community-based programs, the greater apparent safety (i.e., fewer vaccine-induced complications) associated with the Jeryl Lynn strain is offset by the potentially greater effectiveness associated with the Urabe strain (i.e., fewer complications caused by wild mumps virus). Thus, it may not always be in the interest of the community to use the vaccine associated with the lowest rate of complications. Vaccines that use the Jeryl Lynn and Rubini strains are documented to be very safe vaccines, but once vaccine failure has occurred, the rate of complications in vaccinees is not very different from the rate of complications in nonvaccinees. The exact incidence of aseptic meningitis associated with natural mumps is not known, and it probably varies in different settings; a conservative estimate is 1 case of aseptic meningitis per 400 cases of clinical mumps [93]. In a well-studied prevaccination epidemic in Denmark, the CNS was affected in no less than 65% of cases [94]. These figures (or whatever the actual figure is), which apply to nonbenign aseptic meningitis caused by natural mumps, must be weighed against the figures for vaccine-induced meningitis, which is considerably milder [78] and develops with a much lower frequency. The time has arrived to put things in perspective [92, 95].

In the field of immunization, we are spoiled by having several virtually harmless but very effective vaccines (e.g., inactivated polio vaccine and *Haemophilus influenzae* type b vaccine). Current mumps vaccines do not equal those, but they are still of great potential. Money should not be the only decisive factor, but it allows one to rank vaccines in certain order: a single-dose vial (according to the price for the US-manufactured vaccine) costs $.90, $1.20, and $2.50 for MMR vaccine containing L-Zagreb, Urabe, and Jeryl Lynn strains, respectively [96, 97]. If an effective vaccine is generally (although not completely)

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safe but costs much less than a slightly better tolerated but not necessarily more effective vaccine, money becomes an issue. Research is urgently warranted to better characterize the pros and cons of vaccine strains now shadowed by strongly advertised, highly priced competitors.

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Hello, my name is Denise Brusveen. I appreciate the opportunity to speak today and have my full concerns heard. Unfortunately, I was asked to keep my comments to a strict 2 minutes at DHS's public hearing last summer, and the microphone was abruptly ripped from my hand mid-sentence at the 2 minute mark.

While I oppose points 1,2,4, and 5 of CR 19-079, today I am focusing on point 5. To give you a bit of background, I have a master's degree with my primary research specialty being reproductive physiology. I have worked for the last 10 years as a birth doula and childbirth educator in the Madison area, striving always to provide relevant research and information to my students and clients regarding choices they face in order to make the best decisions possible for their babies and families. I am also a mother of three children, and I am concerned that DHS's proposal to require parents to have their child's varicella confirmed by a health care provider has many flaws.

My oldest child got chickenpox 10 years ago, most likely from her cousin who had just received her varicella vaccine the day before our children spent the day together. I didn't realize it at the time that the varicella vaccine is a live virus vaccine and carries the risk of shedding. So, when my daughter began developing a rash a couple weeks later, I didn't know what it was at first. As the rash spread, I began to suspect chickenpox. I called the doctor who recommended bringing her in to confirm. They had us sit in the waiting room of a busy clinic with no mask. We weren't asked to wait in a separate area. We were among all the other people there that day who were waiting to see other doctors. Countless individuals were exposed, and none of the medical professionals made a big deal of it probably because for decades it has not been a big deal.

When it was time for her doctor to see her, he had no idea what he was looking at. He was a younger doctor who admitted that he had never actually seen a case of chickenpox before. We had to wait while he went to find another doctor who was older and able to diagnose her. That doctor confirmed it as chickenpox and sent us on our way. That was a decade ago. Since then, we have lost 10 more years worth of doctors who would feel confident diagnosing chickenpox, and we have gained 10 years of new doctors who would be unable or unwilling to diagnose it because they have never seen a case.

Last year, my other two children got chickenpox. I knew what I was looking at and made the decision not to take them to a doctor simply for confirmation since I was better at identifying it 10 years prior than my child's doctor had been. It was largely uneventful, and they did not need medical attention.

But with this proposed change, my children would be punished for my ability to accurately determine that they had chickenpox, do what was in the best interest of public health, and help them to be comfortable and recover from a mild illness at home.

I can't go back and change things now, but even if I could, I would not want to take them out in public while sick just as I don't take them out when they have a cold, flu, or any other illness. I am not the only parent who feels this way. DHS received 32 written comments from parents concerned about unnecessarily exposing the public to varicella. Their response was, "The administrative rule change proposal does not dictate that a student be seen by a health care provider while ill with varicella. The health care provider may verify the disease with a history of symptoms or laboratory confirmation." Parents are already verifying their child's history of chickenpox based on symptoms, so why does it suddenly become accurate only if they provide those details to a doctor? As stated in my own personal example, a doctor was unable to diagnose my child during an active infection while she was right in front of him. I am highly doubtful that any doctor would be willing to make an official diagnosis without

seeing the patient during the active infection, and I suspect that DHS knows this. That leaves only one other option – titer testing.

But, DHS intentionally chose to leave language out of the administrative rule text that would guarantee this as an option for families despite receiving dozens of written comments from concerned parents. Instead they responded that, "While not stated implicitly in the proposed Administrative Rule, a titer could be ordered by a health care provider and if positive, would provide evidence of immunity, allowing the health care provider to indicate on the form that the individual had a history of disease and was immune." This is concerning because not all states allow for titers as acceptable proof, and without that implicitly stated within the administrative rule, there is nothing stopping Wisconsin from becoming one of those states.

It is also striking to me that the fiscal summary submitted by DHS for the proposed rule changes states that there is no financial impact. They completely failed to account for the cost either to individual families who are covered by private insurance or the state for those covered by Badgercare. Doctor visits are not free, and titer testing is not free. Some are fortunate to have small copays while others would have to pay entirely out of pocket due to having high deductibles while still others would be entirely paid for by Wisconsin taxpayers. There is indeed a financial impact to this proposed rule change, and I would like an honest assessment of what exactly that impact would be.

For these reasons, I firmly oppose removing the right of a parent or adult student to report on the history of varicella in their children or themselves. This rule change would make it impossible for some families to comply, would increase the risk to public health, and would create an unnecessary financial burden for many. It is not in Wisconsin's best interest.

Patient Information about
VARIVAX® (pronounced "VAR ih vax")
Generic name: Varicella Virus Vaccine Live
Refrigerator-stable formulation

This is a summary of information about VARIVAX®. You should read it before you or your child get the vaccine. If you have any questions about the vaccine after reading this leaflet, you should ask your healthcare professional. This is a summary only. It does not take the place of talking about VARIVAX with your doctor, nurse, or other healthcare professional. Only your healthcare professional can decide if VARIVAX is right for you or your child.

What is VARIVAX and how does it work?

VARIVAX is also known as Varicella Virus Vaccine Live. It is a live virus vaccine that is given as a shot. It is meant to help prevent chickenpox. Chickenpox is sometimes called varicella (pronounced VAR ih sell a).

VARIVAX contains a weakened form of chickenpox virus.

VARIVAX works by helping the immune system protect you or your child from getting chickenpox.

VARIVAX may not protect everyone who gets it.

VARIVAX does not treat chickenpox once you or your child have it.

What do I need to know about chickenpox?

Chickenpox is an illness that occurs most often in children who are 5 to 9 years old. It can be passed to others. The illness can include headache, fever, and general discomfort. Then an itchy rash occurs, which can turn into blisters. The most common complication is that the blisters can get infected. Less common but very serious complications can occur. These include pneumonia, inflammation of the brain, Reye syndrome (which affects the liver and the brain), and death. Severe disease and serious complications are more likely to occur in adolescents and adults.

Who should not get VARIVAX?

Do not get VARIVAX if you or your child:

- are allergic to any of its ingredients. (This includes gelatin or neomycin. See the ingredient list at the end of this leaflet.)
- have a weakened immune system, such as an immune deficiency, an inherited immune disorder, leukemia, lymphoma, or HIV/AIDS.
- take high doses of steroids by mouth or in a shot.
- have active tuberculosis that is not treated.
- have a fever.
- are pregnant or plan to get pregnant within the next three months.

What should I tell my healthcare professional before getting VARIVAX?

Tell your healthcare professional if you or your child:

- have or have had any medical problems.
- have received blood or plasma transfusions or human serum globulin within the last 5 months.
- take any medicines. (This includes non-prescription medicines and dietary supplements.)

- have any allergies. (This includes allergies to neomycin or gelatin.)
- had an allergic reaction to any other vaccine.
- are pregnant or plan to become pregnant within the next three months.
- are breast-feeding.

How is VARIVAX given?

VARIVAX is given as a shot to people who are 12 months old or older. If your child is 12 months to 12 years old and your doctor gives a second dose, the second dose must be given at least 3 months after the first shot.

A second dose should be given to those who first get the vaccine when they are 13 years old or older. This second dose should be given 4 to 8 weeks after the first dose.

Your doctor or healthcare professional will use the official recommendations to decide the number of shots needed and when to get them.

If a dose is missed, your healthcare professional will let you know when you should have it.

What should you or your child avoid when getting VARIVAX?

Do not take aspirin or aspirin-containing products for 6 weeks after getting VARIVAX.

It is rare, but possible, that once you have the vaccine, you could spread the chickenpox virus to others. Whenever possible, try to avoid contact with certain groups of people for up to six weeks after receiving the vaccine. This is because the disease for these groups may be quite serious. These groups include:

- people who have a weakened immune system.
- pregnant women who have never had chickenpox.
- newborn babies whose mothers have never had chickenpox.
- newborn babies born at less than 28 weeks of pregnancy.

Tell your doctor or healthcare professional if you or your child expect to have contact with someone who falls into one of these groups.

What are the possible side effects of VARIVAX?

The most common side effects reported after taking VARIVAX are:

- Fever
- Pain, swelling, itching, or redness at the site of the shot
- Chickenpox-like rash on the body or at the site of the shot
- Irritability

Other less common side effects have also been reported.

- Tingling of the skin
- Shingles (herpes zoster)

Tell your healthcare professional if you have any of the following problems within a short time after getting VARIVAX because they may be signs of an allergic reaction:

- Shortness of breath or wheezing
- Rash or hives

Other side effects have been reported. Some of them were serious. These include bruising more easily than normal; red or purple, flat, pinhead spots under the skin; severe paleness; difficulty walking; severe skin disorders; skin infection; and chickenpox. Rarely, swelling of the brain (encephalitis), stroke, inflammation of the coverings of the brain and spinal cord (meningitis), inflammation of the lungs (known as pneumonia or pneumonitis), and seizures with or without a fever have been reported. It is not known if these rare side effects are related to the vaccine.

Your doctor has a more complete list of side effects for VARIVAX.

Tell your doctor or healthcare professional if you or your child have any new or unusual symptoms after getting VARIVAX.

Report the following to your doctor or your child's doctor:

- any adverse reactions following vaccination
- exposure to VARIVAX during pregnancy
- exposure to VARIVAX during the 3 months before getting pregnant.

You may also report these events to Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231, or directly to the Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to www.vaers.hhs.gov.

What are the ingredients of VARIVAX?

Active Ingredient: a weakened form of chickenpox virus.

Inactive Ingredients: sucrose, hydrolyzed gelatin, urea, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, residual components of MRC-5 cells including DNA and protein, neomycin, bovine calf serum.

What else should I know about VARIVAX?

This leaflet summarizes important information about VARIVAX.

If you would like more information, talk to your healthcare professional, visit the web site at www.merckvaccines.com, or call 1-800-Merck-90.

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For patent information: www.merck.com/product/patent/home.html

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144.02 (21) (i); 144.03-A; 144.03 (2) (k)	DHS received 146 comments stating the meningococcal vaccination requirement update is unwarranted because the meningococcal vaccine is ineffective.	Per CDC, since 2005 when the recommendation was made from ACIP for adolescents to receive a meningococcal vaccine, the incidence of meningococcal disease in adolescents has decreased by over 90%. Per an article in *Pediatrics*, meningococcal vaccines were 79% effective in the initial year postvaccination, 69% at 1 to less than 3 years, and 61% at 3 to less than 8 years. The overall effectiveness rate estimate for 0 to 8 years postvaccination was 69%. The vaccine effectiveness estimates data informed ACIP in its decision to add a booster dose at 16 years of age. References Meningococcal Vaccination | What You Should Know | CDC. (n.d.). Retrieved from https://www.cdc.gov/vaccines/vpd/mening/public/index.html#how-well-they-work Cohn, A. C., Macneil, J. R., Harrison, L. H., Lynfield, R., Reingold, A., Schaffner, W., ... Messonnier, N. E. (2017). Effectiveness and Duration of Protection of One Dose of a Meningococcal Conjugate Vaccine. *Pediatrics*, *139*(2). doi: 10.1542/peds.2016-2193
144.02 (21) (h) 144.03 (20) (g)	DHS received 32 comments stating the varicella vaccination requirement update is unwarranted because there is no provision for titer confirmation.	While not stated implicitly in the proposed Administrative Rule, a titer could be ordered by a health care provider and if positive, would provide evidence of immunity, allowing the health care provider to indicate on the form that the individual had a history of disease and was immune.
144.02 (21) (h) 144.03 (20) (g)	DHS received 74 comments stating clinicians should not be required to diagnose patients with suspected varicella infections because of the risk varicella-infected individuals would pose to others at a health care facility.	Per CDC, immunity against from varicella would include any of the following criteria: • Documentation of age-appropriate chickenpox vaccination • Laboratory evidence of immunity or laboratory confirmation of disease • Birth in the United States before 1980 • Diagnosis or verification of a history of varicella by a healthcare provider

		The administrative rule change proposal does not dictate that a student be seen by a health care provider while ill with varicella. The health care provider may verify the disease with a history of symptoms or laboratory confirmation.
144.02 (21) (h) 144.03 (20) (g)	DHS received 22 comments stating the varicella vaccination requirement update is unwarranted because it would force patients and their families into an unwanted relationship with unknown health care providers.	The proposed wording does not specify which health care providers a family must use. Families are free to choose their health care provider based on their own preferences, insurance coverage, etc.
144.02 (21) (h) 144.03 (20) (g)	DHS received 54 comments stating the varicella vaccination requirement and provider verification is unwarranted because it is expensive to the parents. Costs include co-pays, laboratory fees, time off work, & transportation	The administrative rule change proposal does not dictate that a student be seen by a health care provider while ill with varicella. The health care provider may verify the disease with a history of symptoms. In the past, the predictive value of a self-reported positive disease victory for varicella was extremely high in adults in the pre-vaccine era for their children. As disease incidence decreases and the proportion of vaccinated persons with varicella having mild cases increases, varicella will be less readily recognized clinically. A recent study demonstrated that only 75% of unvaccinated children aged 12 months through 4 years who reported a positive history of varicella were in fact immune (confirmed by serological testing), compared with 89% of children aged 5 through 9 and 10 through 14 years. To limit the number of false-positive reports and ensure immunity, ACIP recommends that evidence of immunity should be either a diagnosis of varicella by a health care provider or a health care provider verification of a history of disease rather than parental or self-reporting. Another study published in *Pediatrics,* found that after the introduction of childhood varicella immunization there was a significant reduction in varicella-related hospitalizations and thus a corresponding reduction in hospital charges. *The Journal of Infectious* Diseases reported a substantial societal cost savings with a varicella vaccination program and reduction in morbidity, hospitalization, and mortality due to varicella. References Perella, D., Fiks, A. G., Jumaan, A., Robinson, D., Gargiullo, P., Pletcher, J., ... Spain, C. V. (2009). Validity of Reported Varicella History as a Marker for Varicella Zoster Virus Immunity Among Unvaccinated Children, Adolescents, and Young Adults in the Post-Vaccine Licensure Era. *Pediatrics*, *123*(5). doi: 10.1542/peds.2008-3310

Amber Psket
Wisconsin United for Freedom
(414) 324-4672
amber.smith@wisconsinunitedforfreedom.org

While I am in opposition to rules 1, 2, 4, and 5, I am going to speak today on rule 4, the addition of the meningococcal vaccine or MenACWY vaccine, to the list of vaccines mandated for school entry in Wisconsin.

Rule change 4 states the following - *Neisseria meningitidis is a vaccine-preventable disease and a leading cause of bacterial meningitis and sepsis in the United States. The meningococcal vaccine is recommended by the Wisconsin Chapter of the American Academy of Pediatrics and the Wisconsin Academy of Family Physicians to reduce the incidence of bacterial meningitis and sepsis. Since 2005, the CDC Advisory Committee on Immunization Practices has recommended that the vaccine be administered at the 11-12-year-old health care visit, along with other routine vaccinations such as Tdap (tetanus, diphtheria and pertussis). The department proposes to add the meningococcal vaccine to the list of vaccines required for students entering the 7th grade. This provision will ease the burden on families, providers, and schools by ensuring that both meningococcal and Tdap vaccines are received at the same visit and the same grade level. The department also proposes a booster dose for students entering 12th grade which is in accordance with ACIP recommendations. This will help to ensure students are fully vaccinated prior to leaving school.*

Routine use of the MenACWY vaccine was initially recommended in 2005. Why now, after 15 years, when this disease is at an all-time low, is DHS looking to mandate this vaccine – a vaccine that is available to every single 7th or 12th grade student today.

I would like to provide this committee with a brief history of meningococcal disease as well as the history of the MenACWY vaccine recommendations to support my reasoning for why this vaccine should not be mandated for use, and instead parents should be made aware of this vaccine and provided with the opportunity to accept or decline based on their own risk tolerance and their child's personal health history.

First and foremost, I want this committee to be aware that this vaccine does not provide herd immunity. This means that while the vaccine might be personally protective, it will not keep a person who is colonizing meningococcal strains in the back of their throat from spreading the disease to others.

Secondly, per the CDC, anyone can get meningococcal disease but those most at risk are infants under the age of one, (a population for which this vaccine is not approved for routine use) and college freshman living in dormitories.

Meningococcal disease is a devastating disease, and we are fortunate that this disease is very rare. In the early 1990's, there were an average of 2,400 cases of the disease each year. Rates then decreased by over 50 percent, from 2,725 cases in 1998, to 1,361 cases in 2004, the year prior to the introduction and widespread use of the MenACWY vaccine. There was a meningococcal polysaccharide vaccine available prior to 2005, however, it was only used in the event of an outbreak because it was not effective in children under the age of 2, and the vaccine only offered short-term protection.

The first meningococcal conjugate vaccine targeting strains A, C, W, and Y received FDA approval in January 2005 and was quickly recommended for routine use in all 11 and 12-year olds by the CDC's Advisory Committee on Immunization Practices, otherwise known as ACIP. The MenACWY vaccine was licensed not because it was necessarily any more effective than the meningococcal polysaccharide vaccine, but rather because it was shown not to be inferior in both safety and immunogenicity.

When the recommendation for routine use was made in 2005, CDC health officials estimated that one dose of MenACWY given at 11-12 years of age would be capable of providing immunity on average for at least 22 years – long enough to protect a person through the college years, when the risk of meningococcal disease is elevated.

This wasn't the case. By 2010, public health officials were well aware that this vaccine was not as effective as previously estimated, and reported that within 5 years, over half of the children who received the vaccine at age 11-12 would not be protected. In 2010 alone, there were at least 12 cases of meningococcal disease reported in vaccinated persons. Incidentally, in Wisconsin, there have been at least 3 deaths from meningococcal disease among teens who were vaccinated. The vaccine's failure to provide long lasting vaccine acquired immunity is what prompted the CDC's Advisory Committee on Immunization Practices to recommend a second dose of the vaccine at age 16. However, if the first dose of meningococcal vaccine is administered at age 16, a second dose is not needed because the vaccine is not recommended for persons over the age of 21 due to the low rate of meningococcal disease.

Additionally, in 2017, CDC health officials published a study and concluded that the addition of this second booster dose at age 16 **"should"** provide a longer duration of protection in individuals compared with a single dose, but they also stated that *"given the current low disease burden among adolescents despite low coverage with the booster dose, the additional impact gained from the booster dose in terms of cases prevented is likely to be limited."* In other words, they still don't know for certain if this second dose will offer any additional long-term protection and because of the low disease rates, the vaccine may not even prevent any additional cases.

Remember, they also assumed that one dose of the vaccine would last 22 years, and they were very wrong.

According to the CDC's enhanced meningococcal disease surveillance report, in 2018, there were 329 cases of meningococcal disease in the United States. Of those cases, 155 were attributed to strains targeted by the MenACWY vaccine and only 4 cases occurred among persons between the ages of 11 and 23. **4 cases. In the entire United States.** This data does not support the need for a meningococcal vaccine mandate. In fact, the goal for Healthy Persons 2020 was to decrease meningococcal rates to 0.3 cases per 100,000 or 1,094 cases of meningococcal disease by the year 2020. With 329 cases or 0.1 cases per 100,000, this goal has already been surpassed.

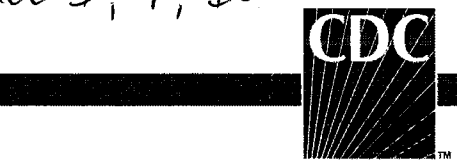
Meningococcal disease is a terrible disease that can affect anyone at any age. Parents should be made aware of the availability of this vaccine and provided with information on risks associated with both the disease and the vaccine. And while many would like to believe that vaccines are risk free, this is false. All pharmaceutical products come with risks and considering the fact that meningococcal disease is especially rare and was rare even prior to the introduction of vaccines targeting the disease, it is entirely possible that the risks associated with meningococcal vaccines may outweigh the potential benefits.

I'd also like to briefly touch on my experience on the hearing held by DHS back in July of 2019. I traveled to Madison from the Milwaukee area, as I have today and I also arranged childcare to attend alone, as I have today, and I was less than impressed on the way in which the meeting was handled. Each individual was given 2 minutes to speak, for which I had edited my speech to adhere to those guidelines. I wasn't able to utter the last few words of what I had written before the microphone was abruptly removed from my hand. While I understand the need for regulation, we are all adults. It was unnecessary for the microphone to be physically removed at the 2-minute mark. Precedence was given to individuals via Skype before those physically in attendance. Some of which had driven hours to attend, such as myself. While there was about a 20-minute lull in time in which technical difficulties were attended to, those in attendance could have spoken but where not afforded the opportunity. A hand full of individuals did not even get a chance to speak at all before the meeting was ended after 1 hours' time. Post hearing, I extended a request to DHS on behalf of Wisconsin United For Freedom to not only hold another hearing to rectify the inadequacies of the prior one but to also request a formal sit down with DHS and a panel of parents to discuss concerns that were had with said rule change. Moms and dads are the primary stakeholders that would be affected by this rule change, yet they were not present in the rule change procedure. This request was denied.

In conclusion, I would like to respectfully request that this committee vote down rules 1, 2, 4 and 5 of Clearinghouse Rule 19-079 due to the failure of DHS to include moms and dads in the rulemaking change, the less than civil manner by which the July 26th 2019 hearing was handled, and because there is no urgent health crisis to mandate a vaccine that has been available to all 11 and 12 year old students for 15 years, and to all 16 year old students for 10 years.

Thank you.

Reference 1, 9, 10



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Prevention and Control of Meningococcal Disease

Recommendations of the Advisory Committee on Immunization Practices (ACIP)

INSIDE: Continuing Education Examination

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

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Centers for Disease Control and Prevention

Julie L. Gerberding, MD, MPH
Director

Dixie E. Snider, MD, MPH
Chief Science Officer

Tanja Popovic, MD, PhD
(Acting) Associate Director for Science

Coordinating Center for Health Information and Service

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* Proposed

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Prevention and Control of Meningococcal Disease

Recommendations of the Advisory Committee on Immunization Practices (ACIP)

Prepared by
Oleg O. Bilukha, MD, PhD
Nancy Rosenstein, MD
Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases

Summary

In January 2005, a tetravalent meningococcal polysaccharide-protein conjugate vaccine ([MCV4] Menactra,™ manufactured by Sanofi Pasteur, Inc., Swiftwater, Pennsylvania) was licensed for use among persons aged 11–55 years. CDC's Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of young adolescents (defined in this report as persons aged 11–12 years) with MCV4 at the preadolescent health-care visit (at age 11–12 years). Introducing a recommendation for MCV4 vaccination among young adolescents might strengthen the role of the preadolescent visit and have a positive effect on vaccine coverage among adolescents. For those persons who have not previously received MCV4, ACIP recommends vaccination before high-school entry (at approximately age 15 years) as an effective strategy to reduce meningococcal disease incidence among adolescents and young adults. By 2008, the goal will be routine vaccination with MCV4 of all adolescents beginning at age 11 years. Routine vaccination with meningococcal vaccine also is recommended for college freshmen living in dormitories and for other populations at increased risk (i.e., military recruits, travelers to areas in which meningococcal disease is hyperendemic or epidemic, microbiologists who are routinely exposed to isolates of Neisseria meningitidis, *patients with anatomic or functional asplenia, and patients with terminal complement deficiency). Other adolescents, college students, and persons infected with human immunodeficiency virus who wish to decrease their risk for meningococcal disease may elect to receive vaccine.*

This report updates previous reports from ACIP concerning prevention and control of meningococcal disease. It also provides updated recommendations regarding use of the tetravalent meningococcal polysaccharide vaccine (MPSV4) and on antimicrobial chemoprophylaxis.

Introduction

Neisseria meningitidis has become a leading cause of bacterial meningitis in the United States after dramatic reductions in the incidence of *Streptococcus pneumoniae* (*1*) and *Haemophilus influenzae* type b (Hib) (*2*) infections have been achieved as a result of using conjugate vaccines. CDC's Advisory Committee on Immunization Practices (ACIP) previously recommended a tetravalent polysaccharide vaccine (Menomune®-A,C,Y,W-135, manufactured by Sanofi Pasteur, Inc., Swiftwater, Pennsylvania) for use among certain populations at increased risk, including travelers to countries with epidemic or hyperendemic meningococcal disease, persons who have certain medical conditions (i.e., terminal complement component deficiencies and anatomic or functional asplenia), and laboratory personnel who are routinely exposed to *N. meningitdis* in solutions that might be aerosolized (*3*). Use of this vaccine also was recommended for control of meningococcal disease outbreaks (*4*). Recommendations permitting use of MPSV4 among college freshmen have been published previously (*5*).

The new tetravalent A, C, Y, W-135 conjugate vaccine (Menactra™, manufactured by Sanofi Pasteur, Inc.) licensed for persons aged 11–55 years should become a key addition to existing meningococcal disease prevention measures. This report provides ACIP's recommendations on prevention and control of meningococcal disease, including recommendations on use of the new tetravalent conjugate vaccine (MCV4) as well as updated recommendations on use of the polysaccharide vaccine (MPSV4) and on antimicrobial chemoprophylaxis.

The material in this report originated in the National Center for Infectious Diseases, Ann Schuchat, MD, Acting Director, Division of Bacterial and Mycotic Diseases, Judith Aguilar, Acting Director; and the National Immunization Program, Stephen Cochi, MD, Acting Director, Epidemiology and Surveillance Division, Gina Mootrey, DO, Acting Director, and Immunization Services Division, Lance Rodewald, MD, Director.

Corresponding preparer: Oleg Bilukha, MD, PhD, National Center for Infectious Diseases, CDC, 1600 Clifton Road NE, MS C-09, Atlanta, GA, 30333. Telephone: 404-639-1367; Fax: 404-639-3059; e-mail: OBB0@cdc.gov.

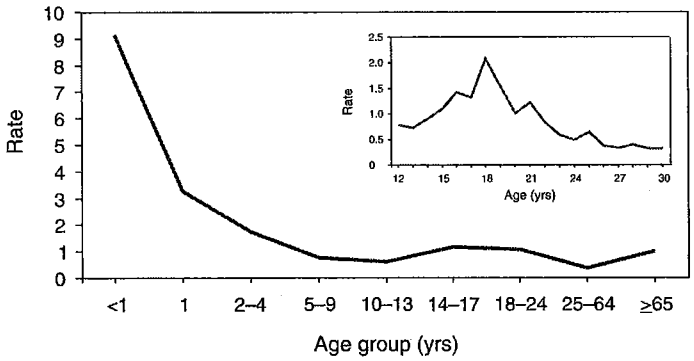
Background

Epidemiology of Meningococcal Disease

Each year, an estimated 1,400–2,800 cases of meningococcal disease occur in the United States, a rate of 0.5–1.1/100,000 population (CDC, unpublished data, 2004). *N. meningitidis* colonizes mucosal surfaces of nasopharynx and is transmitted through direct contact with large droplet respiratory secretions from the patients or asymptomatic carriers. Humans are the only host. Despite the continued sensitivity of meningococcus to multiple widely available antibiotics, including penicillin (*6,7*), the case-fatality ratio for meningococcal disease is 10%–14% (CDC, unpublished data, 2004). Meningococcal disease also causes substantial morbidity; 11%–19% of survivors have sequelae (e.g., neurologic disability, limb loss, and hearing loss) (*8,9*). During 1991–2002, the highest rate of meningococcal disease (9.2/100,000) occurred among infants aged <1 year; the rate for persons aged 11–19 years (1.2/100,000) also was higher than that for the general population (Figure 1). Although rates of disease are highest among children aged <2 years, 62% of meningococcal disease in the United States occurs among persons aged ≥11 years (CDC, unpublished data, 2004).

In the United States, >98% of cases of meningococcal disease are sporadic; however, since 1991, the frequency of localized outbreaks has increased (*10,11*). The proportion of meningococcal cases caused by serogroup Y increased from 2% during 1989–1991 (*12*) to 37% during 1997–2002 (CDC, unpublished data, 2004). Serogroups B, C, and Y are the major causes of meningococcal disease in the United States, each being responsible for approximately one third of cases.

FIGURE 1. Rate* of meningococcal disease, by age — United States, 1991–2002



Source: Active Bacterial Core surveillance data.
* Per 100,000 population.

The proportion of cases caused by each serogroup varies by age group. Among infants aged <1 year, >50% of cases are caused by serogroup B, for which no vaccine is licensed or available in the United States (*13,14*). Of all cases of meningococcal disease among persons aged ≥11 years, 75% are caused by serogroups (C, Y, or W-135), which are included in vaccines available in the United States (CDC, unpublished data, 2004).

Persons who have deficiencies in the terminal common complement pathway (C3, C5–9) (*15,16*) and those with anatomic or functional asplenia (*17*) are at increased risk for acquiring meningococcal disease. Antecedent viral infection, household crowding, chronic underlying illness, and both active and passive smoking also are associated with increased risk for meningococcal disease (*18–25*). During outbreaks, bar or nightclub patronage and alcohol use also have been associated with higher risk for meningococcal disease (*26–28*).

In the United States, blacks and persons of low socioeconomic status (SES) have been consistently at higher risk for meningococcal disease (*12,13*). However, race and low SES are likely risk markers rather than risk factors for this disease. A multistate case-control study in which controls were matched to case-patients by age group indicated that in a multivariable analysis (controlling for sex and education), active and passive smoking, recent respiratory illness, corticosteroid use, new residence, new school, Medicaid insurance, and household crowding all were associated with increased risk for meningococcal disease, whereas income and race were not (*18*). Additional research is needed to identify groups at risk that might benefit from prevention efforts.

Meningococcal Disease and College Students

Multiple studies have been conducted in the United States (*29–31*) and the United Kingdom (*32,33*) concerning the risk for meningococcal disease among college students. The risk for meningococcal disease among U.S. college students was higher for those who resided in dormitories than for those residing in other types of accommodations. Overall incidence among college students usually is similar to or somewhat lower than that observed among persons in the general population of similar age.

The earliest of these studies (conducted during the 1990–91 and 1991–92 academic years) had a poor response rate (38%) and indicated a low overall incidence of meningococcal disease among U.S. college students (1.0/100,000 population/year) (*31*). Cases of meningococcal disease occurred 9–23 times more frequently among students living in dormitories than among those living in other types of accommoda-

tions. A retrospective cohort study conducted in Maryland during 1992–1997 (*30*) indicated that the overall incidence of meningococcal disease among college students was similar to that among the U.S. population of persons the same age (1.7/100,000 and 1.4/100,000, respectively); however, rates of disease among students living in dormitories were higher than rates among students living off campus (3.2/100,000 and 1.0/100,000, respectively; p = 0.05).

U.S. surveillance data from the 1998–99 school year (*29*) indicated that the overall rate of meningococcal disease among undergraduate college students was lower than the rate among persons aged 18–23 years who were not enrolled in college (0.7 and 1.4/100,000, respectively) (Table 1). Rates were somewhat higher among freshmen (1.9/100,000). Among the approximately 600,000 freshmen living in dormitories, rates were higher (5.1/100,000) than among any age group in the population other than children aged <2 years but lower than the threshold (10/100,000) recommended for initiating meningococcal vaccination campaigns (*4*). In a case-control study involving 50 cases detected among college students (*29*), multivariate analysis indicated that freshmen living in dormitories were at higher risk for meningococcal disease than other students (matched odds ratio [OR]: 3.6; 95% confidence interval [CI] = 1.6–8.5).

In the United Kingdom, rates of meningococcal disease were higher among university students than among nonstudents of similar age (*32*). Regression analysis indicated that the main risk factor was catered hall accommodations (the U.K. equivalent of U.S. dormitories). A recent study conducted in the United Kingdom demonstrated a rapid increase in carriage rates of meningococci among university students in the first week of the fall semester, although rates of disease peaked later in the academic year (*33*). The increased rate of disease among university students has prompted the United Kingdom to initiate routine vaccination of incoming university students with a bivalent A/C polysaccharide vaccine as part of a new vaccination program (*34*).

In 2000, ACIP and the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP) concluded that college students, especially those living in dormitories, are at moderately increased risk for meningococcal disease compared with other persons their age (*5*). ACIP and AAP recommended that 1) college students and their parents be informed by health-care providers of the risks of meningococcal disease and of the potential benefits of vaccination with MPSV4; 2) college and university health services facilitate implementation of educational programs about meningococcal disease and the availability of vaccination services; and 3) MPSV4 be made available to those persons requesting vaccination. As of November 2004, a total of 31 states had adopted legislation requiring colleges to provide information on risks of meningococcal disease either to matriculating students or to students residing on campus, and 10 states had mandated vaccination for certain students, unless a vaccination waiver is provided (Figure 2) (*35*).

In 2004, the American College Health Association conducted an Internet-based survey of college policies and practices related to meningococcal vaccination (*36*). Of the 72 (10%) contacted colleges and universities that responded, 60% reported having a written policy on meningococcal vaccination, and 80% reported conducting some type of outreach awareness program among college students or their parents. Median vaccination rates reported for the 2002–03 and 2003–04 academic years were 20% and 35%, respectively;

TABLE 1. Number of cases and rates of meningococcal disease — United States, September 1998–August 1999*

	No. of cases	Population	Rate*
All persons aged 18–23 years	304	22,070,535†	1.4
Nonstudents aged 18–23 years	211	14,579,322†§	1.4
All college and university students	96	14,897,268§	0.6
Undergraduates	93	12,771,228§	0.7
Freshmen¶	44	2,285,001§	1.9
Dormitory residents	48	2,085,618§**	2.3
Freshmen§ living in dormitories	30	591,587§**	5.1

Source: Bruce MG, Rosenstein NE, Capparelle JM, Shutt KA, Perkins BA, Collins M. Risk factors for meningococcal disease in college students. JAMA 2001;286:688–93.

* Per 100,000 population.

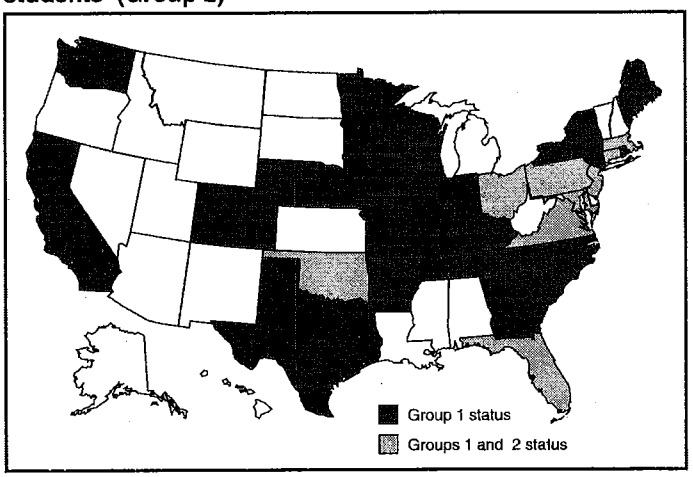
† 1998 census data.

§ **Source:** National Center for Education Statistics, U.S. Department of Education, 1996–1997.

¶ Students enrolled for the first time in any postsecondary educational institution.

** **Source:** National College Health Risk Behavior Survey (NCHRBS) — United States, 1995.

FIGURE 2. States with legislation requiring colleges to provide information on risks of meningococcal disease (Group 1) and states with mandated vaccination for certain students (Group 2)



67% reported an increase in vaccination rates during the previous 3 years. On the basis of the number of vaccine doses sold, during the 2004–05 academic year, approximately 1.1 million college students received MPSV4 before arrival on campus, and an estimated 50,000–100,000 students received vaccine after arrival on campus (Sanofi Pasteur, Inc., unpublished data, 2004).

Evaluation and Management of Suspected Outbreaks of Meningococcal Disease

Since the early 1990s, outbreaks of meningococcal disease have occurred with increasing frequency in the United States. During July 1994–June 2002, a total of 76 outbreaks were identified (annual median: 10; range: 4–16) (*11*), including 48 (63%) outbreaks caused by serogroup C, 19 (25%) by serogroup B, and nine (12%) by serogroup Y. These outbreaks occurred in 32 states and involved 247 patients (accounting for <2% of total cases of meningococcal disease in the United States during this period). Of the 76 outbreaks, 26 (34%) were community-based and accounted for 53% of all outbreak-related cases. Of the 50 (65%) outbreaks that were organization-based, 13 (26%) occurred in colleges; 19 (38%) in primary and secondary schools; and nine (18%) in nursing homes. Vaccination campaigns (using an average of 2,500 doses of MPSV4 per outbreak) were conducted in 34 outbreaks (30 of which were caused by serogroup C and four by serogroup Y) (*11*).

The decision to implement a mass vaccination campaign to prevent meningococcal disease depends on whether the occurrence of more than one case represents an outbreak or an unusual clustering of endemic disease. Because the number of cases in outbreaks is usually not substantial, this determination often requires evaluation and analysis of the patterns of disease occurrence. Mass vaccination campaigns are expensive, require a massive public health effort, and can create unwarranted concern among the public. Detailed information on evaluation and management of suspected outbreaks has been published previously (*4*) and is presented in this report.

Case Definitions

The following case definitions are used in this report:

- **Confirmed case.** A confirmed case of meningococcal disease is one that is defined by isolation of *N. meningitdis* from a normally sterile site (e.g., blood or cerebrospinal fluid) from a person with clinically compatible illness.
- **Probable case.** A probable case of meningococcal disease is one that is defined by detection of polysaccharide antigen in cerebrospinal fluid (e.g., by latex agglutination, polymerase chain reaction, or immunohistochemistry) or the presence of clinical purpura fulminans in the absence of diagnostic culture from a person with clinically compatible illness (*37*).
- **Primary case.** A primary case of meningococcal disease is one that occurs in the absence of previous known close contact with another patient.
- **Secondary case.** A secondary case of meningococcal disease is one that occurs among close contacts of a primary patient ≥24 hours after onset of illness in the primary patient.
- **Co-primary cases.** Co-primary cases are two or more cases that occur among a group of close contacts with onset of illness separated by <24 hours.
- **Close contacts.** Close contacts of a patient who has meningococcal disease include 1) household members; 2) child-care center contacts; and 3) persons directly exposed to the patient's oral secretions (e.g., by kissing, mouth-to-mouth resuscitation, endotracheal intubation, or endotracheal tube management).

Organization- and Community-Based Outbreaks

An outbreak usually is classified as organization-based if it involves the occurrence of three or more confirmed or probable cases of meningococcal disease of the same serogroup in ≤3 months among persons who have a common affiliation but no close contact with each other, resulting in primary disease attack rate of ≥10 cases/100,000 persons. Calculation of attack rates for organization-based outbreaks is most useful for large organizations (e.g., universities). However, in the majority of organization-based outbreaks with three or even two cases of disease, the rate will be >10 cases/100,000 population. In such situations, public health officials also might consider vaccination after only two primary cases are identified.

An outbreak is classified as community-based if it involves the occurrence of three or more confirmed or probable cases of meningococcal disease in ≤3 months among persons residing in the same area who are not close contacts of each other and who do not share a common affiliation, with a primary disease attack rate of ≥10 cases/100,000 persons. Distinguishing whether an outbreak should be classified as organization- or community-based is complicated by the fact that, in certain instances, these types of outbreaks occur simultaneously.

Population at Risk

In addition to close contacts, persons considered to be at increased risk for meningococcal disease compared with historical rates of disease in the same population in the general U.S. population are classified as being at risk. The population at risk is used as the denominator in calculations of the disease attack rate. The population at risk is usually defined on the basis of organizational affiliation or community of residence. In organization-based outbreaks, cases are linked by a common affiliation other than a shared, geographically delineated community; the population at risk is thus usually the group of persons who best represent that affiliation. For example, if the only association between patients is attending the same school or university, the population at risk is all persons attending the school or university. In community-based outbreaks, patients have no common affiliation other than a shared, geographically defined community. The population at risk can be defined as the smallest geographically contiguous population that includes all (or nearly all) patients. This population is usually a neighborhood, town, city, or county, whose size is obtained from census data.

Attack Rate and Decision To Vaccinate

For a primary attack rate to be calculated, all confirmed cases of the same serogroup should be summed; secondary cases should be excluded and each set of co-primary cases counted as one case. Because attack rates are calculated both to characterize the risk for disease among the general population and to determine whether overall rates have increased, related cases (secondary and co-primary) should not be included. From an epidemiologic perspective, secondary and co-primary cases can be considered as representing single episodes of disease with direct spread to one or more close contact(s), which is consistent with endemic disease.

If three or more cases have occurred in either an organization- or a community-based outbreak during ≤3 months (starting at the time of the first confirmed or probable case), a primary attack rate should be calculated. Because of the limited number of cases typically involved and the seasonal patterns of meningococcal disease (more cases occur during fall than other times of the year), rate calculations should not be annualized. The following formula is used to calculate attack rates:

Attack rate per 100,000 = [(number of primary confirmed or probable cases during a 3-month period) / (number of population at risk)] x 100,000

Vaccination of the population at risk should be considered if the attack rate is >10 cases/100,000 persons. The actual attack rate at which the decision to vaccinate is made varies. Public health personnel should consider the following factors: 1) completeness of case reporting and number of possible cases of meningococcal disease for which bacteriologic confirmation or serogroup data are not available; 2) occurrence of additional cases of meningococcal disease after recognition of a suspected outbreak (e.g., if the outbreak occurred 2 months previously and if no additional cases have occurred, in which case vaccination might be unlikely to prevent additional cases of meningococcal disease); and 3) logistic and financial considerations. Because available vaccines are not effective against *N. meningitdis* serogroup B, vaccination should not be considered during serogroup B outbreaks.

Vaccination Group

Those persons designated to be administered vaccine during a vaccination campaign comprise a vaccination group. The vaccination group usually includes either the whole or a subset of the population of risk. Because meningococcal disease outbreak cases occur predominantly among persons aged <30 years (*10,11*), and available vaccines are not recommended among children aged <2 years, the vaccination group usually is that portion of the population at risk aged 2–29 years.

In the majority of organization-based outbreaks, the vaccination group includes the whole population at risk, provided that all persons are aged ≥2 years. If a substantial proportion of patients are aged <2 years and thus are not eligible to receive vaccine, patients aged <2 years should be excluded, and, if at least three patients remain, the attack rate should be recalculated. If the recalculated attack rate remains >10 cases/100,000 persons, vaccination should be considered for part or all of the population at risk aged ≥2 years. In certain organization-based outbreaks, a vaccination group larger than the population at risk might be designated. For example, in a high school in which all outbreak-associated cases occurred among students, authorities might decide to offer vaccine to staff. In community-based outbreaks, the vaccination group usually can be defined as a subset of the population at risk (e.g., persons aged 2–29 years). If a substantial proportion of patients are aged ≤2 years, these patients might be excluded from calculation of an attack rate. In rare situations (e.g., in a town with a limited population) in which multiple cases have occurred among adults aged >29 years, the entire population aged ≥2 years might be considered for vaccination. For more substantial populations, this decision would be costly in terms of finances and human resources, and restricting the vaccination group to the persons in age groups with the highest attack rates might be more appropriate. Age-specific attack rates can be calculated by using the formula previously provided and by restricting the numerator and denominator to

persons within specific age groups (e.g., persons aged 2–29 years).

Genotyping of *N. meningitdis* Isolates

Genotyping of *N. meningitdis* isolates by using such methods as pulsed-field gel electrophoresis or ribotyping might provide useful information for determining whether a group of cases represents an outbreak (*38*). Outbreaks of meningococcal disease usually are caused by closely related strains. Genotyping data can allow identification of an outbreak strain and help to better define the extent of the outbreak. If strains from a group of patients are unrelated by genotyping, the group of cases most likely does not represent an outbreak. Because molecular subtyping testing might not be readily available or accessible, initiation of outbreak-control efforts should not be delayed until genotyping results are available.

Other Control Measures

Mass chemoprophylaxis (i.e., administration of antibiotics to substantial populations) is not recommended to control large outbreaks of disease. Disadvantages of mass chemoprophylaxis include cost of the drug and administration, difficulty of ensuring simultaneous administration of drugs to substantial populations, drug side effects, and emergence of resistant organisms. In addition, multiple sources and prolonged risk for exposure make this approach impractical and unlikely to succeed. In the majority of outbreak settings, these disadvantages outweigh the possible benefit in disease prevention. However, in outbreaks involving limited populations (e.g., an outbreak in a single school), administration of chemoprophylaxis might be considered (*39*), especially in serogroup B outbreaks, for which available vaccines are not effective (*40*). When making a decision about initiating mass chemoprophylaxis in these settings, public health officials should consider not only the potential for prevention of new cases but also the logistics, cost, and potential for developing antimicrobial resistance (*39,41*). If mass chemoprophylaxis is undertaken, it should be administered to all targeted persons at the same time. In the United States, measures that have not been recommended for control of meningococcal disease outbreaks include restricting travel to areas with an outbreak, closing schools or universities, or canceling sporting or social events.

Educating communities, physicians, and other health-care workers about meningococcal disease to promote an early case recognition and early care-seeking behaviors is an important part of managing suspected meningococcal disease outbreaks. Education efforts should be initiated as soon as an outbreak of meningococcal disease is suspected (*4*). Information about the signs and symptoms of meningococcal disease is available at http://www.cdc.gov/ncidod/dbmd/diseaseinfo/meningococcal_g.htm.

Meningococcal Tetravalent Polysaccharide Vaccine

Vaccine Composition

MPSV4 is a tetravalent meningococcal polysaccharide vaccine (Menomune-A,C,Y,W-135, manufactured by Sanofi Pasteur, Inc., Swiftwater, Pennsylvania) available in the United States (*42*). Each dose consists of the four (A, C, Y, W-135) purified bacterial capsular polysaccharides (50 μg each). MPSV4 (Menomune) is available in single-dose (0.5-mL) and 10-dose (5-mL) vials; 50-dose vials are no longer available.

Vaccine Immunogenicity and Efficacy

The immunogenicity and clinical efficacy of the serogroups A and C meningococcal vaccines have been well established. The serogroup A polysaccharide induces antibody response among certain children as young as age 3 months, although a response comparable with that occurring in adults is not achieved until age 4–5 years; the serogroup C component is poorly immunogenic among recipients aged <18–24 months (*43,44*). The serogroups A and C vaccines have demonstrated estimated clinical efficacies of ≥85% among school-aged children and adults and are useful in controlling outbreaks (*45–49*). Serogroups Y and W-135 polysaccharides are safe and immunogenic among adults and children aged >2 years (*50–52*); although clinical protection has not been documented, vaccination with these polysaccharides induces production of bactericidal antibodies. The antibody responses to each of the four polysaccharides in the tetravalent vaccine are serogroup specific and independent.

Persons whose spleens have been removed because of trauma or nonlymphoid tumors and persons who have inherited complement deficiencies have acceptable antibody responses to polysaccharide meningococcal vaccine (*53–55*). A 2003 study indicated that tetravalent polysaccharide vaccine substantially reduced the incidence of invasive meningococcal disease among patients with terminal complement deficiency compared with similar patients who were unvaccinated (*16*).

Reduced clinical efficacy has not been demonstrated among persons who have received multiple doses of vaccine. However, recent serologic studies have reported that multiple doses of serogroup A and C polysaccharide vaccine might cause immunologic hyporesponsiveness (i.e., a reduced antibody

response after subsequent challenge with the same polysaccharide antigen) to group A (*56,57*) and C (*58,59*) polysaccharide. The clinical relevance of such hyporesponsiveness is unclear.

Duration of Protection

Among infants and children aged <5 years, measurable levels of antibodies against group A and C polysaccharides decreased substantially during the first 3 years after a single dose of vaccine; among healthy adults, antibody levels also decreased, but antibodies were still detectable ≤10 years after vaccine administration (*43,60–63*). Similarly, although vaccine-induced clinical protection likely persists among school-aged children and adults for ≥3 years, the efficacy of the group A vaccine among children aged <5 years might decrease markedly within this period. In one study, efficacy among children aged <4 years at the time of vaccination declined from >90% to <10% within 3 years after vaccination; efficacy was 67% among children who were aged ≥4 years when vaccinated (*64*).

Precautions and Contraindications

Meningococcal polysaccharide vaccines have been used extensively in mass vaccination programs as well as in the military and among international travelers. Adverse reactions to polysaccharide meningococcal vaccines are usually mild; the most frequent reaction is pain and redness at the injection site, lasting for 1–2 days. Estimates of the incidence of such local reactions have varied (range: 4%–56%) (*65,66*). In certain studies, transient fever occurred among ≤5% of persons vaccinated, more commonly among infants (*44,67*).

Severe reactions to polysaccharide meningococcal vaccine are uncommon (*44,52,65–71*). The majority of studies report the rate of systemic allergic reactions (e.g., urticaria, wheezing, and rash) as 0–0.1/100,000 vaccine doses (*44,71*). Anaphylaxis has been documented among <0.1/100,000 vaccine recipients (*42,70*). Neurologic reactions (e.g., seizures, anesthesias, and paresthesias) have also been observed infrequently (*65,70*).

Meningococcal Conjugate Vaccines

Advantages of Meningococcal Conjugate Vaccines

Bacterial polysaccharides, including those comprising the capsule of *N. meningitdis,* are T-cell–independent antigens. T-cell–independent antigens do not elicit a memory response; they stimulate mature B-lymphocytes but not T-lymphocytes, thus inducing a response that is neither long-lasting nor characterized by an anamnestic response after subsequent challenge with the same polysaccharide antigen (*72*). Thus, meningococcal polysaccharide vaccines have inherent limitations. The serogroup C polysaccharide is poorly immunogenic among children aged <2 years (*73–75*). The A polysaccharide induces antibody response in infants, but vaccine efficacy declines rapidly (*64*). Meningococcal polysaccharide vaccines do not confer long-lasting immunity (*61,64*); they also do not cause a sustainable reduction of nasopharyngeal carriage of *N. meningitdis* (*76,77*) and therefore do not substantially interrupt transmission to elicit herd immunity. Finally, multiple doses of serogroup A and C polysaccharide vaccine might cause immunologic hyporesponsiveness to the group A (*56,57*) and C (*58,59*) polysaccharide, although clinical implications of this phenomenon are unknown.

Conjugation (i.e., covalent coupling) of polysaccharide to a protein carrier that contains T-cell epitopes changes the nature of immune response to polysaccharide from T-cell–independent to T-cell–dependent, leading to a substantial primary response among infants and a strong anamnestic response at re-exposure (*78*). Both conjugate Hib and conjugate *S. pneumoniae* vaccines (introduced for mass infant immunization in the United States in 1990 and 2000, respectively) have reduced incidence of disease caused by vaccine-preventable serotypes (*1,79*). In addition, both vaccines reduce asymptomatic carriage of respective bacteria (*80–82*), thus protecting unvaccinated persons through a herd immunity effect (*1*).

Meningococcal Serogroup C Conjugate Vaccine in the United Kingdom

In November 1999, monovalent serogroup C conjugate vaccines were introduced in the United Kingdom. The national vaccination campaign introduced a routine 3-dose infant vaccination series and implemented a mass catch-up campaign during 1999–2000 targeting all persons aged 12 months–17 years (*34*). The three serogroup C conjugate vaccines used in the United Kingdom are Meningtec™ (Wyeth Lederle Vaccines and Pediatrics, Pearl River, New York); Menjugate™ (Chiron Vaccines, Siena, Italy); and NeisVac™ (Baxter Hyland Immuno, Beltsville, Maryland). Two vaccines (Meningtec and Menjugate) contain short-chain oligosaccharide (O-acetylated) derived from serogroup C capsular polysaccharide, conjugated to CRM197, a nontoxic mutant diphtheria toxin. The third vaccine (NeisVac) contains serogroup C polysaccharide (de-O-acetylated) conjugated to tetanus toxoid (*83,84*). The serogroup C conjugate meningococcal vaccines used in this campaign were licensed on the

basis of data on safety and immunogenicity but without data on clinical efficacy (*85*).

By 2001–2002, vaccine coverage in the United Kingdom was estimated as 80% among infants, 84% among toddlers, 76% among preschoolers, and 86%–87% among schoolchildren (*86*). Effectiveness of the vaccine within the first year of vaccination ranged from 88% to 98% among different age groups (*87–89*). Insufficient data are available to differentiate efficacy of the three meningococcal conjugate vaccines. Because the vaccine campaign was initiated only in 1999, long-term data on duration of protection are not yet available. However, among infants who received 3 doses of vaccine at ages 2, 3, and 4 months, efficacy declined to -81% (95% CI = -7,430–71) after only 1 year (*88*). Although the number of cases remains low, likely in part as a result of vaccine-induced herd immunity, this study raises questions about the meningococcal vaccine schedule and the need for a booster dose.

During 1999–2000, carriage rates of group C meningococci in the United Kingdom declined 66% (*90*). In addition, incidence of meningococcal serogroup C disease declined 67% among unvaccinated persons aged 1–17 years and 35% among persons aged >25 years who were not targeted for vaccination, indicating the additional vaccine benefit of eliciting herd immunity (*86*).

Meningococcal Tetravalent Conjugate Vaccine

Vaccine Composition

MCV4 is a tetravalent meningococcal conjugate vaccine (Menactra, manufactured by Sanofi Pasteur, Inc., Swiftwater, Pennsylvania) that was licensed for use in the United States in January 2005. A 0.5-mL single dose of vaccine contains 4 μg each of capsular polysaccharide from serogroups A, C, Y, and W-135 conjugated to 48 μg of diphtheria toxoid. MCV4 is available only in single-dose vials.

Immunologic Correlates of Protection

Studies among U.S. military recruits conducted in the 1960s indicated that the absence of naturally acquired bactericidal antibodies, measured by a serum bactericidal antibody assay (SBA) using an intrinsic human complement source, was associated with susceptibility to meningococcal group C disease. SBA titers ≥4 using human serum as an exogenous complement source (hSBA) are considered the standard correlate of clinical protection against serogroup C meningococcal disease (*91*).

Serogroup C conjugate meningococcal vaccines were licensed in the United Kingdom on the basis of data on safety and immunogenicity, without data on clinical efficacy (*85*). The immunologic data supporting the use of conjugate serogroup C vaccines were generated by serum bactericidal assay by using baby rabbit complement (rSBA). The threshold values were validated by comparing rSBA titers with those obtained by using hSBA (*85,92*). For licensure in the United Kingdom, rSBA titers of ≥128 were considered to predict protection; however, only 60% of rSBA titers in the range of 8–64 had hSBA titers of ≥4. For rSBA titers in this equivocal range, a fourfold rise in titers pre- to postvaccination was also proposed as a correlate of protection (*92*).

Further evaluation of these threshold values was performed by using vaccine efficacy estimates from postlicensure surveillance, which indicated that these threshold values provided a conservative estimate of short-term clinical efficacy; rSBA threshold of ≥128 underestimated efficacy, with rSBA cutoffs of ≥4–≥8 at 4 weeks after vaccination being most consistent with observed clinical efficacy (*93*). On the basis of these efficacy estimates, the proportion of responders in multiple clinical trials of meningococcal C conjugate vaccines, and the group C seroprevalence study conducted before introduction of group C conjugate vaccines (*94*), rSBA titers of <8 have been proposed to be predictive of susceptibility to invasive meningococcal disease, and rSBA titers of ≥8 have been proposed to correlate with short-term protection (*95*). Limited or no similar data exist to link immune response with clinical efficacy for serogroups A, Y, or W-135.

In 1981, MPSV4 (Menomune) was licensed in the United States on the basis of data on safety and immunogenicity. Immunogenicity of this vaccine was compared with that of the vaccine then licensed for use in the United States, A/C meningococcal polysaccharide vaccine, which had demonstrated 97% efficacy against serogroup A and 90% efficacy against serogroup C (*96*). The immunologic criterion used for licensing was a fourfold or greater rise in SBA among 90% of adults at 3–4 weeks after vaccination. As a result, in 2005, MCV4 (Menactra) was licensed on the basis of findings indicating that it was not inferior to MPSV4 in terms of immunogenicity and safety (i.e., demonstrated noninferiority). A primary criterion in determining immunogenic noninferiority of the new vaccine was the percentage of vaccinees having a fourfold or greater increase in bactericidal antibody for MCV4 compared with MPSV4.

Immunogenicity

Immunogenicity Among Persons Aged 11–18 Years

A randomized controlled trial conducted among persons aged 11–18 years compared immunogenicity of MCV4 with that of MPSV4 at 28 days after vaccination. A similar percentage of subjects achieved at least a fourfold rise in rSBA titers in MCV4 and MPSV groups (Table 2). The percentage of subjects with at least a fourfold rise in rSBA was highest for serogroup W-135 (96.7% in MCV4 group and 95.3% in MPSV4 group), and lowest for serogroup Y (81.8% and 80.1%, respectively). The percentage of subjects achieving an rSBA geometric mean titer (GMT) of ≥128 was high (>98% for all serogroups) in both MCV4 and MPSV4 groups (*97,98*).

Immunogenicity Among Persons Aged 18–55 Years

Another randomized controlled trial conducted among persons aged 18–55 years compared immunogenicity of MCV4 and that of MPSV4 at 28 days after vaccination. Although the percentage of subjects achieving at least a fourfold increase in rSBA titer for each serogroup was higher in the MPSV4 group than in the MCV4 group (Table 2), the criteria for demonstrating immunologic noninferiority to MPSV4 were still achieved. As was the case among persons aged 11–18 years, this percentage was highest for serogroup W-135 (89.4% in the MCV4 group and 94.4% in the MPSV4 group) and lowest for serogroup Y (73.5% and 79.4%, respectively). The percentage of subjects achieving an rSBA GMT of ≥128 was high (>97% for all serogroups) in both MCV4 and MPSV4 groups (*97,98*).

Persistence of Antibodies After 3 Years and Response to Revaccination

MCV4 was administered to 76 subjects previously vaccinated with MCV4, 77 subjects previously vaccinated with MPSV4, and 88 age-matched vaccine-naïve subjects (*97*) (Sanofi Pasteur, Inc., unpublished data, 2004). Immunologic indices were measured before revaccination (day 0) and at days 8 and 28 after revaccination (Table 3).

Subjects initially vaccinated with MCV4 had higher rSBA GMT at day 0 than those vaccinated with MPSV4 (Table 3); this difference was statistically significant for serogroups A ($p<0.001$) and W-135 ($p<0.001$). In addition, a higher percentage of those initially vaccinated with MCV4 had rSBA titers of ≥128 than those initially vaccinated with MPSV4 (Table 3). Vaccine-naïve subjects had lower rSBA on day 0 than subjects previously vaccinated with either MCV4 or MPSV4.

Response to revaccination with MCV4 was assessed by administering MCV4 to subjects previously vaccinated with MPSV4 or MCV4 and to vaccine-naïve control subjects. All subjects in all three groups achieved rSBA titers of ≥128 at both 8 and 28 days after receiving MCV4 (Table 3). Subjects initially primed with MCV4 achieved higher rSBA GMTs than naïve control subjects for all serogroups except A. In contrast, rSBA GMTs of those primed with MPSV4 were lower than those of vaccine-naïve control subjects on both days 8 and 28 for all serogroups (Table 3).

TABLE 2. Percentage of subjects achieving a fourfold rise or greater in serum bactericidal activity by using baby rabbit complement (rSBA), rSBA geometric mean titer (GMT) of ≥128, and rSBA GMT, 28 days after vaccination with meningococcal conjugate vaccine (MCV4) and meningococcal polysaccharide vaccine (MPSV4)

	Fourfold or greater increase in rSBA titer				rSBA GMT		rSBA GMT ≥128	
	MCV4		MPSV4		MCV4	MPSV4	MCV4	MPSV4
Age group, serogroup	%	(95% CI*)	%	(95% CI)	GMT	GMT	%	%
Persons aged 11–18 yrs†								
A	92.7	(89.8–95.0)	92.4	(89.5–94.8)	5,483	3,246	99.8	100.0
C	91.7	(88.7–94.2)	88.7	(85.2–91.5)	1,924	1,639	98.8	98.4
Y	81.8	(77.8–85.4)	80.1	(76.0–83.8)	1,322	1,228	99.5	99.3
W-135	96.7	(94.5–98.2)	95.3	(92.8–97.1)	1,407	1,545	98.6	98.8
Persons aged 18–55 yrs§								
A	80.5	(78.2–82.6)	84.6	(82.3–86.7)	3,897	4,114	99.8	99.9
C	88.5	(86.6–90.2)	89.7	(87.8–91.4)	3,231	3,469	98.8	98.5
Y	73.5	(71.0–75.9)	79.4	(76.9–81.8)	1,750	2,449	97.0	98.5
W-135	89.4	(87.6–91.0)	94.4	(92.8–95.6)	1,271	1,871	97.1	98.5

Sources: Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee, September 22, 2004: briefing information. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration; 2004. Available at http://www.fda.gov/ohrms/dockets/ac/04/briefing/2004-4072b1.htm; Food and Drug Administration. Product approval information—licensing action. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research; 2005. Available at http://www.fda.gov/cber/products/mpdtave011405.htm.

* Confidence interval.

† N = 423 in MCV4 group; 423 in MPSV4 group.

§ N = 1,280 in MCV4 group; 1,098 in MPSV4 group.

TABLE 3. Geometric mean titer (GMT) of serum bactericidal activity by using baby rabbit complement (rSBA) and percentage of subjects aged 14–21 years achieving rSBA GMT of ≥128 before (day 0) and at days 8 and 28 after revaccination with meningococcal conjugate vaccine (MCV4) at 3 years after previous vaccination in three groups (primed with MCV4, primed with meningococcal polysaccharide vaccine [MPSV4], and vaccine-naïve)

	Day 0, rSBA GMT			Day 8, rSBA GMT			Day 28, rSBA GMT		
Indicator, serogroup	Primed with MCV4 (n = 76)	Primed with MPSV4 (n = 77)	Vaccine-naïve (n = 88)	Primed with MCV4 (n = 76)	Primed with MPSV4 (n = 77)	Vaccine-naïve (n = 88)	Primed with MCV4 (n = 76)	Primed with MPSV4 (n = 77)	Vaccine-naïve (n = 88)
GMT									
A	1,082	171	84	9,393	4,406	12,936	4,326	3,271	6,399
C	211	109	43	18,113	1,196	7,453	8,192	665	2,955
Y	592	380	211	12,808	2,896	7,053	5,846	2,327	4,366
W-135	447	120	22	9,566	1,921	5,657	4,612	1,578	2,955
% GMT ≥128									
A	94.7	70.1	58.0	100.0	100.0	100.0	100.0	100.0	100.0
C	71.1	57.1	45.5	100.0	92.1	98.9	100.0	100.0	100.0
Y	96.1	83.1	74.7	100.0	97.4	100.0	100.0	100.0	100.0
W-135	83.1	67.5	28.4	100.0	100.0	100.0	100.0	100.0	100.0

Sources: Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee, September 22, 2004: briefing information. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration; 2004. Available at http://www.fda.gov/ohrms/dockets/ac/04/briefing/2004-4072b1.htm; Sanofi Pasteur, Inc., unpublished data, 2004.

Concomitant Administration of MCV and Other Vaccines

The concomitant administration of MCV4 and tetanus and diphtheria toxoids adsorbed for adult use (Td, manufactured by Sanofi Pasteur, Inc., Swiftwater, Pennsylvania) was evaluated in a double-blind, controlled trial of participants aged 11–17 years. One group received Td and MCV4 concomitantly at separate injection sites, followed by a saline placebo 28 days later; the other group received Td and a saline placebo at separate injection sites, followed 28 days later by MCV4. Concomitant administration of Td and MCV4 did not adversely affect immune response to either vaccine (*97,98*).

When MCV4 and Td were administered concomitantly, antibody response to diphtheria antigen 28 days after vaccination was greater (diphtheria GMT 120.9 IU/mL) than when Td and MCV4 were administered sequentially, Td first (diphtheria GMT 8.4 IU/mL 28 days after Td dose) followed by MCV4 28 days after Td (diphtheria GMT 16.9 IU/mL 28 days after MCV4 dose) (*97*). The prelicensure data demonstrated comparable overall safety profiles among adolescents who received simultaneous and sequential vaccination (Td followed by MCV4 28 days later). The immunological and safety profiles among adolescents receiving MCV4 followed by Td on a later date were not evaluated during prelicensure trials (see "Safety of Concomitant Administration of MCV4 and Other Vaccines").

Among adults aged 18–55 years, a randomized controlled trial assessed immunogenicity of MCV4 and typhoid vaccine 1) when MCV4 and typhoid vaccine were administered concomitantly and 2) when typhoid vaccine was administered concomitantly with placebo and MCV4 was administered 28 days later. Concomitant administration did not adversely affect immune response to either typhoid vaccine or MCV4 (*97,98*).

Safety

Systemic and Local Adverse Reactions

Among persons aged 11–18 years, safety of MCV4 and MPSV4 was assessed in two randomized controlled trials (*97,98*). The percentage of subjects reporting systemic adverse events was similar for persons who received either vaccine. In one study, approximately half of the participants experienced at least one systemic adverse reaction, and <5% experienced at least one severe systemic reaction. Fever (i.e., temperature ≥100°F [≥38°C]) was reported by 5.1% of those who received MCV4 and by 3.0% of those who received MPSV4 (Table 4).

Among persons aged 18–55 years, the safety of MCV4 and of MPSV4 also were compared in two randomized controlled trials. The percentage of subjects reporting systemic adverse events was similar for persons who received either vaccine. In one study, 62% of participants experienced at least one systemic adverse reaction, and <4% experienced severe systemic reaction after receiving MCV4. Fever was reported by 1.5% of those who received MCV4 and by 0.5% of those who received MPSV4 (Table 4).

Local adverse reactions were more common among those persons aged 11–18 years who received MCV4 than among those who received MPSV4 (Table 5); 13% of those who

TABLE 4. Percentage of subjects aged 11–18 years and those aged 18–55 years reporting systemic adverse reactions* 0–7 days after vaccination with either meningococcal conjugate vaccine (MCV4) or meningococcal polysaccharide vaccine (MPSV4)

Reaction	Persons aged 11–18 yrs (%) MCV4 n = 2,265	MPSV4 n = 970	Persons aged 18–55 yrs (%) MCV4 n = 1,371	MPSV4 n = 1,159
Any systemic adverse reaction	55.1	48.7	61.9	60.3
Any severe† systemic adverse reaction	4.3	2.6	3.8	2.6
Fever				
≥100.0°F (≥38.0°C)	5.1§	3.0§	1.5§	0.5§
≥103.1°F (≥39.5°C)	0.6	0.4		
≥104.0°F (≥40.0°C)			0.3	0.1

Sources: Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee, September 22, 2004: briefing information. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration; 2004. Available at http://www.fda.gov/ohrms/dockets/ac/04/briefing/2004-4072b1.htm. Food and Drug Administration. Product approval information—licensing action. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research; 2005. Available at http://www.fda.gov/cber/products/mpdtave011405.htm. Sanofi Pasteur, Inc., unpublished data, 2004.

* Including fever, headache, fatigue, malaise, chills, arthralgia, anorexia, vomiting, diarrhea, seizures, or rash.

† Fever ≥103.1°F (≥39.5°C) for persons aged 11–18 years or >104.0°F(≥40.0°C) for adults aged 18–55 years; headache, fatigue, malaise, chills, or arthralgia requiring bed rest; anorexia or skipping three or more meals; three or more episodes of vomiting; five or more episodes of diarrhea; or presence of rash or seizures.

§ Values in MCV4 and MPSV4 groups that are statistically different (p<0.05). P values were calculated by using chi-square tests.

TABLE 5. Percentage of persons aged 11–18 years and persons aged 18–55 years reporting local adverse reactions 0–7 days after vaccination with either meningococcal conjugate vaccine (MCV4) or meningococcal polysaccharide vaccine (MPSV4)

Reaction	Persons aged 11–18 yrs (%) MCV4 (n = 2,265)	MPSV4 (n = 970)	Persons aged 18–55 yrs (%) MCV4 (n = 1,371)	MPSV4 (n = 1,159)
Redness				
Any	10.9*	5.7*	14.4	16.0
1–2 inches	1.6*	0.4*	2.9	1.9
>2 inches	0.6*	0*	1.1*	0.1*
Swelling				
Any	10.8*	3.68*	12.6*	7.6*
1–2 inches	1.9*	0.3*	2.3*	0.7*
>2 inches	0.5*	0*	0.9*	0*
Induration				
Any	15.7*	5.2*	17.1*	11.0*
1–2 inches	2.5*	0.5*	3.4*	1.0*
>2 inches	0.3	0	0.7*	0*
Pain†				
Any	59.2*	28.7*	53.9*	48.1*
Moderate	12.8*	2.6*	11.3*	3.3*
Severe	0.3	0	0.2	0.1

Sources: Food and Drug Administration. Vaccines and Related Biological Products Advisory Committee, September 22, 2004: briefing information. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration; 2004. Available at http://www.fda.gov/ohrms/dockets/ac/04/briefing/2004-4072b1.htm. Food and Drug Administration. Product approval information—licensing action. Rockville, MD: US Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research; 2005. Available at http://www.fda.gov/cber/products/mpdtave011405.htm. Sanofi Pasteur, Inc., unpublished data, 2004.

* Denotes values in MCV4 and MPSV4 groups that are statistically different (p<0.05). P values were calculated for each category and severity by using chi-square tests.

† Mild = symptoms present, but arm movement not affected; moderate = usual arm movement limited; and severe = disabling.

received MCV4 reported pain that limited movement in the arm of injection, compared with 3% of those who received MPSV4. These differences in frequency of local reactions are related to the amount of diphtheria toxoid contained in each vaccine (*99*). The frequency of local adverse reactions reported after MCV4 was similar to that reported after Td vaccine (*97,98*).

As with persons aged 11–18 years, local adverse reactions among persons aged 18–55 years were reported more commonly by those who received MCV4 than by those who received MPSV4 (Table 5). However, the frequency of local adverse reactions reported by adults after MCV4 was similar to that reported after typhoid vaccine (*97,98*).

Safety of Concomitant Administration of MCV4 and Other Vaccines

Among persons aged 11–17 years, frequency of reported local adverse effects at MCV4 injection site in the group for which MCV4 was administered concomitantly with Td was similar to those in which MCV4 was administered 28 days after Td. The percentage (58.6%) of subjects reporting at least one systemic adverse reaction after concomitant administration of MCV4 and Td was similar to the percentage (54.1%) of systemic reactions reported after Td was administered concomitantly with a placebo. Among persons aged 18–55 years, the frequency of local and systemic adverse effects was similar for those receiving concomitant administration of MCV4 and typhoid vaccine and those who received MCV4 28 days after receiving typhoid vaccine (*97,98*).

Serious Adverse Events in All Safety Studies

A total of 5,453 subjects aged 11–55 years who received MCV4 and 2,923 subjects in the same age group who received MPSV4 completed follow-up 6 months after vaccination. Serious adverse events reported within a 6-month period after vaccination occurred at the same rate (1.3%) in the MCV4 and MPSV4 groups. The events reported were consistent with events expected among healthy adolescent and adult populations (*98*).

Cost-Effectiveness Analyses

Cost-Effectiveness Analysis of MPSV4 Vaccine Among College Students

From a societal perspective, the economic costs and benefits of vaccinating 1) a cohort of 591,587 freshmen who live in dormitories and 2) all freshmen enrolled in U.S. colleges, regardless of housing status (N = 2.4 million) were evaluated, on the basis of an assumption that the benefits of vaccination would last 4 years (*100*). Best- and worst-case scenarios were evaluated by varying the cost of vaccine and administration (range: $54–$88), costs per hospitalization ($10,924–$24,030), the value of premature death on the basis of lifetime productivity ($1.3 million–$4.8 million), the cost per case of vaccine side effects ($7,000–$24,540/1 million doses), and the average long-term cost of treating a case of sequelae of disease ($1,298–$14,600). Vaccination coverage (60% and 100%, respectively) and vaccine efficacy (80% and 90%, respectively) also were varied for evaluation purposes.

Vaccination of freshmen who live in dormitories would result in the administration of approximately 354,950–591,590 doses of vaccine each year, preventing 16–30 cases of meningococcal disease and one to three deaths each year. The cost per case prevented would be an estimated $617,000–$1.85 million, at a cost per death prevented of $6.8–$20.4 million and a cost per life-year saved (LYS)* of $62,042–$489,185 (*100*). Vaccination of all freshmen would result in the administration of approximately 1,364,400–2,274,000 doses of vaccine each year, preventing 37–69 cases of meningococcal disease and two to five deaths each year. The cost per case prevented would be $1.4–$2.9 million, at a cost per death prevented of $22–$48 million (*100*). These data are similar to data derived from previous studies (*101*).

Cost-Effectiveness Analysis of MCV4 Vaccine Among Adolescents Aged 11 Years

From a societal perspective, the economic costs and benefits of vaccinating a cohort of approximately 4,238,670 U.S. adolescents aged 11 years were evaluated, on the basis of an assumption that the benefits of vaccination would last 22 years (*102*). A multivariable (Monte Carlo) analysis was performed in which multiple parameters were varied simultaneously over specified probability distributions. These parameters included disease incidence (46%–120% of the 10-year average), case-fatality ratio (34%–131% of the 10-year average), rates of long-term sequelae, acute meningococcal disease costs (i.e., inpatient care, parents' work loss, and public health response), lifetime costs of meningococcal disease sequelae, and cost of vaccine and administration (range: $64–$114). Vaccination coverage (16%–95%) and vaccine efficacy (39%–99%) also were varied for evaluation purposes.

Median program costs for vaccination of adolescents aged 11 years would be $227 million (5th–95th percentile: $158–$406 million). If a 3% discount rate were used for costs and benefits, during a 22-year period, vaccination among adolescents would prevent 270 cases and 36 deaths (21 cases and three deaths in the first year). The median cost would be $633,000 (5th–95th percentile: $329,000–$1,299,000)/case prevented; $5.0 million (5th–95th percentile: $2.4–$10.9 million)/death prevented; and $121,000 (5th–95th percentile: $69,000–$249,000)/LYS saved (*102*).

Cost-Effectiveness Analysis of a Catch-Up Vaccination Campaign with MCV4

The direct and indirect (herd immunity) benefits of a one-time catch-up vaccination campaign with MCV4 of adolescents aged 11–17 years followed by routine annual vaccination of adolescents aged 11 years were analyzed (CDC, unpublished data, 2005). For this purpose, a probabilistic model of disease burden and economic impacts was built for a 10-year period with and without an adolescent catch-up program. U.S. age- and serogroup-specific surveillance data on incidence and case fatality rates were used, as were hypothetical age-specific reductions in attack rates among unvaccinated persons obtained on the basis of U.K. data (*86,103*). Medical, work loss, and public response costs were estimated with and without a catch-up campaign, as were lifetime costs of meningococcal disease sequelae. After disease and vaccination program costs were projected, estimated costs per case averted, deaths prevented, LYS, and quality-adjusted life years (QALY)† saved were estimated.

With herd immunity effects equivalent to recent experience in the United Kingdom, catch-up vaccination of adolescents plus an added routine program would prevent 5,263 cases

* The number of life-years saved as a result of a preventive intervention (i.e., the number of potential years of life expected if disease-specific events leading to premature death not occur [healthy life expectancy]). The number of life-years saved will be less or at the most equal to the number of potential years lost pre-intervention. Because life expectancy is age-specific, life-years saved is often calculated as the difference between the age-specific healthy life expectancy and the age when a disease-specific event leading to premature mortality could occur without the intervention.

† A measure based on individual preferences for states of health that assigns a value of 1 to a year of perfect health and 0 to death. QALYs measure not only years of life saved but also functioning and health preserved. QALYs are highly relevant when disease-specific outcomes lead to both mortality (i.e., premature death) and substantial morbidity (i.e., temporal or permanent disability). Thus, effectiveness outcomes are expressed as change in health status.

during a 10-year period, a 32% reduction in the number of cases. Excluding program costs, the catch-up program would save $338 million in medical and public response costs and $591 million in time off from work, long-term disability, and premature death. At a hypothetical cost of $83 per vaccinee, a catch-up vaccination program (including 9 years of routine vaccination) would cost society approximately $3.6 billion (45% of this sum in the first year). At a 3% discount rate, the catch-up program would cost society $532,000/case averted, $5.9 million/death prevented, $138,000/LYS, and $64,000/QALY saved. A 20% reduction in herd immunity effects would increase the cost per LYS by $21,000; a $30 decrease in the cost of vaccination would decrease the cost per LYS by $55,000. On the basis of the assumption that herd immunity can be generated, targeting only those U.S. counties in which the disease is highly endemic would decrease the cost per LYS by two thirds.

Catch-up vaccination of adolescents can have a substantial impact on disease burden and costs. However, these data demonstrate that catch-up and routine vaccination programs with MCV4 among adolescents are more costly per health outcome than existing vaccination strategies for Hib and *S. pneumoniae* (*104,105*). Compared with routine vaccination of children aged 11 years, catch-up vaccination could cost up to 20% more/LYS.

Recommendations for Use of Meningococcal Vaccines

Routine Vaccination of Adolescents

ACIP recommends routine vaccination of young adolescents (defined in this report as persons aged 11–12 years) with MCV4 at the preadolescent health-care visit (i.e., a visit to a health-care provider at age 11–12 years, at which time ACIP and other professional organizations [e.g., AAP and the American Medical Association] recommend that persons aged 11–12 years receive appropriate vaccinations and other preventive services [*106–109*]). Introducing a recommendation for MCV4 vaccination among persons aged 11–12 years might strengthen the role of the preadolescent health-care visit and have a positive effect on vaccine coverage during adolescence. For those adolescents who have not previously received MCV4, ACIP recommends vaccination before high school entry (at approximately age 15 years) as an effective strategy to reduce meningococcal disease incidence among adolescents and young adults. By 2008, the goal will be routine vaccination with MCV4 of all adolescents beginning at age 11 years. Other adolescents who wish to decrease their risk for meningococcal disease may elect to receive vaccine.

Other Populations at Increased Risk for Meningococcal Disease

Routine vaccination also is recommended for certain persons who have increased risk for meningococcal disease (Table 6). Use of MCV4 is preferred among persons aged 11–55 years; however, use of MPSV4 is recommended among children aged 2–10 years and persons aged >55 years. If MCV4 is unavailable, MPSV4 is an acceptable alternative for persons aged 11–55 years.

The following populations are at increased risk for meningococcal disease:

- college freshmen living in dormitories (*29,30*);
- microbiologists who are routinely exposed to isolates of *N. meningitdis* (*110*);
- military recruits (*111*);
- persons who travel to or reside in countries in which *N. meningitdis* is hyperendemic or epidemic, particularly if contact with the local population will be prolonged (*112*);
- persons who have terminal complement component deficiencies (*15,16,113*); and
- persons who have anatomic or functional asplenia (*17*).

Because of feasibility constraints in targeting freshmen in dormitories, colleges can elect to target their vaccination campaigns to all matriculating freshmen. The risk for meningococcal disease among nonfreshmen college students is similar to that for the general population of similar age (age 18–24 years) (*29*). However, the vaccines are safe and immunogenic and therefore can be provided to nonfreshmen college students who want to reduce their risk for meningococcal disease.

For travelers, vaccination is especially recommended to those visiting the parts of sub-Saharan Africa known as the "meningitis belt" (*112*) during the dry season (December–June). Vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj. Advisories for travelers to other countries will be issued when epidemics of meningococcal disease caused by vaccine-preventable serogroups are detected. Travelers' health information is available from CDC at 877-FYI-TRIP (toll-free) or at http://www.cdc.gov/travel. Further information concerning geographic areas for which vaccination is recommended can be obtained from international health clinics for travelers and state health departments.

Patients with human immunodeficiency virus (HIV) are likely at increased risk for meningococcal disease, although not to the extent that they are at risk for invasive *S. pneumoniae* infection (*20,114*). Although the efficacy of MCV4 among HIV-infected patients is unknown, HIV-infected patients may

TABLE 6. Recommendations for the use of meningococcal vaccines among persons not vaccinated previously

Population group	Age group (yrs) <2	2–10	11–19	20–55	>55
General population	Not recommended	Not recommended	A single dose of MCV4* is recommended at age 11–12 years (at preadolescent assessment visit) or at high school entry (at approximately age 15 years)	Not recommended	Not recommended
Groups at increased risk	Not usually recommended†	A single dose of MPSV4	A single dose of MCV4 is preferred (MPSV4 is an acceptable alternative)	A single dose of MCV4 is preferred (MPSV4 is an acceptable alternative)	A single dose of MPSV4
College freshmen living in dormitories					
Certain travelers§					
Certain microbiologists¶					
Certain populations experiencing outbreaks of meningococcal disease**					
Military recruits					
Persons with increased susceptibility††					

* Meningococcal conjugate vaccine.

† Meningococcal polysaccharide vaccine (MPSV4) (2 doses, 3 months apart) can be considered for children aged 3–18 months to elicit short-term protection against serogroup A disease (a single dose should be considered for children aged 19–23 months).

§ Persons who travel to or in areas where *Neisseria meningitidis* is hyperendemic or epidemic are at increased risk of exposure, particularly if contact with the local population will be prolonged. Vaccination is especially recommended to those visiting the "meningitis belt" of sub-Saharah Africa during the dry season (December–June), and vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj. Advisories for travelers are available at http://www.cdc.gov/travel/outbreaks.htm, http://www.cdc.gov/travel, or by calling CDC's Travelers' Health Hotline at 877-FYI-TRIP (toll-free).

¶ Microbiologists who are routinely exposed to isolates of *N. meningitidis* should be vaccinated.

** The use of vaccination in outbreak settings has been described previously (**Source:** CDC. Control and prevention of meningococcal disease, and Control and prevention of serogroup C meningococcal disease: evaluation and management of suspected outbreaks: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1997;46 [No. RR-5]:13–21).

†† Includes persons who have terminal complement component deficiencies and persons with anatomic or functional asplenia.

elect vaccination. For persons aged 11–55 years who have been previously vaccinated with MPSV4, revaccination with MCV4 is not indicated unless vaccination occurred 3–5 years previously and the person still remains at increased risk for meningococcal disease (see Revaccination).

Adults Aged 20–55 Years

MCV4 is licensed for use among adults aged 20–55 years. It is safe, immunogenic (*97,98,115,116*), and likely to provide relatively long-lasting protection against meningococcal disease caused by serogroups A, C, Y, and W-135. The rates of meningococcal disease are low in this age group, and vaccination will decrease but not eliminate risk. Therefore, routine vaccination is not recommended; however, persons who wish to decrease their risk for meningococcal disease may elect to be vaccinated.

Children Aged <11 Years and Adults Aged >55 Years

MCV 4 is not licensed for use among children aged <11 years or adults aged >55 years. Routine vaccination with MPSV4 is not recommended for children aged <2 years because it is relatively ineffective and offers a short duration of protection. Routine vaccination with MPSV4 is not recommended for children aged 2–10 years and adults aged >55 years who are not identified as being at increased risk for meningococcal disease.

Outbreaks of Meningococcal Disease

Both MPSV4 (*4*) and MCV4 are recommended for use in control of meningococcal outbreaks caused by vaccine-preventable serogroups (A, C, W-135, and Y) of *N. meningitdis*. An outbreak is defined by the occurrence of at least three[§] confirmed or probable primary[¶] cases of serogroup C meningococcal disease in ≤3 months, with a resulting primary attack rate of ≥10 cases/100,000 population. For calculation of this threshold, population-based rates are used rather than age-specific attack rates. These recommendations are based on experience with serogroup C meningococcal outbreaks, but these principles might be applicable to outbreaks caused by the other vaccine-preventable meningococcal serogroups, including Y, W-135, and A. Both MCV4 and MPSV4 can be used for outbreak control, although use of

§ Calculation of attack rates for organization-based outbreaks is most useful for sizable organizations (e.g., certain universities). However, for the majority of organization-based outbreaks with three cases of disease, the rate will be >10 cases/100,000 population. Thus, occurrence of three cases in these settings should prompt consideration of vaccination. In certain situations, public health officials also might consider vaccination after only two primary cases are identified.

¶ To calculate a primary attack rate, sum all confirmed cases; exclude secondary cases, and count each set of co-primary cases as one case. A primary case is one that occurs in the absence of previous known close contact with another patient. A secondary case is one that occurs among close contacts of a primary patient ≥24 hours after onset of illness in the primary patient. If two or more cases occur among a group of close contacts with onset of illness separated by <24 hours, these cases are considered to be co-primary.

MCV4 is preferred if the population targeted for vaccination includes age groups for which MCV4 is licensed. Detailed recommendations on evaluation and management of suspected outbreaks of meningococcal disease have been published previously (*4*).

Administration

For persons aged 11–55 years, MCV4 is administered intramuscularly as a single 0.5-mL dose. MPSV4 is administered subcutaneously as a single 0.5-mL dose to persons aged >2 years. MCV4 and MPSV4 can be administered concomitantly with other vaccines, but at a different anatomic site (*4,117*). Protective levels of antibodies are usually achieved within 7–10 days of vaccination (*60,118*).

Revaccination

Revaccination might be indicated for persons previously vaccinated with MPSV4 who remain at increased risk for infection (e.g., persons residing in areas in which disease is epidemic), particularly children who were first vaccinated at age <4 years. Such children should be considered for revaccination after 2–3 years if they remain at increased risk. Although the need for revaccination among adults and older children after receiving MPSV4 has not been determined, antibody levels decline rapidly after 2–3 years, and, if indications still exist for vaccination, revaccination might be considered after 5** years (*4*). Repeated vaccination with serogroup A and C polysaccharide vaccine might induce immunologic hyporesponsiveness (*56–59*), although clinical implications of such hyporesponsiveness are not known. Hyporesponsiveness to serogroup C polysaccharide can be overcome by vaccination with serogroup C conjugate vaccine (*119,120*). MCV4 is recommended for revaccination of persons aged 11–55 years; however, use of MSPV4 is acceptable.

ACIP expects that MCV4 will provide longer protection than MPSV4; however, studies are needed to confirm this assumption (*87*). More data will likely become available within the next 5 years to guide recommendations on revaccination for persons who were previously vaccinated with MCV4.

Precautions and Contraindications

Recommended vaccinations can be administered to persons with minor acute illness (e.g., diarrhea or mild upper-respiratory tract infection with or without fever) (*117*). Vaccination should be deferred for persons with moderate or severe acute illness until the person's condition improves. Vaccination with MCV4 or MPSV4 is contraindicated among persons known to have a severe allergic reaction to any component of the vaccine, including dipththeria toxoid (for MCV4), or to dry natural rubber latex. Any adverse effect suspected to be associated with MCV4 or MPSV4 vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). More information about VAERS is available at 800-822-7967 (toll-free) or from http://www.vaers.org.

Because both MCV4 and MPSV4 are inactivated vaccines, they may be administered to persons who are immunosuppressed as a result of disease or medications; however, response to the vaccine might be less than optimal (*117*).

Studies of vaccination with MPSV4 during pregnancy have not documented adverse effects among either pregnant women or newborns (*121–123*). On the basis of these data, pregnancy should not preclude vaccination with MPSV4, if indicated. MCV4 is safe and immunogenic among nonpregnant persons aged 11–55 years, but no data are available on the safety of MCV4 during pregnancy. Women of childbearing age who become aware that they were pregnant at the time of MCV4 vaccination should contact their health-care provider or the vaccine manufacturer.

Future Meningococcal Vaccines, Areas for Research, and Public Education

MCV4 has been licensed on the basis of data regarding safety and short-term immunogenicity. Postmarketing studies are planned (*98*), including a study to evaluate the duration of the antibody response among participants who had received a single dose of MCV4 vaccine or MPSV4 vaccine 5 and 10 years earlier and a study to evaluate safety and immunogenicity when MCV4 is given concomitantly with tetanus and reduced diphtheria and acellular pertussis vaccine adsorbed (Tdap). However, immunogenicity data alone are insufficient to predict vaccine effectiveness and herd immunity effect, which depends largely on the ability of vaccine to alter transmission patterns. Additional studies are needed to evaluate vaccine effectiveness, vaccine impact on nasopharyngeal carriage of meningococci, and indirect effects of vaccine on disease rates among unvaccinated populations.

Meningococcal conjugate vaccines might be considered for licensing in the United States among persons in other age groups, including infants and children aged ≤10 years (*98*). These vaccines are undergoing clinical trials and are likely to have better immunogenicity among infants and young children than MPSV4 (*124–126*), which is the only vaccine available for these age groups in the United States. Information on vaccine effectiveness, duration of protection, and herd

** Certain sources recommend revaccination after 3 years (*4*).

immunity obtained from MCV4 evaluation studies will be valuable in guiding prevention policies and formulating recommendations for vaccination of persons in other age groups.

Because serogroup B capsular polysaccharide is poorly immunogenic in humans, vaccine development for serogroup B meningococci have focused on common proteins, including the outer membrane proteins (OMP) of specific epidemic strains. Efficacy of OMP vaccines has been demonstrated among older children and adults but not among infants and young children, in whom rates of disease are highest (*127–130*). In addition, the variability in OMP strains causing endemic disease will likely limit their usefulness in the United States (*131,132*).

Because of the potential limitations of these vaccines, other new approaches to serogroup B vaccines are being pursued, including the conjugation of a modified serogroup B polysaccharide (after substitution of the N-acetyl group with an N-propionyl group) to a recombinant serogroup B meningococcal porin protein. Although this vaccine is immunogenic in mice and nonhuman primates, concern exists that the vaccine might not be safe (*132*). In addition, with the recent sequencing of the serogroup B meningococcal genome, new genes encoding putative membrane proteins have been identified, indicating potential new targets for serogroup B vaccines (*133–135*). The availability of new meningococcal conjugate vaccines and the development of new vaccine strategies should lead to substantial improvements in global control and prevention of meningococcal disease.

Although the signs and symptoms of meningococcal disease are frequently nonspecific, increasing awareness for meningococcal disease can result in earlier medical care-seeking behavior and improved clinical outcomes. In addition, educating adolescents and their parents about the benefits of receiving MCV4 is key to preventing a substantial number of cases of meningococcal disease. Finally, educating policy makers and the general public about the benefits of receiving MCV4 vaccine might improve vaccination coverage rates and substantially decrease the burden of meningococcal disease in the United States.

Antimicrobial Chemoprophylaxis

In the United States, the primary means for prevention of sporadic meningococcal disease is antimicrobial chemoprophylaxis of close contacts of a patient with invasive meningococcal disease (Table 7). Close contacts include 1) household members (*136,137*), 2) child-care center contacts (*136,138*), and 3) anyone directly exposed to the patient's oral secretions (e.g., through kissing, mouth-to-mouth resuscitation, endotracheal intubation, or endotracheal tube management). For travelers, antimicrobial chemoprophylaxis should be considered for any passenger who had direct contact with respiratory secretions from an index-patient or for anyone seated directly next to an index-patient on a prolonged flight (i.e., one lasting ≥8 hours). Guidelines for chemoprophylaxis of travelers have been published previously (*139*). The attack rate for household contacts exposed to patients who have sporadic meningococcal disease was estimated to be four cases/1,000 persons exposed, which is 500–800 times greater than the rate for the total population (*137*). In the United Kingdom, the attack rate among health-care workers exposed to patients with meningococcal disease was determined to be 25 times higher than among the general population (*140*).

Because the rate of secondary disease for close contacts is highest immediately after onset of disease in the index patient, antimicrobial chemoprophylaxis should be administered as soon as possible (ideally <24 hours after identification of the index patient). Conversely, chemoprophylaxis administered >14 days after onset of illness in the index patient is probably of limited or no value. Oropharyngeal or nasopharyngeal cultures are not helpful in determining the need for chemoprophylaxis and might unnecessarily delay institution of this preventive measure.

TABLE 7. Schedule for administering chemoprophylaxis against meningococcal disease

Drug	Age group	Dosage	Duration and route of administration*
Rifampin†	Children aged <1 mo	5 mg/kg body weight every 12 hrs	2 days
	Children aged ≥1 mo	10 mg/kg body weight every 12 hrs	2 days
	Adults	600 mg every 12 hrs	2 days
Ciprofloxacin§	Adults	500 mg	Single dose
Ceftriaxone	Children aged <15 yrs	125 mg	Single IM¶ dose
Ceftriaxone	Adults	250 mg	Single IM dose

* Oral administration unless indicated otherwise.

† Not recommended for pregnant women because it is teratogenic in laboratory animals. Because the reliability of oral contraceptives might be affected by rifampin therapy, consideration should be given to using alternative contraceptive measures while rifampin is being administered.

§ Not usually recommended for persons aged <18 years or for pregnant and lactating women because it causes cartilage damage in immature laboratory animals. Can be used for chemoprophylaxis of children when no acceptable alternative therapy is available. Recent literature review identified no reports of irreversible cartilage toxicity or age-associated adverse events among children and adolescents (**Source:** Burstein GR, Berman SM, Blumer JL, Moran JS. Ciprofloxacin for the treatment of uncomplicated gonorrhea infection in adolescents: does the benefit outweigh the risk? Clin Infect Dis 2002;35:S191–9).

¶ Intramuscular.

Rifampin, ciprofloxacin, and ceftriaxone are 90%–95% effective in reducing nasopharyngeal carriage of *N. meningitdis* and are all acceptable antimicrobial agents for chemoprophylaxis (*141–144*). Systemic antimicrobial therapy of meningococcal disease with agents other than ceftriaxone or other third-generation cephalosporins might not reliably eradicate nasopharyngeal carriage of *N. meningitdis*. If other agents have been used for treatment, the index patient should receive chemoprophylactic antibiotics for eradication of nasopharyngeal carriage before being discharged from the hospital (*145*).

One recent study has reported that a single 500-mg oral dose of azithromycin was effective in eradicating nasopharyngeal carriage of *N. meningitdis* (*146*). Azithromycin, in addition to being safe and easy to administer, is also available in a suspension form and is approved for use among children. Further evaluation is warranted of both the effectiveness of azithromycin in eradicating carriage of *N. meningitdis* and potential for development of microbial resistance to this drug if it is widely used for chemoprophylaxis.

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Centers for Disease Control and Prevention

Vaccines and Preventable Diseases

Meningococcal Vaccination: What Everyone Should Know

Key Facts

There are 2 types of meningococcal vaccines:

- Meningococcal conjugate or MenACWY vaccines
- Serogroup B meningococcal or MenB vaccines

Who Should Get Meningococcal Vaccines?

CDC recommends meningococcal vaccination for all preteens and teens. In certain situations, CDC also recommends other children and adults get a meningococcal vaccine. Below is more information about which meningococcal vaccines CDC recommends for people by age.

Talk to your or your child's clinician about what is best for your specific situation.

Preteens and Teens

Taking a complement inhibitor such as eculizumab (Soliris®) or ravulizumab (Ultomiris®) increases your risk for meningococcal disease. Even if you received meningococcal vaccines, you could still get meningococcal disease.

All 11 to 12 year olds **should** get a MenACWY vaccine, with a booster dose at 16 years old. Teens **may** also get a MenB vaccine, preferably at 16 through 18 years old.

While any teen **may** choose to get a MenB vaccine, certain preteens and teens **should** get it if they:

- Have a rare type of immune disorder called complement component deficiency
- Are taking a type of medicine called a complement inhibitor (for example, Soliris® or Ultomiris®)
- Have a damaged spleen or their spleen has been removed
- Are part of a population identified to be at increased risk because of a serogroup B meningococcal disease outbreak

Get more information about meningococcal vaccine recommendations for teenagers: Meningococcal Vaccination for Preteens and Teens: Information for Parents.

Babies and Children

Helpful Terms

- ***Neisseria meningitidis*:** The bacteria that cause meningococcal disease
- **Serogroup:** A group of bacteria that are closely related; there are 6 serogroups of *Neisseria meningitidis* that cause most meningococcal disease in the world — A, B, C, W, X, and Y

CDC recommends a MenACWY vaccine for children who are between 2 months and 10 years old if they:

- Have a rare type of immune disorder called complement component deficiency

- Have a rare type of immune disorder called complement component deficiency
- Are taking a type of medicine called a complement inhibitor (for example, Soliris® or Ultomiris®)
- Have a damaged spleen or their spleen has been removed
- Have HIV
- Are traveling to or residing in countries in which the disease is common
- Are part of a population identified to be at increased risk because of a serogroup A, C, W, or Y meningococcal disease outbreak

Talk to your child's clinician to find out if, and when, they will need booster shots.

CDC recommends a MenB vaccine for children 10 years or older if they:

- Have a rare type of immune disorder called complement component deficiency
- Are taking a type of medicine called a complement inhibitor (for example, Soliris® or Ultomiris®)
- Have a damaged spleen or their spleen has been removed
- Are part of a population identified to be at increased risk because of a serogroup B meningococcal disease outbreak

Adults

CDC recommends a MenACWY vaccine for adults if they:

- Have a rare type of immune disorder called complement component deficiency
- Are taking a type of medicine called a complement inhibitor (for example, Soliris® or Ultomiris®)
- Have a damaged spleen or their spleen has been removed
- Have HIV
- Are a microbiologist who is routinely exposed to *Neisseria meningitidis*
- Are traveling to or residing in countries in which the disease is common
- Are part of a population identified to be at increased risk because of a serogroup A, C, W, or Y meningococcal disease outbreak
- Are not up to date with this vaccine and are a first-year college student living in a residence hall
- Are a military recruit

Talk to your clinician to find out if, and when, you will need booster shots.

CDC recommends a MenB vaccine for adults if they:

- Have a rare type of immune disorder called complement component deficiency
- Are taking a type of medicine called a complement inhibitor (for example, Soliris® or Ultomiris®)
- Have a damaged spleen or their spleen has been removed
- Are a microbiologist who is routinely exposed to *Neisseria meningitidis*
- Are part of a population identified to be at increased risk because of a serogroup B meningococcal disease outbreak

Who Should Not Get These Vaccines?

Because of age or health conditions, some people should not get certain vaccines or should wait before getting them. Read the guidelines below and ask your or your child's clinician for more information.

Tell the person who is giving you or your child a meningococcal vaccine if:

You or your child have had a life-threatening allergic reaction or have a severe allergy.

- Do not get a meningococcal vaccine if

- You have ever had a life-threatening allergic reaction after a previous dose of that meningococcal vaccine.
- You have a severe allergy to any part of that vaccine. Your or your child's clinician can tell you about the vaccine's ingredients.

You are pregnant or breastfeeding.

- Pregnant women who are at increased risk for serogroup A, C, W, or Y meningococcal disease may get MenACWY vaccines.
- Pregnant or breastfeeding women who are at increased risk for serogroup B meningococcal disease may get MenB vaccines. However, they should talk with a clinician to decide if the benefits of getting the vaccine outweigh the risk.

You or your child are not feeling well.

- People who have a mild illness, such as a cold, can probably get these vaccines. People who have a moderate or severe illness should probably wait until they recover. Your or your child's clinician can advise you.

What Types of Meningococcal Vaccines Are There?

There are 2 types of meningococcal vaccines available in the United States:

- MenACWY (conjugate) vaccines (Menactra® and Menveo®)
- MenB (recombinant) vaccines (Bexsero® and Trumenba®)

MenACWY Vaccines

Helpful Terms

- **Conjugate:** A type of vaccine that joins a protein to an antigen in order to improve the protection the vaccine provides
- **Recombinant:** A type of vaccine where the protein antigen is put into a harmless virus or bacterium that then makes copies of the antigen that the immune system recognizes and creates protective antibodies against

- **Menactra®** : Clinicians give 2 doses to preteens and teens. Clinicians also give it to certain people at increased risk of meningococcal disease. It helps protect against 4 types of the bacteria that cause meningococcal disease (serogroups A, C, W, and Y).
- **Menveo®** : Clinicians give 2 doses to preteens and teens. Clinicians also give it to certain people at increased risk of meningococcal disease. It helps protect against 4 types of the bacteria that cause meningococcal disease (serogroups A, C, W, and Y).

MenB Vaccines

- **Bexsero®** : Clinicians give it as a 2-dose series to people 16 through 23 years old who are not at increased risk of meningococcal disease. Clinicians also give it as a 2-dose series to people 10 years or older at increased risk of meningococcal disease. It helps protect against serogroup B meningococcal disease.
- **Trumenba®** : Clinicians give it as a 2-dose series to people 16 through 23 years old who are not at increased risk of meningococcal disease. Clinicians give it as a 3-dose series to people 10 years or older at increased risk of meningococcal disease. It helps protect against serogroup B meningococcal disease.

How Well Do These Vaccines Work?

Summary

Vaccines that help protect against meningococcal disease work well, but cannot prevent all cases.

As part of the licensure process, MenACWY and MenB vaccines showed that they produce an immune response. This immune response suggests the vaccines provide protection, but data are limited on how well they work. Since meningococcal disease is uncommon, many people need to get these vaccines in order to measure their effectiveness.

Available data suggest that protection from MenACWY vaccines decreases in many teens within 5 years. Getting the 16-year-old booster dose is critical to maintaining protection when teens are most at risk for meningococcal disease. Available data on MenB vaccines suggest that protective antibodies also decrease quickly (within 1 to 2 years) after vaccination.

In Depth

Today, meningococcal disease is at a historic low in the United States. Rates of meningococcal disease have been declining in the United States since the 1990s. Much of the decline occurred before the routine use of MenACWY vaccines. In addition, serogroup B meningococcal disease declined even though MenB vaccines were not available until the end of 2014.

CDC first recommended preteens and teens get a MenACWY vaccine in 2005. Since then, rates of meningococcal disease in teens caused by serogroups C, Y, and W has decreased by over 90%. This is a larger percent decline than seen in other groups for which CDC does not recommend routine MenACWY vaccination. These data suggest MenACWY vaccines provide protection to those vaccinated, but probably not to the larger, unvaccinated community (herd immunity). Experts also believe MenB vaccines do not provide protection to unvaccinated people through herd immunity.

What Are the Possible Side Effects of Meningococcal Vaccines?

Most people who get a meningococcal vaccine do not have any serious problems with it. With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own within a few days, but serious reactions are possible.

Mild Problems

MenACWY Vaccines

Mild problems following MenACWY vaccination can include:

- Reactions where the shot was given
  - Redness
  - Pain
- Fever
- Muscle or joint pain
- Headache
- Feeling tired

If these problems occur, they usually last for 1 or 2 days.

MenB Vaccines

Mild problems following a MenB vaccination can include:

- Reactions where the shot was given
  - Soreness
  - Redness
  - Swelling
- Feeling tired
- Headache
- Muscle or joint pain
- Fever or chills

- Fever or chills
- Nausea or diarrhea

If these problems occur, they can last up to 3 to 5 days.

Problems that Could Happen After Getting Any Injected Vaccine

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell the clinician if you or your child feel dizzy, have vision changes, or have ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where the clinician gave a shot. This happens very rarely.
- Any medicine can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses. These reactions happen within a few minutes to a few hours after the vaccination.
- As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

For more information on possible side effects from vaccination, visit CDC's Possible Side effects from Vaccines webpage.

Where Can I Find These Vaccines?

Your clinician is usually the best place to receive recommended vaccines for you or your child.

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These vaccines are part of the routine childhood immunization schedule. Therefore, vaccines for children and teens are regularly available at

- Pediatric and family practice offices
- Community health clinics
- Public health departments

If your clinician does not have these vaccines for adults, ask for a referral.

Vaccines may also be available at

- Pharmacies
- Workplaces
- Community health clinics
- Health departments
- Other community locations, such as schools and religious centers

Federally funded health centers can also provide services if you do not have a regular source of health care. Locate one near you. You can also contact your state health department to learn more about where to get vaccines in your community.

When receiving any vaccine, ask the provider to record the vaccine in the state or local registry, if available. This helps clinicians at future encounters know what vaccines you or your child have already received.

How Do I Pay for These Vaccines?

People can pay for meningococcal vaccines in several ways:

Private Health Insurance

Most private health insurance plans cover these vaccines. Check with your insurance provider for details on whether there is any cost to you. Ask your insurance provider for a list of in-network vaccine providers.

Vaccines for Children Program

The Vaccines for Children (VFC) Program provides vaccines to children whose parents or guardians may not be able to afford them. A child is eligible if they are younger than 19 years old and meet one of the following requirements:

- Medicaid-eligible
- Uninsured
- American Indian or Alaska Native
- Underinsured (have health insurance that does not cover vaccines or does not cover certain vaccines)

If your child is VFC-eligible, ask if your clinician is a VFC provider. For help in finding a VFC provider near you, contact your state or local health department's VFC Program Coordinator. You can also call CDC at 1-800-CDC-INFO (232-4636).

Related Pages

CDC's Meningococcal Disease Website

Educational Materials on Meningococcal Disease

- Adult Vaccine Assessment Tool: What Vaccines Do You Need?
- Meningococcal Vaccination for Preteens and Teens: Information for Parents

Immunization Schedules

- Recommended Vaccinations for Children (7 through 18 Years Old)
- Recommended Adult Immunization Schedule for Ages 19 Years or Older

Meningococcal Vaccine Information Statements

- MenACWY (English / Other Languages)
- MenB (English / Other Languages)

Vaccine Safety

- CDC's Vaccine Safety Website
- Meningococcal Vaccine Safety Website: A Closer Look at the Safety Data
- Frequently Asked Questions about Vaccine Safety

Meningococcal ACWY State Mandates for Elementary and Secondary Schools
Find out the MenACWY vaccination mandates for elementary and secondary schools in your state

Vaccines for Children Program

Information for the General Public: Cochlear Implants and Vaccination Recommendations

Page last reviewed: July 26, 2019

Reference #3

Centers for Disease Control and Prevention

Meningococcal Disease

Age as a Risk Factor

Infants, teens, and young adults have the highest rates of meningococcal disease in the United States.

Infants

CDC recommends a meningococcal conjugate (MenACWY) vaccine for children as young as 2 months old if they

- Have certain medical conditions
- Are traveling to specific countries
- Are at risk because of an outbreak in their community

Teens and Young Adults

CDC recommends MenACWY vaccination for all 11 through 18 year olds. Preteens 11 to 12 years old should visit their clinicians to receive one dose and other preventive services. Since protection decreases over time, CDC recommends a booster dose at age 16. This allows teens to continue having protection during the ages when they are at highest risk.

Teens and young adults (16 through 23 year olds) may also be vaccinated with a serogroup B meningococcal (MenB) vaccine, preferably at 16 through 18 years old. Healthy teens and young adults who choose to get vaccinated need two doses of the same vaccine brand.

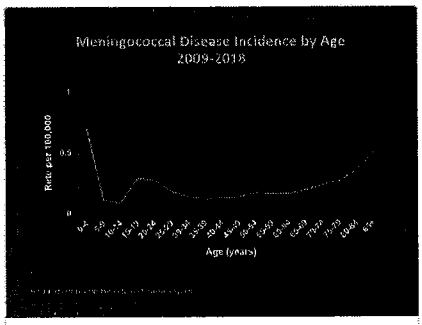
Learn more about meningococcal vaccination recommendations.

Related Pages

Meningococcal Vaccination for Preteens and Teens: Information for Parents
Get information about CDC's meningococcal vaccine recommendations.

Meningococcal ACWY State Mandates for Colleges and Universities
Heading off to college? Read about the MenACWY mandates for the state in which your college or university resides.

Meningococcal ACWY State Mandates for Elementary and Secondary Schools
Find out the MenACWY vaccination mandates for elementary and secondary schools in your state.



Anyone can get meningococcal disease, but rates of disease are highest in children younger than 1 year old, with a second peak in adolescence. Among teens and young adults, those 16 through 23 years old have the highest rates of meningococcal disease.

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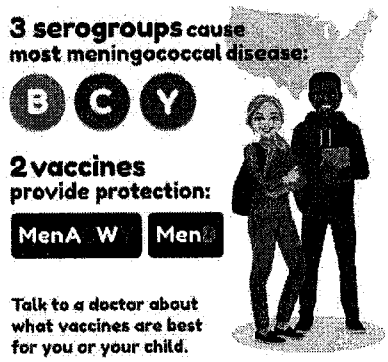

Ask your healthcare professional which meningococcal vaccines they recommend for you or your child.

Page last reviewed: May 31, 2019

Reference #4

Centers for Disease Control and Prevention

Meningococcal Disease

Group Settings as a Risk Factor

Infectious diseases tend to spread wherever large groups of people gather. Recent data show that the risk for meningococcal disease in college students is slightly higher than the risk in other teens and young adults who are not attending college. Many states require colleges to provide information on risks of meningococcal disease to incoming students or students residing on campus. Some states require vaccination for certain students, unless the students provide a vaccination waiver.

CDC recommends a meningococcal conjugate (MenACWY) vaccine for first-year college students living in residence halls. If they received it before their 16th birthday, they need a booster dose for maximum protection before going to college. However, the vaccine is safe and effective and therefore doctors can give it to non-first-year college students.

College campuses have reported outbreaks of serogroup B meningococcal disease in recent years. MenACWY vaccines do not include protection against serogroup B meningococcal disease. CDC recommends the use of a serogroup B meningococcal vaccine for people identified to be at increased risk because of a serogroup B meningococcal disease outbreak.

Learn more about meningococcal vaccine recommendations.

Related Pages

Meningococcal Vaccination

Meningococcal ACWY Prevention Mandates for Colleges and Universities
Heading off to college? Read about the MenACWY mandates for the state in which your college or university resides.

Page last reviewed: May 31, 2019

Reference # 5 ; # 8

The Changing Epidemiology of Meningococcal Disease in the United States, 1992–1996

Nancy E. Rosenstein,[1] Bradley A. Perkins,[1] David S. Stephens,[4] Lewis Lefkowitz,[5] Matthew L. Cartter,[6] Richard Danila,[7] Paul Cieslak,[8] Kathleen A. Shutt,[3] Tanja Popovic,[1] Anne Schuchat,[2] Lee H. Harrison,[9] Arthur L. Reingold,[10] and the Active Bacterial Core Surveillance Team[a]

[1]Meningitis and Special Pathogens Branch, [2]Respiratory Diseases Branch, and [3]Biostatistics and Information Management Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, and the [4]Department of Veterans Affairs Medical Services and Emory University School of Medicine, Atlanta, Georgia; [5]Vanderbilt Medical Center, Nashville, Tennessee; [6]Connecticut Department of Public Health, Hartford; [7]Minnesota Department of Health, Minneapolis; [8]Oregon Emerging Infections Program, Portland; [9]Johns Hopkins University School of Hygiene and Public Health, Baltimore, Maryland, and University of Pittsburgh Graduate School of Public Health and School of Medicine, Pittsburgh, Pennsylvania; [10]University of California, Berkeley

New meningococcal vaccines are undergoing clinical trials, and changes in the epidemiologic features of meningococcal disease will affect their use. Active laboratory-based, population-based US surveillance for meningococcal disease during 1992–1996 was used to project that 2400 cases of meningococcal disease occurred annually. Incidence was highest in infants; however, 32% of cases occurred in persons ≥30 years of age. Serogroup C caused 35% of cases; serogroup B, 32%; and serogroup Y, 26%. Increasing age (relative risk [RR], 1.01 per year), having an isolate obtained from blood (RR, 4.5), and serogroup C (RR, 1.6) were associated with increased case fatality. Among serogroup B isolates, the most commonly expressed serosubtype was P1.15; 68% of isolates expressed 1 of the 6 most common serosubtypes. Compared with cases occurring in previous years, recent cases are more likely to be caused by serogroup Y and to occur among older age groups. Ongoing surveillance is necessary to determine the stability of serogroup and serosubtype distribution.

Neisseria meningitidis is an important cause of morbidity and mortality worldwide and a leading cause of bacterial meningitis and septicemia in children and young adults in the United States [1]. Since 1991, the frequency of outbreaks of meningococcal disease has increased [2]; however, outbreak-associated cases account for only 2% of cases in the United States each year [3]. Therefore, the majority of meningococcal disease in the United States is endemic. In the 5 years since the last complete description of the epidemiologic features of meningococcal disease in the United States [4], significant changes have occurred in serogroup and age distribution of cases as well as in the progress toward new meningococcal vaccines.

Vaccines against meningococcal disease, based on the polysaccharide capsule, have been used in the US military since the 1970s [5]. The formulation currently available in the United States is a quadrivalent meningococcal vaccine, which consists of the purified polysaccharide capsules of serogroups A, C, W-135, and Y. Because of its relative ineffectiveness in children <2 years of age and its relatively short duration of protection, use of this vaccine among civilians has been limited to control of outbreaks. Widespread use of *Haemophilus influenzae* type b (Hib) conjugate vaccines, in which a carrier protein is conjugated to the polysaccharide to produce a T cell–dependent response, has resulted in near-elimination of Hib in the United States [6]. New serogroup A and C meningococcal conjugate vaccines based on similar principles, with enhanced immunogenicity in infants and toddlers, have undergone clinical trials [7–9]. Information concerning the current trends in meningococcal disease in the United States is essential to aid in decision making about use of these vaccines as they approach licensure.

We report herein the results of laboratory-based surveillance for invasive meningococcal disease, conducted in a large US population from January 1992 through December 1996.

Methods

Active surveillance. Population-based surveillance for invasive disease caused by *N. meningitidis* is part of an ongoing multistate

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[a] Study group members are listed after text.

Reprints or correspondence: Dr. Nancy E. Rosenstein, Division of Bacterial and Mycotic Diseases (Mailstop C-09), National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd. N.E., Atlanta, GA 30333 (NAR5@cdc.gov).

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active surveillance project coordinated by the Centers for Disease Control and Prevention (CDC) [1, 4]. Between 1992 and 1996, the CDC collaborated on active surveillance with investigators in state and local health departments and universities in up to 7 geographically dispersed areas of the United States. Active surveillance was not conducted continuously in all 7 surveillance areas. In 1992, surveillance for meningococcal disease was conducted in 4 sites (8 counties in metropolitan Atlanta, 3 counties in the San Francisco Bay Area, 4 counties in Tennessee, and the state of Maryland) with an aggregate population of 12.2 million. During 1995, as part of the National Center for Infectious Diseases Emerging Infections Program site activities, the states of Connecticut, Minnesota, and Oregon were added, bringing the aggregate population to 21.8 million. For Connecticut, Minnesota, and Oregon, only cases from 1996, the first complete year of surveillance, are included in this report. This report includes only those cases reported as of June 1997. Surveillance is continuous, but this report focuses on 1992–1996, a 5-year period during which additional laboratory analysis was done for all available isolates.

Because surveillance was not continuous in all areas, analyses comparing annual surveillance and changes in serogroup distribution for 1992–1996 were done only for the 4 surveillance areas (8 counties in metropolitan Atlanta, 3 counties in the San Francisco Bay Area, 4 counties in Tennessee, and the state of Maryland) with continuous surveillance during those 5 years (an aggregate population of 12.2–12.8 million).

A case of meningococcal disease was defined as the isolation of *N. meningitidis* from a normally sterile site, such as blood or cerebrospinal fluid (CSF), from a resident of the surveillance area between 1 January 1992 and 31 December 1996. Cases were reported to surveillance workers by contacts in each hospital laboratory in the surveillance area. A case report form was completed for each case, including information about the patient's age, sex, race, outcome, and clinical syndrome, as well as the site of isolation, serogroup, and antibiotic sensitivities of the organism. A case of invasive disease was considered to be meningitis if a clinical diagnosis of meningitis had been entered into the patient's medical record or if *N. meningitidis* was isolated from CSF. To evaluate the sensitivity of reporting and to ensure ascertainment of all cases, hospitals were periodically audited by review of microbiology records. Between 1992 and 1996, 96%–98% of cases were detected by surveillance personnel before the audit was done. Cases identified by audit are included in the analysis.

Because race is a likely risk marker for meningococcal disease, data were analyzed by race, and the projected national incidence and annual number of cases based on incidence among surveillance area residents were adjusted for race.

Laboratory methods. All available isolates of *N. meningitidis* were sent to the CDC for further study. Serogrouping was done at hospital microbiology laboratories, at state health departments, and at the CDC; CDC serogroup results were used in the analysis if discrepant serogroup results were obtained in multiple laboratories.

Multilocus enzyme electrophoresis (MEE) with use of 24 constitutive enzymes was done at the CDC on a sample of isolates [10, 11]. Numbers were assigned to enzyme alleles on the basis of enzyme mobilities, and each unique set of alleles was defined as an electrophoretic type (ET). An index of genetic relatedness was determined by weighing the degree of diversity at each of the 24 enzyme loci, and similarities among the ETs were assessed by dendrogram analysis [12]. The isolates tested included all available isolates from 1992–1996 from the 4 sites with continuous surveillance (California, Georgia, Maryland, Tennessee).

Serosubtyping by dot-blotting was done as described elsewhere for serogroup B isolates from the 4 sites with continuous surveillance (California, Georgia, Maryland, Tennessee) as well as for serogroup B isolates collected from Oregon in 1996 [13, 14]. The whole cell suspensions were dotted on nitrocellulose, and strips were blocked for 30 min with 3% bovine serum albumin in PBS. Monoclonal antibodies were pipetted into the blocking buffer at dilutions ranging from 1 : 4000 to 1 : 32,000. After overnight incubation, strips were washed 3 times with PBS and incubated for 2 h with goat anti-mouse IgG conjugated to peroxidase (1 : 4000) (Sigma, St. Louis). Strips were developed with the substrate 3-amino-9-ethyl-carbazole (Sigma) and hydrogen peroxidase. Monoclonal antibodies with specificities for serotypes 2a (5D4-5), 2b (2H10-2), 2c (6-D9-5.6-F3), 4 (5DC4-C8-G8), 5 (7BG5-H2), 11 (9-1-P11), 15 (8-B5-5-B9), and 21 (6B11-C2-F1) and serosubtypes P1.2 (OD6-4), P1.3 (5G8-B2-F9), P1.15 (7A2-11), and P1.16 (OF11-4) were supplied by W. D. Zollinger (Walter Reed Army Medical Center, Washington, DC). Monoclonal antibodies against serotypes 1 (MN3C6B) and 14 (MN5C8C) and serosubtypes P1.1 (MN14C2.3), P1.4 (MN20B9.34), P1.5 (MN22A9.19), P1.6 (MN19D6.13), P1.7 (MN14C11.6), P1.9 (MN5A10.7), P1.10 (MN20F4.17), P1.12 (MN20A7.10), P1.13 (MN25H10.75), and P1.14 (MN21G3.17) were purchased from the National Institute for Biological Standards and Control (Hertfordshire, UK). Monoclonal antibody against serotype 17 (F4-3C1/1A6) was provided by C. T. Sacchi (Institute Adolfo Lutz, São Paolo, Brazil) [15].

Statistical analysis. Cumulative incidences were calculated with use of population data from the US Bureau of the Census for 1992–1996. χ^2 or Fisher's exact test was used to assess statistical significance. Poisson regression was used to estimate rate ratios and confidence intervals. Multivariate, stepwise logistic regression analysis with the SAS software system (version 6.03; SAS Institute, Cary, NC) was done to determine independent risk factors (e.g., case fatality).

Results

In the years 1992–1996, 807 cases of meningococcal disease were detected in the 7 surveillance areas, for an average annual incidence of 1.1/100,000 population during this period. On the basis of this rate and adjustments for differences in racial distribution between the populations of the surveillance areas and of the US population, an estimated 2454 cases of invasive meningococcal disease occurred annually in the United States during this time period. If Oregon, which was having a serogroup B outbreak in 1996 with an incidence of 3.4/100,000 (figure 1) is excluded, the average incidence was 1.0/100,000. Because the incidence in Oregon was higher than that in the other states, we excluded Oregon and used race-adjusted rates to project to the other 49 states, none of which reported serogroup B outbreaks. We then added the cases that would occur in Oregon

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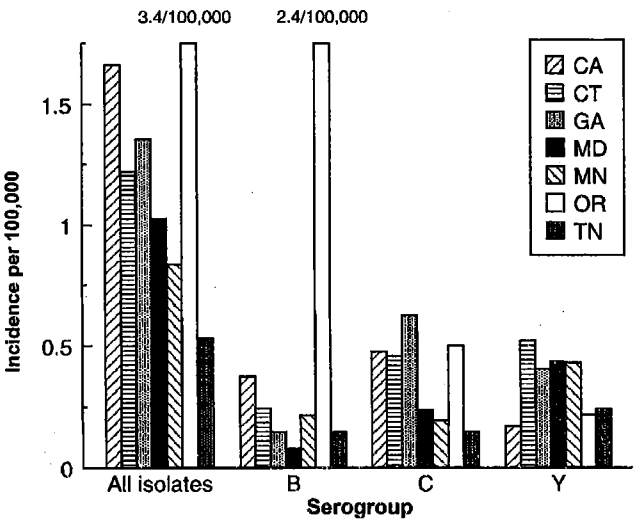

Figure 1. Rates of meningococcal disease by serogroup and area (California, CA; Georgia, GA; Maryland, MD; Tennessee, TN; Connecticut, CT; Minnesota, MN; Oregon, OR), 1996.

and estimated that 2363 cases of meningococcal disease occurred annually in the United States between 1992 and 1996. By use of data from the 4 sites in which surveillance was continuous during the study period and with adjustment for race, the incidence was 0.8 in 1992, 0.9 in 1993, 0.8 in 1994, 1.0 in 1995, and 1.0 in 1996 (χ^2 for linear trend, $P = .006$). Seasonal variation occurred, with the highest proportion of cases occurring in January and December and the lowest in September (figure 2). Of the 769 cases for which outcome information was available, 79 persons died, for an overall case-fatality ratio (CFR) of 10%.

The highest age-specific incidence of meningococcal disease occurred in infants <1 year of age, with a peak incidence of 15.9/100,000 population in infants 4–5 months of age (figure 3). Seventeen percent of case-patients were infants <1 year of age, 22% were children <2 years of age, and 32% were persons ≥30 years of age. Males accounted for 52% of case-patients, with an incidence among males of 1.2/100,000 compared with 1.0/100,000 among females (relative risk [RR], 1.2; 95% confidence interval [CI], 0.9–1.6; $P = .2$). Female case-patients were significantly older than male case-patients (median, 19 vs. 15 years; Kruskal-Wallis χ^2, $P = .0001$). The difference was in part attributable to persons ≥55 years of age, among whom the rate of meningococcal disease in women was 1.0/100,000 versus 0.4/100,000 among men ($P = .0001$; figure 3). The incidence of meningococcal disease was higher in blacks (1.4/100,000) than in nonblacks (0.9/100,000; RR, 1.5; 95% CI, 1.1–2.2; $P = .02$). Hispanic ethnicity was reported by 10% of case-patients.

N. meningitidis was isolated from blood in 625 cases (77%), CSF in 284 (35%), joint fluid in 14 (2%), and peritoneal and pericardial fluid in 1 (0.1%) each. In 118 cases (15%), *N. meningitidis* was isolated from both the blood and CSF. Meningitis occurred in 377 cases (47%). Other syndromes were much less common, with pneumonia reported in 48 cases (6%), arthritis in 17 (2%), otitis media in 7 (1%), epiglottitis in 2 (0.3%), and pericarditis in 1 (0.1%). For some case-patients (0.9%), >1 clinical syndrome was reported. Three hundred forty-nine case-patients (43%) had primary bacteremia without another clinical syndrome. Patients with pneumonia were older than patients without pneumonia (median, 57 vs. 16 years; $P < .001$).

Isolates were available for serogrouping at the CDC for 608 (75%) of the 807 cases; serogroup information was collected locally and recorded on the case report form for 468 (58%). Serogroup data were available from either or both sources for 681 (84%). For 395 isolates, serogroup information was available from both sources; the sources agreed in 354 cases (90%).

Serogroup C organisms accounted for 35%, serogroup B organisms for 32%, and serogroup Y organisms for 26% of isolates for which serogroup information was available. W-135, Z, and nongroupable serogroups accounted for 4%, 3%, and 0.3% of isolates, respectively. Two isolates were reported to be serogroup A, but viable isolates were not submitted to the CDC for confirmation. If Oregon, which has been experiencing an epidemic of serogroup B meningococcal disease, was excluded, serogroup B, serogroup C, and serogroup Y accounted for 25%, 38%, and 29%, respectively.

By use of data from the 4 sites from which continuous data were available (California, Georgia, Maryland, and Tennessee), the estimated serogroup-specific incidences, adjusted for race, for serogroups B and C remained stable over the 5-year period at an average rate of 0.2 and 0.3/100,000, respectively (figure 4). However, the incidence of serogroup Y meningococcal disease increased during the study period from 0.1/100,000 in 1992 to 0.2/100,000 in 1996 (RR, 2.4; 95% CI, 1.3–4.6).

The incidence of serogroup-specific disease varied by sur-

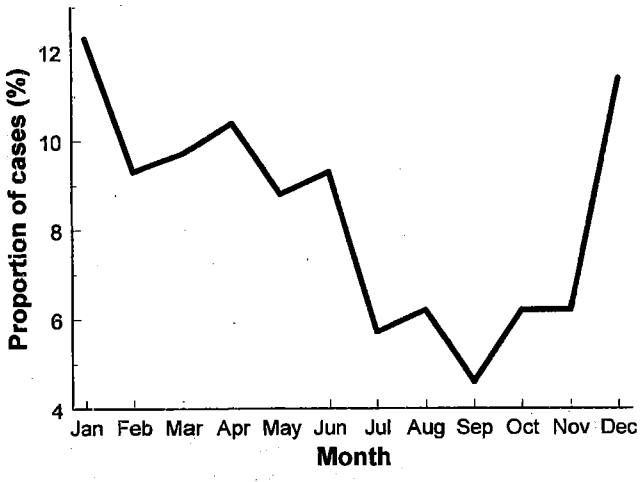

Figure 2. Seasonal variation in cases of meningococcal disease in California, Georgia, Maryland, Tennessee, Connecticut, Minnesota, and Oregon, 1992–1996.

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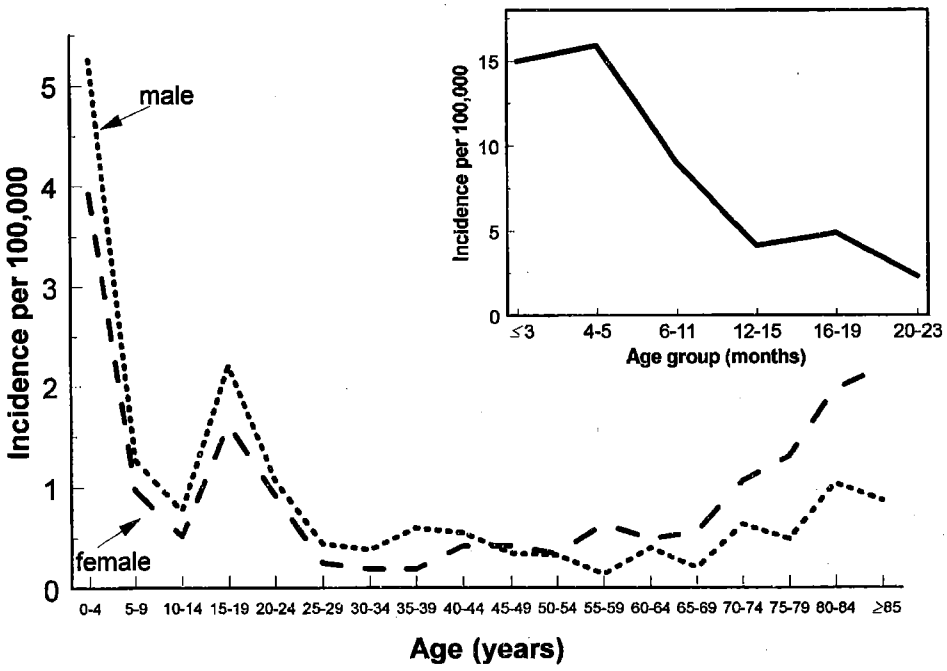

Figure 3. Race-adjusted rates of meningococcal disease by age group and sex in California, Georgia, Maryland, Tennessee, Connecticut, Minnesota, and Oregon, 1992–1996.

veillance area (figure 1). In 1996, the rate of serogroup B disease in Oregon was 2.4/100,000, substantially higher than in any of the other surveillance areas ($P < .005$).

A higher proportion of serogroup B disease occurred in younger age groups (table 1), with 30% of serogroup B disease occurring in persons <1 year of age, compared with 14% of cases due to other serogroups ($P = .001$). The median age was 6 years for patients with serogroup B, 17 for patients with serogroup C, 24 for patients with serogroup Y, and 33 for patients with serogroup W-135.

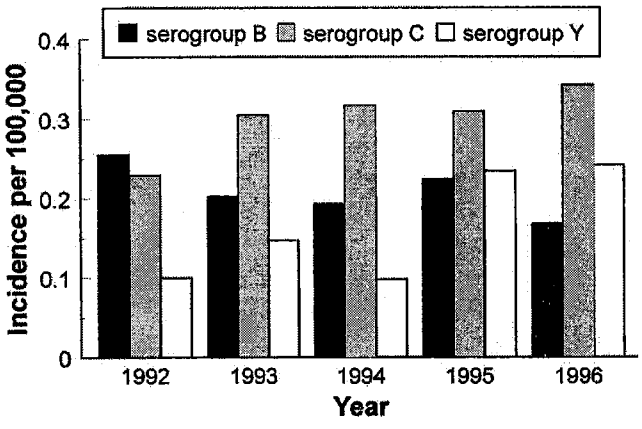

Figure 4. Rates of meningococcal disease by serogroup and year, adjusted for race, at 4 sites with continuous surveillance (California, Georgia, Maryland, and Tennessee), 1992–1996.

After age was adjusted for, a higher proportion of patients with serogroup Y disease than of patients with serogroups B and C disease had pneumonia (14% vs. 2%; $P < .001$). Similarly, after adjustment for age, a higher proportion of patients with serogroup W-135 disease than of patients with serogroups B and C disease reported pneumonia (26% vs. 2%; $P < .001$). The proportions of meningitic and nonmeningitic disease caused by serogroups B and C were similar.

A higher proportion of serogroup Y disease than of disease due to other serogroups occurred among blacks (50% vs. 23%; $P = .001$). Case-patients with serogroup Y disease were more likely to be female than were those with disease due to other serogroups (55% vs. 46%; $P = .03$). Female case-patients with serogroup Y disease were significantly older than were male case-patients with serogroup Y disease (median, 42 vs. 18 years; Kruskal-Wallis χ^2, $P = .0001$). In a multivariate model including only patients with known serogroup, patients with serogroup Y were more likely to be black than white (RR, 1.9; $P < .00001$), to have pneumonia (RR, 1.6; $P < .0002$), and to be older (age >17 years; RR, 1.4; $P = .0002$).

Ten (9%) of the 108 isolates for which sensitivity to sulfonamides was reported were reported to be resistant. Resistance to sulfonamides did not vary by serogroup. The results of rifampin sensitivity testing were reported for 99 isolates. One (1%) of these was reported to be resistant. Although penicillin resistance was reported from local laboratories for only 1 of these isolates, testing among active surveillance isolates from 1 July 1997 to 31 December 1997 as part of a separate study

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Table 1. Annual incidence and estimated number of cases of meningococcal disease by serogroup and age group, adjusted for race—United States, 1992–1996.

Age group, years	Cases/100,000 population/year			Estimated no. of cases		
	Group B	Group C	Group Y	Group B	Group C	Group Y
<1	4.5	2.3	2.1	186	87	84
1–2	1.7	0.9	0.4	68	35	16
2–5	0.4	0.7	0.1	79	109	8
6–1	0.1	0.4	0.1	37	96	20
12–17	0.2	0.5	0.3	46	110	62
18–29	0.2	0.3	0.2	92	140	79
≥30	0.1	0.2	0.2	124	215	216
All ages	0.2	0.3	0.2	633	792	485

NOTE. Rates were calculated excluding Oregon and were adjusted for differences in racial distribution to project to the other 49 states. Cases from Oregon were then added to estimate cases in the United States.

found that 3 of the 90 isolates tested had penicillin MICs ≥0.12 μg/mL [16].

The CFR varied by serogroup and was higher for serogroup W135 (21%) and serogroup C (14%) than for serogroup Y (9%) and serogroup B (6%). The CFR was higher among blacks than whites (14% vs. 9%; $P = .04$). The CFR was lower among those who had a CSF isolate only than among those with an isolate from another source (2% vs. 12%; $P = .001$). The median age of those who died was older than that of those who survived (32 vs. 16 years). Case-fatality did not differ significantly by surveillance area. In a multivariate model, age (RR, 1.01 per year; 95% CI, 1.00–1.02), having a blood isolate (regardless of whether *N. meningitidis* was also isolated from another site; RR, 4.5; 95% CI, 1.63–12.44), and serogroup C (RR, 1.6; 95% CI, 1.04–2.55) were associated with increased case-fatality.

Of 462 *N. meningitidis* isolates available from the 4 sites with continuous data, MEE was done on 399 (86%). The proportion of total isolates from those 4 sites that were typed by MEE varied by year as follows: 60% in 1992, 55% in 1993, 75% in 1994, 69% in 1995, and 64% in 1996.

Of the 154 serogroup C isolates for which MEE results were available (78% of the total), 138 (90%) were of a closely related enzyme type, the ET-37 complex, and 52 (34%) were ET-24, a single enzyme type in the ET-37 complex. The proportion of serogroup C isolates of the ET-24 complex varied over the 5-year period, although not linearly (36% in 1992, 9% in 1993, 15% in 1994, 49% in 1995, and 50% in 1996). Race, sex, and median age did not vary significantly by enzyme type. In a multivariate model adjusting for age and for having a blood isolate ($P = .02$), ET-24 was not associated with an increased CFR (RR, 1.0; $P = .2$).

Of the 110 serogroup B isolates for which MEE results were available (87% of the total), 24 (22%) were ET-5. Among patients with serogroup B isolates, the CFR did not differ significantly among those with ET-5 and those with other enzyme types (8% vs. 4%; $P = .4$). Patients with ET-5 isolates were marginally more likely to have a blood isolate (88% vs. 69%; $P = .07$). Among the 101 serogroup Y isolates for which MEE results were available (84% of the total), 2 major enzyme type complexes could be distinguished by a difference in peptidase mobility. One (ET-501/508) accounted for 51 isolates (50%) and the other (ET-516) for 33 isolates (33%). Patients with ET-501 or ET-508 isolates were more likely to be black than were patients with ET-516 isolates (74% vs. 47%; $P < .005$).

Serotyping and serosubtyping were done for 107 of the 112 serogroup B isolates available from the 4 sites with continuous data, with 84% (107/127) of the total cases from those sites due to serogroup B. Of the 107 isolates, 36 could not be serotyped and 10 could not be serosubtyped. The most common serotype was 4, and the most commonly expressed serosubtype was P1.15 (table 2, table 3). Overall, 68% of isolates expressed 1 of the 6 most common serosubtypes, specifically P1.15; P1.14; P1.5,2; P1.7,16; P1.7,1; and P1.7,13. Of the 107 isolates, 9 (8%) were 15:P1.7,16 and 8 (7%) were 4:P1.7,1. All other serotype/serosubtype combinations accounted for <5% of isolates. Of 76 cases of serogroup B meningococcal disease reported from Oregon in 1996, 72 isolates (95%) were available for testing. Fifty-one (71%) of these isolates were serotype 15, and 59 (82%) were serosubtype P1.7,16.

Discussion

The cumulative incidence of meningococcal disease in the United States increased from 0.8/100,000 in 1992 to 1.0/100,000 in 1996. An earlier study found that between 1989 and 1991, the rate of meningococcal disease decreased from 1.3 to 0.9/100,000 [4]. In 1997 and 1998, the projected rates of meningococcal disease based on the same 4 surveillance areas decreased to 0.8 and 0.7/100,000 (CDC, unpublished data), consistent with natural fluctuations in incidence. However, although the overall incidence of meningococcal disease decreased in 1997 and 1998, the incidence of serogroup Y disease remained elevated at 0.2/100,000 (CDC, unpublished data).

The proportion of meningococcal cases due to serogroup Y increased during the study period from 10.6% in 1992 to 32.6% in 1996. In the period 1989–1991, serogroup Y accounted for

Table 2. Serotyping of serogroup B *Neisseria meningitis* isolates, 1992–1996, from 4 sites with continuous surveillance (California, Georgia, Maryland, Tennessee).

Serotype	Cases (n = 107)
1	5 (5)
2A	4 (4)
2B	2 (2)
4	32 (30)
14	9 (8)
15	15 (14)
17	2 (2)
21	2 (2)
Nontypable	36 (34)

NOTE. Data are no. (%).

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Table 3. Serosubtype data, *Neisseria meningitidis* isolates, 1992–1996, from 4 sites with continuous surveillance (California, Georgia, Maryland, Tennessee).

Serosubtype	Cases (n = 107)
P1.15	15 (14)
P1.14	14 (13)
P1.5,2	13 (12)
P1.7,16	13 (12)
P1.7,1	12 (11)
P1.7,13	5 (5)
P1.5	3 (3)
P1.6	3 (3)
P1.7,4	3 (3)
P1.5,10	2 (2)
P1.7	2 (2)
P1.9	2 (2)
P1.10	2 (2)
P1.10,14	2 (2)
P1.1	1 (1)
P1.3,6	1 (1)
P1.7,3,6	1 (1)
P1.12	1 (1)
P1.12,13	1 (1)
P1.16	1 (1)
Nontypable	10 (9)

NOTE. Data are no. (%).

2% of endemic disease [4], whereas in the time period 1978–1981, serogroup Y caused 7% of cases reported through nationwide surveillance [17]. The majority of the serogroup Y isolates we studied were of 2 major enzyme type complexes, 1 of which (ET501/508) was found in only 1 of 39 military and civilian isolates characterized during 1970–1975, when serogroup Y accounted for 18% of isolates submitted to the CDC [18]. One possible explanation for both the increased rate of serogroup Y disease and the elevated median age of patients is waning population immunity. However, the increase may also reflect the emergence of a distinct clone, as characterized by MEE. To distinguish between these explanations and predict whether this shift in serogroup distribution will continue requires additional investigation of the stability of clonal groups in populations over time and of the association between changes in enzyme type and pathogenicity.

Patients with serogroup Y meningococcal disease were more likely to have pneumonia than were patients with disease due to other serogroups, as has been reported in other studies [19, 20]. Meningococcal pneumonia may be underdiagnosed, because of the difficulty in distinguishing persons who are meningococcal carriers from those with meningococcal pneumonia through isolation of the organism from the sputum and because physicians may not consider *N. meningitidis* as a possible cause of pneumonia. As a result, meningococcal infections that occur in the absence of meningitis or bacteremia may be underreported in the current surveillance system, which requires culture confirmation from a normally sterile site.

Consistent with earlier studies, infants continue to have the highest age-specific attack rates of meningococcal disease, but 54% of patients were between 2 and 29 years, a higher proportion than in earlier studies [4]. The elevated incidence among 15- to 19-year-olds may reflect enhanced risk factors for meningococcal transmission and invasion, such as crowding, active or passive smoking, exposure to oral secretions, or increased mixing of this population through such factors as college attendance [21–25]. Outbreaks of meningococcal disease have been associated with a shift toward disease in school-age children and young adults and may be caused by exposure among these age groups to new strains of *N. meningitidis* to which they were not exposed in earlier childhood [2]. If the increase in endemic disease among this age group is also due to introduction of new strains, age-specific rates of meningococcal disease should vary by strain, as defined by enzyme typing. We were unable to document these differences within our study population, suggesting that increased disease among young adults may instead be due to such risk factors as active and passive smoking and college attendance [23, 26]. The increased rate of meningococcal disease among older adults may be attributable to age-related declines in humoral immunity [27], but the increased proportion of disease among older women may be due to sex-specific differences in risk factors, such as crowding, socioeconomic status, underlying illnesses, or exposure to children, or to selective survival of a healthier male cohort [28].

Changes in the age and serogroup distribution of meningococcal disease will influence decision making about use of new conjugate meningococcal vaccines for control of endemic disease. Unlike Hib disease, rates of meningococcal disease remain elevated through adulthood, so effective vaccines must either provide long-lasting protection or be readministered during childhood and adolescence. Initial efforts have focused on conjugating the serogroup C and serogroup A polysaccharides to carrier proteins in an effort to duplicate the remarkable success of conjugated Hib vaccines, and these vaccines have completed or are already in phase II clinical trials. Although it is difficult to predict whether the high proportion of disease due to serogroup Y will persist, currently a combined conjugate vaccine that protects against serogroups C and Y would be superior to a monovalent conjugate serogroup C vaccine.

An outbreak of ET-5 serogroup B meningococcal disease, occurring since 1994, has not spread beyond the Pacific Northwest [29]. Although rates of serogroup B meningococcal disease in Oregon in 1996 were 2.4/100,000, 1997 data suggest that the outbreak there may be subsiding, a pattern that is consistent with outbreaks in other countries [30, 31] (P.C., unpublished data). Prevention of serogroup B meningococcal disease has been hindered by the absence of a vaccine licensed for use in the United States. Because of apparent immune tolerance to a self-antigen, the purified serogroup B capsular polysaccharide is not immunogenic in humans [32]. Strategies to develop serogroup B meningococcal vaccines have focused on the use of noncapsular antigens to elicit protective immunity [30]. In large

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clinical trials, 3 vaccines based on the outer membrane proteins of epidemic serogroup B strains were found to be safe, immunogenic, and protective in older children and adults [33–36]. However, there is considerable antigenic diversity among the outer membrane proteins of serogroup B strains that cause endemic disease, and their ability to elicit cross-protection against strains other than those used to produce the vaccine as well as strains of other serogroups that share the same serosubtype has not been established. Analysis of serogroup B strains from endemic disease in the United States, excluding strains from Oregon, demonstrates that a multivalent vaccine against 6 common serosubtypes may provide protection against only 68% of disease caused by serogroup B strains. In contrast, in 1996, because of the ongoing outbreak, 82% of cases of serogroup B disease in Oregon were due to a single serosubtype (P1.7,16). The predominant serosubtype also varies between countries. In 1996, 30% of serogroup B cases reported from Europe were due to P1.4, which accounted for only 1% of isolates in this study [37]. Ongoing surveillance for all serogroups is necessary both to determine the stability of serosubtypes in the United States over a longer time period and to determine the representativeness of this sample.

Since 1991, the frequency of serogroup C meningococcal disease outbreaks has increased, with many outbreaks due to a clone identified by MEE as ET-24 [2] (CDC, unpublished data). Although outbreaks are usually caused by closely related strains, ET-24 or the ET-37 complex strains are also a common cause of endemic disease, making their presence alone not a sufficient criterion to distinguish an outbreak [38]. The high proportion of endemic serogroup C disease due to these clones suggests that the appearance of this strain may be the result of waning population immunity and that, on exposure, a person is more likely to develop invasive disease as opposed to colonization [24]. Furthermore, patients who have meningococcal disease due to ET-24 may be more likely to die, because ET-24 is associated with having a blood isolate, a likely correlate of the pathogenicity of the strain.

Mortality from meningococcal disease is likely related to both strain and host characteristics. Although infection with the ET-24 clone was not itself associated with a worse outcome, it was associated with finding *N. meningitidis* in the bloodstream. The CFR differed dramatically between those with a blood isolate (12%) and those without (2%). Proliferation of bacteria in vivo is associated with release of endotoxin, which initiates an inflammatory cascade leading to altered immune response, disseminated intravascular coagulopathy, and circulatory collapse. The concentration of endotoxin has been correlated with severity of disease [39]. Rapid clearance of the organism from the blood may be able to interrupt this cascade, resulting in a better outcome. Disease due to infection with serogroup C was also associated with an increased CFR, suggesting that outcome is also affected by the characteristics of the organism, including the polysaccharide capsule, outer membrane proteins, and lipopolysaccharides.

The overall CFR for meningococcal disease in the United States is similar to that found in many other developed countries [37]. New Zealand, currently experiencing a serogroup B epidemic, has a lower CFR of 5% [40], consistent with the 6% CFR of serogroup B disease in the United States [4]. Nevertheless, patients with meningococcal disease, especially those with meningococcemia, continue to die, even with optimal medical care. Although prompt antibiotic therapy is considered to be very important, clinical data conclusively linking early antimicrobial treatment to improved outcome are lacking [41]. Although research in the optimal use of antibiotics and other experimental therapies should continue, development of better meningococcal vaccines and utilization of such vaccines among high-risk groups, including infants and toddlers, will be the most effective means of preventing the morbidity and mortality associated with meningococcal disease.

Study Group Members

The following are members of the Active Bacterial Core Surveillance Team: California Emerging Infections Program, Berkeley: G. Rothrock, N. Mukerjee, P. Daily, L. Gelling, and D. Vugia; Vanderbilt Medical Center, Nashville: B. Barnes and C. Gilmore; Department of Veterans Affairs Medical Services and Emory University School of Medicine, Atlanta: M. Farley, W. Baughman, S. Whitfield, and M. Bardsley; Johns Hopkins University, Baltimore: L. Billmann; Maryland Department of Health and Mental Hygiene, Baltimore: D. Dwyer; Connecticut Emerging Infections Program, Hartford: J. Hadler, P. Mshar, N. Barrett, C. Morin, and Q. Phan; Minnesota Emerging Infections Program, Minneapolis: M. Osterholm, R. Danila, J. Rainbow, C. Lexau, L. Triden, K. White, and J. Besser; Oregon Emerging Infections Program, Portland: K. Stefonek, J. Donegon, and S. Ladd-Wilson; and Centers for Disease Control and Prevention, Atlanta: G. Ajello, M. Berkowitz, B. Plikaytis, M. Reeves, K. Robinson, S. Schmink, and M. L. Tondella.

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Referenca #6

NOTIFIABLE DISEASES — Reported cases, by geographic division and area, United States, 1998 — Continued

Area	Malaria	Measles		Meningo-coccal disease	Mumps	Pertussis
		Indigenous	Imported*			
United States	**1,611**	**74**	**26**	**2,725**	**666**	**7,405**
New England	**98**	**1**	**2**	**123**	**10**	**1,114**
Maine	5	—	—	8	—	5
N.H.	6	—	—	13	—	149
Vt.	2	—	1	5	—	80
Mass.	27	1	1	59	6	805
R.I.	15	—	—	8	1	21
Conn.	43	—	—	30	3	54
Mid. Atlantic	**426**	**11**	**5**	**295**	**207**	**695**
Upstate N.Y.	93	3	1	84	14	352
N.Y. City	240	—	—	35	167	54
N.J.	58	7	1	60	6	29
Pa.	35	1	3	116	20	260
E.N. Central	**147**	**12**	**4**	**399**	**82**	**919**
Ohio	15	—	1	143	29	299
Ind.	11	2	1	74	7	185
Ill.	59	1	—	104	10	173
Mich.	50	9	1	44	33	71
Wis.	12	—	1	34	3	191
W.N. Central	**110**	**—**	**—**	**231**	**34**	**756**
Minn.	71	—	—	37	13	439
Iowa	8	—	—	46	11	78
Mo.	15	—	—	80	4	59
N. Dak.	3	—	—	5	2	46
S. Dak.	1	—	—	9	—	8
Nebr.	2	—	—	17	—	21
Kans.	10	—	—	37	4	105
S. Atlantic	**349**	**4**	**5**	**482**	**57**	**380**
Del.	3	—	1	2	—	5
Md.	89	—	1	35	—	66
D.C.	19	—	—	4	—	1
Va.	61	—	2	49	13	56
W. Va.	2	—	—	19	—	7
N.C.	30	1	—	59	12	112
S.C.	6	—	—	57	8	29
Ga.	43	1	1	102	2	38
Fla.	96	2	—	155	22	66
E.S. Central	**35**	**—**	**2**	**205**	**19**	**168**
Ky.	7	—	—	38	1	95
Tenn.	17	—	1	75	2	40
Ala.	6	—	1	55	9	27
Miss.	5	—	—	37	7	6
W.S. Central	**101**	**—**	**—**	**338**	**67**	**427**
Ark.	2	—	—	31	13	93
La.	17	—	—	69	8	13
Okla.	4	—	—	44	4	33
Tex.	78	—	—	194	42	288
Mountain	**68**	**9**	**2**	**157**	**40**	**1,324**
Mont.	1	—	—	5	—	17
Idaho	8	—	—	14	7	263
Wyo.	—	—	—	8	1	8
Colo.	18	—	—	31	7	357
N. Mex.	12	—	—	26	NN	100
Ariz.	15	9	2	48	6	241
Utah	2	—	—	15	5	297
Nev.	12	—	—	10	14	41
Pacific	**277**	**37**	**6**	**495**	**150**	**1,622**
Wash.	30	—	1	77	11	407
Oreg.	17	—	—	91	NN	89
Calif.	217	5	4	319	110	1,085
Alaska	4	32	1	3	3	15
Hawaii	9	—	—	5	26	26
Guam	2	—	—	2	5	1
P.R.	1	—	—	11	7	10
V.I.	NA	NA	NA	NA	NA	NA
American Samoa	NA	NA	NA	NA	NA	NA
C.N.M.I.	NA	NA	NA	NA	NA	NA

*Imported cases include only those resulting from importation from other countries.

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TABLE 2. (*Continued*) Reported cases of notifiable diseases,* by geographic division and area — United States, 2004

Area	Lyme disease	Malaria	Measles		Meningococcal disease	Mumps	Pertussis	Plague
			Indigenous	Imported†††				
UNITED STATES	19,804	1,458	10	27	1,361	258	25,827	3
NEW ENGLAND	3,630	102	1	1	75	6	2,328	—
Maine	225	7	—	—	12	—	196	—
N.H.	226	5	—	—	7	1	134	—
Vt.	50	4	—	—	4	1	180	—
Mass.	1,532	53	1	1	40	4	1,698	—
R.I.	249	11	—	—	2	—	53	—
Conn.	1,348	22	—	—	10	—	67	—
MID. ATLANTIC	11,783	386	2	5	168	47	2,948	—
Upstate N.Y.	4,744	62	—	1	44	6	1,969	—
N.Y. City	356	206	1	3	29	20	196	—
N.J.	2,698	74	1	1	37	8	223	—
Pa.	3,985	44	—	—	58	13	560	—
E.N. CENTRAL	1,340	129	—	1	203	26	8,628	—
Ohio	50	30	—	—	71	11	766	—
Ind.	32	17	—	—	26	2	364	—
Ill.	87	47	—	1	36	10	1,554	—
Mich.	27	21	—	—	50	2	303	—
Wis.	1,144	14	—	—	20	1	5,641	—
W.N. CENTRAL	1,103	71	2	3	85	20	4,302	—
Minn.	1,023	30	—	—	24	4	1,368	—
Iowa	49	4	2	1	17	2	1,066	—
Mo.	25	20	—	2	20	3	595	—
N. Dak.	—	3	—	—	2	1	757	—
S. Dak.	1	1	—	—	4	—	169	—
Nebr.	2	4	—	—	4	—	97	—
Kans.	3	9	—	—	14	10	250	—
S. ATLANTIC	1,702	351	1	4	230	33	1,106	—
Del.	339	5	—	—	6	—	16	—
Md.	891	81	—	1	11	4	159	—
D.C.	16	13	—	—	5	—	13	—
Va.	216	59	—	—	24	11	400	—
W.Va.	38	2	—	—	7	2	51	—
N.C.	122	23	1	1	37	5	101	—
S.C.	22	10	—	—	18	—	206	—
Ga.	12	65	—	1	15	2	28	—
Fla.	46	93	—	1	107	9	132	—
E.S. CENTRAL	41	34	—	—	75	8	337	—
Ky.	15	5	—	—	18	—	98	—
Tenn.	20	12	—	—	23	4	173	—
Ala.	6	12	—	—	17	4	49	N
Miss.	—	5	—	—	17	—	17	—
W.S. CENTRAL	103	135	—	—	139	33	1,422	—
Ark.	—	8	—	—	20	—	95	—
La.	2	6	—	—	37	9	23	—
Okla.	3	10	—	—	10	1	120	—
Tex.	98	111	—	—	72	23	1,184	—
MOUNTAIN	26	56	—	1	68	17	2,134	3
Mont.	—	1	—	—	3	—	84	—
Idaho	6	2	—	—	7	3	66	—
Wyo.	4	1	—	—	4	1	35	—
Colo.	—	16	—	1	16	3	1,184	3
N. Mex.	1	5	—	—	9	—	158	—
Ariz.	13	17	—	—	15	7	278	—
Utah	1	8	—	—	7	2	276	—
Nev.	1	6	—	—	7	1	53	—
PACIFIC	76	194	4	12	318	68	2,622	—
Wash.	14	24	—	7	42	2	842	—
Oreg.	11	18	—	—	60	—	627	—
Calif.	48	146	3	3	203	55	1,109	—
Alaska	3	2	—	—	4	2	14	—
Hawaii	N	4	1	2	9	9	30	—
Guam	—	—	—	3	1	4	—	—
P.R.	—	—	—	—	18	7	5	—
V.I.	—	—	—	—	—	—	—	—
Amer. Samoa	—	—	—	—	1	—	—	—
C.N.M.I.	—	—	—	—	—	—	—	—

N: Not notifiable. U: Unavailable. —: No reported cases. P.R.: Puerto Rico V.I.: U.S. Virgin Islands C.N.M.I.: Commonwealth of Northern Mariana Islands

††† Imported cases include only those directly related to importation from other countries.

Reference #11 & #13

Updated Recommendations for Use of Meningococcal Conjugate Vaccines — Advisory Committee on Immunization Practices (ACIP), 2010

On October 27, 2010, the Advisory Committee on Immunization Practices (ACIP) approved updated recommendations for the use of quadrivalent (serogroups A, C, Y, and W-135) meningococcal conjugate vaccines (Menveo, Novartis; and Menactra, Sanofi Pasteur) in adolescents and persons at high risk for meningococcal disease. These recommendations supplement the previous ACIP recommendations for meningococcal vaccination (*1,2*). The Meningococcal Vaccines Work Group of ACIP reviewed available data on immunogenicity in high-risk groups, bactericidal antibody persistence after immunization, current epidemiology, vaccine effectiveness (VE), and cost-effectiveness of different strategies for vaccination of adolescents. The Work Group then presented policy options for consideration by the full ACIP. This report summarizes two new recommendations approved by ACIP: 1) routine vaccination of adolescents, preferably at age 11 or 12 years, with a booster dose at age 16 years and 2) a 2-dose primary series administered 2 months apart for persons aged 2 through 54 years with persistent complement component deficiency (e.g., C5–C9, properidin, factor H, or factor D) and functional or anatomic asplenia, and for adolescents with human immunodeficiency virus (HIV) infection. CDC guidance for vaccine providers regarding these updated recommendations also is included.

Rationale for Adding a Booster Dose to the Adolescent Schedule

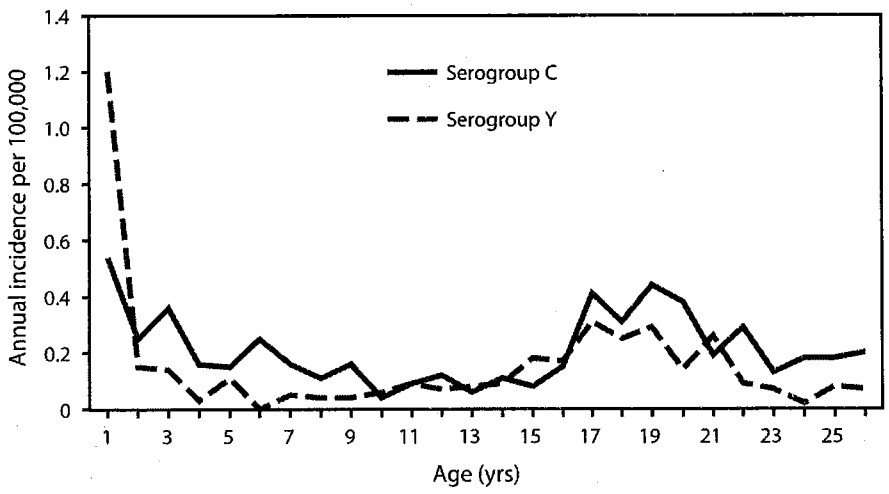
The goal of the 2005 ACIP meningococcal immunization recommendations was to protect persons aged 16 through 21 years, when meningococcal disease rates peak. At that time, vaccination was recommended at age 11 or 12 years rather than at age 14 or 15 years because 1) more persons have preventive-care visits at age 11 or 12 years, 2) adding this vaccine at the 11 or 12 year-old visit would strengthen the pre-adolescent vaccination platform, and 3) the vaccine was expected to protect adolescents through the entire period of increased risk. Meningococcal conjugate vaccines were licensed in 2005 based on immunogenicity (because a surrogate of protection had been defined) and safety data. After licensure, additional data on bactericidal antibody persistence, trends in meningococcal disease epidemiology in the United States, and VE have indicated many adolescents might not be protected for more than 5 years. Therefore, persons immunized at age 11 or 12 years might have decreased protective immunity by ages 16 through 21 years, when their risk for disease is greatest.

Meningococcal disease incidence has decreased since 2000, and incidence for serogroups C and Y, which represent the majority of cases of vaccine-preventable meningococcal disease, are at historic lows. However, the peak in disease among persons aged 18 years (Figure) has persisted, even after routine vaccination was recommended in 2005. In the 2009 National Immunization Survey-Teen, 53.6% of adolescents aged 13 through 17 years had received a dose of meningococcal vaccine (*3*). From 2000–2004 to 2005–2009, the estimated annual number of cases of serogroups C and Y meningococcal disease decreased 74% among persons aged 11 through 14 years but only 27% among persons aged 15 through 18 years. Cases of meningococcal disease caused by serogroups C and Y among persons who were vaccinated with meningococcal conjugate vaccine have been reported. An early VE analysis that modeled expected cases of disease in vaccinated persons estimated a VE of 80%–85% up to 3 years after vaccination (*4*). In 2010, CDC received 12 reports of serogroup C or Y meningococcal disease among persons who had received a meningococcal conjugate vaccine. The mean age of these persons was 18.2 years (range: 16 through 22 years). The mean time since vaccination was 3.25 years (range: 1.5–4.6 years). Five of these 12 persons had an underlying condition that might have increased their risk for meningococcal disease (CDC, unpublished data, 2010).

A case-control study evaluating the VE of meningococcal conjugate vaccine was begun in January 2006 (ACIP meeting, October 2010). Because Menactra was the only licensed vaccine until February 2010, the preliminary results are estimates for Menactra only; no data are available regarding the effectiveness of Menveo. As of October 1, 2010, 108 case-patients and 158 controls were enrolled in the effectiveness study. The overall VE estimate in persons vaccinated 0–5 years earlier was 78.0% (95% confidence interval [CI] = 29%–93%). VE for persons vaccinated less than1 year earlier was 95% (CI = 10%–100%), VE for persons vaccinated 1 year earlier was 91% (CI = 10%–101%), and VE for persons vaccinated 2 through 5 years earlier was 58% (CI = -72%–89%). Although the CIs around the point estimates are wide, the ACIP Work Group concluded that VE wanes.

The ACIP Work Group also concluded that serologic data are consistent with waning immunity. Three characteristics of conjugate vaccines are believed to be important for establishing long-term protection against a bacterial pathogen: memory response, herd immunity, and circulating antibody (*5*). Recent data from the United Kingdom indicate that

FIGURE. Annual incidence of meningococcal disease (serogroup C and serogroup Y), by age — Active Bacterial Core surveillance (ABCs), United States, 1999–2008



although vaccination primes the immune system, the memory response after exposure might not be rapid enough to protect against meningococcal disease. After initial priming with a serogroup C meningococcal conjugate vaccine (MenC), a memory response after a booster dose was not measurable until 5–7 days later (*6*). The incubation period for meningococcal disease usually is less than 3 days. Although herd immunity has been an important component associated with long-term protection with MenC vaccine in the United Kingdom and other countries, immunization coverage has increased slowly in the United States, and to date no evidence of herd immunity has been observed (ACIP meeting, October 2010). Therefore, the Work Group concluded that circulating bactericidal antibody is critical for protection against meningococcal disease. The Work Group took into consideration the proportion of subjects with bactericidal antibody levels above thresholds considered protective, depending on the assay used, evaluating antibody persistence in five studies (Table 1). Although each study tested a small number of vaccine recipients, the Work Group concluded that the studies found sufficient evidence to indicate that approximately 50% of persons vaccinated 5 years earlier had bactericidal antibody levels protective against meningococcal disease. Therefore, more than 50% of persons immunized at age 11 or 12 years might not be protected when they are at higher risk at ages 16 through 21 years.

Two studies evaluated the response after a booster dose of Menactra at 3 and 5 years after the primary vaccination (*7*; ACIP meeting, June 2009). At both 3 and 5 years after the first dose, the booster dose elicited substantially higher geometric mean antibody titers (GMT), compared with the titers elicited by a primary dose. Using a complement serum bactericidal activity (SBA) assay and baby rabbit complement (brSBA) as a measure of immune response, a booster dose administered 5 years after the first dose elicited a GMT for serogroup C of 23,613, compared with 9,045 among subjects administered a primary dose (ACIP meeting, October 2010). As expected with conjugate vaccines, the first dose primes the immune system to have a strong response to the booster dose. Local and systemic reactions to the booster were comparable to those in persons receiving a first dose. The duration of protective antibody after the booster dose is not known but is expected to last through age 21 years for booster doses administered at ages 16 through 18 years.

Optimizing meningococcal vaccination. Despite the current low burden of meningococcal disease, the ACIP Work Group agreed that because of mounting evidence of waning immunity by 5 years postvaccination, vaccinating adolescents with a single dose at age 11 or 12 years is not the best strategy for protection through age 21 years. The Work Group considered two other options for optimizing protection: moving the dose from age 11 or 12 years to age 14 or 15 years or vaccinating at age 11 or 12 years and providing a booster dose at age 16 years. Although a single dose at age 14 or 15 years likely would protect most adolescents through the higher risk period at ages 16 through 21 years, the opportunities to administer vaccine at age 14 or 15 years might be more limited. Data indicate that as adolescents grow older, they are less likely to visit a health-care provider for preventive care (*8*). Adding a booster dose to the recommended schedule would provide more opportunities to increase vaccination coverage, while persons aged 11 through 13 years would continue to be protected. An economic analysis comparing the three adolescent vaccination strategies concluded that administering a booster dose has a cost per quality-adjusted life year similar to that of a single dose at age 11 years or age 15 years but is estimated to prevent twice the number of cases and deaths (CDC, unpublished data, 2010).

Rationale for 2-Dose Primary Series for Persons with a Reduced Response to a Single Dose

Evidence supporting the need for a 2-dose primary meningococcal vaccine series for the small number of persons at increased risk for meningococcal disease was reviewed. Data indicated that SBA could be increased with 2 doses, 2 months apart. For persons who are asplenic or have HIV infection, a 2-dose primary series improves the initial immune response to vaccination. A 2-dose primary series in patients with persistent complement component deficiency will help achieve the high

TABLE 1. Summary of serogroup C bactericidal antibody persistence as determined by serum bactericidal activity (SBA) 2–5 years after vaccination with Menveo and/or Menactra

Age group (yrs) at vaccination	Years postvaccination	Serogroup C SBA	Vaccine	No. of vaccine recipients in study	% of recipients with protective antibody levels
11 through 18*	2	% hSBA ≥1:8	Menveo	273	62
			Menactra	185	58
11 through 18†	3	% hSBA ≥1:4	Menactra	52	35
			MPSV4	48	35
11 through 18§	3	% brSBA ≥1:128	Menactra	71	75
			MPSV4	72	60
2 through 10§	5	% brSBA ≥1:128	Menactra	108	55
			MPSV4	207	42
11 through 18§	5	% brSBA ≥1:128	Menactra	16	56
			MPSV4	10	60

Abbreviations: hSBA = SBA using human complement; brSBA = SBA using baby rabbit complement; MPSV4 = quadrivalent meningococcal polysaccharide vaccine.

* **Source:** Gill C, Baxter R, Anemona A, Ciavarro G, Dull P. Persistence of immune responses after a single dose of Novartis meningococcal serogroup A, C, W-135 and Y CRM-197 conjugate vaccine (Menveo) or Menactra among healthy adolescents. Human Vaccines 2010;6:881–7.

† **Source:** Vu DM, Welsch JA, Zuno-Mitchell P, Dela Cruz JV, Granoff DM. Antibody persistence 3 years after immunization of adolescents with quadrivalent meningococcal conjugate vaccine. J Infect Dis 2006;193:821–8.

§ **Source:** Proceedings of the Advisory Committee on Immunization Practices (ACIP) meeting, June 2009.

levels of SBA activity needed to confer protection in the absence of effective opsonization.

The complement pathway is important to preventing meningococcal disease, and *Neisseria meningitidis* is the primary bacterial pathogen affecting persons with late component complement (LCCD) or properidin deficiency. Although persons with LCCD are able to mount an overall antibody response equal to or greater than complement-sufficient persons after vaccination with quadrivalent meningococcal polysaccharide vaccine (MPSV4), antibody titers wane more rapidly in persons with complement component deficiency, and higher antibody levels are needed for other clearance mechanisms such as opsophagocytosis to function (*9,10*). Asplenic persons are at increased risk for invasive infection caused by many encapsulated bacteria, including *N. meningitidis.* Moreover, the mortality rate is 40%–70% among these persons when they become infected with *N. meningitidis.* Asplenic persons achieve significantly lower geometric mean SBA titers than healthy persons after vaccination with meningococcal C conjugate vaccine, with 20% not achieving brSBA titers ≥1:8. This proportion was reduced to 7% when a second dose of vaccine was administered to nonresponders 2 months later, suggesting a booster might be effective in achieving higher circulating antibody levels and improving immunologic memory (*11*).

Patients with HIV infection likely are at increased risk for meningococcal disease, although not to the extent that they are at risk for invasive *Streptococcus pneumoniae* infection. The risk to persons with HIV infection also is not as great as to persons with complement component deficiency or asplenia. One study has investigated the response rates to a single dose of meningococcal conjugate vaccinate among HIV-infected adolescents. Response to vaccination measured by brSBA titers ≥1:128 was 86%, 55%, 73%, and 72% for serogroups A, C, Y, and W-135, respectively. Response rates were significantly lower among patients with a CD4+ T-lymphocyte percentage of <15% or viral loads >10,000 copies/mL (*12*).

The immunogenicity and safety of a 2-dose primary series has not been studied in older children and adults. However, Menactra and Menveo have been studied following administration as a 2-dose primary series in infants and young children. Infants vaccinated with a 2-dose primary series of Menactra at ages 9 months and 12 through 15 months achieved high antibody titers after the second dose. Administration of 2 doses of Menveo 2 months apart to children aged 2 through 5 years was associated with a similar rate of adverse events as a single dose (*13*).

Recommendation for Routine Vaccination of Persons Aged 11 Through 18 Years

ACIP recommends routine vaccination of persons with quadrivalent meningococcal conjugate vaccine at age 11 or 12 years, with a booster dose at age 16 years. After a booster dose of meningococcal conjugate vaccine, antibody titers are higher than after the first dose and are expected to protect adolescents through the period of increased risk through age 21 years. For adolescents who receive the first dose at age 13 through 15 years, a one-time booster dose should be administered, preferably at age 16 through 18 years, before the peak in increased risk. Persons who receive their first dose of meningococcal conjugate vaccine at or after age 16 years do not need a booster dose. Routine vaccination of healthy persons who are not at increased risk for exposure to *N. meningitidis* is not recommended after age 21 years.

Recommendation for Persons Aged 2 Through 54 Years with Reduced Immune Response

Data indicate that the immune response to a single dose of meningococcal conjugate vaccine is not sufficient in persons with certain medical conditions. Persons with persistent

complement component deficiencies (e.g., C5–C9, properidin, factor H, or factor D) or asplenia should receive a 2-dose primary series administered 2 months apart and then receive a booster dose every 5 years. Adolescents aged 11 through 18 years with HIV infection should be routinely vaccinated with a 2-dose primary series. Other persons with HIV who are vaccinated should receive a 2-dose primary series administered 2 months apart. All other persons at increased risk for meningococcal disease (e.g., microbiologists or travelers to an epidemic or highly endemic country) should receive a single dose.

CDC Guidance for Transition to an Adolescent Booster Dose

Some schools, colleges, and universities have policies requiring vaccination against meningococcal disease as a condition of enrollment. For ease of program implementation, persons aged 21 years or younger should have documentation of receipt of a dose of meningococcal conjugate vaccine not more than 5 years before enrollment. If the primary dose was administered before the 16th birthday, a booster dose should be administered before enrollment in college. The booster dose can be administered anytime after the 16th birthday to ensure that the booster is provided. The minimum interval between doses of meningococcal conjugate vaccine is 8 weeks.

No data are available on the interchangeability of vaccine products. Whenever feasible, the same brand of vaccine should be used for all doses of the vaccination series. If vaccination providers do not know or have available the type of vaccine product previously administered, any product should be used to continue or complete the series. Persons with complement component deficiency, asplenia, or HIV infection who have previously received a single dose of meningococcal conjugate vaccine should receive their booster dose at the earliest opportunity.

These updated meningococcal conjugate vaccine recommendations from ACIP have been summarized (Table 2). Additionally, a meningococcal conjugate vaccine information statement is available at http://www.cdc.gov/vaccines/pubs/vis/default.htm, and details regarding the routine meningococcal conjugate vaccination schedule are available at http://www.cdc.gov/vaccines/recs/schedules/default.htm#child. Adverse events after receipt of any vaccine should be reported to the Vaccine Adverse Event Reporting System at http://vaers.hhs.gov.

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TABLE 2. Summary of meningococcal conjugate vaccine recommendations, by risk group — Advisory Committee on Immunization Practices (ACIP), 2010

Risk group	Primary series	Booster dose
Persons aged 11 through 18 years	1 dose, preferably at age 11 or 12 years	At age 16 years if primary dose at age 11 or 12 years At age 16 through 18 years if primary dose at age 13 through 15 years No booster needed if primary dose on or after age 16 years
HIV-infected persons in this age group	2 doses, 2 months apart	At age 16 years if primary dose at age 11 or 12 years At age 16 through 18 years if primary dose at age 13 through 15 years No booster needed if primary dose on or after age 16 years
Persons aged 2 through 55 years with persistent complement component deficiency* or functional or anatomical asplenia	2 doses, 2 months apart	Every 5 years At the earliest opportunity if a 1-dose primary series administered, then every 5 years
Persons aged 2 through 55 years with prolonged increased risk for exposure†	1 dose	Persons aged 2 through 6 years: after 3 years Persons aged 7 years or older: after 5 years§

Abbreviation: HIV = human immunodeficiency virus.

* Such as C5–C9, properidin, or factor D.

† Microbiologists routinely working with *Neisseria meningitidis* and travelers to or residents of countries where meningococcal disease is hyperendemic or epidemic.

§ If the person remains at increased risk.

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Reference 12

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

This is VAERS ID 381305

Case Details

VAERS ID: 381305 (history)

Form: Version 1.0

Age: 13.0

Sex: Female

Location: Wisconsin

Vaccinated:	2007-08-26
Onset:	2010-02-13
Days after vaccination:	902
Submitted:	2010-02-22
Days after onset:	9
Entered:	2010-02-25
Days after submission:	3

Vaccination / Manufacturer	Lot / Dose	Site / Route
MNQ: MENINGOCOCCAL CONJUGATE (MENACTRA) / SANOFI PASTEUR	U2324AA / 1	LA / IM

Administered by: Private **Purchased by:** Other
Symptoms: Autopsy, Bacterial infection, Death, Joint sprain, Lumbar puncture abnormal, Meningitis meningococcal, Meningococcal infection, Polymerase chain reaction
SMQs:, Guillain-Barre syndrome (broad), Accidents and injuries (narrow), Tendinopathies and ligament disorders (narrow)

Vaccine Adverse Event Reporting System (VAERS) searched with MedAlerts. Deaths associated with Menactra and Menveo in Wisconsin through December 31, 2019 (Accessed Feb. 29, 2020)

Life Threatening? No
Birth Defect? No
Died? Yes
Date died: 2010-02-13
Days after onset: 0
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications:
Current Illness:
Preexisting Conditions: No illness at the time of vaccination. Medical history was unknown.
Allergies:
Diagnostic Lab Data: Autopsy spinal tap revealed gram negative rods, meningococcal type C. 14/Feb/2010: Neisseria Meningitidis PCR and Meningitidis Serogroup PCR of the brain : Neisseria Meningitidis serogroup C DNA detected.
CDC Split Type: 201001159
Write-up: Initial report received on 19 February 2010 from health care professional. A 16 year old female patient with an unknown medical history tested positive for Neisseria Meningitidis 2 years, 7 months, 18 days (963 days) after she received a first dose of MENACTRA (lot number U2324AA) on 26 June 2007 (route and site were unknown). The patient was seen by a physician on 12 February 2010 after an emergency room visit for a sprained ankle after playing in the snow. On 13 February 2010 at 10:30 AM, the patient was found dead in her home. On 14 February 2010 the patient had a real-time PCR assay of the brain for detection of neisseria meningitidis performed which detected Neisseria Meningitidis serogroup C DNA. A spinal tap was done during an autopsy which revealed gram negative rods Meningitis Type C DNA. The physician stated that the patient did not have any symptoms of meningitis. No further information was provided. List of Documents held by Sender: lab results.

Reference 12

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

This is VAERS ID 397123

Case Details

VAERS ID: 397123 (history)

Form: Version 1.0

Age: 14.0

Sex: Male

Location: Wisconsin

Vaccinated:	2007-07-31
Onset:	2010-06-06
Days after vaccination:	1041
Submitted:	2010-09-01
Days after onset:	87
Entered:	2010-09-01

Vaccination / Manufacturer	Lot / Dose	Site / Route
HEPA: HEP A (HAVRIX) / GLAXOSMITHKLINE BIOLOGICALS	AHAVB179AA / 1	RA / UN
MNQ: MENINGOCOCCAL CONJUGATE (MENACTRA) / SANOFI PASTEUR	U2388AA / 1	LA / IM

Administered by: Private **Purchased by:** Private
Symptoms: Bacteraemia, Cardiac failure, Culture positive, Neisseria test positive, Renal disorder
SMQs:, Cardiac failure (narrow), Cardiomyopathy (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Sepsis (broad)
Life Threatening? Yes
Birth Defect? No
Died? Yes

Vaccine Adverse Event Reporting System (VAERS) searched with MedAlerts. Deaths associated with Menactra and Menveo in Wisconsin through December 31, 2019 (Accessed Feb. 29, 2020)

Date died: 2010-06-06
Days after onset: 0
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? Yes
ER or Doctor Visit? No
Hospitalized? Yes, 1 days
Extended hospital stay? No
Previous Vaccinations:
Other Medications: Prednisone 60 mg every other day at time of illness (unknown if taking at time of vaccination)
Current Illness:
Preexisting Conditions:
Allergies:
Diagnostic Lab Data: Neisseria meningitidis serogroup Y isolated from blood, confirmed by culture (collection date: 6/8/2010)
CDC Split Type:
Write-up: Primary bacteremia, complications resulted in heart failure. (Note: Patient was on 60 mg prednisone every other day for kidney problems.)

Reference 12

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

This is VAERS ID 416107

Case Details

VAERS ID: 416107 (history)

Form: Version 1.0

Age: 18.0

Sex: Male

Location: Wisconsin

Vaccinated:	2005-07-12
Onset:	2011-01-13
Days after vaccination:	2011
Submitted:	2011-02-03
Days after onset:	21
Entered:	2011-02-03

Vaccination / Manufacturer	Lot / Dose	Site / Route
MNQ: MENINGOCOCCAL CONJUGATE (MENACTRA) / SANOFI PASTEUR	U1639AA / 1	LA / IM

Administered by: Unknown **Purchased by:** Other
Symptoms: CSF culture positive, Death, Endotracheal intubation, Gram stain, Hypoaesthesia, Lacrimal haemorrhage, Meningitis, Meningococcal bacteraemia, Neisseria test positive, Pyrexia, Rash
SMQs:, Anaphylactic reaction (broad), Angioedema (broad), Peripheral neuropathy (broad), Haemorrhage terms (excl laboratory terms) (narrow), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Guillain-Barre syndrome (broad), Noninfectious meningitis (narrow), Lacrimal disorders (narrow), Hypersensitivity (narrow), Respiratory failure (broad), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Sepsis (broad)

Vaccine Adverse Event Reporting System (VAERS) searched with MedAlerts. Deaths associated with Menactra and Menveo in Wisconsin through December 31, 2019 (Accessed Feb. 29, 2020)

Life Threatening? Yes
Birth Defect? No
Died? Yes
Date died: 2011-01-13
Days after onset: 0
Permanent Disability? No
Recovered? No
Office Visit? No
ER Visit? Yes
ER or Doctor Visit? No
Hospitalized? No
Previous Vaccinations:
Other Medications: No medications
Current Illness: Unknown
Preexisting Conditions: None
Allergies:
Diagnostic Lab Data: Neisseria meningitidis serogroup C confirmed by culture in cerebrospinal fluid sample. Cause of death: meningococcemia and meningitis.
CDC Split Type: 473442WI00010
Write-up: Non-specific symptoms began 1/12/2011, progressed to rash, fever, numbness in arms/legs 1/13. Taken to Emergency Department, experienced blood in tears, was intubated and crashed within 2 hours of arrival to hospital. Cerebrospinal fluid was collected and showed Gram-negative diplococci. Culture later tested positive for Neisseria meningitidis serogroup C.

Reference #14

Effectiveness and Duration of Protection of One Dose of a Meningococcal Conjugate Vaccine

Amanda C. Cohn, MD,[a] Jessica R. MacNeil, MPH,[a] Lee H. Harrison, MD,[b] Ruth Lynfield, MD,[c] Arthur Reingold, MD,[d] William Schaffner, MD,[e] Elizabeth R. Zell, M Stat,[a] Brian Plikaytis, PhD,[a] Xin Wang, PhD,[a] Nancy E. Messonnier, MD,[a] for the Active Bacterial Core Surveillance (ABCs) Team and MeningNet Surveillance Partners

abstract

BACKGROUND: Meningococcal conjugate vaccines were licensed beginning in 2005 on the basis of serologic end points and recommended for use in adolescents. A single dose at age 11 to 12 years was expected to provide protection through late adolescence. We conducted a case-control evaluation of vaccine effectiveness (VE) and duration of protection of a meningococcal (groups A, C, W, and Y) polysaccharide diphtheria toxoid conjugate vaccine (MenACWY-D).

METHODS: Cases of culture- or polymerase chain reaction-confirmed serogroup A, C, W, and Y meningococcal disease among adolescents were identified through meningococcal disease surveillance sites in the United States from January 1, 2006, through August 31, 2013. Attempts were made to enroll 4 friend and school controls per case. VE was calculated using the generalized estimating equation, controlling for underlying medical conditions and smoking.

RESULTS: Serogroup C accounted for 88 (49%), serogroup Y 80 (44%), and serogroup W 13 (7%) of enrolled cases. Thirty-six (20%) cases and 87 (44%) controls received MenACWY-D. The overall VE estimate 0 to 8 years postvaccination was 69% (51% to 80%); VE was 79% (49% to 91%) at <1 year, 69% (44% to 83%) at 1 to <3 years, and 61% (25% to 79%) at 3 to <8 years. VE was 77% (57% to 88%) against serogroup C and 51% (1% to 76%) against serogroup Y.

CONCLUSIONS: MenACWY-D was effective in the first year after vaccination but effectiveness waned 3 to <8 years postvaccination. The estimates of VE from this evaluation informed the Advisory Committee on Immunization Practices in its decision to add a booster dose of MenACWY.

[a]*National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia;* [b]*Department of International Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland;* [c]*Minnesota Department of Health, St Paul, Minnesota;* [d]*School of Public Health, University of California, Berkley, California; and* [e]*Department of Health Policy, Vanderbilt University School of Medicine, Nashville, Tennessee*

Dr Cohn and Ms MacNeil revised the protocol and data collection instruments, coordinated and managed data collection, analyzed the data, and drafted the initial manuscript; Drs Harrison, Lynfield, Reingold, Schaffner, and Messonnier conceptualized the initial study, designed the protocol, and critically reviewed the manuscript; Dr Plikaytis and Ms Zell provided statistical expertise for the protocol and data analysis and critically reviewed the manuscript; Dr Xin Wang provided laboratory expertise and managed confirmatory testing of samples and critically reviewed the manuscript; and all authors approved the final manuscript as submitted.

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WHAT'S KNOWN ON THIS SUBJECT: Because meningococcal disease incidence is low, prelicensure randomized controlled trials of meningococcal (groups A, C, W, and Y) polysaccharide conjugate vaccines used evidence of serologic protection rather than clinical end points. Early estimates of meningococcal (groups A, C, W, and Y) polysaccharide diphtheria toxoid conjugate vaccine (MenACWY-D) effectiveness suggested immunity may wane several years after a single dose.

WHAT THIS STUDY ADDS: This case-control vaccine effectiveness study of a meningococcal conjugate vaccine product (MenACWY-D) was conducted over several years and demonstrates serogroup-specific effectiveness and duration of protection. Preliminary data from this study informed the policy decision to add a booster dose at age 16 years.

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Meningococcal disease incidence has been declining since the late 1990s, and during 2002-2011 there were ~600 to 1200 cases annually in the United States.[1,2] In the absence of vaccination, adolescents have higher rates of disease and nasopharyngeal carriage compared with other age groups.[3–6] Rates of meningococcal disease increase starting at 16 years of age and peak in late adolescence before declining to rates similar to other adult age groups. During 2002 to 2011, rates of meningococcal disease were lower in adolescents aged 11 to 15 years (0.1 to 0.2 cases/100 000 population) compared with adolescents aged 16 to 21 years (0.5 to 0.7 cases/100 000 population).[1] Licensed in 2005, meningococcal (groups A, C, W, and Y) polysaccharide diphtheria toxoid conjugate vaccine, MenACWY-D (Menactra, Sanofi Pasteur, Swiftwater, PA), was the first of 2 meningococcal conjugate vaccines licensed and available for use in adolescents in the United States (package insert available at http://www.fda.gov/downloads//Vaccines/ApprovedProducts/UCM131170.pdf). Because of the relatively low incidence of meningococcal disease, prelicensure randomized controlled trials used evidence of serologic protection rather than clinical end points. An early estimate of MenACWY-D effectiveness by using a simulation approach was 80% to 85% in the first 3 years after vaccination.[7] Because there is an increased incidence of meningococcal disease through late adolescence and vaccination is recommended at age 11 to 12 years, protection for 10 to 12 years is critical to a successful meningococcal vaccination program.

Meningococcal conjugate vaccine has been recommended for all US adolescents since 2005, but vaccination coverage increased slowly. During 2005–2007, because vaccine production was limited soon after licensure, vaccination recommendations focused on certain cohorts of adolescents, including 11- to 12-year-olds, those entering high school at 14 to 15 years of age, and college freshmen living in residence halls. These recommendations were expanded in 2007 to include all 11 through 18 year olds, preferably at 11 to 12 years of age, and in 2010 the Advisory Committee on Immunization Practices (ACIP) recommended a booster dose at age 16 years.

To evaluate the effectiveness of MenACWY-D against meningococcal disease, including duration of protection, we conducted a case-control evaluation in multiple US states. Meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM_{197} conjugate vaccine, MenACWY-CRM (Menveo, Novartis Vaccines, Siena, Italy), was licensed in 2010 and therefore was not included in this evaluation. We evaluated the effectiveness and duration of protection of a single dose of MenACWY-D.

METHODS

Evaluation Population

Cases of meningococcal disease were identified through Active Bacterial Core surveillance (ABCs) and MeningNet sites. ABCs is a population and laboratory based surveillance system coordinated by the Centers for Disease Control and Prevention (CDC) through the Emerging Infections Program.[8] MeningNet sites were state and local health departments funded to conduct enhanced meningococcal disease surveillance through CDC Epidemiology and Laboratory Capacity cooperative agreements. Not all sites participated for the entire course of the evaluation (Supplemental Table 4). Through ABCs, ~13% of the US population was under surveillance. Depending on the year and the number of MeningNet sites participating, an additional 30% to 45% of the US population was under surveillance for this evaluation, for a total of 43% to 58% of the US population under surveillance through ABCs and MeningNet.

Case Identification

Meningococcal disease is a nationally reportable condition, and all cases require public health investigation, including investigation of the case's close contacts. A standardized case report form was used that included information on onset date, hospitalization, and underlying medical conditions. Eligible cases were adolescents living in a surveillance area and ≥11 years of age and born on or after January 1, 1986, at the time of illness. The upper age of eligibility increased each year of the study to include adolescents who were recommended for vaccination in previous years of the study. The upper age limit in 2006 was ≤18 years, in 2007 was ≤19 years, etc). Cases were enrolled from January 1, 2006, through August 31, 2013. Cases of meningococcal disease were defined as those from which *Neisseria meningitidis* was isolated from a normally sterile body site or where *N meningitidis* DNA was detected by polymerase chain reaction (PCR) from a blood or cerebrospinal fluid specimen. Only cases with disease caused by a vaccine serogroup were eligible for the evaluation. There were no serogroup A cases during the evaluation time period.

Laboratory Identification

Meningococcal isolates were serogrouped at the state or local health department laboratory by using slide agglutination. Isolates were sent to the CDC for confirmation of serogroup by slide agglutination and PCR. In suspect

cases that were culture negative, specimens including blood and/or cerebrospinal fluid were either sent to the state or local health department laboratory or the CDC for PCR testing. If *N meningitidis* DNA was detected by PCR at a health department laboratory, confirmatory PCR testing was done at the CDC.[9]

Enrollment

Evaluation personnel used a standard protocol to enroll cases with information collected from the case investigation. Up to 15 attempts were made to contact case patients by telephone on different days and at various times; mobile telephone numbers were used if provided as part of the case investigation. For adolescents <18 years of age, consent was obtained from the parent as well as assent from the minor adolescent. Case patients or the parents who gave oral informed consent were enrolled; written consent was obtained after the interview to obtain provider records of immunization history. Case patients were asked for names of friends for control enrollment, and consent to contact the named friends by the evaluation personnel. Due to difficulties enrolling friend controls, sites were asked to additionally enroll controls through the school that the case attended with consent from the case. Controls were eligible for enrollment if they were within 2 years of age of the case and lived in the state or surveillance site at the time of illness onset of the case. Consent and enrollment procedures for controls were the same as for cases. Attempts were made to enroll 4 controls per case.

Evaluation personnel interviewed cases and controls by telephone to obtain demographic characteristics, history of meningococcal vaccination, and information on underlying medical conditions that are associated with an increased risk for meningococcal disease. Information on social and behavioral characteristics, such as smoking tobacco, was also obtained. Questions about social history and recent medical illness were asked about for the month before the onset date of meningococcal disease in the matched case. For adolescents <18 years of age, questions were asked to the parent or guardian of the case or control. For cases who died as a result of meningococcal disease, a proxy such as a parent was interviewed. Subjects were also asked to provide information on health care providers or other places where they might have received vaccines. Evaluation personnel contacted these providers or used the state electronic immunization registry to obtain information on receipt of meningococcal vaccine, including date of vaccination, vaccine type, and lot number. Vaccine brand was confirmed by using lot numbers when available. Because information on vaccine product was required, cases and controls were considered vaccinated only if the vaccination record could be verified.

Statistical Analysis

Data were collated and entered into a Microsoft Access database (Microsoft, Redmond, WA) at the CDC. Analyses were done with SAS statistical software (version 9.3; SAS Institute, Inc, Cary, NC). We used data from the case report forms and χ^2 analysis to compare characteristics of adolescents who were enrolled with those who were not. For both cases and controls, a dose of vaccine was determined to be valid if it had been received at least 10 days before onset of illness in the case. Cases and controls who reported no history of vaccination and for whom vaccination status could not be verified were considered to be unvaccinated. Cases and controls with history of meningococcal polysaccharide vaccination (n = 12) or a history of 2 doses of MenACWY-D (n = 5) were excluded from the analysis. One case received a dose of MenACWY-CRM and was excluded from the analysis; no controls received MenACWY-CRM. Underlying medical conditions were defined as 1 or more of the following: cancer, complement disorder, other immune deficiency disorder, diabetes mellitus, kidney disease, sickle cell disease, and asplenia.

We used the generalized estimating equation (GEE) to estimate vaccine effectiveness (VE). GEE models incorporate data from concordant case patient/control sets and from case patients with no matched controls. GEE models the correlation among members of clusters to calculate the odds of being a case among vaccinated and unvaccinated subjects.[10] The presence of underlying medical conditions and smoking were controlled for in the model. Conditional logistic regression models were also performed with similar results, which are presented in Supplemental Table 5.

Human Subjects

The evaluation was determined to be public health program evaluation by the National Center for Immunization and Respiratory Diseases at the CDC in 2006. Alabama, Arizona, California (ABCs), Colorado, Connecticut, Florida, Georgia, Houston, Indiana, Kansas, Maryland, Massachusetts, Minnesota, Mississippi, New Mexico, North Carolina, New York, New York City, Oklahoma, Oregon, Philadelphia, Texas, and Washington were approved by their local institutional review board to participate in the evaluation; all other sites determined the evaluation to be public health program evaluation or relied on the CDC's determination.

TABLE 1 Characteristics of Eligible and Enrolled Cases-Patients, and Controls, ABCs and MeningNet Sites, 2006 to 2013

	Eligible Cases, $n = 320$	Enrolled Cases, $n = 181$	Controls, $n = 199$
Mean age, y	18.9 (11 to 27)	19.2 (11 to 27)	18.9 (12 to 25)
Men, *n* (%)	184 (58)	107 (59)	102 (51)
Race, *n* (%)			
White	213 (67)	121 (67)	170 (85)
African American	64 (20)	36 (20)	10 (5)
Other	14 (4)	8 (4)	15 (8)
Reported smoker, *n* (%)	—	62 (34)	49 (25)
Reported underlying condition, *n* (%)[a]	—	22 (12)	4/199 (2)
Serogroup, *n* (%)			
C	156 (49)	88 (49)	—
Y	139 (43)	80 (44)	—
W	25 (8)	13 (7)	—
Outcome, *n* (%)			
Survived	270 (85)	156 (87)	—
Died	46 (15)	23 (13)	—
Year, *n* (%)			
2006	41 (13)	22 (12)	25 (13)
2007	39 (12)	24 (13)	33 (17)
2008	25 (8)	11 (6)	14 (7)
2009	48 (15)	27 (15)	34 (17)
2010	60 (19)	41 (23)	51 (26)
2011	45 (14)	24 (13)	15 (8)
2012	36 (11)	21 (12)	20 (10)
2013	22 (7)	11 (6)	7 (4)

—, not applicable.

[a] Underlying conditions for controls included cancer ($n = 1$), diabetes ($n = 1$), and other immunodeficiency disorder, not specified ($n = 2$). Underlying conditions for cases included cancer ($n = 2$), complement deficiency ($n = 5$), diabetes ($n = 3$), kidney disease ($n = 2$), asplenia ($n = 1$), and other immunodeficiency disorder, not specified ($n = 9$).

RESULTS

We identified 320 adolescents with serogroup C, W, or Y meningococcal disease during January 1, 2006, through August 31, 2013, in the participating sites. Of these cases, 181 (57%) were enrolled. According to the data from the case report form, enrolled cases were similar in demographic characteristics to unenrolled cases (Table 1). A total of 199 controls were enrolled; 1 or more control was matched to 88 (49%) of enrolled case patients. Among the enrolled controls, 153 (82%) were friend controls and 31 (17%) were school controls. Case and control enrollment by year is shown in Table 1. Cases were less likely than controls to be white (67% vs 85%), were more likely to report an underlying medical condition (12% vs 2%), and to smoke (34% vs 25%). Underlying conditions for controls included cancer ($n = 1$), diabetes ($n = 1$), and other immunodeficiency disorder, not specified ($n = 2$). Underlying conditions for cases included cancer ($n = 2$), complement deficiency ($n = 5$), diabetes ($n = 3$), kidney disease ($n = 2$), asplenia ($n = 1$), and other immunodeficiency disorder, not specified ($n = 9$).

Vaccination status was verified by a provider or the immunization registry for 87% of enrolled case patients and controls; 36 (20%) cases and 87 (44%) controls were vaccinated with a single dose of MenACWY-D (Fig 1). Of the 36 case patients vaccinated with MenACWY-D, 13 were serogroup C, 22 were serogroup Y, and 1 was serogroup W. Among the cases who were unvaccinated, 75 were serogroup C, 58 were serogroup Y, and 12 were serogroup W. Case patients ($n = 36$) were vaccinated a median of 34 months before disease onset (range, 3 to 77 months). Controls ($n = 87$) were vaccinated a median of 32 months before disease onset of the matched case (range, 1 to 93 months).

The overall VE of a single dose of MenACWY-D against meningococcal disease caused by serogroups C, Y, or W was 69% (95% confidence interval [CI]: 51% to 80%). Among adolescents with no underlying condition, VE was 71% (95% CI: 54% to 82%). Serogroup C VE was 77% (95% CI: 57%–88%) and serogroup Y VE was 51% (95% CI: 1% to 76%; Table 2). A serogroup W VE could not be calculated because of low sample size. VE was 79% (95% CI: 49% to 91%) in the first year after vaccination, 69% (95% CI: 44% to 83%) at 1 to <3 years, and 61% (95% CI: 25% to 79%) 3 to <8 years after vaccination (Table 3). The GEE model produced point estimates that were not substantially different from those obtained from standard conditional logistic regression but with smaller standard errors (Supplemental Table 5).

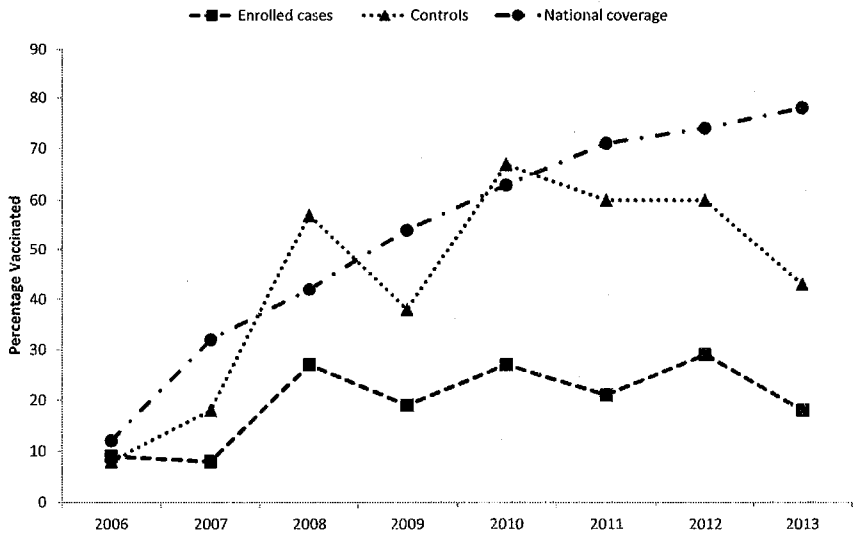

FIGURE 1
Percent of enrolled cases and controls vaccinated, and vaccination coverage among US teenagers aged 13 to 17 years[11], ABCs and MeningNet Sites, 2006 to 2013.

DISCUSSION

MenACWY-D was effective against meningococcal disease caused by serogroups C and Y early after vaccination but effectiveness declined over time. A single dose of MenACWY-D did not provide sufficient protection against meningococcal disease 3 to 8 years after vaccination. These estimates are consistent with immunogenicity data that revealed decreasing levels of serum bactericidal antibody 3 to 5 years postvaccination.[12,13]

Among adolescents and young adults, the risk of meningococcal disease is highest from 16 through 23 years of age. Based on the results of this study, a single dose strategy at 11 to 12 years may not prevent disease during the highest risk period starting at age 16 years. During public discussion of preliminary data from this study at the October 2010 ACIP meeting, the policy options of adding a booster dose at age 16 years or moving the single dose of MenACWY vaccine to age 14 to 15 years were considered. Adding a booster dose of MenACWY at 16 years of age was preferred by ACIP to provide more opportunities to increase vaccination coverage and to continue to protect adolescents ages 11 to 13 years.[14] In 2015, nine years after introduction, coverage with a single dose of meningococcal conjugate vaccines among 13- to 17-year-olds was 81.3% and only 33.3% of teenagers 17 years of age had received 2 doses of MenACWY.[15] However, even with low coverage with the booster dose, only an estimated 30 to 50 cases of serogroup C and Y meningococcal disease occurred among adolescents aged 18 to 24, which may be an effect of a decline in meningococcal disease rates seen in all ages since before and during implementation of the adolescent program.

The waning VE of MenACWY-D demonstrated in this evaluation is different than previous experience with conjugate vaccines such as pneumococcal and *Haemophilus influenzae* type b (Hib) vaccine, which have demonstrated long-term protection even though circulating antibody declines.[16] The reasons for this are unclear, but 1 key difference is that MenACWY-D uses diphtheria toxoid as the protein carrier. Hib vaccines using diphtheria toxoid as the protein carrier were found to be less effective than other Hib conjugate vaccines when compared among infants.[17] MenACWY-D VE is also lower than effectiveness of monovalent serogroup C meningococcal conjugate vaccines in adolescents vaccinated in the United Kingdom, where VE was 93% up to 4 years after vaccination.[18] The low effectiveness of the serogroup Y component of the vaccine contributed to the overall reduced effectiveness and likely the limited duration of protection of this multivalent vaccine. As serogroup Y caused almost half of the vaccine-preventable disease in adolescents before vaccine implementation,

TABLE 2 VE Estimates and Serogroup Specific Estimates, Using the GEE and Controlling for Underlying Medical Conditions and Smoking, ABCs and MeningNet Sites, 2006 to 2013

	VE (95% CI)
All Serogroups (C, Y, and W)[a]	69% (51% to 80%)
Serogroup C	77% (57% to 88%)
Serogroup Y	51% (1% to 76%)

[a] Estimate for serogroup W could not be calculated because of low sample size.

TABLE 3 VE, by Time Interval Since Vaccination, Using the GEE and Controlling for Underlying Medical Conditions and Smoking, ABCs and MeningNet Sites, 2006 to 2013

	Serogroup C Cases	Serogroup Y Cases	VE (95% CI)
Vaccinated <1 y	2	3	79% (49% to 91%)
Vaccinated 1 to <3 y	7	8	69% (44% to 83%)
Vaccinated 3 to <8 y	4	11	61% (25% to 79%)

vaccines that provide protection against serogroup C and Y are important in the United States.[3]

Conducting a case-control evaluation across multiple states, over several years, and in the adolescent age group was challenging. Many adolescents declined to participate, cases and controls were difficult to contact even with use of mobile telephone numbers when available, and frequently the time interval from case onset to enrollment was long. Moreover, meningococcal disease incidence is low, so our overall sample size is small despite the participation of multiple health departments. Although initially the evaluation period was extended to increase power, the long evaluation period allowed for an assessment of duration of protection. Reporting bias may play a role in underestimating the VE if cases were more likely to be enrolled if they were a vaccination failure; however, unenrolled cases did not have their vaccination status verified so assessing this potential bias is difficult. Although case and control enrollment bias may result in underestimating or overestimating point estimates, bias should not have impacted the finding of waning immunity. The CIs overlap between the time periods measured for VE, but the point estimate and upper limit of the CI is lower in persons vaccinated 3 to 8 years before compared with persons vaccinated <1 year before enrollment.

This evaluation demonstrates the critical need to conduct rigorous and systematic postlicensure VE evaluations to inform immunization policymakers. However, it also highlights the limitations and challenges of case-control studies to evaluate VE where disease incidence before vaccination is very low. Two new serogroup B meningococcal vaccines, licensed for use in 2014 and 2015 in the United States by the Food and Drug Administration after an accelerated approval process, target the serogroup that is not prevented by MenACWY vaccines. However, serogroup B incidence has declined over the past decade and is lower in adolescents than serogroups C and Y disease before the MenACWY vaccine recommendations. In February 2015, ACIP recommended serogroup B meningococcal vaccines for persons at increased risk for meningococcal disease, and in June 2015, ACIP recommended that a serogroup B meningococcal vaccine series may be administered to adolescents and young adults aged 16 to 23 years to provide short-term protection against most strains of serogroup B meningococcal disease.[19,20] Implementation of serogroup B vaccination is likely to be highly variable given the recommendation allows for individual clinical decision, the target age group is late adolescence, and the vaccines are multidose series. Therefore, monitoring vaccine impact and effectiveness of these vaccines, although important to inform future decisions around serogroup B vaccine use, will be especially challenging.

CONCLUSIONS

We found that MenACWY-D was effective but that protection waned rapidly over time. These results cannot be extrapolated to other quadrivalent meningococcal conjugate vaccines licensed in the United States and other countries. Although MenACWY-D was originally licensed as a single dose among 2- through 55-year-olds, a booster dose was added to the indication in August 2014, on the basis of a phase 4 safety and immunogenicity evaluation, which revealed a stronger immunogenicity response after the booster dose. A second dose should provide longer duration of protection in individuals compared with a single dose; providers should ensure their adolescent patients are vaccinated with 1 of the MenACWY vaccines after their 16th birthday to optimize protection as they enter the age of highest risk. However, given the current low disease burden among adolescents despite low coverage with the booster dose, the additional impact gained from the booster dose in terms of cases prevented is likely to be limited.

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ABBREVIATIONS

ABCs: Active Bacterial Core surveillance
ACIP: Advisory Committee on Immunization Practices
CDC: Centers for Disease Control and Prevention
CI: confidence interval
GEE: generalized estimating equation
Hib: *Haemophilus influenzae* type b
MenACWY: meningococcal (groups A, C, W, and Y) polysaccharide conjugate vaccine
MenACWY-CRM: meningococcal (groups A, C, W, and Y) oligosaccharide diphtheria CRM_{197} conjugate vaccine
MenACWY-D: meningococcal (groups A, C, W, and Y) polysaccharide diphtheria toxoid conjugate vaccine
PCR: polymerase chain reaction
VE: vaccine effectiveness

Address correspondence to Amanda C. Cohn, MD, National Center for Immunizations and Respiratory Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, MS A-27, Atlanta, GA 30329. E-mail: acohn@cdc.gov

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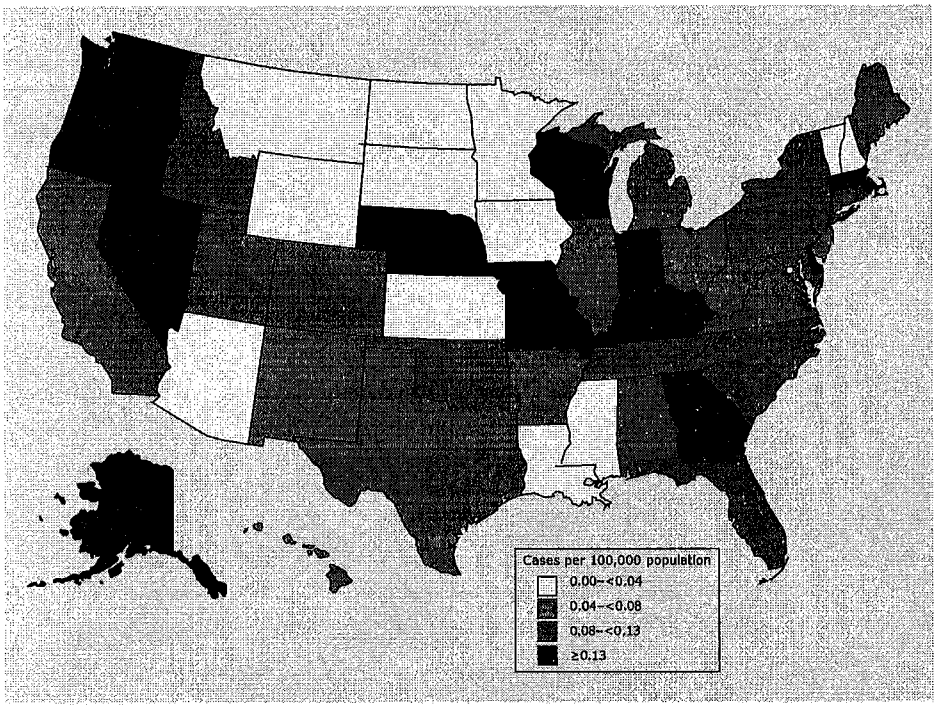
Reference 15 & 17

Enhanced Meningococcal Disease Surveillance Report, 2018*

Confirmed and Probable Cases Reported to the National Notifiable Diseases Surveillance System, 2018



As part of Enhanced Meningococcal Disease Surveillance (EMDS), additional data and isolates were collected from 45 state and 3 large jurisdiction health departments. In 2018, the population under surveillance was 320,863,137 or 98 % of the U.S. population. EMDS focuses on: (1) collecting isolates from all cases; and (2) collecting complete case information, with an emphasis on college attendance for cases 15–24 years; history of sex with men for male cases ≥16 years; and HIV infection status for all cases.**

CSTE case definition: A confirmed case was defined as isolation of *Neisseria meningitidis* or detection of *N. meningitidis* by PCR from a normally sterile body site.

A probable case was defined as detection of *N. meningitidis* antigen by latex agglutination or immunohistochemistry.

*Delaware, Hawaii, Idaho, South Dakota, Wyoming, and the District of Columbia did not participate in EMDS; cases reported from these jurisdictions are only included in the map, incidence, and CFR tables (n=5). All other information is for cases from participating EMDS jurisdictions only (n=324).

**Funding for EMDS is provided by CDC through the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement.

Meningococcal Disease Cases and Incidence by Serogroup and Age

Age (years)	B No. (Incidence†)	C No. (Incidence†)	W No. (Incidence†)	Y No. (Incidence†)	Nongroupable No. (Incidence†)	Other‡/Unknown No. (Incidence†)	Total No. (Incidence†)
<1	21 (0.55)	6 (0.16)	2 (0.05)	1 (0.03)	2 (0.05)	0 (0.00)	32 (0.83)
1–4	12 (0.08)	10 (0.06)	1 (0.01)	4 (0.03)	1 (0.01)	1 (0.01)	29 (0.18)
5–10	2 (0.01)	4 (0.02)	0 (0.00)	1 (0.00)	2 (0.01)	0 (0.00)	9 (0.04)
11–15	6 (0.03)	1 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	7 (0.03)
16–23	21 (0.06)	3 (0.01)	0 (0.00)	0 (0.00)	8 (0.02)	2 (0.01)	34 (0.10)
24–44	16 (0.02)	21 (0.02)	3 (0.00)	9 (0.01)	6 (0.01)	10 (0.01)	65 (0.07)
45–64	25 (0.03)	22 (0.03)	7 (0.01)	14 (0.02)	3 (0.00)	8 (0.01)	79 (0.09)
≥65	16 (0.03)	23 (0.04)	4 (0.01)	19 (0.04)	5 (0.01)	7 (0.01)	74 (0.14)
Total	**119 (0.04)**	**90 (0.03)**	**17 (0.01)**	**48 (0.01)**	**27 (0.01)**	**28 (0.01)**	**329 (0.10)**

Includes all confirmed and probable cases reported from all jurisdictions; †Cases per 100,000 population; and ‡includes 1 serogroup E case.

Case Fatality

Serogroup	No. deaths	CFR†
B	9	7.6
C	13	14.8
W	4	23.5
Y	7	14.6
NG	2	7.4
Unknown	4	16.7
Overall	**39**	**12.0**

Age (years)	No. deaths	CFR†
<1	4	12.9
1–4	0	0.0
5–10	0	0.0
11–15	0	0.0
16–23	0	0.0
24–44	7	10.9
45–64	11	14.1
≥65	17	23.3
Overall	**39**	**12.0**

Includes all confirmed and probable cases reported from all jurisdictions; †Case fatality ratio (CFR): deaths per 100 cases with known outcome; 4 (1%) cases with unknown outcome.

Laboratory Confirmation Method

89.7% (287/320) of confirmed cases were confirmed by culture; of those 250 (87.1%) had isolates submitted to CDC.
6.3% (20/320) of confirmed cases were confirmed by PCR.
3.1% (10/320) of confirmed cases had unknown laboratory confirmation method.

Outbreaks

97.2% (315/324) of cases had information on association with an outbreak; of those, 18 (5.7%) were part of an outbreak.

Complement inhibitor use

77.8% (252/324) of cases had information on use of a complement component inhibitor; of those, 4 (1.2%) were taking eculizumab.

Homelessness

95.1% (308/324) of cases had information on homelessness; of those, 16 (5.2%) were identified as homeless.

History of sex with men among male cases

Among male cases aged ≥16 years, 73.0% (84/115) had information on history of sex with men; of those, 5 (6.0%) were identified as men who had sex with men (MSM).

College attendance among cases 18-24 years

Among cases in patients aged 18-24 years, 100% (34/34) had information on college attendance; 18 (52.9%) were attending college.

Symptoms

69.1% (224/324) of cases had symptom information available; of those 5 (2.2%) had gastrointestinal symptoms (nausea, vomiting, or diarrhea) in the absence of typical meningococcal symptoms (headache, fever, neck stiffness, rash).

Meningococcal Disease Cases and Incidence by Serogroup and College Attendance*

	B No. (Incidence†)	C No. (Incidence†)	W No. (Incidence†)	Y No. (Incidence†)	Nongroupable No. (Incidence†)	Total** No. (Incidence†)
Attending college‡	11 (0.10)	0 (0.00)	0 (0.00)	0 (0.00)	6 (0.05)	**18 (0.16)**
Not attending college‡	9 (0.05)	5 (0.03)	0 (0.00)	0 (0.00)	1 (0.01)	**16 (0.08)**

*Among cases 18-24 years. **Includes 1 case with unknown serogroup and 1 serogroup E case. †Cases per 100,000 population; and ‡assumes 38.3% of 18–24 year olds attending college

Vaccination Status among cases 18-24 years

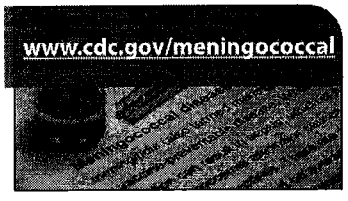
MenACWY* vaccine receipt:

College students: 100% (18/18) had information on MenACWY receipt; of those 94.4% received MenACWY.
Persons not attending college: 50.0% (8/16) had information on MenACWY receipt; of those 75.0% received MenACWY.

MenB** vaccine receipt:

College students: 77.8% (14/18) had information on MenB receipt; of those 14.3% received MenB.
Persons not attending college: 50.0% (8/16) had information on MenB receipt; of those 0 received MenB.

*MenACWY = meningococcal conjugate vaccine, **MenB = serogroup B meningococcal vaccine.



HIV Infection among Meningococcal Disease Cases*

Data collected on HIV status will allow CDC to assess the impact of the recent Advisory Committee on Immunization Practices recommendation for use of MenACWY vaccination in HIV-infected persons.[2]

55.9% (181/324) of cases had information on HIV status; of those, 5 (2.8%) were identified as HIV-infected.

[1]U.S. Department of Education. Institute of Education Sciences NCfES. Integrated Postsecondary Education Data System Fall Enrollment Survey. https://nces.ed.gov/ipeds/Home/UseTheData, 2015.

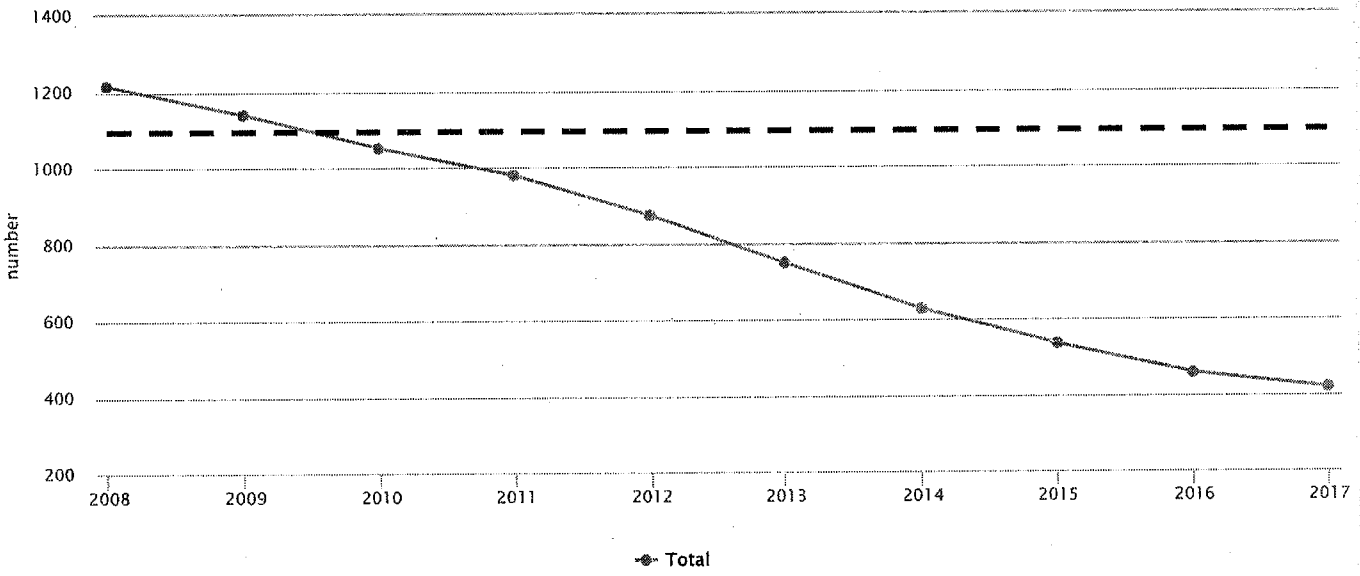
[2]MacNeil JR, Rubin LG, Patton M, Ortega-Sanchez IR, Martin SW. Recommendations for Use of Meningococcal Conjugate Vaccines in HIV-infected Persons — Advisory Committee on Immunization Practices, 2016. *MMWR Morb Mortal Wkly Rep* 2016;65:1189–1194. DOI: http://dx.doi.org/10.15585/mmwr.mm6543a3.

References

HealthyPeople.gov

Cases of meningococcal disease (number)
By Total

2020 Baseline (year): 1,215 (2004–08) --- **2020 Target:** 1,094 **Desired Direction:** Decrease desired



Data Source: National Notifiable Diseases Surveillance System (NNDSS); Centers for Disease Control and Prevention, Center for Surveillance, Epidemiology, and Laboratory Services (CDC/CSELS)
Additional footnotes may apply to these data. Please refer to footnotes below the data table for further information.

IID-3 Reduce meningococcal disease Revised

Cases of meningococcal disease (number)

2020 Baseline (year): 1,215 (2004–08) **2020 Target:** 1,094 [1] **Desired Direction:** Decrease desired

Display Years ▼

POPULATIONS	2011-2015	2012-2016	2013-2017
TOTAL	534	457	418

Data Details Learn more about the methodology and measurement of this HP2020 objective

Download all data for this HP2020 objective [XLS - 21.04 KB]

Footnotes Show Footnotes

Fond du Lac County Health Department
160 S. Macy St, Fond du Lac, WI 54935
Phone: 920-929-3085 | Fax: 920-929-3102 | www.fdlco.wi.gov

Public Health
Prevent. Promote. Protect.
Fond du Lac County Health Department

February 26, 2020

Attn: Members of the Assembly Committee on Constitution and Ethics:

As Chairperson of the Fond du Lac County Board of Health, I am writing to demonstrate my full support of the proposed changes to school immunization requirements. I am fortunate to lead a board of health that includes a physician, a retired school health coordinator, and a nurse specializing in infectious disease prevention. Our Board of Health is pushing forward public health's mission and is committed to preventing disease, protecting the community and promoting healthy living for all.

Local health departments, by statute, are charged with the responsibility to take all measures necessary to prevent, suppress, and control communicable disease, and forbid public gatherings when deemed necessary to control outbreaks or epidemics. The Center for Disease Control (CDC) identifies control of infectious diseases and immunizations as two of the top ten public health achievements in the 20th century.

There are currently 34 other states that require meningococcal vaccine as part of school immunization laws. Twenty states have had this requirement for more than 5 years. It's time for Wisconsin to implement this change. In 2018, Fond du lac County had a 37% completion rate for the adolescent doses of vaccine for meningococcal disease, this is below the state average of 46%. Meningococcal vaccine is not currently a required school immunization. By contrast, in 2018, Fond du Lac County had an 82% vaccination rate for Tdap vaccine (tetanus, diphtheria, acellular pertussis) which is a required school immunization. Meningitis is a life-threatening disease, and any efforts to further reduce a child's risk of this disease should be a priority.

Public health policies often balance the benefits to the community vs. individual rights. Examples include isolation of a person with infectious disease such as tuberculosis, or exclusion of susceptible children for highly infectious diseases like measles or chickenpox. While most people think of chickenpox as a "rash" the disease is spread not only thru direct contact, but also airborne from respiratory secretions. Using lab tests to confirm chickenpox disease, we can better protect other children at the school, and decrease the number of children potentially exposed. Last year, 66% of the chickenpox cases reported to our local health department involved 1) unvaccinated children, and 2) cases that were linked to each other at school. One of the affected students was unable to participate in her graduation ceremony because she was ill with chickenpox.

For multiple other reasons, I ask that the proposed rule changes be implemented as proposed. Thank you for your consideration of this important public health matter.

Sincerely

Sherry Behnke

Sherry Behnke
Chairperson
Fond du Lac County Board of Health

Wisconsin United for Freedom
P.O. Box 894
Cedarburg, WI 53012
info@wisconsinunitedforfreedom.org

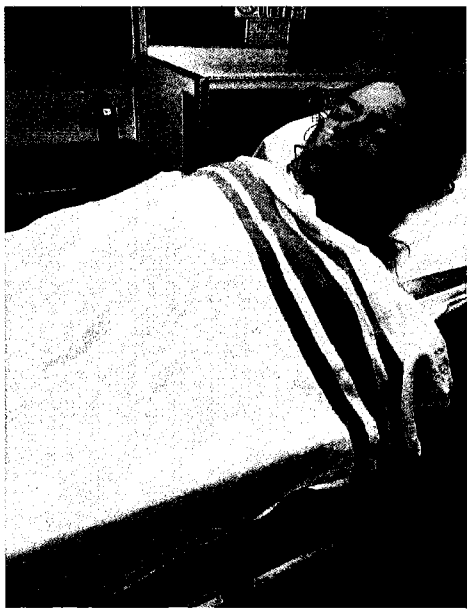
Good morning, thank you for taking the time to acknowledge the public's concerns by holding this hearing regarding CR 19-079. My name is Sarah Cortright and I am here today representing Wisconsin United for Freedom. I have many concerns surrounding the rule changes, but I'm going to address Rule 5. During the summer of 2019, my children contracted chicken pox. Due to my conscientious care for other people, I determined that we would be doing at home activities until all of their spots were completely scabbed over so as not to expose anyone. I was aware of what chicken pox looked like having seen pictures of my siblings and I having it as children. My mother who is a retired LPN was also able to confirm that their sores did indeed look like chicken pox. My eldest son experienced more discomfort than my other children and because his case seemed to be slightly more severe, I decided to take him in to be checked just to be safe. I called the pediatrician ahead of time just to see if we should sit in a different area when we arrived. The office staff actually called back and said that the pediatrician did not want to see us, but told us to take him to urgent care instead. The doctor who took my sons case said that she had not physically seen a case in her 30 years since residency but was fairly certain it was chicken pox. I couldn't help but wonder if the reason she hadn't seen a case was because most parents chose to treat this mild childhood illness at home rather than going in and unintentionally exposing others. I want to stress my opposition to Rule 5 on a few accounts. 1) My son's own pediatrician did NOT want him to come in for fear of unwanted exposure to other children and parents who might be sitting in the same waiting room. So where is the logic behind this rule which now would expose others who may not want that exposure in a waiting room? 2) Despite the fact that I called the pediatrician's office, they made no record of my son having chicken pox, nor did they make any notation of my other children having it even though it was mentioned to them over the phone. Which leads me to my third major concern- Where does that leave us moms and dads whose children have had chicken pox in the past? I see no provision in Rule 5 for a titer test being used as proof of immunity. Would my children's natural immunity gained from chicken pox count? Or would DHS claim that their natural immunity was insufficient? These are the questions that are of great concern because they directly affect my family. Thank you again for your time.

Ashlyn's Story:

Ashlyn is an "A" student at her school in Northeastern WI. She plays in the band and is in several sports including football, softball, track, and dance. She has many friends and loves her social time. She is involved in anything she can be involved in and loves to helps the community and volunteer. She has always been a positive and happy girl.

At Ashlyn's 13-year-old checkup, she was given the HPV vaccination. Before leaving the doctor's office, she had a lump on her arm. The next 3 days following the vaccination, Ashlyn had a temperature over 101 degrees. A few days later, she started experiencing constant muscle and joint pain in her legs and arms. On Tuesday, May 8, 2018, Ashlyn's life changed. She started passing out a few times for several days and then started with the non-epileptic seizures. Ashlyn has been in and out of Hospitals including Children's of Milwaukee, Madison and St. Paul MN without any answers. She has undergone several tests and has tried different treatments. Ashlyn is vaccine injured from the HPV vaccination. In May of 2019, Ashlyn had an episode that left her unconscious for over 17 hours. She was taken by ambulance from a local Wisconsin Hospital, 5 hours away to Children's Hospital of St. Paul. This episode left Ashlyn with an inability to walk "normal" and right-side weakness in her arm and leg. She has been going to regular Physical Therapy appointments and doctor appointments to try to regain her walking. All sports are out of the picture for now. Ashlyn was recently introduced to a doctor in California who specializes in vaccine injuries. We traveled to California to meet with Dr. Flannery in hopes to improve her quality of life. Dr. Flannery ran tests to prove his theory that she has inflammation in and around her brain as well as damage to her blood brain barrier. His testing showed just that. Ashlyn is on a 5-phase process with phase one aimed at decreasing the inflammation to the brain. In the last 22 months, she has had over 300 non-epileptic events, over 70 passing out events, 28 ER visits, 24 ambulance rides, 6 extended hospital stays, approximately 450 doctor appointments and over 50 missing days of school. The numbers increase daily. Her future at this point is unknown. Ashlyn is a strong young lady. We continue to fight for her health every day as well as parental choice on vaccinations. **As Ashlyn's mom, I beg you to please know the risk is there.** I choose not to vaccinate my other child with this vaccination for fear of what could happen. **Please do not take my parental choice away from me!**

Thank you! Heidi (Ashlyn's Mom)



Southern Wisconsin Immunization Consortium

880 Independence Ln

Sauk City, WI 53583

March 3, 2020

Dear Chairperson Wichgers,

My name is Ann Lewandowski and I represent the Southern Wisconsin Immunization Consortium. Thank you for allowing me to testify on the Chapter 144 rule changes proposed. I am here in support of the rule changes.

Like everyone here today, I want what is best for our children and our schools. The proposed rule changes are based on solid information vetted by those who have a sophisticated understanding of epidemiology and science.

With the explosion of Corona Virus, or COVID 19, we should all be aware of how fast misinformation about diseases infect social media. We know social media amplifies messages that divide us, particularly on issues surrounding immunizations and health. Coronavirus is an easy and new example, but I remind you the type of misinformation we are seeing about coronavirus has been circulating about vaccines for years on social media.

Vaccines have been victims of their own success. Parents don't see the diseases we are protecting children against, so it is easy to believe misinformation targeted at explaining diseases and conditions science is still struggling to fully explain by simply dubbing them so called "vaccine injuries". I'd add further that vaccines are effective at saving money. With 1,200 cases of measles in the US last year, the estimated cost according to Clinical Infectious diseases was $142,000 or a total of 42 million dollars.

The rules make common sense. Asking a parent who has never seen chicken pox to see a doctor is reasonable. It ensures the disease is chickenpox and the child does have immunity to chickenpox prior to entering school. It is possible some younger doctors haven't seen chickenpox because the vaccine has been so effective in stopping routine infections. Vaccines are less expensive than blood titers which may cost additional money that families don't have. My personal experience of having wild chicken pox is to have had shingles twice due to immunocompromising condition. I still have pain from the infection 10 years ago.

Meningitis is a rare but deadly disease. We are lucky not to see cases of the vaccine preventable types of meningitis often because the routine immunizations recommended at age 11-12 have worked in preventing them. We don't need to change the goalpost by talking about cases of meningitis serotype B. All of our surrounding states have a meningococcal requirement. Wisconsin is behind, and it is time to catch up.

As I close, I want to share two stories of parents who have been impacted and lost their children to meningitis. They can't be here today, but Donna Knutter wanted me to share the story of her son, Alex who died at 17 hours after being diagnosed with meningitis. If he had been protected at age 11-12 there is the potential he wouldn't have died. His mom didn't even know there was a vaccine that could have saved his life. Our coalition hopes that by adding it to the school schedule, you would simply be encouraging a conversation between a parent and doctor that might save a life in the future.

Thank you,

Ann Lewandowski

Program Manager

Wisconsin Association of School Nurses
www.wischoolnurses.org

Testimony to the Assembly Committee on Constitution and Ethics in Support of Clearinghouse Rule 19-079

March 3, 2020

The Wisconsin Association of School Nurses (WASN) represents school nurses across Wisconsin. The mission of WASN is to support and advance the practice of professional school nurses in order to enhance the health, safety, and educational success of Wisconsin students.

WASN is pleased to submit testimony in support of Clearinghouse Rule 19-079. For nurses working in the school setting, the implementation of Wisconsin's immunization program is of particular interest and concern. School nurses are committed to the health and safety of all school-aged children. School immunization requirements for vaccine-preventable diseases are some of many ways Wisconsin provides health protection for children in our communities and schools.

The rule includes the following changes:

- Changing the current Tdap requirement from 6th to 7th grade.
- Adding a requirement for a meningococcal vaccine for 7th and 12th grades.
- Adding or updating outbreak definitions for selected vaccine-preventable diseases.
- Requiring clinician verification of chickenpox (varicella).
- Modifying reporting of School Report to be in alignment with the process for child care.
- Removing outdated language and text.

Since 2005, the Centers for Disease Control (CDC) has recommended that all children receive routine meningococcal vaccination at the ages outlined in the rule. Teenage children are included in the population groups most at risk of getting meningococcal disease. Due to the disease's potential of quickly progressing to cause infections of the brain, spinal cord, or blood, and cause very serious long-term health consequences, WASN is in agreement with the inclusion of the meningococcal vaccination in our state's school immunization requirements.

Varicella (chicken pox) is also of particular concern to the school nurses caring for Wisconsin's children. Presently, parents may report varicella disease and therefore allow their child to have an acceptable exemption from the varicella vaccination. However, studies demonstrate that among children claiming to have a history of varicella, there is a high rate that are in fact not immune to the disease. Chicken pox is

very contagious and can cause serious complications for some people. Having more reliable information about the immunity of students to varicella, such as only allowing vaccine exception when a health care provider can confirm a child had varicella, offers disease protection to school communities.

Additionally, WASN is in agreement with the plan to use the CDC's definitions, guidance, and recommendations with regard to disease outbreak for consistency in surveillance and reporting of vaccine preventable diseases. We support changing the Tdap requirement to 7th grade to make vaccination compliance more congruent with health care provider practices and to occur at the same time as the first meningococcal vaccine as stated in the proposed changes to DHS rule 144. WASN also agrees that compliance and key indicator reports regarding the immunization program and vaccine preventable disease should be shared with both local health departments and DHS.

Finally, WASN would like to respectfully note our awareness of some public comments in opposition to the proposed changes to DHS Rule 144. WASN requests consideration of the fact that the majority of parents of Wisconsin school aged children vaccinate their children according to the school immunization requirements. Most parents accept that strong recommendations made by health care providers for the vaccination of children and Wisconsin's immunizations requirements for school-aged children are made to protect and reduce risk of vaccine preventable disease and complications in our communities and schools.

Thank you for considering the views of Wisconsin's school nurses.

UWHealth | School of Medicine and Public Health UNIVERSITY OF WISCONSIN-MADISON

Wisconsin Chapter
American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Assembly Committee on Constitution and Ethics
Testimony provided by Theresa Dulski, MD MPH
March 3, 2020
RE: Support for Clearinghouse Rule 19-079

Chairman Wichgers and members of the committee:

My name is Dr. Dulski and I appear before you today as a representative of UW Health, the UW School of Medicine and Public Health, and the Wisconsin Chapter of the American Academy of Pediatrics to express support for the new immunization regulations proposed by the Wisconsin Department of Health Services as outlined in Clearinghouse Rule 19-079. Thank you for your time and attention and this opportunity to share my expertise.

As a primary care pediatrician in Madison, I spend every day working to ensure optimal health and well-being for the children I treat and their families. Immunizations play a significant role in the care I provide. Immunizations help children avoid preventable illnesses that adversely impact their health and the health of others with whom they come into contact within their communities, including babies who are too young to be immunized and people with medically-indicated contraindications to vaccines at risk. I have personally taken care of children with immunization-preventable diseases, including the ones being discussed today, and unfortunately have witnessed firsthand the devastating effects that they can have.

The rule before you seeks to bring student immunization regulations in DHS Chapter 144 into alignment with current recommendations put forth by the CDC, the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and current evidence-based practices.

The rule includes adding the 2-dose meningococcal vaccine series to the list of vaccines required for students. Meningococcus causes meningitis, an infection of the lining of brain and spinal cord that can progress so rapidly that an otherwise healthy child can be in a coma within a matter of hours. While the majority of children already receive this immunization, the small percentage that do not are susceptible to the severe effects of this illness and can decrease the local herd immunity—putting the broader community at risk for an outbreak. What I see in clinic is that some of these children are not immunized because they are brought in only to get the immunizations that are required for school. Adding the meningococcal vaccine to this required list would help provide protection for all children in Wisconsin, similar to the many states that already include this vaccine as a requirement for school. Children in Wisconsin deserve an equal opportunity to be protected from this devastating disease.

The department is also proposing to move the current recommendation for Tdap from 6th grade to 7th grade—or 11 years, which is also when the first meningococcus immunization is given. This would help make sure that children meet the minimum age requirement for the Tdap vaccine and will ease the burden on families, providers, and schools by ensuring that both meningococcal and Tdap vaccines are administered at the same well child visit.

In addition, the rule proposes to remove parent or self-report of varicella, or chickenpox, as an acceptable exception to varicella vaccination. I have personally seen many children in clinic with chief complaint of possible chickenpox, the vast majority of which did not have chickenpox but rather unrelated skin conditions. Due to the success of the varicella immunization, chickenpox is now less common and can be difficult for people to discern from other seemingly similar appearing rashes.

We applaud these proposed updates and the others included in the rule that are the result of many months of work on the part of staff and leaders at the Wisconsin Department of Health Services. They have done an excellent job outlining a plan to protect the public's health based on prevailing recommendations from the scientific community.

I know that everyone in this room has children's best interest at heart. Immunization are a safe, evidence-based, life-saving way to prevent the spread of disease and keep children healthy as they grow. All children in Wisconsin deserve an equal opportunity to be protected from immunization-preventable diseases.

Please join us in supporting Clearinghouse Rule 19-079 as written. Thank you for your consideration.

KIA KJENSRUD
Executive Director
Wisconsin Chapter of the American Academy of Pediatrics and WIAAP Foundation
262.751.7003 - Tel KKjensrud@wiaap.org - Email
wiaap.org - facebook.com/WIAAP - twitter.com/WIAAP

Connie Schulze
Director, Government Affairs
UW Health & UW School of Medicine and Public Health
749 University Row – Suite 233
Madison, WI 53705
PHONE: 608/422-8063 (office); 608/516-2552 (mobile)
EMAIL: cschulze@uwhealth.org

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Wisconsin Chapter

American Academy of Pediatrics

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Assembly Committee on Constitution and Ethics
Testimony provided by Michelle Brenner, DO MS
March 3, 2020
RE: Support for Clearinghouse Rule 19-079

Chairman Wichgers and members of the committee:

My name is Dr. Brenner and I am here today as a representative of UW Health, the UW School of Medicine and Public Health, and the Wisconsin Chapter of the American Academy of Pediatrics to express support for the new immunization regulations proposed by the Wisconsin Department of Health Services as outlined in Clearinghouse Rule 19-079. Thank you for your time and attention.

Currently, I am a first year pediatric resident physician. Briefly, a resident physician is a doctor who has completed medical school and is pursuing additional post-medical school training in a specific specialty of medicine, and in my case that is Pediatrics. In addition, some pediatric doctors receive additional training after residency, through what is called a fellowship, to learn an even more sub-specialized area of medicine. In my case, my goal after residency training is to specialize further in Pediatric Hematology and Oncology, the specialty of blood disorders and cancer. Since I was a child growing up in Wisconsin, I have been passionate about caring for and protecting the youngest of Wisconsin's residents. After completing medical school in Iowa, I have returned to Wisconsin to continue that passion. Immunizations play a key role in the care I provide now and in the future.

Immunization is a safe, life-saving way to keep communities healthy. Through herd immunity, immunizations also protect vulnerable residents who are too young to be vaccinated or have compromised immune systems . Those who have compromised immune systems include my future patients with cancer. As a medical student, I have seen first-hand the dilemma families of children with cancer face when deciding if they feel it is safe for their children to attend school in-person over concerns for immunization-preventable diseases.

The rule before you seeks to bring student immunization regulations in DHS Chapter 144 into alignment with current recommendations put forth by the CDC, the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and current evidence-based practices.

First, the department is proposing to move the current recommendation for Tdap from 6th grade to 7th grade to be sure children meet the minimum age requirement of 11 years old for the vaccine. Second, the department is proposing to add the meningococcal vaccine to the list of vaccines required for students entering the 7th grade and adding a booster dose for students entering the 12th grade. The meningococcal vaccine protects against meningitis, an infection of the spinal cord and covering of the brain that can progress very rapidly even in healthy children to life-threatening complications. I was a medical student in Iowa when the meningococcal vaccine was added to list of vaccines required for students in the 2017-2018 school year. I learned that many children are only brought in for

immunizations required for school and that many families were appreciative of the additional protection their children and others would have after learning about meningococcal disease. Finally, these provisions will ease the burden on families, providers, and schools by ensuring that both meningococcal and Tdap vaccines are administered at the same well child visit.

Other physicians and I across Wisconsin applaud these recommendations and the others included in the rule that are the result of hard work on the part of staff and leaders at the Wisconsin Department of Health Services. Per their mandate by the Wisconsin legislature, they have done an admirable job formulating a plan to protect the health of children and adults throughout Wisconsin based on recommendations from the scientific community. Please join us in supporting Clearinghouse Rule 19-079 as written as it helps to protect all children in Wisconsin. Thank you for your consideration.

KIA KJENSRUD
Executive Director
Wisconsin Chapter of the American Academy of Pediatrics and WIAAP Foundation
262.751.7003 - Tel KKjensrud@wiaap.org - Email
wiaap.org - facebook.com/WIAAP - twitter.com/WIAAP

Connie Schulze
Director, Government Affairs
UW Health & UW School of Medicine and Public Health
749 University Row – Suite 233
Madison, WI 53705
PHONE: 608/422-8063 (office); 608/516-2552 (mobile)
EMAIL: cschulze@uwhealth.org

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American Academy of Pediatrics

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Assembly Committee on Constitution and Ethics
Testimony provided by Michael Kim, MD
Pediatric Emergency Specialist
March 3, 2020
RE: Support for Clearinghouse Rule 19-079

Chairman Wichgers and members of the committee:

My name is Michael Kim and I am a pediatric emergency specialist. I appear before you today as a representative of UW Health, the UW School of Medicine and Public Health, and the Wisconsin Chapter of the American Academy of Pediatrics to express support for the new immunization regulations proposed by the Wisconsin Department of Health Services as outlined in Clearinghouse Rule 19-079. Thank you for your time and attention and this opportunity to share my expertise.

The rule before you seeks to bring student immunization regulations in DHS Chapter 144 into alignment with current recommendations put forth by the CDC, the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and current evidence-based practices.

In addition, the department is proposing to move the current recommendation for Tdap from 6th grade to 7th grade to be sure children meet the minimum age requirement for the vaccine and to add the meningococcal vaccine to the list of vaccines required for students entering the 7th grade. This provision will ease the burden on families, providers, and schools by ensuring that both meningococcal and Tdap vaccines are administered at the same well child visit. The department also proposes a booster dose for students entering 12th grade which is in accordance with ACIP recommendations. This will help to ensure students are fully vaccinated prior to leaving the K-12 environment.

As I mentioned, I have been a pediatric emergency specialist since 1994 working to provide emergency medical care for the children of Wisconsin. Over these years, I have provided emergency care to more than 75,000 Wisconsin children. I see many children with complaints of fever, which is one of the most common reasons parents bring their children to the Emergency Department (ED). Fever accounts for almost 20% of the all ED visits. Most children with fever have common viral illness such as cold, ear or throat infections, and other simple conditions that do not require special tests. However, children who are under-immunized or unimmunized are at a greater risk for more serious infections such as pneumonia, blood infection or meningitis when they have a fever. For this reason, I have had to perform special blood and urine tests, x rays and occasional spinal taps to look for or rule out serious bacterial infections. However, these additional tests may not have been necessary if they were fully immunized. In addition, these children occasionally need pre-emptive antibiotics and even hospital admission simply because they are not immunized. Therefore, children who are under-immunized or un-immunized are at a higher risk of serious infections, unnecessary tests, medications, hospitalizations and higher health care costs.

In the ED, I also care for children with many serious underlying medical conditions including leukemia, liver and kidney transplant patients with immunosuppression, those with congenital heart defects, or complex metabolic diseases. When these children have a fever, they require emergent evaluation for potentially life threatening bacterial or viral infection and must be treated pre-emptively. These medically fragile children are at much greater risk of severe or sometimes catastrophic results from simple virus or bacterial infections. As these children attend day care and schools, they are in very close proximity to many other children who may or may not be immunized. For these kids, the threat of possible infection from a non-immunized school-mate is of grave concern for parents and caregivers alike.

In summary, under-immunized or unimmunized children are at a higher risk of serious bacterial infections, unnecessary tests, medications, hospitalizations and higher health care costs. In addition, they pose a potential threat to their school mates who may have underlying medical conditions.

It is for these reasons that I would like to thank the staff at the Department of Health Services for their thoughtful approach to protecting the public's health based on prevailing recommendations from the scientific community. Please join me in supporting Clearinghouse Rule 19-079 as written.

Thank you for your consideration. I'd be happy to take questions from committee members at this time.

KIA KJENSRUD
Executive Director
Wisconsin Chapter of the American Academy of Pediatrics and WIAAP Foundation
262.751.7003 - Tel KKjensrud@wiaap.org - Email
wiaap.org - facebook.com/WIAAP - twitter.com/WIAAP

Connie Schulze
Director, Government Affairs
UW Health & UW School of Medicine and Public Health
749 University Row – Suite 233
Madison, WI 53705
PHONE: 608/422-8063 (office); 608/516-2552 (mobile)
EMAIL: cschulze@uwhealth.org

State of Wisconsin
Department of Health Services
Tony Evers, Governor
Andrea Palm, Secretary

TO: Members of the Assembly Committee on Constitution and Ethics

FROM: Andrew Hoyer-Booth, Deputy Legislative Director & Dr. Stephanie Schauer, Immunization Program Manager, Division of Public Health

DATE: March 3, 2020

RE: DHS 144, relating to: Immunization of Students

Good morning, Chairman Wichgers and members of the Assembly Committee on Constitution and Ethics. My name is Andrew Hoyer-Booth and I am the Deputy Legislative Director at the Wisconsin Department of Health Services (DHS). With me today is Dr. Stephanie Schauer, Immunization Program Manager within the Division of Public Health. We appreciate the opportunity to provide the committee with information on DHS 144 and how the changes proposed in this administrative rule will positively impact public health in Wisconsin.

Under section 252.04 of the Wisconsin state statutes, the Department of Health Services is charged with administering a statewide immunization program to prevent diseases such as mumps, measles, pertussis, and others, as specified by rule. The purpose of Chapter DHS 144 is to implement this section of state law by updating immunization requirements for entry into Wisconsin schools and child care centers.

The proposed changes to DHS 144 will better reflect current best practice. As you'll hear from Dr. Schauer, the proposed rule changes bring Wisconsin into line with our neighboring states and current national standards based on what science tells us about communicable disease prevention. The rule updates existing school immunization requirements, but does not alter the ability to request exemptions of immunization requirements for medical, religious, or personal beliefs.

Good morning, my name is Stephanie Schauer and I am the Immunization Program Manager at the Department of Health Services. I have held this position since 2015 and have been with the Department since 2008. Previously, I worked with the Massachusetts Department of Public Health as an epidemiologist in their immunization program. My background includes a Bachelor of Science in biology and chemistry from Valparaiso University and a Ph.D. in microbiology with a concentration in immunology from Boston University.

I'd like to start out by highlighting some of the proposed Chapter DHS 144 administrative rule changes:

1. The rule moves the current tetanus, diphtheria, pertussis (Tdap) requirement from 6th to 7th grade to ensure that children are 11 years of age when they receive the vaccine, consistent with guidance from the CDC.
2. The rule adds the meningococcal vaccine to the list of required vaccines for students entering the 7th grade as well as a booster dose for students entering the 12th grade. Currently, there is

no requirement that students be vaccinated against the bacterial infection which causes meningitis.

3. The rule requires a health care provider to verify a medical history of varicella (chickenpox) in order to allow an exception to varicella vaccination.
4. The rule updates the definitions of "substantial outbreaks" for selected vaccine preventable diseases, consistent with CDC guidelines.
5. The rule adds the Department as a recipient of school reports indicating compliance with immunization program requirements. These reports are currently sent to local health departments.

The Department received 460 public comments on the proposed administrative rule changes. The two changes that received the highest number of comments were the addition of the meningococcal vaccine and the verification of varicella, so I'd like to address those specifically.

Neisseria meningitidis can cause headache, fever, rash, stiff neck, and vomiting that can come on suddenly. It is a leading cause of bacterial meningitis and sepsis in the United States and can have serious complications, including death. Among survivors, as many as one in five will have permanent disabilities. Since 2005, the CDC Advisory Committee on Immunization Practices has recommended that the vaccine be administered at the 11-12 year old health care visit, along with other routine vaccinations such as Tdap.

A review of our surrounding states shows that Illinois, Iowa, Michigan, and Minnesota all require at least one dose of the meningococcal vaccine at either 6th or 7th grade and each of these states, with the exception of Michigan, also require a booster dose at either 16-18 years of age or grade 12.

Varicella remains a serious disease; complications include serious skin infections, prolonged hospitalizations, and encephalitis which may lead to seizures, coma and death in 1 out of 60,000 cases. In order to limit the number of false-positive reports and ensure immunity in the school setting, either a diagnosis of varicella by a health care provider or a health care provider verification of a history of the disease is more accurate than self-reporting. This is in line with CDC guidelines and our aforementioned Midwestern neighbors who require verification of varicella by a physician, physician assistant, or other health care provider, depending on the state. This verification can include documentation of the varicella vaccination, laboratory evidence of immunity, or diagnosis of a history of varicella.

When updating an administrative rule, it is common to have stakeholders assist in an advisory capacity. In undertaking this rule revision, the Department formed an advisory committee composed of representatives from the Wisconsin Department of Public Instruction, Wisconsin Chapter of the American Academy of Pediatrics, Wisconsin Department of Health Services Medicaid Program, Wisconsin Association of Local Health Departments and Boards, Wisconsin Academy of Family Physicians, Wisconsin Association of School Nurses, Wisconsin Medical Society, and the Pharmacy Society of Wisconsin. Per the Wisconsin administrative rule process, public notification of these meetings was followed. Proposed rule revision language was drafted based on the recommendations of this committee.

The Department is required under state law to implement provisions to protect the safety and health of Wisconsin's children. We believe that the changes proposed in Chapter DHS 144 align with these requirements and bring the state in line with national standards.

We would be happy to answer any questions the committee has pertaining to Chapter DHS 144.

Wisconsin Medical Society

TO: Assembly Committee on Constitution and Ethics

FROM: Jennifer Zeman, MD

DATE: March 3, 2002

RE: Clearinghouse Rule 19-079: Relating to immunization of students.

Good morning Mr. Chairman and members of the Assembly Committee on Constitution and Ethics. My name is Jennifer Zeman. I am a family physician in Waukesha, and I am here on behalf of the Wisconsin Medical Society to testify in support of the proposed rule change to for student immunizations under DHS 144.

In short, this proposed rule change updates Wisconsin's required immunizations for schools to align with the most recent recommendations from the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP). The main changes include: adding meningitis to the required immunizations for the 7th grade panel, moving the tetanus booster from 6th to 7th grade, and updating definitions for substantial outbreak for varicella and mumps. For physicians, the CDC is the resource that we turn to for recommended vaccination schedules and guidance. Their recommendations are evidence-based and the standard for immunizations across the country. By following these recommendations, we would be aligning with the guidelines adopted by our neighboring states of Iowa, Illinois, Michigan, and Minnesota.

In a normal work week, I provide care to hospitalized patients, clinic patients, the young, the old, those who are healthy and those who are not. One of the more frequent things that I recommend to and educate patients on are recommended vaccines. The resource I turn to is the CDC immunization schedule. One of the top priorities of a family physician is preventive medicine, and a huge part of prevention is immunizations. In my counseling of parents, I will frequently come across those who have hesitancy or questions about these recommendations. Almost always, our conversations focus on shared concerns for the health and well-being of the child, as well as preventing any potential negative health consequences for them. I offer a lot of educational resources and reassurance during these appointments and receive questions based on information the parent has heard about vaccines from different sources.

The most frequent topics that come up are concerns about the ingredients in the vaccines and any long-term consequences. There is overwhelming evidence that immunizations are safe, effective, and improve the health and lives for children and adults alike. The most frequent adverse reactions are local pain or irritation, fatigue, or a slight fever. These are all short-lived reactions, and severe reactions are incredibly rare. Vaccines go through rigorous safety testing before release to the general public and continue to be monitored for safety concerns after. Vaccines contain important ingredients that act as preservatives, compounds to inhibit bacterial or viral growth in the vial, and substances to increase your immune systems response to the vaccine to boost your protection from future infection.

2450 Rimrock Rd. Suite 101• Madison, WI 53713-1109 • wisconsinmedicalsociety.org • Phone 608.442.3800 • Toll Free 866.442.3800 • Fax 608.442.3802

In medical school I was taught about diseases like polio, measles, and rubella. In previous generations of physicians, these would have been lectures to discuss identification and treatment of these devastating diseases. Today, these topics are still taught, but thanks to modern medicine, they are presented more as a success story for vaccines and public health initiatives. I am happy to say that I have not personally seen any cases of diseases such as measles, polio, or tetanus, and I hope that this fact doesn't change. Following recommended vaccination schedules is the most important thing I can do to ensure that I don't see any of these diseases in my lifetime.

I would like to thank you for your time today, and I ask you to support rule changes for chapter DHS 144.

Wisconsin Healthcare Leaders Support Changes to DHS 144 - Immunization of Students

March 3, 2020

Assembly Committee on Constitution and Ethics

Chair Chuck Wichgers
Vice Chair Scott Allen
Rep. Jonathan Brostoff
Rep. Marisabel Cabrera
Rep. Gary Hebl
Rep. Gae Magnafici
Rep. Timothy Neylon
Rep. Timothy Ramthun
Rep. Jeremy Thiesfeldt

Honorable Chair Wichgers:

The undersigned coalition includes key physician organizations, health systems, hospitals, academic centers and other parties with a vested interest in the health and well-being of Wisconsin's children and families.

We strongly support the Wisconsin Department of Health Services' (DHS) proposed updates to the student immunization regulations in DHS 144, as they are necessary to bring those regulations into alignment with current recommendations put forward by the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP) and current evidence-based practices. Further, the proposed changes streamline existing regulations and reporting requirements between state entities and include necessary clerical updates.

Immunization is a safe, life-saving way to prevent the spread of disease and keep children healthy as they grow. Each year in the US, vaccines save approximately 33,000 lives, prevent 14 million cases of disease, and save $9.9 billion in direct cares costs.[1] Vaccines keep communities healthy, and protect some of the most vulnerable in our society, including the elderly, and children who are too young to be vaccinated or have compromised immune systems. This is known as herd immunity or community protection. Children who do not receive immunizations when they are eligible to do so put kids who can't be vaccinated because of medical issues that include autoimmune diseases and cancer at great risk. Children fighting a difficult diagnosis simply should not have to worry about being exposed to a disease that is easily preventable through vaccination.

[1] https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases

There is robust evidence that each of these universally recommended vaccines is both safe and effective. Timely immunization with all of the scheduled vaccines is important to protect every child against serious, potentially disabling, sometimes life-threatening infectious diseases like pertussis, meningitis and measles.

Unfortunately, the percentage of Wisconsin students who met minimum immunization requirements in the 2018-2019 school year was only 91.9%, down from 92.3% the previous year. We know that school settings are of particular concern for outbreaks of infectious disease. Every child across our entire state deserves to be protected against preventable diseases in a timely and equitable fashion.

It is our collective responsibility to provide the healthiest possible learning environment for all students. As such, we urge you to support the proposed rule updates as brought forth in DHS 144.

Sincerely,

Advocate Aurora Healthcare
Ascension Wisconsin
Children's Health Alliance of Wisconsin
Children's Wisconsin
Gundersen Health System
Kids Forward
Medical College of Wisconsin
Pharmacy Society of Wisconsin
Rural Wisconsin Health Cooperative
Sixteenth Street Community Health Center
Southern Wisconsin Immunization Consortium
UW School of Medicine and Public Health
UW Health
UW Health American Family Children's Hospital
Wisconsin Academy of Family Physicians
Wisconsin Chapter of the American Academy of Pediatrics
Wisconsin Medical Society

[2] https://www.dhs.wisconsin.gov/publications.p01894.pdf

IMMUNIZATIONS PROTECT WISCONSIN'S KIDS

Support strong, up-to-date immunization rules for school

- Each year in the US, vaccines save approximately 33,000 lives, prevent 14 million cases of disease, and save $9.9 billion in direct cares costs.

- Vaccines keep communities healthy and protect vulnerable populations, like the elderly and children who are too young to be vaccinated. When children do not receive immunizations on time as recommended, they put kids with compromised immune systems who can't be vaccinated because of medical issues like autoimmune diseases and cancer at risk.

- Children deserve safe schools that are protected against vaccine-preventable diseases. Wisconsin health leaders have a professional obligation to ensure the healthiest possible learning environment for all students.

As such, we urge you to support the proposed rule updates as brought forth in DHS 144.

Wisconsin Chapter

INCORPORATED IN WISCONSIN

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

www.wiaap.org | WIAAP | WIAAP

Dear Member of the Assembly Committee on Constitution and Ethics,

I am writing to respectfully request that you vote against rules 1, 2, 4, and 5 of CR 19-079.

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Rule 2 - Change in the *'substantial outbreak'* definition of mumps from *"an incidence of the disease exceeding 2% of the unvaccinated population"* to define *'substantial outbreak'* as *"three or more cases linked by time and place."*

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As of November 30, 2019, the Vaccine Adverse Events Reporting System (VAERS) has received 34,553 reports of adverse events following the meningococcal vaccine. Wisconsin reported 479 adverse events, with 21 listed as serious. Additionally, in Wisconsin, 3 deaths following vaccination were reported to VAERS – but all 3 deaths occurred in individuals who had received the vaccine but still contracted the disease and died from it.

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There is no provision in the law for a titer test to be used as proof of immunity and this change would impact children who have had the illness in the past. DHS has not provided any evidence where a Wisconsin parent has incorrectly reported a positive history of varicella to justify the need for this rule change.

There is no public health crisis to prompt the need for the above-mentioned rule changes and I respectfully request that you vote against 19-079.

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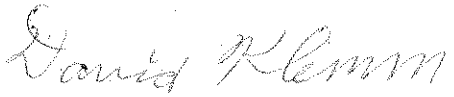

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Sincerely, Joyce Farber Pewaukee, WI 53959

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Nick Jones
Portage WI

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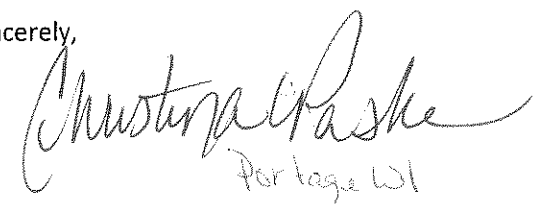

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There is no provision in the law for a titer test to be used as proof of immunity and this change would impact children who have had the illness in the past. DHS has not provided any evidence where a Wisconsin parent has incorrectly reported a positive history of varicella to justify the need for this rule change.

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Sincerely,

Roland Paske
N5887 CTH H
Portage, WI

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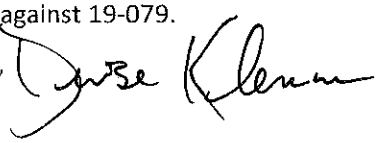

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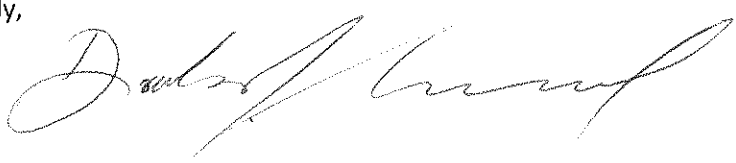

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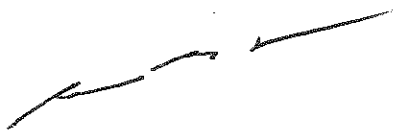

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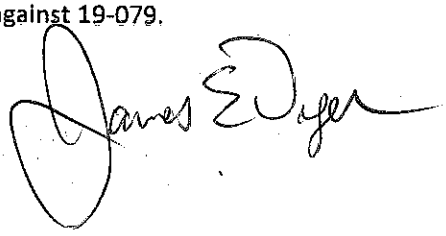

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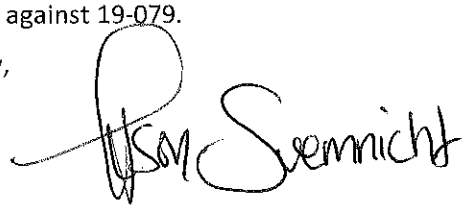

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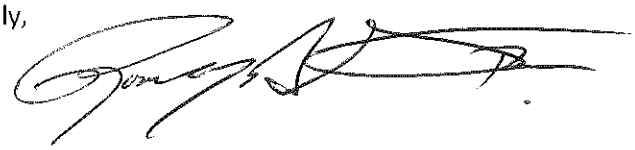

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By changing the definition of *'substantial outbreak,'* unvaccinated children will be excluded from school, even though data collected from DHS clearly shows that unvaccinated individuals are not developing mumps. Vaccine failure related to an ineffective vaccine is responsible for all reported mumps cases in Wisconsin in recent years. This is not unique to Wisconsin. Numerous studies examining mumps outbreaks that have occurred in highly vaccinated populations have experts admitting that both the waning of vaccine-acquired immunity and an ineffective mumps vaccine are to blame.

Rule 4 - Mandate the meningococcal vaccine (MenACWY) for all 7th graders, with a booster dose in 12th grade.

The meningococcal vaccine does not provide herd immunity, and most American children will asymptomatically develop immunity to meningococcal disease as they progress to adulthood. Meningococcal disease is exceptionally rare. Nationally, in 2018, there were 327 reported cases, of which 100 were found to be strains that are targeted by this vaccine. Meningococcal disease caused by serotypes A, C, W, and Y had already decreased to historical lows prior to the introduction of MenACWY vaccine in 2005. While public health officials report that the vaccine has decreased the rates even further, rates of the disease have decreased in all age groups – including the age groups for which the vaccine is not recommended. The incidence of meningococcal disease in the U.S. is already well below the Healthy People 2020 goal. Further, the vaccine is only 80 – 85% effective but after 2 to 5 years, it has been found to be at best only 58% effective. Wisconsin has a high voluntary compliance rate – 83.8% for ages 13-17 – the targeted age group for this rule, and this vaccine will continue to be available to any family desiring it.

As of November 30, 2019, the Vaccine Adverse Events Reporting System (VAERS) has received 34,553 reports of adverse events following the meningococcal vaccine. Wisconsin reported 479 adverse events, with 21 listed as serious. Additionally, in Wisconsin, 3 deaths following vaccination were reported to VAERS – but all 3 deaths occurred in individuals who had received the vaccine but still contracted the disease and died from it.

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There is no provision in the law for a titer test to be used as proof of immunity and this change would impact children who have had the illness in the past. DHS has not provided any evidence where a Wisconsin parent has incorrectly reported a positive history of varicella to justify the need for this rule change.

There is no public health crisis to prompt the need for the above-mentioned rule changes and I respectfully request that you vote against 19-079.

Sincerely,

Jessica Halstead

Dear Member of the Assembly Committee on Constitution and Ethics,

I am writing to respectfully request that you vote against rules 1, 2, 4, and 5 of CR 19-079.

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Lisa Stout

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Sincerely,

Laurel Massingill

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There is no provision in the law for a titer test to be used as proof of immunity and this change would impact children who have had the illness in the past. DHS has not provided any evidence where a Wisconsin parent has incorrectly reported a positive history of varicella to justify the need for this rule change.

There is no public health crisis to prompt the need for the above-mentioned rule changes and I respectfully request that you vote against 19-079.

Sincerely,

Randall S Vergos

Dear Member of the Assembly Committee on Constitution and Ethics,

I am writing to respectfully request that you vote against rules 1, 2, 4, and 5 of CR 19-079.

Rule 1 - Change in the *'substantial outbreak'* classification to include chicken pox.

Chicken pox is a mild childhood illness that can be treated at home and does not warrant the *'substantial outbreak'* classification. By changing the definition of *'substantial outbreak,'* unvaccinated children will be punished and excluded from school, even though data collected from Wisconsin DHS has demonstrated that the vaccine fails to protect, and fully vaccinated individuals can still develop chickenpox. Further, several peer-reviewed studies have shown that the live virus chicken pox vaccine can cause vaccine strain chicken pox infection in others via shedding. This information is also noted in the vaccine package insert published by the vaccine manufacturer.

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Anna Vega

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Shelley Ritter
Portage WI

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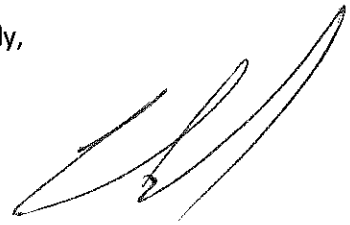

Chad Parahm
Baraboo WI

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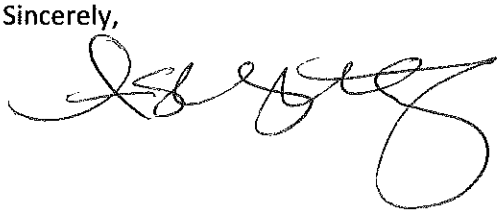

Ashley Write
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Sincerely,

Donna Smalley
53953

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Rule 2 - Change in the *'substantial outbreak'* definition of mumps from *"an incidence of the disease exceeding 2% of the unvaccinated population"* to define *'substantial outbreak'* as *"three or more cases linked by time and place."*

By changing the definition of *'substantial outbreak,'* unvaccinated children will be excluded from school, even though data collected from DHS clearly shows that unvaccinated individuals are not developing mumps. Vaccine failure related to an ineffective vaccine is responsible for all reported mumps cases in Wisconsin in recent years. This is not unique to Wisconsin. Numerous studies examining mumps outbreaks that have occurred in highly vaccinated populations have experts admitting that both the waning of vaccine-acquired immunity and an ineffective mumps vaccine are to blame.

Rule 4 - Mandate the meningococcal vaccine (MenACWY) for all 7th graders, with a booster dose in 12th grade.

The meningococcal vaccine does not provide herd immunity, and most American children will asymptomatically develop immunity to meningococcal disease as they progress to adulthood. Meningococcal disease is exceptionally rare. Nationally, in 2018, there were 327 reported cases, of which 100 were found to be strains that are targeted by this vaccine. Meningococcal disease caused by serotypes A, C, W, and Y had already decreased to historical lows prior to the introduction of MenACWY vaccine in 2005. While public health officials report that the vaccine has decreased the rates even further, rates of the disease have decreased in all age groups – including the age groups for which the vaccine is not recommended. The incidence of meningococcal disease in the U.S. is already well below the Healthy People 2020 goal. Further, the vaccine is only 80 – 85% effective but after 2 to 5 years, it has been found to be at best only 58% effective. Wisconsin has a high voluntary compliance rate – 83.8% for ages 13-17 – the targeted age group for this rule, and this vaccine will continue to be available to any family desiring it.

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There is no provision in the law for a titer test to be used as proof of immunity and this change would impact children who have had the illness in the past. DHS has not provided any evidence where a Wisconsin parent has incorrectly reported a positive history of varicella to justify the need for this rule change.

There is no public health crisis to prompt the need for the above-mentioned rule changes and I respectfully request that you vote against 19-079.

Sincerely,

Stephanie Brenoble
Merrimac WI

Dear Member of the Assembly Committee on Constitution and Ethics,

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Melinda Gruenin

Arkdale WI

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Baraboo WI

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Anthony Schmidt

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Sincerely, Sue Disney

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Sincerely,

Amber Lyn Bittner
1016 Prairie St.
Lodi, WI 53555

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Beth E. Wandrey

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There is no public health crisis to prompt the need for the above-mentioned rule changes and I respectfully request that you vote against 19-079.

Sincerely,

Shawna Buck

Dear Member of the Assembly Committee on Constitution and Ethics,

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Portage WI 53901

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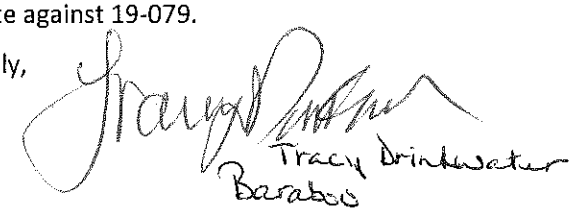

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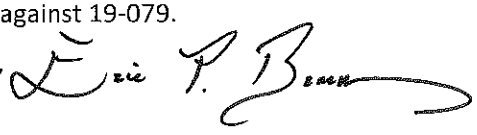

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Barron WI

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Chicken pox is a mild childhood illness that can be treated at home and does not warrant the *'substantial outbreak'* classification. By changing the definition of *'substantial outbreak,'* unvaccinated children will be punished and excluded from school, even though data collected from Wisconsin DHS has demonstrated that the vaccine fails to protect, and fully vaccinated individuals can still develop chickenpox. Further, several peer-reviewed studies have shown that the live virus chicken pox vaccine can cause vaccine strain chicken pox infection in others via shedding. This information is also noted in the vaccine package insert published by the vaccine manufacturer.

Rule 2 - Change in the *'substantial outbreak'* definition of mumps from *"an incidence of the disease exceeding 2% of the unvaccinated population"* to define *'substantial outbreak'* as *"three or more cases linked by time and place."*

By changing the definition of *'substantial outbreak,'* unvaccinated children will be excluded from school, even though data collected from DHS clearly shows that unvaccinated individuals are not developing mumps. Vaccine failure related to an ineffective vaccine is responsible for all reported mumps cases in Wisconsin in recent years. This is not unique to Wisconsin. Numerous studies examining mumps outbreaks that have occurred in highly vaccinated populations have experts admitting that both the waning of vaccine-acquired immunity and an ineffective mumps vaccine are to blame.

Rule 4 - Mandate the meningococcal vaccine (MenACWY) for all 7th graders, with a booster dose in 12th grade.

The meningococcal vaccine does not provide herd immunity, and most American children will asymptomatically develop immunity to meningococcal disease as they progress to adulthood. Meningococcal disease is exceptionally rare. Nationally, in 2018, there were 327 reported cases, of which 100 were found to be strains that are targeted by this vaccine. Meningococcal disease caused by serotypes A, C, W, and Y had already decreased to historical lows prior to the introduction of MenACWY vaccine in 2005. While public health officials report that the vaccine has decreased the rates even further, rates of the disease have decreased in all age groups – including the age groups for which the vaccine is not recommended. The incidence of meningococcal disease in the U.S. is already well below the Healthy People 2020 goal. Further, the vaccine is only 80 – 85% effective but after 2 to 5 years, it has been found to be at best only 58% effective. Wisconsin has a high voluntary compliance rate – 83.8% for ages 13-17 – the targeted age group for this rule, and this vaccine will continue to be available to any family desiring it.

As of November 30, 2019, the Vaccine Adverse Events Reporting System (VAERS) has received 34,553 reports of adverse events following the meningococcal vaccine. Wisconsin reported 479 adverse events, with 21 listed as serious. Additionally, in Wisconsin, 3 deaths following vaccination were reported to VAERS – but all 3 deaths occurred in individuals who had received the vaccine but still contracted the disease and died from it.

Rule 5 - Parents would no longer be able to report their child's chicken pox illness and would be required to see a healthcare provider to confirm infection.

Chicken pox is generally a mild disease not requiring medical attention. Insisting that parents take their highly contagious child to a doctor puts others, including those who may be immunocompromised, at risk of contracting the illness. Further, families would take on the financial burden of all charges involved with visiting the doctor for a diagnosis of what has always been considered a benign and routine childhood illness.

There is no provision in the law for a titer test to be used as proof of immunity and this change would impact children who have had the illness in the past. DHS has not provided any evidence where a Wisconsin parent has incorrectly reported a positive history of varicella to justify the need for this rule change.

There is no public health crisis to prompt the need for the above-mentioned rule changes and I respectfully request that you vote against 19-079.

Sincerely, Dakota Bittner

106 Prairie St Lodi, WI

Dear Member of the Assembly Committee on Constitution and Ethics,

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There is no public health crisis to prompt the need for the above-mentioned rule changes and I respectfully request that you vote against 19-079.

Sincerely,

Paul Macnaghy JR
Reedsburg WI

State Capitol
PO Box 2953
Madison, WI 53708

Dear Representative Wichgers,

I am writing to respectfully request that you hold a public hearing with public comment on CR 19-079. This administrative rule change would significantly affect all school children in Wisconsin, and further discussions are needed prior to implementation.

In creating the rule, Wisconsin Department of Health Services (DHS) formed an Advisory Committee consisting of representatives from the Wisconsin Department of Public Instruction, Wisconsin Chapter of the American Academy of Pediatrics, Wisconsin Department of Health Services Medicaid Program, Wisconsin Association of Local Health Departments and Boards, Wisconsin Academy of Family Physicians, Wisconsin Association of School Nurses, Wisconsin Medical Society, and Pharmacy Society of Wisconsin. Parents of school-age children, the primary stakeholder and population that would be affected by the changes, were not included on the Advisory Committee and were denied the opportunity to have a voice on the proposed changes.

The overwhelming majority of individuals who submitted written comment regarding CR 19-079 opposed one or more of the proposed rule changes, and most who participated in the public hearing held on July 26th, 2019, were recorded as being opposed to the changes. Further, many attendees were not afforded the opportunity to speak as the hearing was limited to one hour, of which nearly 20 minutes was spent dealing with technical difficulties. Additionally, several stakeholders contacted DHS following the public hearing to request a meeting with officials and were denied.

My primary concerns are:

Rule 1 - Change in the 'substantial outbreak' classification to include chicken pox, an illness historically considered mild prior to the introduction of a vaccine. This rule change would exclude children who are not immune from the illness even though data collected from DHS displays the significant failure of the vaccine to provide protection.

Rule 2 - Change in the 'substantial outbreak' definition of mumps from *"an incidence of the disease exceeding 2% of the [school] population"* to define 'substantial outbreak' as *"three or more cases linked by time and place."* Again, children who are not immune would be excluded from school, even though DHS's data once again shows that unvaccinated individuals are not developing mumps.

Rule 3 - Mandating one meningococcal vaccine (MenACWY) for all 7th graders, with a booster dose in 12th grade. This vaccine does not prevent spread of the illness, though it may provide personal protection. This illness is especially rare, but the vaccine is and will continue to be available to all families who wish to receive it.

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These changes would impact all Wisconsin school children. Coupled with the fact that parents were not included as stakeholders when the changes were proposed by DHS, I am requesting that the Committee on Constitution and Ethics hold a public hearing to ensure parental concerns are addressed.

Sincerely,

Ellen Weiss

Address: E11720 Gall Rd, Baraboo WI 53913

State Capitol
PO Box 8953
Madison, WI 53708

Dear Representative Wichgers,

I am writing to respectfully request that you hold a public hearing with public comment on CR 19-079. This administrative rule change would significantly affect all school children in Wisconsin, and further discussions are needed prior to implementation.

In revising the rule, Wisconsin Department of Health Services (DHS) formed an Advisory Committee consisting of representatives from the Wisconsin Department of Public Instruction, Wisconsin Chapter of the American Academy of Pediatrics, Wisconsin Department of Health Services Medicaid Program, Wisconsin Association of Local Health Departments and Boards, Wisconsin Academy of Family Physicians, Wisconsin Association of School Nurses, Wisconsin Medical Society, and Pharmacy Society of Wisconsin. Parents of school-age children, the primary stakeholder and population that would be affected by the changes, were not included on the Advisory Committee and were denied the opportunity to have a voice on the proposed changes.

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Sincerely,

Eleanor Chaves

Address: 1042 204th St Prairie du Sac, WI 53578

State Capitol
P.O. Box 8953
Madison, WI 53708

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Sincerely,

Laura Ferdon

Address: E11842 S City View Rd, Baraboo, WI 53913