Statement of Need and Reasonableness (SONAR)

Immunization Reporting Rule

Minnesota Department of Health

April 4, 2013

Minnesota Department of Health

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Proposed Amendment to Rules Governing Child Care and School Immunizations, Minnesota Rules Part 4604.0100 – 4604.1020

Note: A glossary of terms can be found in Attachment A.

I. INTRODUCTION

The Minnesota Department of Health (the department) is proposing amendments to rules governing Child Care and School Immunizations.

In 1967, the Minnesota Legislature enacted the Minnesota School Immunization law (Minnesota Statutes, section 121A.15) to ensure that school children are protected against vaccine-preventable diseases in an appropriate and timely manner and to prevent epidemics of vaccine-preventable diseases in the community.

The law requires that parents or guardians provide the school or child care with documentation that shows their child received the required immunizations according to medically acceptable standards or they have taken a legal exemption. The law allows for two types of legal exemptions: a medical exemption or a conscientiously held belief exemption. “Medically acceptable standards” mean immunization recommendations formally adopted at the national level by the Advisory Committee on Immunization Practices (ACIP). The ACIP is a statutorily created federal advisory committee that meets three times a year to make immunization recommendations for all U.S. licensed vaccines. Every year, the Centers for Disease Control and Prevention (CDC) publishes the national immunization schedules for children, adolescents and adults that reflects the most current ACIP recommendations. They are approved by the ACIP, American Academy of Pediatrics (AAP), and American Academy of Family Physicians (AAFP) and distributed by state health departments and national medical association to ensure health care providers have the most current immunization recommendations. (*See Attachment B, 2013 Recommended Childhood and Adolescent Immunization Schedule*.)

In 2002, the department was given authority to modify the school and child care immunization requirements through rulemaking. This was the last time the requirements were updated. Since then, local and national medical experts have recommended new vaccines and the schedule and timing of various vaccines have changed. Thus, if providers are only using the current law to guide their practice, children are no longer being protected against some vaccine-preventable diseases. The department’s proposed changes will update the current child care and school immunization requirement to reflect new, evidence-based, national immunization recommendations.

Diseases such as measles, mumps, rubella, polio, hepatitis A and B, tetanus, pertussis, meningitis, and chickenpox are all vaccine-preventable diseases. Those diseases can be prevented or their severity greatly reduced, by immunization. School immunization requirements ensure that persons enrolling in a child care facility, a school-based early childhood program, and elementary or secondary school have documentation of immunization or a legal exemption. As repeated research has shown, immunization requirements result in high levels of immunization coverage, reduction in disease, and a healthy school and community. In addition, effective immunization programs, which include

school and child care requirements, produce substantial savings for the state by reducing the number of children who need state-provided medical assistance and special education programs for blindness, deafness, neurological disorders, and congenital heart defects. It is estimated that for every one dollar spent on vaccines, five dollars of direct medical costs are saved and approximately 11 dollars in additional costs to society are saved.[i]

Vaccines prevent:

- **Serious childhood diseases**. Prior to the introduction of vaccines, many diseases were so common that nearly every child developed them. Now, thanks to the success of vaccines, these diseases are rare in the United States, e.g., polio, rubella (German measles), and diphtheria.
- **Diseases that could easily reemerge**. Some diseases in this country continue to occur, albeit at low levels (e.g., *Haemophilus influenzae* type b, mumps, pneumococcal). When immunization rates in a school or community drop, outbreaks do occur. Minnesota has experienced several outbreaks in the last 30 years. During the late 1980s and early 1990s, thousands of children were hospitalized and more than 132 died in the United States from measles. Three of the deaths were children in Minnesota. More recently, in 2011 in Minnesota, there were 26 cases of measles. (Twenty of these cases were linked to a person who travelled internationally, 16 were unvaccinated, and four had unknown vaccination history).
- **Diseases that are still common in other parts of the world**. Some diseases in the United States have been eliminated (polio) or virtually eliminated (measles). But children are commonly paralyzed by polio in Pakistan or dying from measles in Africa. The increased availability and accessibility to travel overseas for business and leisure open the door for these diseases to be brought into the United States.

The department believes that requiring immunizations according to current, evidence-based national recommendations for children in child care, school-based early childhood programs, and elementary and secondary school is reasonable and necessary to ensure the health of children and the entire community.

The department began work on potential rules revisions in January 2012. The agency published a Request for Comments in the State Register on April 30, 2012 with a closing date of June 30, 2012. The department notified affected parties of the Request for Comments through multiple means. (*See Attachment C for efforts the department used to notify affected parties.*)

During the Request for Comments period, the department held two public meetings. The first meeting was held on Thursday, June 14, 2012 from 5:30 p.m. to 8:00 p.m. in St. Paul. Approximately 15 people attended. Of the people who spoke, most were proponents of the proposed changes. One school nurse expressed concerns about administrative issues but was not opposed to the changes themselves.

The second meeting was a statewide video conference held on Monday, June 18, from 11:30 a.m. to 2:00 p.m. There were 13 video conference sites with approximately two people attending at each site. (*See Attachment D for list of video conference sites*.) Of the people who spoke, most were proponents of the proposed changes. One attendee at the St. Paul site voiced reservations about the changes. The department also received a few comments via email.

The department also formed an Immunization Rule Advisory Committee ("Advisory Committee"), which included persons representing infectious disease physicians, pediatricians, infection control practitioners, nurses, school nurses, health plans, child care, local public health agencies, and parents. (*See Attachment E for a list of advisory committee members.)* MDH held two advisory meetings that provided participants an opportunity to express their views on the proposed amendments to the law. The agency also asked Advisory Committee members to distribute information on the proposed amendments to their organizational lists during the Request for Comment period.

In summary, the department received comments on the proposed amendments to the rules as a result of the Request for Comments, the Advisory Committee, and the distribution of the proposed rules by the department and Advisory Committee members. The proposed amendments to the rules are the product of this process.

II. ALTERNATIVE FORMAT REQUEST

Upon request, this Statement of Need and Reasonableness (SONAR) can be made available in an alternative formats, such as large print, Braille, CD, or audio. To make a request, contact Patricia Segal Freeman, Minnesota Department of Health, 625 Robert Street N., P.O. Box 64975, St. Paul, MN 55164-0975: (651) 201-5503, 1-877-676-5414, FAX (651) 201-5501 or *health.immrule@state.mn.us.* TTY users may call the Minnesota Department of Health at (651) 201-5797.

III. STATUTORY AUTHORITY FOR MODIFYING THE RULES

The Commissioner of Health has the statutory authority to adopt rules modifying school immunization requirements under Minnesota Statutes, section 121A.15, subdivision 12 paragraphs (a) and (c) which state:

> *Subdivision 12 (a).* "*The commissioner of health may adopt modifications to the immunization requirements of this section."*
>
> *Subdivision 12 (c). "The commissioner shall comply with the requirements of chapter 14 regarding the adoption of any proposed modifications to the immunization schedule."*

Minnesota Statues, section 121A.15, subdivision 12 also lays out other requirements that the commissioner must follow in order to modify the requirements. These are discussed below.

- M.S.§121A.15, subd. 12(a) states that the proposed modification made under this subdivision must be part of the current immunization recommendations of each of the following organizations: the United States Public Health Service's Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians, and the American Academy of Pediatrics.
- M.S.§121A.15, subd. 12(a) also states the commissioner must consult with the Minnesota Natural Health Coalition, Vaccine Awareness Minnesota, and Biological Education for Autism Treatment (BEAT). On April 30, 2012 the department notified two out of the three groups and corresponded via email with the third group on June 19, 2012. A representative from the Minnesota Natural Health Coalition attended the June 18 statewide video conference. Initially, the department could not find any address for BEAT. Further efforts, however, were successful in contacting the primary contact for BEAT.
- M.S.§121A.15, subd. 12(a)(1) states that "the commissioner of health must consult with (i) the commissioner of education [MDE]; the commissioner of human services [DHS]; the chancellor of the Minnesota State Colleges and Universities [MNSCU]; and the president of the University of Minnesota."

  The department consulted with representatives of MDE and DHS through an interagency immunization group and conferred with MNSCU and the University of Minnesota through phone calls and email. The representatives of these agencies support the proposed changes and did not oppose them.
- M.S.§121A.15, Subd.12(2) states, "that the commissioner must consider the following criteria: the epidemiology of the disease, the morbidity and mortality rates for the disease, the safety and efficacy of the vaccine, the cost of a vaccination program, the cost of enforcing vaccination requirements, and a cost-benefit analysis of the

vaccination." These factors are discussed under Section IV of the Regulatory Analysis and each relevant part in Section VI, the Rule by Rule Analysis.

- M.S.§121A.15, subd.12(2)(b) states that before a proposed modification may be adopted, the commissioner must notify the chairs of the house of representatives and senate committees with jurisdiction over health policy issues."

  The department sent all the chairs and the lead minority representative of the relevant committees the Request for Comments on April 30, 2012. The department will send each of these legislators the Notice of Intent to Adopt, including both the SONAR and rule when the department publishes the Notice of intent to Adopt in the State Register. (See additional notice plan in Section V(B))

- M.S.§121A.15, subd. 12(d) states, "in addition to the publication requirements of chapter 14, the commissioner of health must inform all immunization providers of any adopted modifications to the immunization schedule in a timely manner."

  As soon as the rules are final and adopted, the department will notify affected parties through mail, email, the department Facebook, Twitter and workspace accounts, broadcast fax, available listservs, health publications, and other health-related websites.

Under these statutes, the department has the necessary statutory authority to amend the rules. This rulemaking amends existing rules that were amended in 2003. Previous rulemaking satisfied the requirements of *Minnesota Statutes*, section 14.125, so the department retains its rulemaking authority.

IV. REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, lists eight factors for regulatory analysis that state agencies must include in a SONAR. Paragraphs A through H that follow quote these factors and the department's response to them. Additionally, Section VI of the SONAR, the Rule-by-Rule Analysis, addresses some of these factors.

A. A description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

1. Classes of Persons Affected by the Proposed Rule

   The proposed rules affect a wide variety of persons and entities. They include:

   - Children and adolescents both immunized and unimmunized, who attend child care, school-based early childhood programs, or elementary or secondary schools.
   - Parents or guardians of children affected by the rule.
   - Licensed child care providers as defined in Minnesota Statutes, Chapter 245A and Minnesota Rules, chapters 9502 and 9503. Child care providers are required to verify immunization documentation and compliance when a child enrolls in their program and exclude children not in compliance.
   - Elementary and secondary schools and school-based early childhood programs that are responsible for documenting a child's immunization history when they first enroll, enter seventh grade, or transfer from another school. Schools are responsible for enforcing compliance with the School Immunization Law.

- Health care providers who are responsible for educating parents about immunizations and providing the immunizations to the child.
- Health care insurance companies, both public (i.e., MinnesotaCare) and private, and self-insured health care plans that pay for immunizations in the private sector.
- Public sector health clinics that provide immunizations.
- The general public and all visitors to the state.
- Minnesota Department of Health staff who inform providers of current requirements and collect immunization report information from child care and schools.

2. Classes of Persons Who Will Bear the Costs of the Proposed Rule

- *Children and Parents or guardians.* Parents or guardians with children who are uninsured (do not have health insurance) do not have to pay for vaccines for their children. Parents may be asked to pay an administrative fee. The provider, however, must waive the fee if the parent is unable to pay. The Minnesota Vaccines for Children (MnVFC) program provides vaccine to over 700 clinics in Minnesota to be given to eligible children. The MnVFC program is the state version of the federal Vaccines for Children (VFC) program. MnVFC is completely federally funded. Children (0 through 18 years old) eligible to receive vaccine from the MnVFC program include:
  - Uninsured,
  - American Indian/Alaskan Native,
  - Covered by a Minnesota Health Care Program[1], or
  - Underinsured (if seen at local public health, Federally Qualified Health Centers, Rural Health Centers, tribal health, and Indian Health Services clinics located in Minnesota).

  The majority of children with private health insurance have coverage for preventable services, including immunizations. The Affordable Care Act (ACA) requires full coverage of all federal ACIP (Advisory Committee on Immunization Practices) recommended vaccines. Currently, some insurance plans have grandfathered status in relation to the ACA and are able to require payment for immunizations, but the number of grandfathered plans is quickly decreasing.
- *Child Care Facilities.* Under the revised rules, child care facilities, along with schools, will bear the administrative burden because they are responsible for enforcing additional immunization requirements. But they will incur no direct costs for the vaccines.

  The Immunization Rule Advisory Committee had representatives from both family- and center-based child care and they were not concerned with cost for the additional requirements.
- *Schools.* Under the revised rules, schools, along with child care, will bear the administrative burden because they are responsible for enforcing additional immunization requirements. But they will incur no direct costs for the vaccines.

[1] These programs include Medical Assistance (MA), MinnesotaCare (MnCare), or a Prepaid Medical Assistance Program

The Immunization Rule Advisory Committee included two school nurse representatives. In addition, the department communicated the proposed changes to school superintendents through a conference call and a mailing. The nurses were generally supportive of the changes, though one of the nurses representing the School Nurse Organization of Minnesota (SNOM) was concerned about an additional administrative burden on nurses and costs to upgrade the immunization portion of the school's electronic information system. Staff from the Department of Education told the department that schools and districts normally update these systems on a regular basis and, as a result, should be able to update the immunization portion along with other updates, thus lowering costs. No other school officials have expressed this concern.

During the comment period, the department also heard from a few school nurses who were worried about an increasing administrative burden on school nurses if they had to check immunizations at every grade. However, their concerns were alleviated after department staff explained implementation procedures and clarified the proposed requirements.

- *Insurance Companies and Health Plans*. These companies bear the cost of vaccination.[2] But these companies and plans should not see a significant increase in costs due to this rule change since they are already required to cover the costs of the immunizations under the ACA. In addition, immunization is cost-effective because it prevents future disease costs.
- *Minnesota State Health Care Programs* (i.e., Medicaid, Minnesota Care, etc.). Federally recommended vaccines provided to MHCP children are provided at no cost through the federal vaccines for children program (VFC).
- *Health Care Professionals*. Under the revised rules, health care professionals will provide vaccinations to meet the new requirements of the revised rules, all of which are part of the national recommended schedule. The majority of clinics that provide vaccine to pediatric patients already provide all ACIP-recommended vaccines since it is the medically accepted standard of care. Since insurance is required to reimburse for the immunization services under the ACA, health care professionals should receive adequate payment for any additional immunizations given due to this rule change. Likewise any children not privately insured can receive vaccine from the Minnesota Vaccines for Children (MnVFC) program.

[2] Under the ACA, insurance companies must cover the full cost of ACIP-recommended vaccinations unless they are an exempt ERISA plan.

3. Classes of Persons Who Will Benefit from the Proposed Rule

   The potential beneficiaries of these proposed rules include every child, adolescent, and adult who lives in Minnesota and all visitors to the state.

   - *Immunized Children, Youth, and Their Parents*. Children and their parents or guardians will benefit because the revised rules will increase the number of vaccinated persons thus lowering the risk of disease in those vaccinated and unvaccinated.
   - *Non-immunized Children and Youth*. These persons will benefit because of herd immunity. Herd immunity is the concept that immunizing a large percentage of individuals who can be vaccinated protects those who have not been or cannot be vaccinated from that disease or those who unknowingly did not develop an immunization response to the vaccine (e.g., weakened immune system). Herd immunity is achieved when the vast majority (90 percent) of the population is immune to a disease because the infectious agent cannot readily spread in a highly immunized community.
   - *The General Adult Population*. These persons will benefit because there will be fewer outbreaks or cases of vaccine-preventable diseases.
   - *Society*. Society in general will benefit because there will be fewer deaths and disabilities and lower medical treatment costs associated with these diseases.

B. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

1. Probable costs to the agency of implementation and enforcement

   The probable costs to the department for implementing the proposed rule amendment will be minimal. There will be one-time costs associated with development and distribution of educational materials on the revised rules to establish public awareness and inform health care providers, schools, and child care providers. The department will incorporate most of these costs into other educational information already provided.

2. Probable costs to any other agency of the implementation and enforcement

   There should be no cost to another state agency or to local public health agencies. The Minnesota Department of Human Services (DHS) licenses child care providers and checks to ensure that immunization records are up-to-date. DHS and county human services agencies should not incur any additional costs due to the addition of two more vaccines (hepatitis A and B). There should be no new costs to the Minnesota Department of Education (MDE). Both agencies expressed their support for the rule changes and did not express any concern about costs.

3. Anticipated effect on state revenues

   The proposed rule amendments will not affect state revenues. Minnesota Health Care Programs (MHCP) and the federally funded Minnesota Vaccines for Children (MnVFC) program already support the usage of all ACIP-recommended immunizations, including those in the proposed rules.

C. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

The department has proposed the least costly and least intrusive methods necessary for achieving the purpose of the proposed rules.

1. Less Costly Method

   - The least costly method would be to have no new or amended immunization requirements. But based on the scientific evidence and national recommendations, the department has concluded that these new requirements are necessary and reasonable and will save medical and societal costs in the long run. (Also see performance-based standard discussion under section V(A).
   - Another option would be to have schools distribute educational materials about vaccinations, but not require proof of vaccination. However, this would not help us achieve the high immunization rates necessary to prevent vaccine-preventable disease outbreaks and achieve the state's goal (and the national goal) of 90 percent immunization rates by 2020. Immunization laws have been proven to raise immunization rates to the level necessary to protect the community as a whole.[ii,iii,iv] In addition, this option would put the costs on the education system.
   - The department also discussed not requiring certain immunizations to decrease the administrative burden on schools and child care facilities. But the department concluded the epidemiological data describing the harmful effects of these specific diseases outweigh the additional administrative burden.

2. Less intrusive methods

   The proposed rule is intrusive because it requires children to be immunized against certain diseases (or take an exemption) before entering child care, school-based early childhood programs and elementary and secondary schools.[3] The less intrusive methods considered were the same as the less costly methods described above (i.e., no immunization requirements, fewer immunization requirements, or an educational campaign only). But based on the scientific evidence, the department concluded that these proposed requirements are reasonable and necessary and ensure that children are protected against potentially dangerous diseases.

   In addition, the Minnesota School Immunization Law, Minnesota Statutes, §121A.15, Subd. 3, allows parents or guardians who are opposed to immunizations to seek a legal exemption from immunization for their children.

D. A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

The department considered not requiring any new immunizations and instead conducting a health education campaign to encourage parents or guardians to vaccinate their children. This was rejected because the state would not be able to reach the high

[3] It is important to note that if children receive well-child care, they are usually receiving these recommended immunizations on schedule and will be in compliance with the new requirement.

immunization levels necessary to protect children and achieve herd immunity. For example, a recent study found that middle school vaccination requirements are associated with higher coverage rates for Td/Tdap and meningococcal vaccines, while education-only requirements do not increase coverage levels for either vaccine.[v] As mentioned earlier, it is imperative that immunization coverage levels reach a minimum of 90 percent to achieve herd immunity and to protect the larger community, including both children and adults.

E. The probable costs of complying with the proposed rule, including the portion of the total costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.

As is true with school immunization laws, child care facilities, school-based early childhood programs, and elementary and secondary schools will be responsible for helping in the enforcement of these requirements. Health plans, insurers (both public and private), and the federal Vaccines for Children (VFC) program cover the cost for the vaccine and its administration.

- **Health plans and insurers**. Under the federal Affordable Care Act (ACA), health insurance plans are required to cover the entire cost of any ACIP-recommended vaccine.
- **Schools**. Even though schools will need to assess for two additional vaccines (Tdap and meningococcal) in middle school and certain immunizations for children in certain school-based early childhood programs, the department expects schools to incur minimal additional costs if any, due to a variety of factors. These factors are:
    - According to the most recent National Immunization Survey (NIS), approximately 82.5 percent of seventh through 12th graders have received the Tdap vaccine and 63.1 percent have received the meningococcal vaccine; thus reducing the need for follow-up when they enter seventh grade. In addition, schools currently check for Td vaccination and the proposed new Tdap requirement would replace the current Td requirement.
    - According to the most recent NIS, approximately 79.3 percent of children ages 19 to 35 months have completed the 4:3:1:3:3:1 series;[4] thus reducing the need for follow-up when they enter the early childhood program. It is important to note that the survey had a 6.8 point confidence interval. This means that the true rate could be anywhere from 72.5 to 86.1.
    - Tdap vaccine is already widely accepted by health care providers and routinely given to an adolescent at the 11-12 year-old well-child visit. It was licensed in and added to the ACIP-recommended schedule in 2005.
    - Most of the ACIP-recommended vaccines for children in early childhood programs are widely accepted by health care providers and routinely given to children at their well-child visit.
    - Regarding school-based early childhood programs, many school districts already require immunization documentation for these types of programs.

[4] The 4:3:1:3:3:1 vaccination series refers to a child who has 4 DTaP, 3 polio, 1 MMR, 3 Hib, 3 hepatitis B, and 1 varicella.

- Most schools have access to the Minnesota Immunization Information Connection (MIIC). This confidential immunization information system is a partnership of health care clinics, public health agencies, and schools. MIIC compiles immunizations that a client has received into a single record, even if the shots were given by different health care providers in the state. MIIC is fully operational throughout the state and has significantly reduced the work parents, clinics, and schools have to go through to collect immunization histories.

  There are approximately 1,478,406 immunization records of children age 0-18 years in MIIC and there are 3,585 organizations using MIIC. These organizations include pediatric and family practice clinics, as well as specialty clinics, local public health, and hospitals.

  Finally, most schools have electronic systems to track a variety of student information, including immunizations. The School Nurse Organization of Minnesota (SNOM) expressed concern about the cost to upgrade the immunization portion of the electronic system. Staff from the Department of Education told the department these systems are normally updated on regular basis and, as a result, should be able to update the immunization portion along with other updates, thus lowering costs. No other school officials have expressed this concern.

- **Child Care Facilities**. The cost to most child care facilities should be minimal because they already check for immunization requirements. The department did not receive any comments opposing these requirements from any child care provider. In addition, the Minnesota Child Care Association, which represents licensed child care facilities, and the Minnesota Licensed Family Child Care Association had representatives on the Immunization Rulemaking Advisory Committee. Both representatives expressed support for the changes because it is in the best interest of the children in their care and their staff. The two new immunization requirements proposed (hepatitis A and B) are already ACIP-recommended for children in child care and should already be given when the child goes in to the doctor's office. The department will work with child care providers before implementation to help them reduce any new administrative burden. Similar to schools, child care facilities can look up immunization records of children they serve in MIIC. The department is working on getting more child care facilities onto MIIC to make it administratively easier and more efficient to look up a child's record for one who is in their care.

F. The probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.

1. Probable costs of not adopting the proposed rules

   There are significant costs incurred by not going forward with the proposed amendment to the rules. If the rule does not go forward, it is unlikely the state will achieve the high immunization rates necessary to prevent vaccine-preventable disease outbreaks. More people will get sick from these diseases, which will result in higher medical costs to treat the disease and possibly death or permanent disability. Studies have shown that vaccination reduces health care costs in the long run. [vi, vii]

In 2012, Minnesota experienced its worst outbreak of pertussis (whooping cough) since the 1940s with over 4,400 cases. This resulted in 52 hospitalizations and many visits to emergency rooms and doctor's offices, all adding to the increased cost of medical care.

G. An assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.

There are no federal regulations regarding school and child care immunization laws. This is a state function.

H. An assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule.

There are no federal regulations on school and child care immunizations. It is a state function and all 50 states have school immunization laws. The current School and Child Care Immunization Law is the only regulatory scheme for childhood immunizations in Minnesota. It not only saves lives and prevents lifelong disability but also reduces health care costs. The legislature first enacted the Minnesota School Immunization Law in 1967 and has updated it periodically to align it with current medical standards based on new scientific research. This proposed change continues that process to ensure children and all Minnesotans are protected from vaccine-preventable diseases.

V. ADDITIONAL STATUTORY REQUIREMENTS

A. Performance-Based Rules

Minnesota law (Minnesota Statutes, sections 14.002 and 14.131) requires that the SONAR describe how the department, in developing the rules, considered and implemented performance-based standards that emphasize superior achievement in meeting the department's regulatory objectives and maximum flexibility for the regulated party and the department in meeting those goals.

The objective of school immunization requirements is to protect the individual and community from death and illnesses associated with vaccine-preventable diseases. If the proposed requirements become law, the state will see a reduction in death and illness from vaccine-preventable diseases.

True performance-based rules would set specific outcomes and leave the means of achieving those outcomes up to the provider. But a true performance-based approach is impossible or impracticable for this proposed immunization rule. Allowing too much flexibility in the timing of vaccinations would expose many children to vaccine-preventable disease. Vaccinations are recommended at specific ages to achieve maximum protection.

Nonetheless, a few areas of the proposed rules give health care providers, schools, and parents or guardians some flexibility.

- All of the requirements provide for an exemption if there is a medical reason why the immunization should not be given, or if the parent's or guardian's conscientiously held beliefs prohibit the immunization.

- Proposed part 4604.0410 extends the time that schools and child facilities have to submit their annual reports from 60 to 90 days to ease the administrative burden on these institutions.
- All of the standards relate to entry of the child into child care or school, and parents have the option of delaying entry of their child into these settings.
- If a child is in the midst of completing a vaccination series, they are allowed to attend school while they complete the series.

B. Additional Notice

Minnesota law (Minnesota Statutes, sections 14.131 and 14.23) requires that the SONAR contain a description of the department's efforts to provide additional notice to persons who may be affected by the proposed amendments to the rules.

The department submitted an additional notice plan to the Office of Administrative Hearings, which reviewed and approved it on April 11, 2013 by Administrative Law Judge Eric L. Lipman.

The additional notice plan consists of the following steps:

1. Mail or email the proposed rules and the dual notice to all persons who have registered to be on the department's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a.

2. Post the proposed rules, the dual notice, the SONAR, and the fact sheet containing a summary of the substantive changes on the department's Immunization Rule web site at http://www.health.state.mn.us/divs/idepc/immunize/immrule/index.html. On the webpage there is also an option for people to "subscribe" to receive an alert when information on the Immunization Rule Revisions webpage is added or updated.

3. Post information on the department's Facebook page and Twitter feed.

4. Provide a two-page summary of the "Notice of the Proposed Immunization Rules and Hearing" and a web link to the proposed rules and SONAR via mail, email, directly or through a listserv, to various individuals. The department will also request that these individuals share this information with colleagues, post the information on their website, and send it to their listserv. This list includes:
   - Health care providers, such as physicians, nurses, physician assistants, infection control practitioners, and hospital personnel. The department has a mailing list of pediatricians, family practitioners, local public health agencies, hospitals, and other affected health care providers.
   - School officials, such as principals, superintendents, and school nurses. The department has a mailing list with this information and will also work with the school nurse association to ensure that school nurses receive the information.
   - All licensed child care providers, both center and family based. The department has a current list of all licensed providers.
   - A representative of the Minnesota Natural Health Coalition
   - A representative of Vaccine Awareness Minnesota
   - A representative of the Minnesota Vaccine Safety Council

- A representative of Biological Education for Autism Treatment (BEAT)

5. Publish information about the proposed changes, and where people can get further information in publications that reach affected parties. These include:
   - The department "Got Your Shots," a newsletter sent to over 6,000 subscribers, which includes nurses, doctors, physician assistants, and other interested parties.
   - The Minnesota Department of Health Intranet, which publishes pertinent briefings to department employees.

6. Provide rule information in presentations and at health conferences to health professionals and school personnel.

7. Provide a two-page summary of the "Notice of the Proposed Immunization Rules and Hearing," the SONAR, the fact sheet containing a summary of the substantive changes, and a web link to the proposed rules to members of the Immunization Rulemaking Advisory Committee; and asking them to forward this information to the organization they represent and their colleagues. (*See Attachment E for list of advisory committee members*)

8. Provide a two-page summary of the "Notice of the Proposed Immunization Rules and Hearing," the SONAR, the fact sheet containing a summary of the substantive changes, and a web link to the proposed rules via email, directly or through a listserv, to various organizations. The department will also request that they post this information on their website and send it out to their listserv. This list includes:
   - Minnesota Medical Association
   - Minnesota Chapter of the Academy of Pediatrics
   - Minnesota Chapter of the Academy of Family Physicians
   - Minnesota Nurses Association
   - Minnesota School Nurse Organization (SNOM)
   - Minnesota Chapter of the National Association of Pediatric Nurse Practitioners
   - Physician Assistant groups
   - Early childhood providers, including school readiness, ECFE, and screening coordinators
   - Child Care Resource and Referral
   - Minnesota Association of School Administrators
   - Minnesota Association of Secondary School Principals
   - Minnesota Elementary School Principal Association
   - American Liver Foundation
   - March of Dimes
   - Minnesota Hospital Association
   - Immunization Action Coalition
   - Minnesota Council of Health Plans

9. Notify the Legislature per Minnesota Statutes, section 14.116 and Minnesota Statutes, sections 121A.15, subdivision 12(2)(b) and 135A.14, subdivision 7(d). This will include sending the proposed rules, SONAR, dual notice, and summary of substantive changes to the chairs and ranking minority members of the legislative policy and budget committees with jurisdiction over the subject matter.

10. Publish a press release about the proposed rules and send it to all news organizations in the state..

C. Consultation with the Minnesota Department of Finance on Local Government Impact

Minnesota Statutes, section 14.131, requires agencies to consult with the Department of Finance (DOF) to help evaluate the fiscal impact and benefits of the proposed rules on local governments. The department delivered a copy of the proposed rules and SONAR to the Executive Budget Officer (EBO) for the agency on November 27, 2012.

The department does not anticipate costs to local agencies as a result of the proposed rules (see section 2B. of the Regulatory Analysis). Local jurisdictions will benefit from an updated School Immunization Law because there will be less disease in the community.

On January 28, 2013, the department received a letter for DOF stating that they believe that these rule changes will have minimal impact on local governments.

D. Cost Determination

As required by Minnesota Statues, section 14.127, the department has considered whether the cost of complying with the proposed rules in the first year after the rules take effect will exceed $25,000 for any small business or small city. Since the cost of the vaccine and administering it is covered by insurance or the parent or guardian themselves, the department has determined that the rules will not exceed $25,000 for any small business or small city.

E. Section 14.128 Analysis

The department has considered the requirements of Minnesota Statutes, section 14.128, subdivision 1, which requires that “an agency must determine if a local government will be required to adopt or amend an ordinance or other regulation to comply with a proposed agency rule.” The School adopts the School Immunization Law; it does not require a local government to adopt or amend an ordinance or regulation to comply with the proposed rules.

F. List of Non-Agency Witnesses

If the rules go to a public hearing, the department anticipates the following non-agency witnesses will testify in support of the need for and reasonableness of the proposed amendments to the rules:

1. Dr. Robert Jacobson, Minnesota Chapter – American Academy of Pediatrics President. Dr. Jacobson will testify in support of the changes, his experience as a pediatrician with vaccine-preventable diseases, the impact vaccines have on these diseases, and the importance of the changes.

2. Dr. William F. Pomputius III, Pediatric Infectious Disease Physician, Children's Hospital and Clinics of Minnesota. Dr. Pomputius will testify in support of the changes and the impact these diseases have on children.

VI. RULE-BY-RULE ANALYSIS

The department proposes the following recommended changes to the school immunization requirements. The department has concluded, after careful consideration, that each amendment is reasonable and necessary to further the goals of the rules.

Part 4604.0200 Definitions

Subpart 2a. Medically Acceptable Standards. This term appears throughout the school immunization law in both statute (Minn. Stat. §121A.15) and rules (Minn. R. 4604), but is not defined in either statute or rule, which has caused confusion among providers and school officials. This proposed amendment clarifies that medically acceptable standards mean immunization recommendations promulgated at the national level by the Advisory Committee on Immunization Practices (ACIP). (*See Attachments B and F, 2013 Recommended Childhood and Adolescent Immunization Schedule and ACIP fact sheet.*)

Subpart 4a(A). School-based early childhood program. This term is new to the law. The definition includes programs that serve children from birth to kindergarten entry in a classroom setting, whether in a school building or not, that meets at least once a week for at least six weeks or more during the year with the purpose of providing instructional or other services to support children's learning and development. It does not include drop-in playtime provided through a school-based early childhood program in a school or classroom setting.

Subpart 4a(B). School-based early childhood program. This subpart adds school-based early childhood programs that meet certain criteria to the Minnesota School Immunization Law (e.g., Early Childhood Family Education (ECFE), School Readiness, and other pre-kindergarten programs). Currently, the School Immunization Law only includes Early Childhood Special Education (ECSE) and certain child care settings for young children. This results in children from two different early education programs receiving services in the same classroom but having different immunization standards even though they are there for the same purpose, to prepare children to enter and succeed in school. For example, often children in ECFE, School Readiness programs, or other pre-kindergarten programs are co-mingled with children being served by ECSE through integrated classes. Federal law requires that children in ECSE be served in "the least restrictive environment"[5] settings. But only ECSE children are subject to the School Immunization Law; ECFE, School Readiness, and other pre-kindergarten programs enrolled children are not. Some school nurses expressed their frustration, based on how confusing it can be for parents and school health personnel to have two sets of enforcement criteria even though the children are receiving services together.

In addition, diseases do not discern between children in ECFE, School Readiness, other pre-kindergarten programs and ECSE; children in all of these programs are equally susceptible to disease. In fact, children in ECSE are more likely to have medical conditions, including immunosuppression, than those in ECFE, School Readiness, or other pre-kindergarten programs making them more vulnerable to vaccine-preventable disease and vaccine failure. In addition, children participating in School Readiness programs are most

[5] Least Restrictive Environment (LRE) § 300.114 LRE requirements**. (**a) General. …. "(2) Each public agency must ensure that—(i) To the maximum extent appropriate, children with disabilities, including children in public or private institutions or other care facilities, are educated with children who are nondisabled; and(ii) Special classes, separate schooling, or other removal of children with disabilities from the regular educational environment occurs only if the nature or severity of the disability is such that education in regular classes with the use of supplementary aids and services cannot be achieved satisfactorily."

often children with high needs (e.g., poverty, developmental concerns but not eligible for ECSE) which might make them more susceptible to vaccine-preventable diseases. In most cases, importantly, younger children are more at risk for death or disability due to vaccine-preventable disease complications.

Finally, many school districts already require immunization documentation for these types of programs, however, it is not consistent across the state. This change will ensure consistency across all school districts and equally protect young children, families, and staff across Minnesota. The Minnesota Department of Education's Early Childhood Program Specialist was consulted throughout the rulemaking process and was supportive of this change.

Some school nurses expressed concern that this would be difficult to enforce for those programs that do not meet often or do not have a set schedule, such as "drop in" classes. To address this concern, the department worked with early childhood staff from MDE to ensure this new requirement took this issue into consideration, which is why the school-based early childhood program must fit certain criteria to be included. This criterion is similar to "drop in" child care programs that are not included in the current immunization law.

Based on the information above and the ACIP's recommendation that all children are immunized according to the recommended childhood immunization schedule (See A*ttachment B, 2013 Recommended Childhood and Adolescent Immunization Schedule*), the department believes this proposed change is reasonable and necessary to protect all children and their family against vaccine-preventable diseases.

Part 4604.0410 Report

In this part, there are two proposed changes to the school and child care report requirements in Minnesota Statutes, section 121A.15, subdivision 8.

School Report. The first amendment to the school report is technical and requires schools to send their Annual Immunization Status Report (AISR) directly to the commissioner of the Minnesota Department of Health (MDH). Current law states that each school must submit an AISR to the Minnesota Department of Education, who then forwards it to MDH. But in current practice, the report is a web-based application managed by MDH. Changing this part of the law would formalize an efficiency made possible by technology that was not available when the law was written.

The second amendment changes the timing of the filing of the AISR. It states that a school must file the report within 90 days of the commencement of each new school term. Currently, the AISR must be filed within 60 days of the commencement of each new school term. This close proximity to the beginning of the school year burdens the schools administratively so that many schools ask for an extension each year, which is usually granted.

The AISR report contains unidentified, aggregated student immunization data. This information helps the department determine state-wide immunization rates and assists in planning immunization outreach and educational efforts. The department believes that this amendment will not change immunization rates, prompt disease outbreaks, or inhibit prevention efforts. Thus the change is reasonable and necessary to help the schools more accurately report their information.

Child Care Report. The first amendment is technical and requires child care centers to send their Annual Child Care Report (ACCR) directly to the commissioner of the Minnesota

Department of Health (MDH). Current law states that each school must submit an ACCR to the Minnesota Department of Human Services (DHS), who then forwards it to MDH. But in current practice, the report goes directly to MDH for administrative efficiency since DHS is not involved in the review of the report. This change would formalize the efficiency made possible by sending it directly to MDH.

The second amendment changes the timing of the filing of the ACCR. It states that the report must be filed by December 1 of each year. Currently, the ACCR must be filled by November 1 of each year. This change would make it consistent with the change for the school report. Even though many children attend child care year round, many centers have an influx of children in the fall that coincides with the beginning of the school year.

Similar to the school report, this report contains unidentified, aggregated child care immunization data. This information helps the department determine state-wide immunization rates and assists in planning immunization outreach and educational efforts. The department believes that this amendment will not change immunization rates, prompt disease outbreaks, or inhibit prevention efforts. Thus, the change is reasonable and necessary to help the child care centers more accurately report their information.

Part 4604.0520 Polio Vaccination Requirement

This part amends the polio vaccine requirement so that a child's age-based dose corresponds to current medically accepted standards. Currently, under Minnesota Statutes, §121A. subdivision 4(b) a person aged six or younger who is enrolling in an elementary school must have a statement showing that he or she has received "no less than four doses of vaccine for poliomyelitis, unless the third dose was given after the fourth birthday". . . . The statute further contains an exception that if the third dose was after the child's fourth birthday, "then three doses are minimum."

This medical standard is outdated. The current ACIP standard states that the last dose should always be given on or after the child's fourth birthday. But under Minnesota law, if a child younger than four years old had all four doses, he or she he or she would not be required to have another dose at age 4. . . . That goes against the national recommendation, which the ACIP developed to ensure the optimum protection for the child and the community in which he or she lives. Even though polio disease has been eradicated in the United States and the western hemisphere, persons in other parts of the world still get the disease, which can be spread through international travel. For example, in 2011, Nigeria experienced a four-fold increase in polio cases and the disease spread to other countries.[viii,ix] There were 650 reported cases of polio globally that year.[x] Closer to home, in the past decade, in Minnesota two situations occurred in which non traveling, immunosuppressed Minnesotans were diagnosed with polio infection and disease that originated from the oral polio vaccination. High vaccination rates stopped a disastrous outbreak from occurring.

Moreover, the difference between the immunization law and the national recommendation causes confusion among school nurses and health care providers. To ensure that health care providers, schools, and parents are not administratively burdened by this proposed change, children who completed their polio vaccination series before September 1, 2014, will be excluded from this amendment.

Based on the information above, the department believes this amendment is reasonable and necessary to ensure children are protected against this devastating disease and allow the department to keep up with new recommendations.

Part 4604.0530 Tetanus, Diphtheria, and Pertussis Vaccination Requirement

This part amends the dose requirement for a child's DTaP vaccine so that it will correspond to current medically accepted standards. The DTaP vaccine contains antigens against diphtheria, tetanus, and pertussis diseases.

Currently, under Minnesota Statutes, Section 121A, subdivision 4(b), a child aged six years or younger, who is enrolling in an elementary school, must show proof of having received "no less than five doses of vaccine for diphtheria, tetanus, and pertussis." The statute continues with an exception: "unless the fourth dose was given after the fourth birthday, then four doses are minimum." This means that if a child under 4 years old had all five doses, he or she would not be required to have another one between the ages of 4 and 6. But the statute is outdated. The ACIP's current medical standard states that the last dose should be given between 4 and 6 years of age. Thus, current law goes against the national recommendation, which the ACIP developed to ensure the optimum protection for children and the communities where they live.

Pertussis (also referred to as whooping cough) is still very much present in the United States and is highly contagious. In fact, as of December 31, 2012, the number of pertussis cases in Minnesota surged to 4,433, which exceeded the total number of cases (661) reported in 2011 and the highest number of cases seen since the 1940s. (For more information on pertussis disease, see pages 38-42 in this SONAR.)

Moreover, the difference between the immunization law and the recommendation causes confusion among school nurses and health care providers. To ensure that health care providers, schools, and parents are not administratively burdened by this proposed change, children who completed their DTaP vaccination series before September 1, 2014, will be excluded from this amendment.

Based on the information above, the department believes this amendment is reasonable and necessary to ensure children are protected against pertussis, which is a highly contagious disease.

Parts 4604.0600, Changes in Measles, Mumps, and Rubella Vaccination Requirement; 4604.0810 Hepatitis B Vaccination; and 4604.0900, Subpart 2 New Varicella Vaccination Requirement

These three amendments reflect a change that many school nurses have requested. It allows elementary and secondary schools to verify immunizations no matter what grade the student is in and thus require that they get missing ones to enroll or remain in school. Current law only requires enrolling students show proof of MMR, hepatitis B, and varicella immunizations or a legal exemption in kindergarten and seventh grade. This change will give schools the authority to verify that a child is immunized or has taken a medical or conscientious exemption, regardless of the grade. (Note: The department is not proposing a change in the Annual Immunization Status Report (AISR) requirement for these vaccines. Reporting to the department will still only be at kindergarten and seventh grade.)

There are several reasons for this change. First, many school nurses have pointed out that it is confusing to parents that some vaccines are required in every grade (such as polio and tetanus) and some are not (varicella, hepatitis B, MMR). The law is not consistent because one child entering kindergarten may be required to show documentation for MMR but their sibling entering 3rd grade does not. It is not practical in terms of disease prevention because diseases can occur regardless of what grade a child attends. A child can get any of these vaccine-preventable diseases no matter the age; there is no "artificial line protecting students in one grade but not another. This change will treat all immunizations the same and reflect current medical standards. A nurse on the Immunization Rulemaking Advisory Committee stated that it is difficult to have conversations with parents about inconsistent recommendations and she would rather see a kindergarten through 12th grade requirement.

Second, the diseases for which these three vaccines protect against still circulate globally, albeit at smaller numbers than in the past. In fact, Minnesota and the United States have seen a resurgence of measles. In Minnesota in 2011, there were 26 cases of measles (20 of these cases were linked to a person who travelled internationally) and an estimated 436 cases of chickenpox, 80 percent of which occurred in students in kindergarten through sixth grade. Having "check points" for kindergarten and seventh grade for some vaccines (e.g., varicella and MMR) and only providing recommendation for all other grades is not effective in a mobile population. Children are sometimes missed in either kindergarten or seventh grade. Allowing schools to check for the immunization documentation at any grade will ensure that all children and the school community are protected from these vaccine-preventable diseases.

Finally, a physician who sees a majority of Latino families expressed strong support for this provision during one of the public meetings in June. She said that this population tends to be very mobile, moving from school to school and sometimes from state to state. Therefore, being able to check at every grade is crucial to ensure that these children are protected against vaccine-preventable diseases and do not spread infectious diseases to others.

The department believes these amendments are reasonable and necessary to ensure children are protected against these diseases that are still circulating in the community.

Part 4604.0900, Subpart 1 New Varicella Requirement

Subpart 1. Requirement for child care enrollees. This part amends the current law by changing the age that parents or guardians must produce documentation showing receipt of

the varicella (chickenpox) vaccine, history of disease, or a legal exemption from 18 months to 15 months for children enrolling in child care and school-based early childhood programs. The current rule states that children who are 18 months or older enrolled in child care in the state must submit this documentation. When the rule was implemented in 2003, the medically acceptable standard for receiving the first varicella vaccine was 15 to 18 months. The current medical standard for the timing of the first varicella vaccine is now between 12 and 15 months (*See Attachment B, 2013 Recommended Childhood and Adolescent Immunization Schedule)*. The department believes this change is reasonable and necessary to align the immunization law with current medical standards to ensure children are protected from this vaccine-preventable disease.

To ensure that health care providers, schools, and parents are not administratively burdened by this proposed change, children who received their first varicella vaccination before September 1, 2014, will be excluded from this amendment.

Part 4604.0900, Subpart 4 New Varicella Requirement

Subpart 4(D). Documentation of disease history. This proposed amendment is technical and clarifies the original intent of the law when it was written in 2003. Currently, if a child has varicella, the law allows for four different methods of documentation. One of these methods is,

> "on or before August 31, 2010, the signature of the child's parent or legal guardian and must include the year that the child had the varicella disease. This item expires September 1, 2010."

When this documentation method in the law expired in 2010, parents could no longer sign off, saying their children had had the chickenpox. They now have to get a health care provider's signature for this requirement. The intent of the 2003 law was that only children who had varicella disease in 2010 or later must have provider documentation of disease, such as a provider's signature or an electronic immunization record from the provider's office. Children who had varicella disease before 2010 were only required to provide the month and year of the disease and the parent's or guardian's signature; no health care provider's signature was needed. But it was confusing to parents, school nurses, and health care provides because, as the rule was written, it appears that no matter what year the child had the disease a provider's signature is needed after 2010.

This change is necessary and reasonable to clear up the confusion regarding the 2003 law.

Part 4604.0815 Documentation of Hepatitis B Vaccination

This new vaccination requirement adds hepatitis B vaccination to the list for all children over 2 months old enrolling or enrolled in child care or a school-based early childhood program. They must show documentation of either receipt of the hepatitis B vaccine according to medically acceptable standards or a legal exemption. Currently, both the ACIP and the department recommend children begin the three-dose series of hepatitis B vaccine at birth. But there is no hepatitis B immunization requirement for children in child care. Only children in kindergarten and seventh grade must show documentation of receipt of this vaccine or a legal exemption.

The department concludes that this change is reasonable and necessary to ensure that all children are protected against this serious and sometimes fatal disease. Rates of hepatitis B infection are highest in adults, but chronic infection is more likely to occur in infants and young children.[xi] There is no cure for chronic hepatitis B infection. The hepatitis B vaccine is the most effective means to prevent transmission of the hepatitis B virus (HBV) and to offset the clinical (disease) consequences and health care costs associated with it. Hepatitis B is a potentially life-threatening virus. Disease in young children disproportionately contributes to chronic hepatitis B in adults, which can cause severe liver disease, including liver cancer.

This proposed change reflects national immunization recommendations made in 1991 by ACIP[xii], as well as standard medical practice as recommended by the AAP and the AAFP. Currently, 47 states (94 percent) require the hepatitis B vaccine for children in child care, elementary, or secondary school. Forty-one of these states (82 percent) require it for child care enrollment. This is up from 34 states in 2003 when the department last revised the School Immunization Law.

The vaccination strategy to reduce the incidence of disease and death due to hepatitis B has evolved over the years.[xiii]

- In 1982, ACIP published its first official recommendation on the use of the vaccine, initially recommending vaccination of persons at increased risk of hepatitis B infection.
- In 1988, ACIP recommended screening all pregnant women and treating infants born to hepatitis B-infected women.
- In 1991, recognizing the difficulty of identifying persons at risk for hepatitis B and the fact that 30 to 40 percent of chronic hepatitis B infections occur in childhood, the ACIP recommended universal infant vaccination.
- In 1995, the ACIP recommended the routine vaccination of all adolescents at 11 to 12 years of age who had not been vaccinated previously.
- Finally, in 1999, the ACIP recommended all previously unvaccinated children less than 19 years old be vaccinated.

The original strategy to vaccinate only those thought to be at increased risk for hepatitis B disease was unsuccessful for several reasons: 1) it was hard to reach certain at risk persons for vaccinations; 2) the disease can be transmitted to those who do not have a risk factor – about 16 percent of adults did not have an identified risk factors; 3) many people who have the disease do not know it and therefore do not take precautions to prevent transmission; and 4) providers were unable to adequately identify those persons at increased risk of HBV infection. As a result, the incidence of hepatitis B in the United States remained unchanged 10 years after the vaccine was introduced (1981-1991). In addition, targeting vaccination only to adults with risk factors did not address prevention of chronic hepatitis B in which young children play a major role. Hepatitis B could not be eliminated unless chronic disease was prevented. For this reason, in 1991, the vaccine strategy was changed to recommend vaccination of hepatitis B for all infants. If we continue with this strategy, we have a chance of eliminating or greatly reducing the incidence of this disease in the United States in one or two generations.

Epidemiology and Morbidity/Mortality Rates of the Disease

Clinical Manifestations

Hepatitis B is a serious disease that affects the liver. Chronically infected people may suffer health problems, such as cirrhosis (liver damage) or liver cancer.[xiv,xv] The hepatitis B virus (HBV) is a leading cause of liver cancer in the United States.[xvi] HBV can also cause short-term and sometimes severe (acute) illness that leads to loss of appetite, tiredness, diarrhea, vomiting, jaundice, and pain in the muscles, joints, and stomach, and in some instances death.

Hepatitis B is known as the "silent epidemic" because many chronically-infected people, especially children, do not experience symptoms until decades later when they develop liver disease, including cirrhosis or liver cancer.[xvii] Fifty percent of adults and up to 90 percent of children who have acute infections show no symptoms.[xviii] Some people who become infected with HBV may not have any symptoms but will become chronically infected and be able to infect others.

Epidemiology
Since routine hepatitis B vaccination was implemented, the rates of hepatitis B disease have dramatically decreased in the United States, particularly among children -- 82 percent since 1991.[xix]

Worldwide it is estimated that 240 million persons are infected with hepatitis B and an estimated 600,000 people die each year from hepatitis B and its complications. In the United States today, approximately 800,000 to 1.4 million persons have chronic HBV infection. From 2005-2010, there were approximately 3,300-5,400 new (acute) hepatitis B infections reported in the United States annually. But this number is likely higher as many infections are unreported due to asymptomatic HBV infections. CDC estimates that 3,000 Americans die each year from hepatitis B and its complications.[xx]

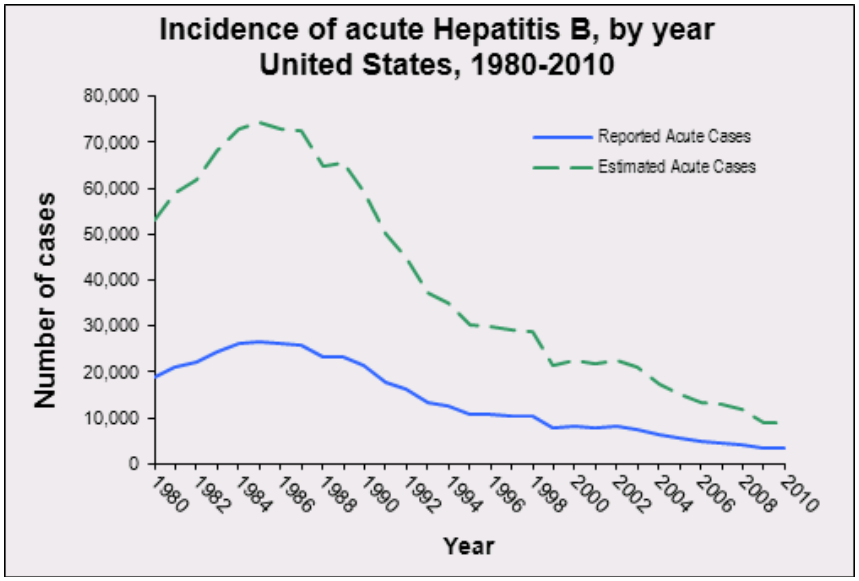
Disease Burden for Hepatitis B in the United States[xxi]

	2005	2006	2007	2008	2009	2010
Number of acute cases reported[6]	5,494	4,758	4,519	4,033	3,374	3,350
Estimated number of acute clinical cases	15,000	13,000	13,000	12,000	9,000	9,000
Estimated number of new infections	53,000	46,000	43,000	38,000	38,000	38,000
Percent ever infected	4.3% - 5.6%					
Number of persons living with chronic infections	800,000 – 1.4 million					
Annual number of chronic liver disease deaths associated with HBV	3,000					

In 2010 (the most recent data), 3,350 cases of acute hepatitis B in the United States were reported to CDC; the lowest incidence ever recorded.[xxii] But because many hepatitis B infections are either asymptomatic or never reported, the actual number of

[6] Number of cases reported to the National Notifiable Disease Surveillance System (NNDSS)

new infections is estimated to be tenfold higher. In 2010, an estimated 38,000 persons in the United States were newly infected with hepatitis B virus (HBV).[xxiii] The graph below shows the decline in incidence of acute hepatitis B infection over the last 30 years.



Childhood Risk

Before routine infant hepatitis B vaccination of infants was recommended in the early 1990s, it was estimated that HBV was infecting 16,000 children younger than 10 years annually. The total estimate, not including perinatal infections, ranged from 12,000 to 24,900.[xxiv] This is significant because the younger a person is infected the more likely he or she is to develop a chronic hepatitis B infection and its long term consequences. In infants, initial infection is asymptomatic in nearly 100 percent of cases. As many as 90 percent of infants who acquire HBV infection from their mothers at birth become chronically infected if not treated immediately.[xxv] Of children who become infected with HBV between one and five years of age, 30 to 50 percent become chronically infected. In addition, up to 25 percent of persons who acquire chronic HBV infection as infants and young children develop chronic liver disease which can lead to cirrhosis or liver cancer compared to 15 percent of adolescents and young adults who acquire chronic HBV infection. By adulthood, the risk of chronic HBV infection is approximately five percent in those who get a new infection.[xxvi,xxvii,]

Transmission

Hepatitis B virus is spread by direct contact with infected blood, semen, saliva, or wounds that secrete fluids. It is not spread through food, water, or casual contact. The hepatitis B virus is 50-100 times more infectious than the HIV virus that causes AIDS. You get hepatitis B by:

- birth (spread from an infected mother to her baby during birth)
- having sex with an infected person,
- sharing equipment used to inject drugs,
- getting a tattoo, or body piercing with unsterile equipment
- getting pricked with a needle or some other instrument that has infected blood on it,

- sharing a toothbrush, razor, washcloth, or some other contact with bodily fluids of an infected person, or
- being bitten by an infected person.

The CDC estimates that 63 percent of hepatitis B cases result from sexual contact, 16 percent result from injection drug use, 5 percent result from household contact with a chronic carrier, travel, and health care. Sixteen percent have no identified risk factor for infection.

A person who has acute HBV is infectious from one to two months before and after onset of symptoms.

While a number of children infected acquired HBV from their mother during birth and screening of pregnant women can identify those who have HBV infection, many young children do not acquire the infection from their mother at birth. Some children acquire HBV infections from either another family member or someone else who comes in contact with the child. Unvaccinated children in families with no known risk factors are still at risk of infection through normal play activities. The sources of their infection are unknown, but HBV could be transmitted through contact with sores (as occurs in playground abrasions), by sharing contaminated objects (such as toothbrushes), and by being bitten.[xxviii, xxix, xxx] In addition, HBV is very stable on environmental surfaces. The virus can live on surfaces for up to seven days, even when no obvious blood is present, thus allowing for indirect infection.

Because hepatitis B can be transmitted by routes other than sexual contact and injection drug use, and because many people who are infected with hepatitis B virus do not know that they have it, it is virtually impossible to be "careful enough" to avoid this infection, which is why vaccination is the best way to protect against it.

Safety and Efficacy of Hepatitis Vaccine

There are two manufacturers of hepatitis B vaccine, GlaxoSmithKline and Merck, and the vaccines were licensed in 1986 and 1989 respectively.[7] Before licensure, the Food and Drug Administration (FDA) reviewed safety and efficacy information on these vaccines and concluded that they were safe and effective. In addition, before adding a vaccine to the childhood schedule, the ACIP reviews safety and efficacy data from both the clinical trials that led to its licensure and peer-reviewed literature. Finally, on-going safety monitoring occurs after the vaccine is licensed. (*See Attachment G, Ensuring the Safety of Vaccines in the United States Fact Sheet.)*

Safety

Studies have found that the hepatitis B vaccine is safe.[xxxi] It has been in use for over 25 years and few serious side effects have been noted. The most common adverse reaction following hepatitis B vaccination is pain at the injection site, a condition reported in three to nine percent of children. Mild systemic complaints, such as fatigue, headache, and irritability have been reported in zero to 20 percent of children. Low-grade fever has

[7] The hepatitis B vaccine is available in four different formulations: Hep B Recombinant (alone); Hep B in combination with *Haemophilus influenzae* type b (Hib) vaccine; Hep B in combination with DTaP (Diphtheria-Tetanus-acellular Pertussis) and inactivated polio vaccines; Hep B in combination with hepatitis A vaccine.

been reported in 0.4 to 6.4 percent of children. Serious systemic events and allergic reaction are rarely reported following the hepatitis B vaccine.[xxxii]

While the hepatitis B vaccine can cause mild side effects like those mentioned above, major complications are rare. One of out every 600,000 hepatitis B vaccinations has been alleged to cause or exacerbate multiple sclerosis (MS). But several studies have evaluated this possible relationship and the weight of evidence does not support this hypothesis.[xxxiii,xxxiv,xxxv]

Critics of immunizations cite Vaccine Adverse Reporting System (VAERS) data to show that the hepatitis B vaccination is unsafe. VAERS is a post-licensure safety surveillance program, collecting information about possible adverse events (side effects) that occur after the administration of vaccines licensed for use in the United States. Health care providers, manufacturers, and the public may submit a report to VAERS. FDA continually monitors VAERS reports for any unexpected pattern or change in rates of adverse events. CDC reviews each report as well. The report of an adverse event to VAERS is not proof that a vaccine caused an event. The CDC VAERS website states:

> "When evaluating data from VAERS, it is important to note that for any reported event, no cause-and-effect relationship has been established. Reports of all possible associations between vaccines and adverse events (possible side effects) are filed in VAERS. Therefore, VAERS collects data on any adverse event following vaccination, be it coincidental or truly caused by a vaccine. The report of an adverse event to VAERS is not documentation that a vaccine caused the event."
> http://vaers.hhs.gov/data/index

Physicians and other health care providers are encouraged to report adverse events, whether or not they believe the vaccination was the cause. Anybody can report to VAERS and it is considered a passive surveillance system. If VAERS data suggest a possible link between an adverse event and vaccination, the relationship will be furthered studied. Analyzing VAERS reports is a complex task. Without fully understanding its limitations, results from VAERS can easily be misinterpreted. For this reason, it is incorrect and misleading to cite VAERS data to show that a vaccine causes a specific number of adverse events or deaths. (*For more information on VAERS see Attachment H, Understanding the Vaccine Adverse Events Reporting System*.)

Efficacy

The hepatitis B vaccine has been shown to be very effective in children. After three doses, over 95 percent of infants, children, and adolescents develop protective antibody responses. [xxxvi] A recent study in Taiwan found that vaccination against hepatitis B appears to protect against the virus for at least 25 years. The authors found that study participants younger than age 25 were far less likely to be infected than those between the ages of 26 and 30 -- who were born before universal vaccination.[xxxvii]

A study of Alaskan natives in a region where HBV is endemic found that transmission of HBV infection was eliminated among children born since the introduction of a hepatitis B immunization program that included routine vaccination of all infants and screening of pregnant women.[xxxviii]

> Critics of the vaccine believe that the hepatitis B vaccine does not induce long-term immunity because the protective antibody specific for the hepatitis B virus wanes and may reach low or even undetectable levels (titers) within a few years. However, studies, such as the one cited above, show that this decline does not imply loss of protection from the vaccine, as long as there is immunologic memory for the antigen. Exposure to hepatitis B virus infection is usually followed by an extended incubation period lasting for several weeks or months. During that time, the virus stimulates memory cells produced as a result of the vaccine which then multiply and produce sufficient antibodies to prevent an infection. In addition, if a vaccinated person is exposed to HBV and gets the disease, they do not become as ill because the immune memory in both adults and children provide sufficient protection against significant HBV infection. Chronic HBV infection has rarely been seen among vaccine recipients.[xxxix,xl,xli]

Cost-Effectiveness of Hepatitis B Vaccine

Children who start the series at birth will need a total of three doses of the vaccine. Each dose is approximately $9 in the public sector and approximately $26 in the private sector.

A study in the Journal of the American Medical Association found that from a medical cost perspective, hepatitis B immunization does not result in a cost saving. But from a societal perspective, routine infant and early childhood immunization would save millions in medical and work-loss costs.[xlii] The authors point out:

> "Even though the risk of HBV infection is relatively low in the United States, HBV-related morbidity and mortality are greater than for most vaccine-preventable diseases. Because the large reservoir of persons with chronic HBV infection allows disease transmission over a wide range of ages, vaccination of all infants, children, and adults would be the ideal means to stop HBV infection."

Furthermore, childhood hepatitis B infection has implications not only for one's personal health outcomes but also for the public's health, including the adequacy of the nation's blood supply because persons with HBV infection cannot donate blood.

Cost of Enforcing Hepatitis B Vaccination Requirement

This is a new requirement for child care and early childhood programs, which will be responsible for enforcing it along with other required childhood vaccines. The cost to most child care facilities should not be high because providers will check for this vaccine upon enrollment, which will be at the same time they check for all other vaccinations. Child care facilities by law must also check a child's vaccination history each time a child moves to a new class. Some of the school districts that have early childhood programs might find their administrative burden increased with the new requirement. But many school districts already require immunization documentation for school-based early childhood programs, though it is not consistent across the state. The department is committed to helping these facilities implement this requirement. For example, most schools and many child care facilities have access to the Minnesota Immunization Information Connection (MIIC), a secured web-based system that keeps track of a child's immunization record. The department is currently working with child care facilities to increase usage of MIIC.

Finally, the Immunization Rulemaking Advisory Committee included representatives from two child care organizations. They were the Minnesota Licensed Family Child Care Association (MLFCCA), which represents family child care, and the Minnesota Child Care

Association (MCCA), which represents child care facilities. Both of these representatives expressed support for this requirement to ensure that children and staff are protected from this disease. The Minnesota Department of Education's Early Childhood Program Specialist, who was consulted throughout the rulemaking process, supports this change.

There will be no cost to the state to implement this requirement. Currently, the hepatitis B vaccine is part of the federal Vaccines for Children (VFC) program, which covers ACIP-recommended vaccines. The VFC program is a federally funded entitlement program that pays for vaccines for children who are uninsured, Minnesota Health Care Program (MHCP) enrollees, American Indians, Alaskan Natives, and certain underinsured children. Because hepatitis B vaccine is ACIP-recommended, most private insurers already cover the cost of the vaccine for infants and children, thus the costs are included in their standard plans. The department did not hear from any private insurers opposing this requirement. Moreover, the federal Affordable Care Act (ACA) requires full coverage of all ACIP-recommended vaccines. Some insurance plans currently have grandfathered status in relation to the ACA and are able to require consumers to pay for immunizations, but the number of grandfathered plans is quickly decreasing.

Opposition to New Hepatitis B Requirement

Critics of the hepatitis B vaccine argue that it should be targeted to only those at increased risk (e.g., injection drug users, gay men, health care workers, those who have multiple sexual partners, and immigrants). However, there are many reasons why this is not a reasonable strategy. First, as the ACIP pointed out in their 1991 hepatitis B recommendations, targeting only those at increased risk did not stop the spread or lower the incidence because many of those who have the disease do not know it. More importantly, the disease also spreads to those who are not at high-risk and have no known identified risk factor. Finally, our society does not segregate people; children in child care and early childhood programs go to school with children whose parents may be at increased risk for HBV infection.

Critics of the vaccine also argue that since there is a recommendation that pregnant woman are tested for hepatitis B, we can identify infants at risk of acquiring the disease and treat them at birth. But this proposed change addresses all children in child care and early childhood programs, not just infants. As pointed out earlier, about 16 percent of cases have no identified risk factor for infection and not all disease is passed from mother to child at birth.

According to the National Immunization Survey (NIS), Minnesota's hepatitis B vaccination rate is currently at 89.5 percent among children ages 19 to 35 months. Critics of immunization laws cite this statistic as a reason for not including the hepatitis B vaccine for children in child care and school-based early childhood programs in the proposed changes. They believe the rate is high enough The department does not agree with this conclusion. It is important to ensure that all children entering child care and early childhood programs are immunized to protect against HBV. Though the current immunization rate of 89 percent is good, this is no guarantee that it will remain at that level. Only an immunization requirement can guarantee the vaccination rate will increase. Studies have also shown that immunization laws help decrease health disparities by ensuring that children are immunized regardless of where they live, their socioeconomic status, or their race and ethnicity.[xliii]

Summary – Hepatitis B

There are many misperceptions about hepatitis B disease, including the dangerous misperception that young children are not at risk. While the majority of acute hepatitis B disease is diagnosed in young adults who partake in risky behaviors, young children are still at risk for contracting hepatitis B disease through normal play activities since the virus is transmitted through blood and other body fluids such as saliva. Without vaccination, the burden of chronic hepatitis B disease would continue to reside in our younger population. High immunization levels prevent the deadly and costly consequences of chronic hepatitis B disease. Thus, the department believes that it is reasonable and necessary to require hepatitis B vaccine for all children over 2 months entering child care or a school-based early childhood program. As always, parents or guardians will have the option of a legal exemption if they are conscientiously opposed to the vaccination or the vaccine is medically contraindicated.

Part 4604.0820 Documentation of Hepatitis A Vaccination

This is a new vaccination requirement for all children 12 months and older who are enrolling or enrolled in child care or a school-based early childhood program to show documentation of receipt of the hepatitis A vaccine according to medically acceptable standards or a legal exemption. Currently, both the ACIP and the department recommend children begin the hepatitis A vaccine two-dose series at 12 months, but there is no hepatitis A immunization requirement for children in child care or school-based early childhood programs.

The department concludes that this change is reasonable and necessary to ensure that all children are protected against this disease, and indirectly, the older members of the community. The hepatitis A vaccine is one of the most effective means to prevent transmission of the hepatitis A virus (HAV) and to offset the clinical (disease) consequences and health care costs associated with it. Hepatitis A is a potentially life-threatening virus, and young children disproportionately contribute to the spread of hepatitis A.

This recommended change reflects national immunization recommendations made in 2006 by the ACIP[xliv], as well as medically acceptable standards as recommended by the AAP, and the AAFP. Currently, 16 states require the hepatitis A vaccine for children in child care. Eleven of these states implemented the requirement after 2003, when the department last revised the School Immunization Law.

The vaccination strategy to reduce the incidence of disease and death due to hepatitis A has evolved over the years. Following its introduction in 1995, hepatitis A vaccine was primarily targeted to persons at increased risk for HAV infection, such as international travelers and injection drug users. In addition, hepatitis A was recommended for routine vaccination in children 2 years or older living in communities with high rates of hepatitis A. While this strategy prevented infection in travelers and reduced disease in high incidence communities, it had little or no impact on the overall incidence of HAV infection in the United States.

In 1999, ACIP expanded their recommendation for routine hepatitis A vaccination to include all children 2 years of age and older. The ACIP urged that it recommendation for hepatitis A vaccine be implemented in states, counties or communities where there was moderate incidence of hepatitis A disease. As a result, the largest declines in disease incidence were in areas in which routine vaccination of children was occurring. In comparison, the highest rates of disease incidence occurred in areas where vaccination was not recommended.

Based on the successful implementation of childhood hepatitis A vaccination programs in high-incidence areas and the availability of a vaccine product that could be given as early as 1 year of age, ACIP recommended in 2005 that all children should receive hepatitis A vaccine at 12 through 23 months of age. ACIP continues to recommend that the previously targeted regions with existing hepatitis A vaccination programs for children 2 through 18 years of age maintain these programs.[xlv]

Epidemiology and Morbidity/Mortality Rates of the Disease

Clinical Manifestations

Hepatitis A is a serious viral disease that affects the liver. Symptoms usually occur suddenly with onset of fever, fatigue, nausea, abdominal discomfort, dark urine, and yellowing of the eyes and skin (jaundice). The period between exposure to hepatitis A virus and onset of illness is usually 28 days, with a range of 15 to 50 days. Clinical illness usually does not last longer than two months, although 10 to 15 percent of persons have a longer illness or relapsing signs and symptoms for up to six months. Hepatitis A disease does not become a chronic (long-term) infection, but it can result in severe consequences, such as liver failure and death.

The likelihood of symptomatic illness is related to age of infection. Most infections (70 percent) are asymptomatic in children younger than six years of age. In older children and adults, the infection is usually symptomatic, with jaundice occurring in more than 70 percent of patients.

Hepatitis A disease can be quite serious. Among reported cases of hepatitis A, eleven to twenty-two percent required hospitalization, with people age 60 and over more likely to be hospitalized.[xlvi] Days to weeks of school or work are missed due to the illness. Death and hospitalization from hepatitis are rare in healthy young people. But in the United States, every year about 60-100 people die from hepatitis A virus infection with older persons being the most likely to die from it.[xlvii] In 2007, a person in Minnesotan contracted hepatitis A and subsequently died from complications of hepatitis A.

Epidemiology

Hepatitis A virus infections occur throughout the world and there are an estimated 1.4 million cases per year globally.[xlviii] In 2010, 1,670 cases of hepatitis A were reported in the United States. But this number is likely higher as many infections are unreported due to asymptomatic HAV infections. CDC estimates that there are about 17,000 infections a year. In particular, cases in children are less likely to be reported since children are often asymptomatic or have mild disease. Moreover, one-third of Americans exhibit evidence of past infection.[xlix] However, once a person is infected, they develop antibodies and will have lifelong protection from the disease.[l]

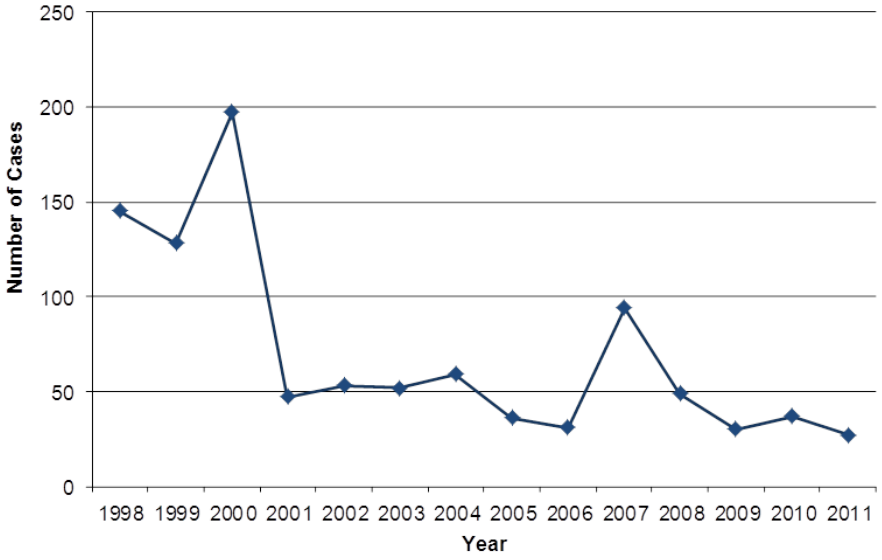
In general, the incidence of hepatitis A infection in the United States has been cyclic, with nationwide increases occurring every 10 to 15 years. But in the United States, the rates of hepatitis A infections are the lowest they have been in 40 years. Many experts believe hepatitis A vaccination (licensed in 1995) has dramatically reduced the incidence, though it remains one of the most frequently reported vaccine-preventable diseases in the United States.

Disease Burden for Hepatitis A in the United States[li]

	2004	2005	2006	2007	2008	2009	2010
Number of acute cases reported[8]	5,683	4,488	3,579	2,979	2,585	1,987	1,670
Estimated number of acute clinical cases	24,000	19,000	15,000	13,000	11,000	9,000	7,000
Estimated number of new infections	56,000	42,000	32,000	25,000	22,000	21,000	17,000
Persons ever infected	29.1% - 33.5%						

Minnesota Information
In Minnesota, rates have followed the national downward trend. See graph below.

Number of Hepatitis A Cases per Year in Minnesota, 1998-2011



In 2007, there were a surge of cases due to eight separate hepatitis A outbreaks in Minnesota, which accounted for 45 percent of the cases. Three of the outbreaks were foodborne outbreaks, including an outbreak in Slayton, Minnesota, which was traced back to a restaurant. The Slayton outbreak accounted for 16 of the cases, and resulted in three hospitalizations, and one death.[lii] In addition, the contact investigation included two child care facilities and resulted in vaccinating children who should have been vaccinated but were not.

In 2010, within the 37 cases reported, there were three outbreaks of three, four and 11 cases respectively. Three cases with an unidentified source occurred in family members from Anoka and LeSueur counties. An outbreak in a family who recently adopted a child

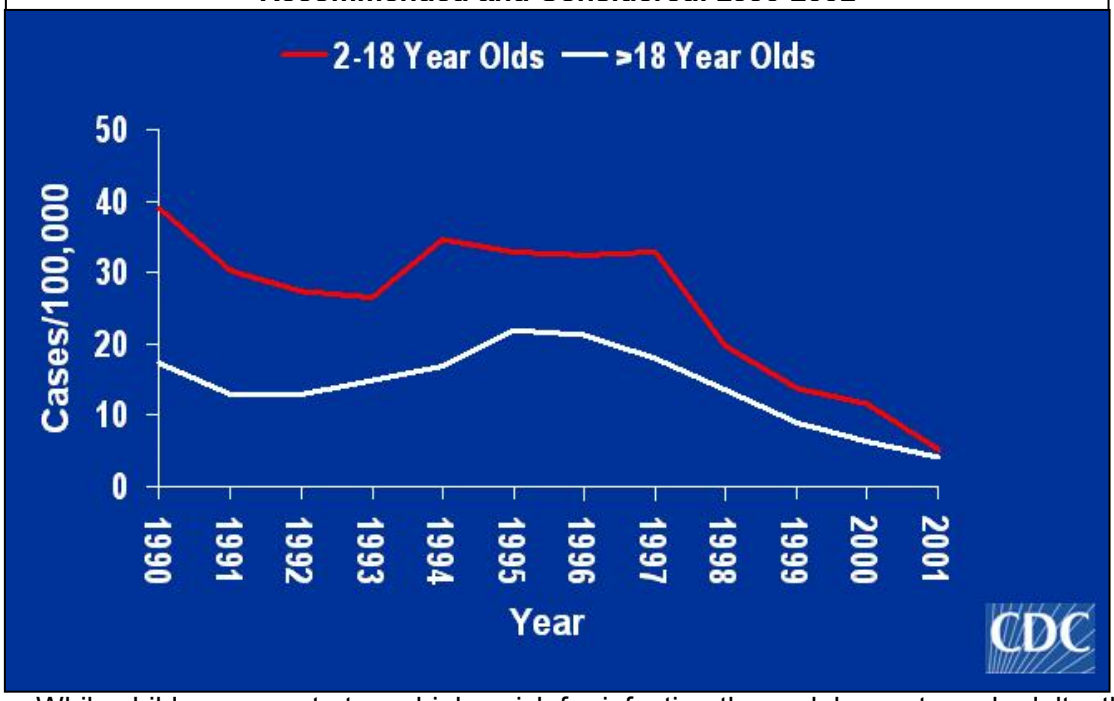
[8] Number of cases reported to the National Notifiable Disease Surveillance System (NNDSS)

from Haiti accounted for four cases. Thirteen cases were associated with an outbreak in Cottonwood County with no identified source.

Data from the most recent year, 2011, reveals that there were 27 cases of HAV reported. Cases ranged in age from 3 to 86 years (median age 27 years). A risk factor was identified for 20 cases, including two who were exposed to a confirmed hepatitis A case and 12 were associated with travel.

Childhood Risk
Historically, children 2 through 18 years of age have had the highest rates of hepatitis A disease, with children under five having the highest incidence of infection. [liii] (See graph below.) However since 2002, rates among children have declined, which many believe is due to the introduction of hepatitis A vaccine in 1995 and the expanded recommendation for routine hepatitis A vaccination to include all children 2 years of age and older.

Incidence of Hepatitis A By Age Group in States Where Vaccinations is Recommended and Considered. 1990-2001



While children are not at any higher risk for infection than adolescents and adults, they can spread hepatitis A virus to their contacts when infected but asymptomatic. Approximately 70 percent of infections in children 6 years of age and under are asymptomatic. Because young children are often still in diapers, are not aware of hygiene practices, and explore their environment with their mouths as well as their hands, they are at increased risk for acquiring and transmitting fecal-oral pathogens, such as hepatitis A virus. Thus, they play an important role in transmission of the disease and serve as an unknowing source of infection, particularly for household or other close contacts, such as child care contacts.

As stated earlier, incidence of hepatitis A declined sharply in states with historically consistent elevated rates that were included in the 1996 and 1999 ACIP

recommendations for routine vaccination of children in high incidence communities. As a result, the majority of hepatitis A cases during recent years have been reported from states with historically low rates of vaccination where hepatitis A vaccination of children was not routine.[liv] In addition, the narrowing or elimination of national differences in age, race/ethnicity, and state-specific rates can be attributed largely to changes that occurred in the targeted communities in which routine hepatitis A vaccination of children was recommended and implemented. For example, in 2004, prior to the universal recommendation, approximately two thirds of the nearly 6,000 cases were reported from states without childhood vaccination recommendations.[lv]

Transmission

Hepatitis A is spread by a virus found in the feces (stool) of a person who has hepatitis A infection. A person gets infected when the hepatitis A virus gets into his or her mouth. The route of transmission can be person-to-person or ingestion of contaminated food or water.

Some common examples of how it is spread include:

- When an infected person touches objects or food after using the toilet without proper hand washing
- When changing the diaper of someone infected but not washing hands afterwards
- During some sexual practices, such as oral-anal contact
- By eating or drinking something contaminated with HAV. The food and drinks most likely to be contaminated are fruits, vegetables, shellfish, ice, and water. In the United States, chlorination of water kills Hepatitis A virus that enters the water supply.
- Sharing equipment used to inject drugs

A person with hepatitis A infection can spread the disease beginning two weeks before symptoms develop until one week after the onset of jaundice. If a person does not have jaundice, he or she is considered infectious for two weeks after the onset of symptoms. Symptoms, if they occur, develop two to seven weeks (usually about one month) after exposure to hepatitis A. Children may pass the virus to family members or caregivers without ever appearing ill. Approximately 70 percent of children do not exhibit symptoms of the disease.

Most people do not get infected with HAV when a food handler at a restaurant has Hepatitis A. But if an infected food handler is infectious and has poor hygiene, the risk increases. A review of published studies about foodborne outbreaks in the United States found that infected food handlers who handled uncooked food, or food after it was cooked during their infectious period, were the most common sources of published foodborne outbreaks.[lvi]

On rare occasions, the source of the infection can be traced to contaminated food in non-restaurant settings. Foods can become contaminated at any point along the food distribution process: growing, harvesting, processing, handling, and even after cooking.

Historically, in the United States, most hepatitis A cases occur during community-wide outbreaks in which many cases did not have an identified source for infection. One study found that person-to-person transmission, both within and between households, occurred frequently and often involved young children with unrecognized HAV

infection.[lvii] In the study, persons reporting no identified source were found to have lived in households where infection among young children was common and frequently undetected. Serological testing found that nearly one half of household contacts under 6 years of age had antibodies to HAV, meaning they previously or currently had the disease. This investigation found that children did have symptoms of illness, but these symptoms were nonspecific and, in most cases, not recognized as hepatitis A. These HAV-infected children were frequently the source of infection for others. The presence of children under 3 years of age was associated with transmission within the household, consistent with other reports that implicate diapered children as the most important vectors of HAV transmission in child care centers. Although not associated with household transmission, one half of all the 3- to 5-year-old children tested were positive for HAV antibodies, and many were previously unrecognized links in clusters of transmission between households. While the most common source of infection for hepatitis A has changed to international travelers since these studies were conducted, the risk of transmission from children to their contacts exists when children are infected with hepatitis A virus.

According to a recent study, among reported cases of hepatitis A, the most frequently reported source for infection is international travel, accounting for approximately 45 percent of cases. But the study also found that 36.4 percent of reported cases had no known risk factor. The authors concluded that vaccination of children and high-risk groups in the United States has reduced the incidence of HAV disease to record lows. The authors commented that "further reductions will depend on the continuation of routine, universal vaccination as well as health care providers encouraging vaccination of susceptible travelers."[lviii]

Safety and Efficacy of Hepatitis A Vaccine

There are two manufacturers of hepatitis A vaccine, GlaxoSmithKline and Merck.[9] Before licensure, the Food and Drug Administration (FDA) reviewed safety and efficacy information on these vaccines and concluded that they were safe and effective. Both vaccines were studied for compatibility with other routinely recommended and neither interference of protection nor safety concerns were identified. In addition, before adding a vaccine to the childhood schedule, the ACIP reviews safety and efficacy data from both the clinical trials that led to its licensure and peer-reviewed literature. Finally, on-going safety monitoring occurs after the vaccine is licensed. (*See Attachment G, Ensuring the Safety of Vaccines in the United States Fact Sheet.)*

Safety

Studies have found that the hepatitis A vaccine is safe.[lix,lx] Since the licensure of the first hepatitis A vaccine in 1995, millions of doses of hepatitis A vaccine have been distributed and administered worldwide, as well as in the United States. The most common adverse reaction following hepatitis A vaccination in children was pain (19 percent) and warmth (17 percent) at the injection site. It has been reported that one out of 25 children report a headache and one out of 12 have a loss of appetite. If these problems occur, they usually last one to two days.

9 The hepatitis A vaccine is available in three different formulations: as a single adult vaccine, a single pediatric vaccine and a combination vaccine with the hepatitis B vaccine for adults.

While the hepatitis A vaccine can cause mild side effects like those mentioned above, no pattern of serious adverse events have been associated definitively to the hepatitis A vaccine. A very rare but serious side effect is generalized allergic reaction, which typically occurs within a few minutes to a few hours following vaccination.

Similar to the hepatitis B vaccine discussed earlier, critics of immunizations cite Vaccine Adverse Reporting System (VAERS) data to show the hepatitis A vaccination is unsafe. But as discussed earlier, VAERS is a passive reporting system and only generates hypotheses to be studied. It does not provide evidence of causation. For this reason, it is incorrect and misleading to cite VAERS data to show that a vaccine causes a specific number of adverse events or deaths. For more information on VAERS see discussion on page 24 and *Attachment H, Understanding the Vaccine Adverse Events Reporting System*.

During the Request for Comment period, one person asked if any of the proposed new vaccination requirements contained "human fetal DNA," and if so, to please address the issue. This person said, "There is emerging science about concerns about human DNA being in vaccines." First, it is important to clarify that the hepatitis A vaccine does not contain human cells or tissues; but the antigen is grown in cell cultures that were originally obtained from two human cell lines. Fetal tissue is not used to produce vaccines; cell lines generated from a single fetal tissue source are used; vaccine manufacturers obtain human cell lines from FDA-certified cell banks. After processing, a small amount of fragments of DNA may remain in the vaccine. The cell cultures are merely the biological system in which the antigens are grown. The fragmented DNA are insufficient to create a whole protein.

When this theory was brought to the department's attention, staff contacted two experienced University of Minnesota geneticists who work in this area.[lxi] Both geneticists agreed that the biologically plausibility of DNA remnants from the cells "mixing" with the vaccine recipient's DNA and causing harm was nil. In addition, they said that if this was biologically plausible, it would be one of the greatest medical advancements ever. One of the scientists pointed out the following flaws in the theory.

- Because DNA is not stable when exposed to certain chemicals, much of it is destroyed in the process of making the vaccine. Therefore, the amount of human DNA in the final vaccine preparation is minimal (trillionths of a gram) and highly fragmented. Because the DNA is fragmented, it cannot possibly create a whole protein. The amounts of contaminating DNA are very small, and our system is exposed to many other sources of DNA daily.
- Fragmented DNA from the vaccine is not able to incorporate itself into cellular DNA. DNA does not enter cells without some significant manipulations. Physiologically, cell membranes do not allow passage of foreign DNA.

Moreover, there are no published scientific studies that corroborate this theory. As stated earlier, vaccines undergo years of testing before being licensed and after licensure, they are continually monitored.

Efficacy
The effectiveness of hepatitis A vaccine has been studied in demonstration projects and by analysis of surveillance and immunization coverage data. It has been shown to be

very effective in children and adults. Among children and adolescents, more than 97 percent will have protection from the virus within a month after the first dose and nearly 100 percent will be protected after receiving two doses of the hepatitis A vaccine.[lxii] Data concerning the long-term persistence of protection are limited because the current vaccines have only been available since 1995 and 1996. But estimates of antibody persistence indicate that protective levels could be present for 20 years or longer. Post marketing surveillance studies are ongoing and will help determine whether a booster dose is needed or not.

One recent study found that annual hospitalizations fell dramatically following the Department of Defense's 1995 and 1996 policies for use of hepatitis A vaccine in the Armed Forces. The authors concluded that these low rates "likely reflect not only recruit screening and immunization but also the widespread use of hepatitis A virus vaccine among children and adolescents in the United States."[lxiii]

Finally, the most comprehensive study of the efficacy of the hepatitis A vaccines was derived from analysis of trends in hepatitis A incidence after implementation of ACIP's 1996 and 1999 recommendations for routine vaccination of children living in regions with consistently elevated hepatitis A rates. The 2003 rate in these states represented a decline of approximately 88 percent compared with the average rate during the baseline pre-vaccine period on which the recommendations were based.[lxiv]

Cost-Effectiveness of Hepatitis A Vaccine

A child needs a total of two doses of hepatitis A vaccine to be fully protected from hepatitis A infection. The cost of each childhood dose is about $15 in the public sector and about $30 in the private sector. Hepatitis A vaccine that is given in combination with the hepatitis B vaccine (Twinrix) costs more, but it is not licensed for persons younger than 19 years of age.

One study concluded that childhood hepatitis A vaccination is most cost-effective in areas with the highest incidence rates but would also meet accepted standards of economic efficiency in most of the United States. An immunization program extended to the entire country would prevent substantial morbidity and mortality, with cost-effectiveness similar to that of other childhood immunizations.[lxv]

Cost of Enforcing Hepatitis A vaccination Requirement

This is a new requirement for child care and school-based early childhood programs, which will be responsible for enforcing it along with other required childhood vaccines. The cost to most child care facilities should not be high because the providers will check for this vaccine at the same time they check for all other vaccinations. Child care facilities by law must also check a child's vaccination history each time a child moves to a new class. Some of the school districts that have early childhood programs may find their administrative burden increased with the new requirement. But many school districts already require immunization documentation for school-based early childhood programs, though it is not consistent across the state. The department is committed to helping both child care facilities and school-based early childhood programs facilities implement this requirement. For example, most schools and many child care facilities have access to the Minnesota Immunization Information Connection (MIIC), a secured web-based system that keeps track of a child's immunization record. The department is currently working with child care facilities to increase usage of MIIC.

The Immunization Rulemaking Advisory Committee included representatives from two child care organizations. They were the Minnesota Licensed Family Child Care Association (MLFCCA), which represents family child care, and the Minnesota Child Care Association (MCCA), which represents child care facilities. Both of these representatives expressed support for this requirement to ensure that children and staff are protected from this disease. The Minnesota Department of Education's Early Childhood Program Specialist, who was consulted throughout the rulemaking process, supports this change.

There will be no cost to the state to implement this requirement. Currently, the hepatitis A vaccine is part of the federal Vaccines for Children (VFC) program, which covers ACIP-recommended vaccines. The VFC program is a federally funded entitlement program that pays for vaccines for children who are uninsured, Minnesota Health Care Program (MHCP) enrollees, American Indians, Alaskan Natives, and certain underinsured children. Because hepatitis A vaccine is ACIP-recommended, most private insurers already cover the cost of the vaccine for children, thus the costs are included in their standard plans. The department did not hear from any private insurers opposing this requirement. Moreover, the federal Affordable Care Act (ACA) requires full coverage of all ACIP-recommended vaccines. Some insurance plans currently have grandfathered status in relation to the ACA and are able to require consumers to pay for immunizations; but the number of grandfathered plans is quickly decreasing.

Summary – Hepatitis A
Young children often show no signs of Hepatitis A disease, but they can be the major disease reservoir for older children and adults.

Because the disease can be transmitted through person-to-person contact or contaminated food or water; and because children, in particular, who are infected with the virus transmit it easily to others without knowing it, it is reasonable and necessary to require the hepatitis A for all children over age 1 year entering child care or a school-based early childhood program. As always, parents or guardians will have the option of a legal exemption if they are conscientiously opposed to the vaccination or have a medical contraindication.

Part 4604.1010 Tetanus, Diphtheria, and Pertussis Vaccination Requirement

This new requirement addresses the growing problem of pertussis in the population by replacing the current Td (tetanus, diphtheria) requirement in Minnesota Statutes, section 121A.15. All students entering seventh grade would have to show documentation of either receipt of the Tdap vaccine (tetanus, diphtheria and acellular pertussis) according to medically acceptable standards or a legal exemption. Furthermore, students in eighth through 12th grades would have to be able to show, upon request, either proof of vaccination consistent with medically acceptable standards against tetanus, diphtheria, and pertussis, or documentation of a legal exemption. Currently, both ACIP and the department recommend that persons ages 11 and older receive the Tdap vaccine, but there is no Tdap immunization requirement in the law for these children, only a Td requirement. Thus, there is no current requirement for pertussis vaccination for older students.

When the department first proposed this change, many school nurses were concerned that they would be required to ask for Tdap documentation for seven through 12th grades. But that is not the intent of the proposed rules. As stated above, the proposed Tdap requirement actually replaces the Td requirement and should be implemented in the same manner. Schools currently have the ability to check Td status when needed for students in any grade,

but they do not have to. They are only required to check in 7th grade. Moreover, schools will only report the vaccine as part of the AISR in seventh grade.

Currently, 41 states require the Tdap vaccine for children in sixth or seventh grade. Four of these states also require it in seventh through 12th grades.

The Tdap vaccine protects adolescents and adults from three diseases: diphtheria, tetanus, and pertussis (also known as whooping cough). Since the Td vaccine has been part of the School Immunization Law for many years, the department will only discuss pertussis disease in this SONAR, tetanus and diphtheria disease will not be addressed.

The department concludes that this change is reasonable and necessary to protect adolescents from pertussis which, in turn, also prevents the disease from spreading to family members and other students and school staff.

This proposed change reflects national immunization recommendations made in 2005 by the ACIP, [lxvi] as well as medically accepted standards as recommended by the AAP and the AAFP. This vaccine was not licensed in 2003 and thus not available for consideration when the department last revised the School Immunization Law.

Epidemiology and Morbidity/Mortality Rates of the Disease

Clinical Manifestations

Pertussis, also known as whooping cough, is a serious disease that affects the respiratory tract. It is endemic in the United States. Pertussis is a cough illness that begins like a common cold and progresses into a cough phase, characterized by sudden spasms of coughing, making it difficult to breath and sometimes resulting in vomiting. This cough can last up to three months and is commonly called the “100-day cough.” Although the cough usually disappears after a few months, it may recur if the person gets a subsequent respiratory infection.

The period between exposure to the pertussis bacterium and onset of illness is usually seven to 10 days, with a range of four to 21 days.

Pertussis in infants is often severe and infants are more likely than older children or adults to develop complications. Between 2000 and 2004, infants accounted for 19 percent of pertussis cases but 92 percent of pertussis deaths nationally.[lxvii] Two-thirds of infants with pertussis disease will have apnea (slowed or stopped breathing). The most common complication of pertussis is bacterial pneumonia. Rare complications include seizures, inflammation of the brain, and death. The disease is usually milder in adolescents and adults but is not necessarily insignificant. Adolescents and adults are less likely to become seriously ill with pertussis, but often make repeated visits for medical care and miss school or work.[lxviii,lxix] The cough illness itself contributes to missed school days and work due to exhaustion from coughing spells and lack of sleep. People with pertussis are also subject to an exclusion period from work and school until they have taken antibiotics for five days. Adolescents and adults can also suffer complications from pertussis, often caused by the cough itself. For example, a person might faint or fracture a rib during a violent coughing fit.

Epidemiology

Pertussis is caused by the bacterium *Bordetella pertussis.* It is one of the most contagious vaccine-preventable diseases. Data shows that among non-immune family members of people with pertussis, an average of 80 percent develop pertussis themselves.[lxx] In the 20th century, pertussis was one of the most common childhood diseases and a major cause of childhood mortality in the United States. Before the availability of a pertussis vaccine in the 1940s, more than 200,000 cases and 8,000 deaths from pertussis were reported annually in the United States.[lxxi] Following the introduction of pertussis vaccine[10] in the 1940s, cases of pertussis gradually declined, reaching 15,000 reported cases in 1960. By 1970, the annual number of cases was fewer than 5,000 per year, and during 1980–1990, an average of 2,900 cases per year was reported. Incidence had decreased more than 80 percent compared with the pre-vaccine era. [lxxii]

But since the early 1980, pertussis incidence has been gradually increasing in the United States. A total of 33,380 cases have been reported as of October 2012, the largest number since 1959. Because many cases go unreported, the true number of cases is likely higher.

In the United States between 2001 and 2003, the highest average annual pertussis incidence was among infants younger than 6 months of age. But in recent years, adolescents (11–18 years of age) and adults (19 years and older) have accounted for an increasing proportion of cases. The annual incidence of pertussis among persons aged 10–19 years in the United States increased from 5.5 per 100,000 in 2001 to 10.9 in 2003. In 2004 and 2005, approximately 60 percent of reported cases were among persons 11 years of age and older. The main reason for this increase is believed to be the earlier-than-expected waning of pertussis immunity from the DTaP vaccine[11], which replaced the whole cell DTP vaccine, leaving adolescents susceptible to pertussis as early as age 10. In addition, growing awareness of pertussis disease in adolescents and adults and better diagnostic tools might account for some of the increase.[lxxiii] [lxxiv]

Minnesota Information

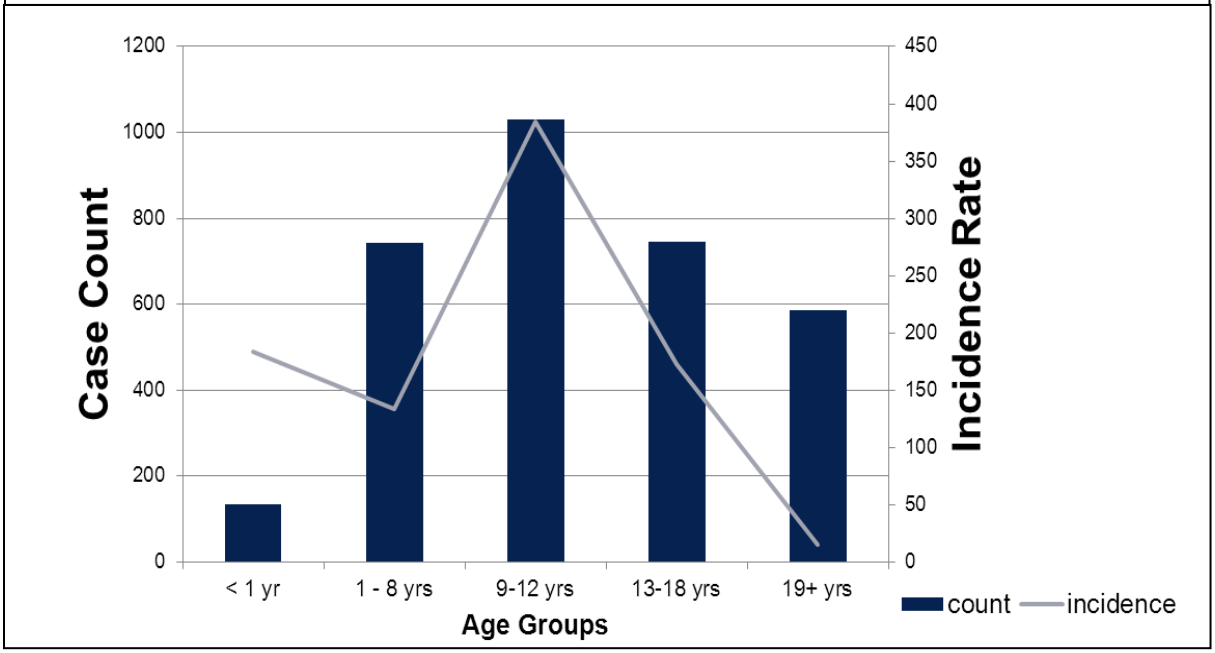
As of December 31, 2012, the total number of reported cases of pertussis in Minnesota for the year was 4,443. This number included confirmed, probable, and suspect cases. This is over six times the total number of cases reported in all of 2011, which were 661.

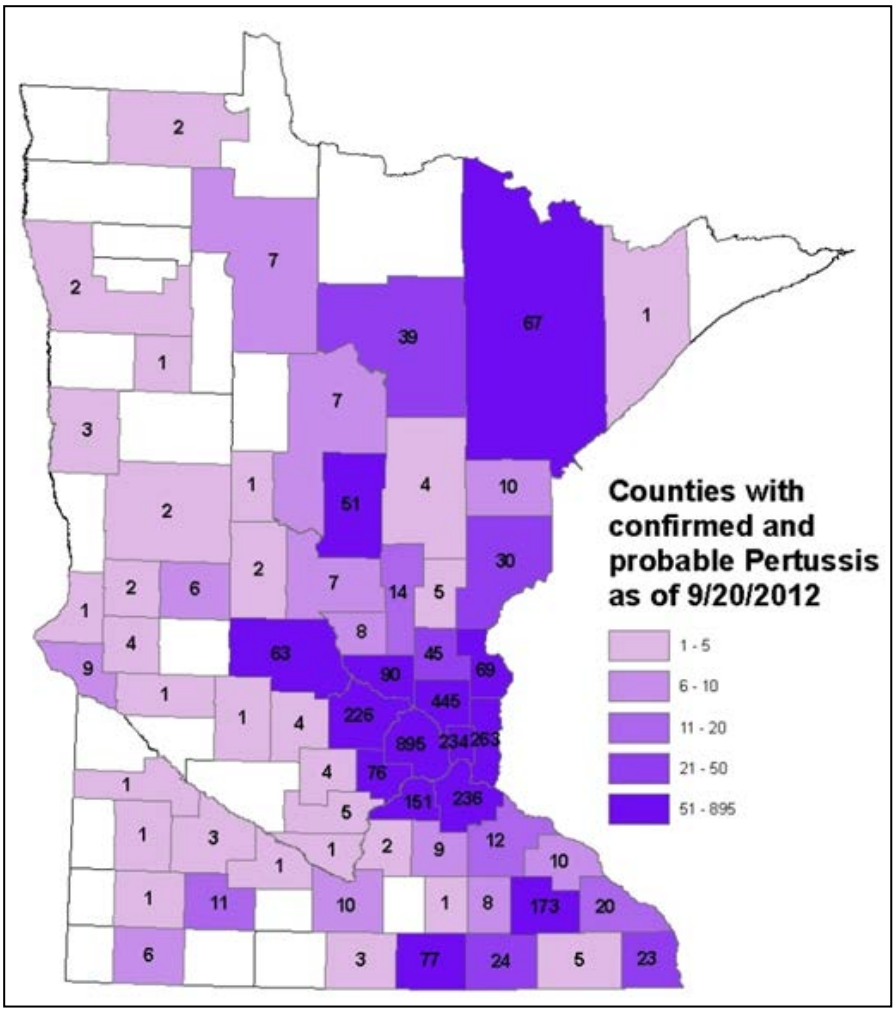
State age group trends mirror the national trends with a growing proportion of cases among adolescents (see graph below), but the greatest concern is the rates among infants who are most vulnerable to complications from the disease. As stated above, the increase in pertussis cases is due to a combination of increased recognition of pertussis disease and earlier-than-expected waning of immunity from the current pertussis-containing vaccine. All of which illustrate the need for high Tdap vaccination rates in adolescents and adults.

The largest number of cases has been reported in the seven-county metro area (65 percent of all cases statewide). There are cases, however, around the entire state (see map below). While some areas of the state appear to have no cases; it was possible that cases have occurred in those areas but were undiagnosed or have not been confirmed and reported.

[10] The first pertussis vaccine was a whole-cell pertussis vaccine called DTP.
[11] The DTaP vaccine is part of the recommended schedule for children under 7 years of age.

Pertussis Cases and Incidence Rate, Minnesota 2012
(YTD 10/18/2012)





Transmission

Pertussis is a contagious disease only found in humans. It is spread from person to person through the air by infectious droplets and is most likely to spread to others early in the illness. People with pertussis usually spread the disease by coughing or sneezing while in close contact with others, who then inhale the pertussis bacteria. Transmission is possible but less likely to occur through contact with freshly contaminated articles from an infected person. Many infants who get pertussis are infected by older siblings (especially adolescents), parents, or caregivers, who might not even know they have the disease.[lxxv,lxxvi]

Persons who have pertussis but have completed five days of antibiotics can no longer spread the disease. But persons who have the disease but do not take antibiotics can spread the disease during the first three weeks they are coughing.

Safety and Efficacy of Tdap Vaccine

There are two manufacturers of the Tdap vaccine: GlaxoSmithKline (Boostrix) and Sanofi Pasteur (Adacel). Boostrix is licensed for persons 10 years of age and older, and Adacel is licensed for persons 11 to 64 years of age. Before licensure, the Food and Drug Administration (FDA) reviewed safety and efficacy information on these vaccines and concluded that they were safe and effective. In addition, before adding a vaccine to the childhood schedule, the ACIP reviews safety and efficacy data from both the clinical trials that led to its licensure and peer-reviewed literature. Finally, on-going safety monitoring occurs after the vaccine is licensed.

Safety

Studies have found that the Tdap vaccine is safe.[lxxvii,lxxviii] Since the licensure of both Tdap vaccines in 2005, millions of doses of Tdap vaccine have been distributed and administered worldwide as well as in the United States. (*See Attachment G, Ensuring the Safety of Vaccines in the United States Fact Sheet.)*

Pre-licensure studies evaluated the safety of Tdap vaccines. The most common adverse reaction following administration of either Tdap vaccine is a local reaction, such as pain (66 percent), redness (25 percent) or swelling (21 percent) at the site of injection. Temperature of 100.4°F or higher was reported by 1.4 percent of Tdap recipients as compared to 1.1 percent of Td recipients. Tdap recipients also reported a variety of nonspecific systemic events, such as headache, fatigue, and gastrointestinal symptoms. Local reactions, fever, and nonspecific systemic symptoms occurred at approximately the same rate in recipients of Tdap and the comparison group that received Td without the acellular pertussis vaccine."[lxxix] A rare but serious side effect is an allergic reaction, which typically occurs within a few minutes to a few hours following the vaccination. But to date, no other serious adverse events have been attributed to Tdap.

A post-licensure study using data from the Vaccine Safety Datalink (VSD) [12] compared the safety of the Tdap vaccine to that of the Td vaccine. Td vaccine has been used for several decades and is considered to be very safe. The study found that Tdap vaccine is similar in safety to the Td vaccine and there was no association between Tdap and five

[12] The VSD is a CDC-sponsored collaboration among 8 geographically diverse managed care organizations in the U.S. It collects medical data on over 8.8 million people per year to study vaccine safety after vaccine licensure.

predefined adverse events: encephalopathy-encephalitis-meningitis, paralytic syndromes, seizures, cranial nerve disorders, or Guillain-Barré syndrome.[lxxx]

Similar to the hepatitis A and B vaccines discussed earlier, critics of immunizations cite Vaccine Adverse Reporting System (VAERS) data to argue that Tdap is unsafe. But as discussed earlier, VAERS is a passive reporting system and only generates hypotheses to be studied. It does not provide evidence of causation. For further discussion on VAERS, see discussion on page 24 and *Attachment H, Understanding the Vaccine Adverse Events Reporting System*.

Critics also express concern about the possible role of vaccines with pertussis components in neurologic reactions. But in recent years, studies have found that there is no increased risk of neurologic reactions in children who have received a vaccine containing a pertussis component, either whole-cell (DTP) or acellular (Tdap or DTaP). A Canadian study did not find any acute encephalopathy cases causally related to either whole-cell or acellular pertussis vaccine among a population that received 6.5 million doses of pertussis-containing vaccines.[lxxxi] A re-examination of 14 patients with encephalopathy originally attributed to DTP vaccine revealed that 12 of the 14 actually had Dravet syndrome, also called severe myoclonic epilepsy of infancy (a genetic condition in which encephalopathy is inevitable) and specific epilepsy syndromes were identified in the remaining two cases.[lxxxii] This study made clear that DTP vaccine did not cause these patients' neurological deterioration. A follow-up study confirmed that the clinical outcomes of patients whose first symptoms of Dravet syndrome emerged after vaccination were indistinguishable from those of other Dravet patients.[lxxxiii] Therefore, even if it were assumed that DTP-induced fevers provoked the first Dravet symptoms in these patients, it would not follow that accelerating the timing of these symptoms had an adverse effect.

Efficacy

Estimates of acellular pertussis vaccine efficacy in adolescents and adults range from 80 percent to 85 percent.[lxxxiv] Also, those who have received the vaccine yet subsequently get pertussis are likely to experience milder illness. One pre-licensure study even found a vaccine efficacy rate of 92 percent for adolescents and adults.[lxxxv] However, these studies included adolescents that had received whole cell pertussis (DTP) as infants, and as pertussis disease incidence rises, CDC has concerns about the duration of immunity in adolescents that received Tdap following an all acellular infant series (DTaP) beginning around 1999. CDC is carefully monitoring disease trends and is working with expert scientists to determine the issues and solutions, including additional doses of Tdap.

Cost-Effectiveness of Tdap Vaccine

The Tdap vaccine costs approximately $30 in the public sector and $38 in the private sector. Studies have found that immunizing adolescents 10 to 19 years old is cost-effective. An extensive 2004 literature review found that, over a decade, vaccinating adolescents would prevent between 700,000 and 1.8 million pertussis cases and save between $600 million and $1.6 billion.[lxxxvi] Another study published in 2005, also found that Tdap vaccination for adolescents would be cost-effective.[lxxxvii]

Cost of Enforcing Tdap Vaccination Requirement
This new requirement is replacing the current Td vaccine for middle school and high school students. While schools will be responsible for enforcing it, it should not be an additional burden on schools.

The Immunization Rulemaking Advisory Committee included school nurse representatives. And the department did outreach to schools, including superintendents, regarding this requirement. None of the groups expressed any major concerns with this requirement. In fact, most comments that the department heard were positive. But during one of the public meetings and at an Immunization Rulemaking Advisory Committee meeting, school nurses did express a concern about using the Minnesota Immunization Information Connection (MIIC) to ascertain whether students have received Td or Tdap. To help schools with this issue, the MIIC system runs a computer program (a script) nightly that takes any data that has been entered since the previous day and codes the trade name based on what type of shot was given so a school nurse or health care provider can discern between Td and Tdap One school nurse also expressed concern that MIIC does not always "flag" a child who needs a booster Td dose because ten years had not passed since the last Td. MDH staff are currently working on this issue, which be fixed by the beginning of .

There will be no cost to the state to implement this requirement. Currently, the Tdap vaccine is part of the federal Vaccines for Children (VFC) program, which covers ACIP-recommended vaccines. The VFC program is a federally funded entitlement program that pays for vaccines for children who are uninsured, Minnesota Health Care Program (MHCP) enrollees, American Indians, Alaska natives, and certain underinsured children. Because Tdap is ACIP-recommended, most private insurers already account for the cost of the vaccine in their standard plans. The department did not hear from any private insurers opposing this requirement. Moreover, the Affordable Care Act (ACA) requires full coverage of all ACIP-recommended vaccines. Some insurance plans currently have grandfathered status in relation to the ACA and are able to require consumers to pay for immunizations, but the number of grandfathered plans is quickly decreasing.

Summary
Pertussis continues to be endemic in the United States because it is highly infectious and immunity from the childhood vaccination or disease wanes. To reduce the disease burden of pertussis and protect vulnerable infants and others, the department contends it is necessary and reasonable to include the Tdap vaccine in the School Immunization Law for all children in seventh through 12th grades. As always, conscientious and medical exemptions will be available to parents or guardians.

Part 4604.1020 Meningococcal Vaccination Requirement

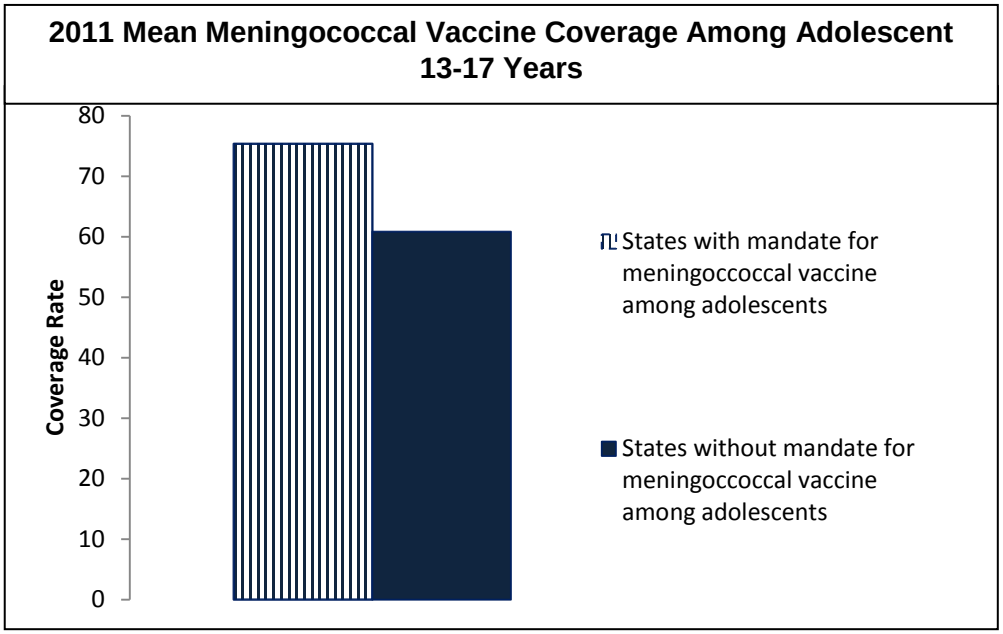
Meningococcal vaccination is a new vaccination requirement for all students entering seventh grade. Students must show documentation of either receipt of the meningococcal vaccine according to medically acceptable standards or a legal exemption. It would also require students in eighth through 12th grades to be able to show, upon request, either proof of vaccination consistent with medically acceptable standards against meningococcal disease, or documentation of a legal exemption.

Currently, per medically acceptable standards, the department recommends meningococcal vaccine (MCV4) for all children at 11-12 years. A booster dose is recommended at 16 years for children who received meningococcal vaccine at 11-12 years old or at 16-18 years for

children who received meningococcal vaccine at ages 13-15. Adolescents who receive a first dose of meningococcal vaccine at or after age 16 do not require a booster dose. This proposed amendment will require schools to obtain documentation in seventh grade, similar to the procedures that currently apply to varicella, hepatitis B, MMR, and Td. It will also give schools the authority to enforce the requirement in eighth through 12th grades.

Since the initial ACIP adolescent recommendation for MCV4 in 2005, several adjustments have occurred due to a vaccine shortage and the results of data from ongoing immunogenicity studies. The department's recommendation above follows the current ACIP recommendations.[lxxxviii]

Currently, 22 states require meningococcal vaccination for students in sixth or seventh grade.[13] States with meningococcal vaccination requirements have higher rates of immunization against meningococcal disease: 75 percent vs. 61 percent respectively (see graph below). Minnesota's current meningococcal vaccination rate, according to the National Immunization Survey, is 63.1 percent.



The department concludes that this change is reasonable and necessary to ensure that all children are protected against this serious and often fatal disease.

This proposed change reflects national immunization recommendations made in 2005 by the ACIP, [lxxxix] as well as the acceptable medical standard as recommended by the AAP and the AAFP. This vaccine was not licensed in 2003, when the department last revised the School Immunization Law.

Epidemiology and Morbidity/Mortality Rates of the Disease

Clinical Manifestations

[13] Two of these states only require it in residential schools.

Meningococcal infection is a serious disease caused by the bacterium *Neisseria meningitidis*. Meningococcal bacterial causes severe illness by infecting the blood (meningococcemia) or infecting the fluid in the spinal cord and around the brain (meningitis).[14] Meningococcal disease can cause death, neurologic damage, and loss of limbs. Symptoms can include high fever, severe headache, a stiff neck, confusion, nausea, sensitivity to light, vomiting, and exhaustion. In persons with meningococcemia, a rash may also develop. Less common presentations of meningococcal disease include pneumonia, (five to 15 percent of cases), arthritis (two percent), otitis media (one percent), and epiglottitis (less than one percent).[xc]

Often a person becomes seriously ill quickly, and early symptoms can easily be mistaken for influenza. In overwhelming meningococcal infections, shock, coma, and death can follow within several hours, even with appropriate medical treatment.

The disease is very serious. About nine to 12 percent of people with meningococcal disease die, even with appropriate antibiotic treatment. Of those who survive, up to 20 percent will have permanent disabilities, such as deafness, loss of limbs, mental retardation, or seizures. In those who get blood stream infections, the fatality rate is 40 percent.

The incubation period of meningococcal disease is three to four days, with a range of two to 10 days.

Epidemiology

Neisseria meningitidis is the leading cause of bacterial meningitis and sepsis in children 2 to 18 years old in the United States. Sixty-two percent of cases occur in persons 11 years of age and older. This bacterium has at least 13 different strains, also referred to as serogroups. Three of the serogroups (B, C, and Y) cause almost all disease in the United States. Approximately 75 percent of cases among adolescents and young adults are caused by serogroups C, Y, and W-135, which are included in the vaccine and thus preventable. Serotype B causes most cases of meningococcal disease in infants; there is no licensed vaccine that contains protection against serotype B.

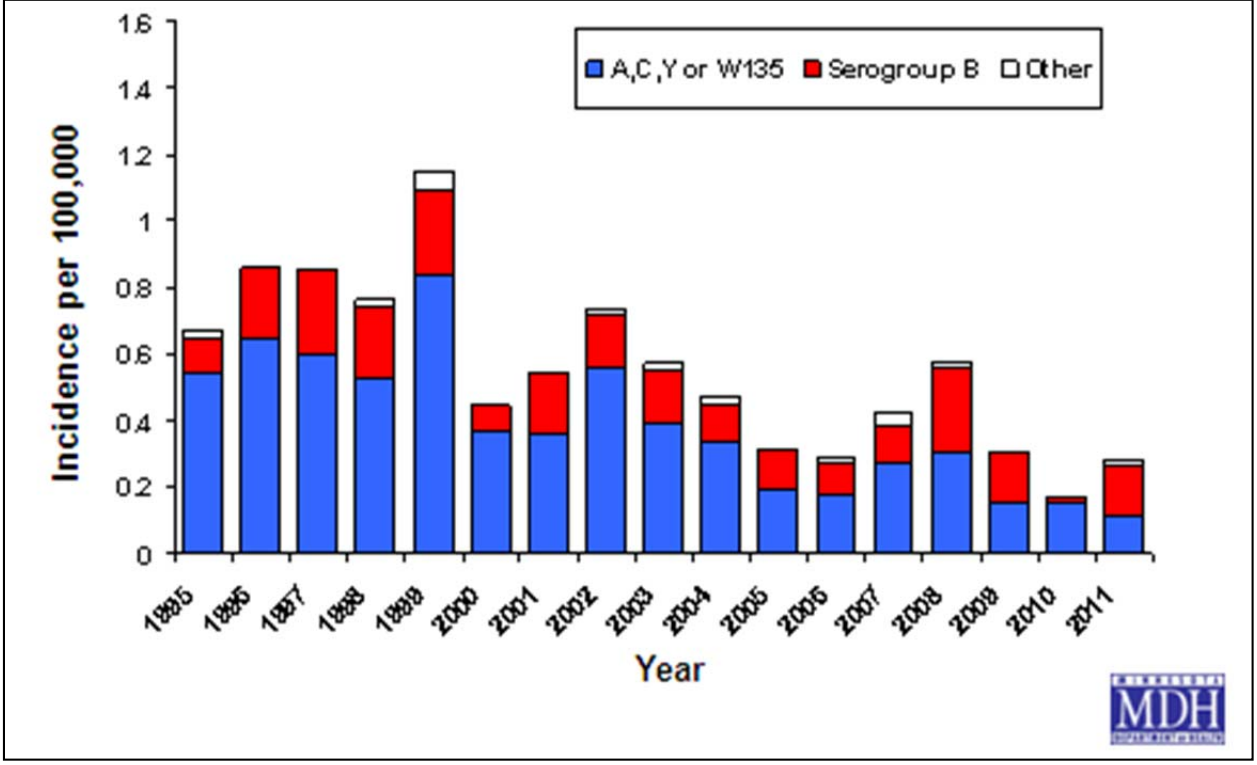
Anyone can get meningococcal disease, but it is most common in infants less than 1 year of age and in people with certain medical conditions, such as asplenia (lack of a spleen). Although adolescents are less likely to be infected than infants, disease incidence increases beginning around age 11 and reaches a secondary peak around age 19. About 2,000 to 3,000 people get meningococcal disease each year in the United States and about 10-15 percent of these people die. Of those who recover, up to 20 percent experience serious long-term effects, such as hearing loss, loss of limbs, or diminished mental capacity.[xci]

Minnesota Information

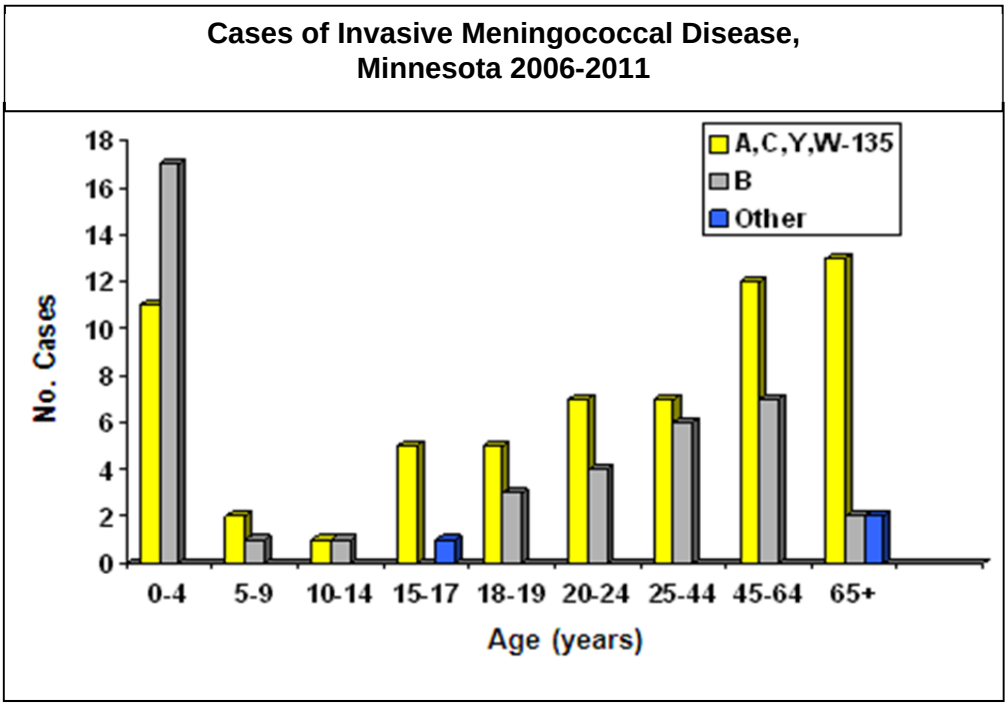
The department conducts active, statewide, laboratory-based surveillance for meningococcal disease. Between 1996 and 2011, the overall incidence (number of new cases) of meningococcal disease in Minnesota declined. See graph below.

[14] Viral meningitis, bacterial meningitis, and fungal meningitis must not be confused. Viral meningitis is usually not as serious as bacterial meningitis and there is no specific treatment for it. Fungal meningitis is also different than bacterial meningitis and the treatment is different. There are no immunizations to prevent viral or fungal meningitis so they will not be discussed here.

Incidence of Invasive Meningococcal Disease, Minnesota
January 1, 1995 – December 31, 2011



Cases of Invasive Meningococcal Disease,
Minnesota 2006-2011



Similar to the rest of the United States, Minnesota adolescents and young adults experience rates of meningococcal disease that exceed those of the general population. As the graph below shows, there is a decrease around age 5 and then an increase in adolescence. Between 2006-2011, 27 percent of cases of meningococcal disease caused by serogroups C, Y and W-135 were in adolescent and young adults (ages 10-24 years) and preventable by vaccination.

From 2006-2011, there were nine deaths due to *Neisseria meningitidis*, four of which were vaccine-preventable serogroups. Two of the vaccine-preventable deaths were in pediatric patients and one was in a young adult.

Transmission
At any given time, about 10-15 percent of all people are believed to carry *Neisseria meningitidis* bacteria in their throats and nasal passages. This means the bacteria is always present in the community, and given the right circumstances, it can cause disease.

The disease is spread by close or direct contact (person to person) through the exchange of secretions from the nose and throat. Kissing, sharing silverware, drinking directly from the same container, sharing a cigarette or lipstick, coughing, and having close social contact (living in the same household) are examples of how this disease spreads. Because the risk increases with close or prolonged contact with an infected person, family members in the same household and caregivers are at an increased risk. Estimates of the risk of secondary transmission are generally two to four cases per 1,000 household members at risk. But this risk is 500–800 times that of the general population.

Meningococcal bacteria cannot live for more than a few minutes outside the body, so the disease is not spread as easily as the common cold. Close contact and secretion exchange are key elements of transmission.

Due to the severity of illness and risk of transmission to close contacts, in-depth contact investigations are conducted for all confirmed cases of *Neisseria meningitidis* so that antibiotic prophylaxis can be initiated. While these investigations can be resource-intensive, they are considered critical public health practice. Outbreaks of *Neisseria meningitidis* are uncommon, but there have been several noted national outbreaks recently, including an outbreak in 2010 among a hockey team in Fort Collins Colorado, with seven confirmed cases and five deaths. The cases were confirmed to be serogroup C, which is vaccine-preventable; therefore, that community initiated a large-scale vaccination effort.

Safety and Efficacy of Vaccine
There are two quadrivalent meningococcal conjugate vaccines (MCV4) licensed in the United States: Menactra, manufactured by Sanofi Pasteur, and Menveo, manufactured by Novartis. Both vaccines contain *Neisseria meningitidis* serogroups A, C, Y and W-135. Menactra is approved for use in persons 9 months through 55 years of age. Menveo is approved for use in persons 2 through 55 years of age.

Before licensure, the Food and Drug Administration (FDA) reviewed safety and efficacy information on these vaccines and concluded that they were safe and effective. In addition, before adding a vaccine to the childhood schedule, the ACIP reviews safety and efficacy

data from both the clinical trials that led to its licensure and peer-reviewed literature. Finally, on-going safety monitoring occurs after the vaccine is licensed. (*See Attachment G, Ensuring the Safety of Vaccines in the United States Fact Sheet.)*

There is also a licensed (1981) meningococcal polysaccharide vaccine (MPSV4) for persons age two years and older. It is not routinely recommended for adolescents, so it will not be discussed in this SONAR.

Safety

Studies have found that the meningococcal vaccine is safe. Since the licensure of the vaccine, millions of doses of vaccine have been distributed and administered worldwide, as well as in the United States.

Up to half of the people who get meningococcal vaccine have mild side effects, such as redness or pain at the injection site. These symptoms usually last for one or two days. A small percentage of people who receive the vaccine develop a fever. Severe reactions, such as serious allergic reactions, are very rare. Fever (100°–103°F), within seven days of vaccination, is reported for up to five percent of recipients. Systemic reactions within seven days of vaccination (events such as headache and malaise) are reported in up to 60 percent of recipients. Less than three percent of recipients reported these reactions as severe.[xcii]

When MCV4 vaccine was first routinely recommended for adolescents, Menactra was the only brand available. Following the ACIP recommendation, there were a cluster of VAERS reports of Guillain-Barré Syndrome (GBS) among those vaccinated.[15] The reported incidence of GBS after receipt of Menactra was too low to establish a statistical association between GBS and Menactra. Regardless, ACIP recommended that persons with a history of GBS be advised about the potential risks verses benefits of vaccination. Additionally, the FDA and CDC began conducting enhanced surveillance for GBS following Menactra vaccination. In 2010, the ACIP removed the precaution based on two large population studies that showed no increased incidence of GBS among those vaccinated with Menactra compared to what would be expected in the general population without vaccination.

The first study[xciii] looked at a total of over 12.5 million people between the ages of 11 and 21. The investigators concluded that the study provided no evidence of increased risk of GBS associated with Menactra. The second study[xciv] was conducted through the Vaccine Safety Datalink (VSD).[16] The study found no link between Menactra and GBS with zero cases of GBS following 889,684 doses of Menactra administered. Combining the two studies, in over 2.3 million observed vaccinations, there was no finding of an increased risk of GBS associated with Menactra.

Efficacy

Meningococcal vaccine is highly effective at protecting against four serotypes of the meningococcal bacterium: A, C, Y, and W-135. Three of the serotypes are common in

[15] As stated earlier in this SONAR, VAERS is a passive reporting system and only generates hypotheses to be studied. It does not provide evidence of causation.

[16] The VSD allows for timely investigations of vaccine safety hypotheses arising from the medical literature, pre-licensure studies, reports to VAERS, changes in immunization schedules, or the introduction of new vaccines. It was established in 1990 and is a CDC-sponsored collaboration among eight geographically diverse managed care organizations in the United States. It currently collects medical data on over 9.2 million members annually.

the United States (C, Y, and W-135); the fourth strain (A) protects travelers to certain countries where the disease is common. The vaccine does not contain the B strain, which is the most common cause of *Neisseria meningitidis* in infants and may cause some cases in adolescents. Because the vaccines do not protect against all strains of meningitis, it is possible that someone could get the vaccine and get meningitis from a meningococcal strain not in the vaccine or from a non-meningococcal infection.

In pre-licensure studies, adolescents who received Menactra had a high seroconversion rate, around 98 percent. That means that 98 percent of adolescents who were immunized developed antibodies to the disease and were protected from disease. Since that time, studies have shown a decline in antibodies three to five years after vaccination. As a result, the ACIP now recommends a booster dose for those vaccinated before age 16. But it should be noted that even though there is an observed decline in antibodies in the three to five years following vaccine administration, there has been no rise in observed disease. The booster recommendation is based on serological studies, not disease rates.

When a booster dose was administered either three or five years after the first dose, the mean antibody titer elicited after the booster dose was substantially higher than that after the primary dose. This finding suggests that the first dose of MCV4 primes the immune system and results in a strong response to the booster dose. The duration of protective concentrations of antibody after a booster dose is not known. A booster dose administered at 16 through 18 years of age is expected to result in protective antibody concentrations through the age of 21 years, if not longer, in healthy individuals.[xcv]

Cost-Effectiveness/Cost-Benefit of Meningococcal Vaccine

The meningococcal vaccine costs approximately $82 in the public sector and $110 in the private sector. A study conducted at the time of licensure in 2005 found that, considering only direct medical costs, routine vaccination of MCV4 was not cost-effective. But the study pointed out that "the impact of meningococcal disease cannot be wholly accounted for by any single analysis, and cost effectiveness is only one of the measures that should be used to inform a policy decision on the routine use of conjugate meningococcal vaccines in the United States."[xcvi] Additionally, a 2007 study found that catch-up[17] and routine vaccination program for adolescents would prevent 8,251 cases of meningococcal disease in a 10-year period. It also found that even though such a program would yield net economic costs, it would hold the "greatest promise" for substantial and quick reductions in overall meningococcal disease in the United States.[xcvii]

Because of the severe nature of the disease and the high incidence of life-long disabilities, in 2005, the ACIP determined that the benefit of meningococcal vaccination was worth the cost and recommended MCV4 in adolescents.

Cost of Enforcing Meningococcal Vaccination Requirement

This is a new requirement for middle school and high school students and schools will be responsible for enforcing it. The Immunization Rulemaking Advisory Committee included school nurse representatives. Also, the department did outreach to schools, including superintendents, regarding this requirement. The school groups did not oppose the concept of a meningococcal requirement but did express concern about the prospect of a booster-dose verification in high school. The department is not recommending that at this time. At

[17] A catch-up program is one that attempts to vaccinate those who did not get vaccinated at the recommended age.

present, we do not have sufficient information about how widespread the booster dose has been adopted. And if the booster rates were low, the requirement would add an undue burden on the schools to get students into compliance.

There will be no new costs to the state to implement this requirement. The meningococcal vaccine is part of the federal Vaccines for Children (VFC) program, which covers ACIP-recommended vaccines. The VFC program is a federally funded entitlement program that pays for vaccines for children who are uninsured, Minnesota Health Care Program (MHCP) enrollees, American Indians, Alaska Natives, and certain underinsured children. Because the meningococcal vaccine is ACIP-recommended, most private insurers already cover the cost of the vaccine, thus the cost is included in their standard plans. The department did not hear from any private insurers opposing this requirement. Moreover, the Affordable Care Act (ACA) requires full coverage of all ACIP-recommended vaccines. Some insurance plans currently have grandfathered status in relation to the ACA and are able to require consumers to pay for immunizations, but the number of grandfathered plans is quickly decreasing.

Discussion of 2007 Meningococcal. Vaccine Report to the Minnesota Legislature
During the 2007 Minnesota legislative session, Senators Tarryl Clark and Sandy Pappas sent a letter to then Commissioner of Health Dianne Mandernach requesting that the Minnesota Immunization Practices Advisory Committee (MIPAC) review the need for meningococcal immunization in high school and college students. The report was completed in November 2007. At that time, the department did not recommend a meningococcal immunization requirement in either high school or college for several reasons:

First, MCV4 was a new vaccine recommendation and clinicians needed time to fully incorporate the recommendation into their medical practice. In the five years since the report, clinicians have incorporated the meningococcal vaccine into their practice and the vaccine is now routinely given to adolescents 12 to 18 year olds.

Second, a new vaccine coupled with a large number of children who were not vaccinated meant that a school requirement would have caused a surge in vaccine use. Vaccine supply might not have been able to keep up with the demand. Since there has not been a shortage since 2006, the department believes this will not be a problem now.

Third, there was concern that the cost of the vaccine would limit public access to it. But the VFC program and most insurers now cover the cost of the vaccine. In addition, as pointed out earlier in this SONAR, the Affordable Care requires full coverage of all federal ACIP-recommended vaccines.

Finally, the department hesitated to impose a compliance burden on schools for a new vaccine. It is the department's view that, before implementing a new immunization requirement for school-age children, there must be wide-spread acceptance and usage of the vaccine. At the time, that was not the case. But five years have passed since the report was written and meningococcal vaccine acceptance by health care providers has grown.

Summary – Meningococcal Vaccine
Since the rates of meningococcal disease, which can cause serious disability and death, rise among adolescents, and the meningococcal vaccine is highly effective in preventing the three strains of the disease that cause the most disease, the department believes requiring the meningococcal vaccine for all children in seventh through 12th grade is both reasonable

and necessary. The reasons for not adding it to the School Immunization Law in 2007 are no longer valid. As always, parents or guardians will have the option of obtaining a legal exemption if they are conscientiously opposed to the vaccination or have a medical contraindication to MCV4.

VIII. CONCLUSION

Based on the foregoing, the proposed rules are both needed and reasonable.

4/11/13
DATE

Edward P. Ehlinger, MD, MSPH, Commissioner
Minnesota Department of Health

IX. LIST OF ATTACHMENTS

ATTACHMENT A

Glossary of Terms

AAFP. American Academy of Family Physicians

AAP. American Academy of Pediatrics

ACIP. The U.S. Public Health Service's Advisory Committee on Immunization Practices. A statutorily created advisory committee that meets three times a year to make immunization recommendations for every U.S. licensed vaccines.

acute disease. A disease that comes on suddenly and sharply. Having a rapid onset and following a defined, intense illness course.

antibody. A protein produced in the blood by the immune system that helps identify and destroy foreign germs (virus or bacteria) that attack the body. Antibodies can be produced in response to a vaccine or natural infection. They circulate in blood to protect against future infections.

antigen. A protein on the surface of a virus, bacteria or cell that can stimulate the immune system to produce antibodies as a defense mechanism.

adverse reaction. An "untoward" effect caused by a vaccine that is extraneous to the vaccine's primary purpose of production of immunity. They are also called vaccine side effects.

CDC. Centers for Disease Control and Prevention in Atlanta, Georgia.

chronic disease. A disease/illness that is prolonged in duration, does not often resolve spontaneously, and is rarely cured completely; long lasting or frequently recurring.

cirrhosis. Severe liver disease that can lead to death.

communicable. Capable of being transmitted from one person or species to another, as a communicable disease; contagious.

cranial nerve disorders. Disorders of the nerves that control functions and movements of the face. These include Meniers disease, vertigo and dizziness, and facial spasms/twitching.

CSTE: Council of State and Territorial Epidemiologists, a national organization that recommends policies for state health department epidemiologists.

direct costs. Relating to vaccination, these include medical care for treating vaccine-preventable disease, its complications, and its sequelae; institutional care of cases of permanent damage, and special schooling and institutionalization.

disease incidence. The number of new cases of a specific disease occurring during a certain period of time in the population.

disease prevalence. The number of cases of a certain disease that are present in a population at one point in time.

DNA (deoxyribonucleic acid). A nucleic acid that carries the genetic information in the cell and is capable of self-replication. It is the nucleic acid that is the genetic material determining the makeup of all living cells and many viruses.

DTaP. The diphtheria, tetanus and acellular pertussis vaccine. This vaccine began to replace DTP vaccine beginning in 1996 in the United States.

DTP. The diphtheria, tetanus and whole-cell pertussis vaccine. This vaccine is no longer used in the United States.

encelphalitis-meningitis. Encephalitis is an acute inflammation of the brain, often caused by a virus or bacteria. Meningitis is an acute inflammation of the lining of the brain and spinal cord. Encephalitis with meningitis is known as meningoencephalitis. Symptoms include headache, fever, confusion, drowsiness, and fatigue. More advanced and serious symptoms include seizures or convulsions, tremors, hallucinations, memory problems, and unconsciousness

endemic. A disease that is constantly present to a greater or lesser degree in people of a certain class or in people living in a particular location.

epidemic. A large outbreak (see outbreak) of disease. An epidemic could include many people in the same city or community, or even in an entire country. A world-wide epidemic is called a pandemic.

epidemiology. The study of the distribution and determinants of disease, injury, and other health-related events.

Guillain-Barré Syndrome (GBS). A serious, but rare, temporary inflammation of the nerves, causing pain, weakness, and paralysis in the extremities and often progressing to the chest and face. It can occur spontaneously or after certain events, such as an infection.

herd immunity. The concept that immunizing a large percentage of persons who can be vaccinated stops the transmission of disease, thereby protecting those who have not been or cannot be vaccinated from that disease and those who unknowingly did not develop a response to the vaccine

i**mmunogenicity**. Eliciting an immune response. How successful a vaccine is in getting the body to develop antibodies to fight against a particular disease.

immunologic memory. The ability for the body's immune system to remember certain disease-causing germs and develop antibodies to fight against them to protect against the disease.

immunity. Protection from disease. Having antibodies (see above) to a disease makes a person immune. A person who is immune is no longer susceptible. Immunity is achieved through obtaining a disease and successfully recovering or through vaccination.

Immunocompromised. Individuals who are immunocompromised are less capable of battling infections because of an immune response that is not properly functioning. Examples of immunocompromised people are those that have HIV or AIDS, are pregnant, or are undergoing chemotherapy or radiation therapy for cancer.

immunosuppression. Loss of the body's ability to fight infection. Immunosuppression may result from certain diseases, such as AIDS or lymphoma, or from certain drugs, such as some of those used to treat cancer

incubation period. The time it takes from the point of becoming infected to the time an infection becomes strong enough (the disease-causing microorganism to multiply) to cause illness in a person.

indirect costs. Include earnings lost due to premature mortality or disability, and loss of earnings for both caregiver and persons with disease.

medically acceptable standards. Medically acceptable standards mean the establishment of practices that have been determined acceptable and expected by the majority of health professionals; for the purposes of immunization, these are recommendations promulgated at the national level by the Advisory Committee on Immunization Practices (ACIP).

MCCA. Minnesota Child Care Association

MCHP. Minnesota Health Care Programs, which are publicly funded including Medical Assistance (MA), Minnesota Care (MnCare), or a Prepaid Medical Assistance Program (PMAP).

MLFCCA. Minnesota Family Licensed Family Child Association

MMR. A combination vaccine against measles, mumps, and rubella diseases.

Morbidity rate. The incidence or prevalence of a disease in a population.

Mortality rate. The frequency or number of deaths in ratio to population.

outbreak. A greater than expected number of cases of a disease occurring around the same time and place, involving people who all got the disease from the same source or from each other.

paralytic syndromes. These are conditions in which muscle function is lost and include cerebral palsy, Bell's palsey, poliomyelitits, multiple sclerosis, Guillain-Barré syndrome, etc.

prevalence. The number of cases of a disease that are present in a population at a specified time, either at a point in time or over a period of time.

serology. Pertaining to the testing of blood. In infectious disease serology is used to measure whether someone has antibodies to a disease in their system.

susceptible. Vulnerable to disease. Someone who has never had a disease or has never been vaccinated against it is susceptible to that disease. Opposite of immune**.**

vaccine-preventable diseases. Diseases that can be prevented, or their severity greatly reduced, by immunization. Diseases such as measles, mumps, rubella, polio, tetanus, pertussis, meningitis, and chickenpox are vaccine-preventable diseases.

Vaccine Safety Datalink (VSD): The VSD is a Centers for Disease Control and Prevention sponsored collaboration among 8 geographically diverse managed care organizations in the U.S. to study vaccine safety after licensure.

VAERS. Vaccine Adverse Events Reporting System, a post-licensure safety monitoring program that collects reports about adverse events (possible side effects) that occur after the administration of vaccines licensed for use in the United States. http://vaers.hhs.gov/index

varicella. Another name for chickenpox. The varicella vaccine is a vaccine to prevent the varicella disease (chickenpox).

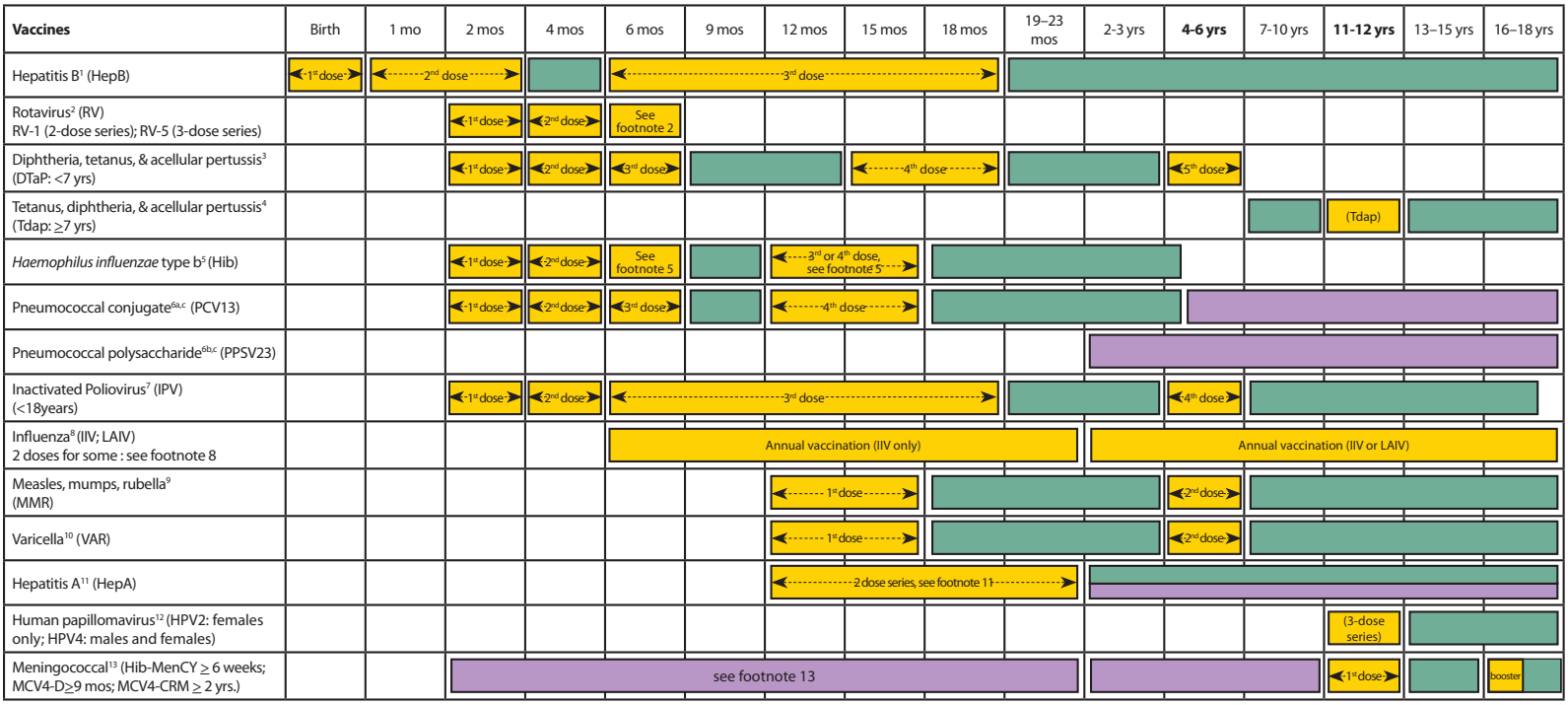
ATTACHMENT B

Recommended Childhood Immunization Schedule

Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – 2013.

(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are in bold.



This schedule includes recommendations in effect as of January 1, 2013. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967).Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (http://www.cdc.gov/vaccines) or by telephone (800-CDC-INFO [800-232-4636]).

This schedule is approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/vaccines/acip/index.html), the American Academy of Pediatrics (http://www.aap.org), the American Academy of Family Physicians (http://www.aafp.org), and the American College of Obstetricians and Gynecologists (http://www.acog.org).

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Footnotes — Recommended immunization schedule for persons aged 0 through 18 years—United States, 2013

For further guidance on the use of the vaccines mentioned below, see: http://www.cdc.gov/vaccines/pubs/acip-list.htm.

1. **Hepatitis B (HepB) vaccine. (Minimum age: birth)**
   Routine vaccination:
   At birth
   - Administer monovalent HepB vaccine to all newborns before hospital discharge.
   - For infants born to hepatitis B surface antigen (HBsAg)–positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) 1 to 2 months after completion of the HepB series, at age 9 through 18 months (preferably at the next well-child visit).
   - If mother's HBsAg status is unknown, within 12 hours of birth administer HepB vaccine to all infants regardless of birth weight. For infants weighing <2,000 grams, administer HBIG in addition to HepB within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if she is HBsAg-positive, also administer HBIG for infants weighing ≥2,000 grams (no later than age 1 week).

   Doses following the birth dose
   - The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.
   - Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine on a schedule of 0, 1 to 2 months, and 6 months starting as soon as feasible. See Figure 2.
   - The minimum interval between dose 1 and dose 2 is 4 weeks and between dose 2 and 3 is 8 weeks. The final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks, and at least 16 weeks after the first dose.
   - Administration of a total of 4 doses of HepB vaccine is recommended when a combination vaccine containing HepB is administered after the birth dose.

   Catch-up vaccination:
   - Unvaccinated persons should complete a 3-dose series.
   - A 2-dose series (doses separated by at least 4 months) of adult formulation Recombivax HB is licensed for use in children aged 11 through 15 years.
   - For other catch-up issues, see Figure 2.
2. **Rotavirus (RV) vaccines. (Minimum age: 6 weeks for both RV-1 [Rotarix] and RV-5 [RotaTeq]).**
   Routine vaccination:
   - Administer a series of RV vaccine to all infants as follows:
     1. If RV-1 is used, administer a 2-dose series at 2 and 4 months of age.
     2. If RV-5 is used, administer a 3-dose series at ages 2, 4, and 6 months.
     3. If any dose in series was RV-5 or vaccine product is unknown for any dose in the series, a total of 3 doses of RV vaccine should be administered.

   Catch-up vaccination:
   - The maximum age for the first dose in the series is 14 weeks, 6 days.
   - Vaccination should not be initiated for infants aged 15 weeks 0 days or older.
   - The maximum age for the final dose in the series is 8 months, 0 days.
   - If RV-1(Rotarix) is administered for the first and second doses, a third dose is not indicated.
   - For other catch-up issues, see Figure 2.
3. **Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. (Minimum age: 6 weeks)**
   Routine vaccination:
   - Administer a 5-dose series of DTaP vaccine at ages 2, 4, 6, 15–18 months, and 4 through 6 years. The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.

   Catch-up vaccination:
   - The fifth (booster) dose of DTaP vaccine is not necessary if the fourth dose was administered at age 4 years or older.
   - For other catch-up issues, see Figure 2.
4. **Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine. (Minimum age: 10 years for Boostrix, 11 years for Adacel).**
   Routine vaccination:
   - Administer 1 dose of Tdap vaccine to all adolescents aged 11 through 12 years.
   - Tdap can be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.
   - Administer one dose of Tdap vaccine to pregnant adolescents during each pregnancy (preferred during 27 through 36 weeks gestation) regardless of number of years from prior Td or Tdap vaccination.

   Catch-up vaccination:
   - Persons aged 7 through 10 years who are not fully immunized with the childhood DTaP vaccine series, should receive Tdap vaccine as the first dose in the catch-up series; if additional doses are needed, use Td vaccine. For these children, an adolescent Tdap vaccine should not be given.
   - Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter.
   - An inadvertent dose of DTaP vaccine administered to children aged 7 through 10 years can count as part of the catch-up series. This dose can count as the adolescent Tdap dose, or the child can later receive a Tdap booster dose at age 11–12 years.
   - For other catch-up issues, see Figure 2.
5. ***Haemophilus influenzae* type b (Hib) conjugate vaccine. (Minimum age: 6 weeks)**
   Routine vaccination:
   - Administer a Hib vaccine primary series and a booster dose to all infants. The primary series doses should be administered at 2, 4, and 6 months of age; however, if PRP-OMP (PedvaxHib or Comvax) is administered at 2 and 4 months of age, a dose at age 6 months is not indicated. One booster dose should be administered at age 12 through15 months.
   - Hiberix (PRP-T) should only be used for the booster (final) dose in children aged 12 months through 4 years, who have received at least 1 dose of Hib.

   Catch-up vaccination:
   - If dose 1 was administered at ages 12-14 months, administer booster (as final dose) at least 8 weeks after dose 1.
   - If the first 2 doses were PRP-OMP (PedvaxHIB or Comvax), and were administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.
   - If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a final dose at age 12 through 15 months, regardless of Hib vaccine (PRP-T or PRP-OMP) used for first dose.
   - For unvaccinated children aged 15 months or older, administer only 1 dose.

For further guidance on the use of the vaccines mentioned below, see: http://www.cdc.gov/vaccines/pubs/acip-list.htm.

- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- Hib vaccine is not routinely recommended for patients older than 5 years of age. However one dose of Hib vaccine should be administered to unvaccinated or partially vaccinated persons aged 5 years or older who have leukemia, malignant neoplasms, anatomic or functional asplenia (including sickle cell disease), human immunodeficiency virus (HIV) infection, or other immunocompromising conditions.

6a. Pneumococcal conjugate vaccine (PCV). (Minimum age: 6 weeks)

Routine vaccination:

- Administer a series of PCV13 vaccine at ages 2, 4, 6 months with a booster at age 12 through 15 months.
- For children aged 14 through 59 months who have received an age-appropriate series of 7-valent PCV (PCV7), administer a single supplemental dose of 13-valent PCV (PCV13).

Catch-up vaccination:

- Administer 1 dose of PCV13 to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- For children aged 24 through 71 months with certain underlying medical conditions (see footnote 6c), administer 1 dose of PCV13 if 3 doses of PCV were received previously, or administer 2 doses of PCV13 at least 8 weeks apart if fewer than 3 doses of PCV were received previously.
- A single dose of PCV13 may be administered to previously unvaccinated children aged 6 through 18 years who have anatomic or functional asplenia (including sickle cell disease), HIV infection or an immunocompromising condition, cochlear implant or cerebrospinal fluid leak. See MMWR 2010;59 (No. RR-11), available at http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf.
- Administer PPSV23 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnotes 6b and 6c).

6b. Pneumococcal polysaccharide vaccine (PPSV23). (Minimum age: 2 years)

Vaccination of persons with high-risk conditions:

- Administer PPSV23 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnote 6c). A single revaccination with PPSV should be administered after 5 years to children with anatomic or functional asplenia (including sickle cell disease) or an immunocompromising condition.

6c. Medical conditions for which PPSV23 is indicated in children aged 2 years and older and for which use of PCV13 is indicated in children aged 24 through 71 months:

- Immunocompetent children with chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy), diabetes mellitus; cerebrospinal fluid leaks; or cochlear implant.
- Children with anatomic or functional asplenia (including sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, or splenic dysfunction);
- Children with immunocompromising conditions: HIV infection, chronic renal failure and nephrotic syndrome, diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas and Hodgkin disease; or solid organ transplantation, congenital immunodeficiency.

7. Inactivated poliovirus vaccine (IPV). (Minimum age: 6 weeks)

Routine vaccination:

- Administer a series of IPV at ages 2, 4, 6–18 months, with a booster at age 4–6 years. The final dose in the series should be administered on or after the fourth birthday and at least 6 months after the previous dose.

Catch-up vaccination:

- In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk for imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
- If 4 or more doses are administered before age 4 years, an additional dose should be administered at age 4 through 6 years.
- A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
- IPV is not routinely recommended for U.S. residents aged 18 years or older.
- For other catch-up issues, see Figure 2.

8. Influenza vaccines. (Minimum age: 6 months for inactivated influenza vaccine [IIV]; 2 years for live, attenuated influenza vaccine [LAIV])

Routine vaccination:

- Administer influenza vaccine annually to all children beginning at age 6 months. For most healthy, nonpregnant persons aged 2 through 49 years, either LAIV or IIV may be used. However, LAIV should NOT be administered to some persons, including 1) those with asthma, 2) children 2 through 4 years who had wheezing in the past 12 months, or 3) those who have any other underlying medical conditions that predispose them to influenza complications. For all other contraindications to use of LAIV see MMWR 2010; 59 (No. RR-8), available at http://www.cdc.gov/mmwr/pdf/rr/rr5908.pdf.
- Administer 1 dose to persons aged 9 years and older.

For children aged 6 months through 8 years:

- For the 2012–13 season, administer 2 doses (separated by at least 4 weeks) to children who are receiving influenza vaccine for the first time. For additional guidance, follow dosing guidelines in the 2012 ACIP influenza vaccine recommendations, MMWR 2012; 61: 613–618, available at http://www.cdc.gov/mmwr/pdf/wk/mm6132.pdf.
- For the 2013–14 season, follow dosing guidelines in the 2013 ACIP influenza vaccine recommendations.

9. Measles, mumps, and rubella (MMR) vaccine. (Minimum age: 12 months for routine vaccination)

Routine vaccination:

- Administer the first dose of MMR vaccine at age 12 through 15 months, and the second dose at age 4 through 6 years. The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.
- Administer 1 dose of MMR vaccine to infants aged 6 through 11 months before departure from the United States for international travel. These children should be revaccinated with 2 doses of MMR vaccine, the first at age 12 through 15 months (12 months if the child remains in an area where disease risk is high), and the second dose at least 4 weeks later.
- Administer 2 doses of MMR vaccine to children aged 12 months and older, before departure from the United States for international travel. The first dose should be administered on or after age 12 months and the second dose at least 4 weeks later.

Catch-up vaccination:

- Ensure that all school-aged children and adolescents have had 2 doses of MMR vaccine; the minimum interval between the 2 doses is 4 weeks.

10. Varicella (VAR) vaccine. (Minimum age: 12 months)

Routine vaccination:

- Administer the first dose of VAR vaccine at age 12 through 15 months, and the second dose at age 4 through 6 years. The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose. If the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.

Catch-up vaccination:

- Ensure that all persons aged 7 through 18 years without evidence of immunity (see MMWR 2007;56 [No. RR-4], available at http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have 2 doses of varicella vaccine. For children aged 7 through 12 years the recommended minimum interval between doses is 3 months (if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid); for persons aged 13 years and older, the minimum interval between doses is 4 weeks.

11. Hepatitis A vaccine (HepA). (Minimum age: 12 months)

Routine vaccination:

- Initiate the 2-dose HepA vaccine series for children aged 12 through 23 months; separate the 2 doses by 6 to 18 months.
- Children who have received 1 dose of HepA vaccine before age 24 months, should receive a second dose 6 to 18 months after the first dose.
- For any person aged 2 years and older who has not already received the HepA vaccine series, 2 doses of HepA vaccine separated by 6 to 18 months may be administered if immunity against hepatitis A virus infection is desired.

Catch-up vaccination:

- The minimum interval between the two doses is 6 months.

Special populations:

- Administer 2 doses of Hep A vaccine at least 6 months apart to previously unvaccinated persons who live in areas where vaccination programs target older children, or who are at increased risk for infection.

12. Human papillomavirus (HPV) vaccines. (HPV4 [Gardasil] and HPV2 [Cervarix]). (Minimum age: 9 years)

Routine vaccination:

- Administer a 3-dose series of HPV vaccine on a schedule of 0, 1-2, and 6 months to all adolescents aged 11-12 years. Either HPV4 or HPV2 may be used for females, and only HPV4 may be used for males.
- The vaccine series can be started beginning at age 9 years.
- Administer the second dose 1 to 2 months after the **first** dose and the third dose 6 months after the **first** dose (at least 24 weeks after the first dose).

Catch-up vaccination:

- Administer the vaccine series to females (either HPV2 or HPV4) and males (HPV4) at age 13 through 18 years if not previously vaccinated.
- Use recommended routine dosing intervals (see above) for vaccine series catch-up.

13. Meningococcal conjugate vaccines (MCV). (Minimum age: 6 weeks for Hib-MenCY, 9 months for Menactra [MCV4-D], 2 years for Menveo [MCV4-CRM]).

Routine vaccination:

- Administer MCV4 vaccine at age 11–12 years, with a booster dose at age 16 years.
- Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of MCV4, with at least 8 weeks between doses. See MMWR 2011; 60:1018–1019 available at: http://www.cdc.gov/mmwr/pdf/wk/mm6030.pdf.
- For children aged 9 months through 10 years with high-risk conditions, see below.

Catch-up vaccination:

- Administer MCV4 vaccine at age 13 through 18 years if not previously vaccinated.
- If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks between doses.
- If the first dose is administered at age 16 years or older, a booster dose is not needed.
- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- For children younger than 19 months of age with anatomic or functional asplenia (including sickle cell disease), administer an infant series of Hib-MenCY at 2, 4, 6, and 12-15 months.
- For children aged 2 through 18 months with persistent complement component deficiency, administer either an infant series of Hib-MenCY at 2, 4, 6, and 12 through 15 months or a 2-dose primary series of MCV4-D starting at 9 months, with at least 8 weeks between doses. For children aged 19 through 23 months with persistent complement component deficiency who have not received a complete series of Hib-MenCY or MCV4-D, administer 2 primary doses of MCV4-D at least 8 weeks apart.
- For children aged 24 months and older with persistent complement component deficiency or anatomic or functional asplenia (including sickle cell disease), who have not received a complete series of Hib-MenCY or MCV4-D, administer 2 primary doses of either MCV4-D or MCV4-CRM. If MCV4-D (Menactra) is administered to a child with asplenia (including sickle cell disease), do not administer MCV4-D until 2 years of age and at least 4 weeks after the completion of all PCV13 doses. See MMWR 2011;60:1391–2, available at http://www.cdc.gov/mmwr/pdf/wk/mm6040.pdf.
- For children aged 9 months and older who are residents of or travelers to countries in the African meningitis belt or to the Hajj, administer an age appropriate formulation and series of MCV4 for protection against serogroups A and W-135. Prior receipt of Hib-MenCY is not sufficient for children traveling to the meningitis belt or the Hajj. See MMWR 2011;60:1391–2, available at http://www.cdc.gov/mmwr/pdf/wk/mm6040.pdf.
- For children who are present during outbreaks caused by a vaccine serogroup, administer or complete an age and formulation-appropriate series of Hib-MenCY or MCV4.
- For booster doses among persons with high-risk conditions refer to http://www.cdc.gov/vaccines/pubs/acip-list.htm#mening.

Additional information

- For contraindications and precautions to use of a vaccine and for additional information regarding that vaccine, vaccination providers should consult the relevant ACIP statement available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm.
- For the purposes of calculating intervals between doses, 4 weeks = 28 days. Intervals of 4 months or greater are determined by calendar months.
- Information on travel vaccine requirements and recommendations is available at http://wwwnc.cdc.gov/travel/page/vaccinations.htm.
- For vaccination of persons with primary and secondary immunodeficiencies, see Table 13, "Vaccination of persons with primary and secondary immunodeficiencies," in General Recommendations on Immunization (ACIP), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm; and American Academy of Pediatrics. Passive immunization. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS eds. Red book: 2012 report of the Committee on Infectious Diseases. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics.

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Centers for Disease Control and Prevention

FIGURE 2. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind —United States • 2013

The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table in conjunction with Figure 1 and the footnotes that follow.

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to dose 2	Dose 2 to dose 3	Dose 3 to dose 4	Dose 4 to dose 5
Persons aged 4 months through 6 years					
Hepatitis B[1]	Birth	4 weeks	8 weeks and at least 16 weeks after first dose; minimum age for the final dose is 24 weeks		
Rotavirus[2]	6 weeks	4 weeks	4 weeks[2]		
Diphtheria, tetanus, pertussis[3]	6 weeks	4 weeks	4 weeks	6 months	6 months[3]
Haemophilus influenzae type b[5]	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose) if first dose administered at age 12–14 months No further doses needed if first dose administered at age 15 months or older	4 weeks[5] if current age is younger than 12 months 8 weeks (as final dose)[5] if current age is 12 months or older and first dose administered at younger than age 12 months and second dose administered at younger than 15 months No further doses needed if previous dose administered at age 15 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 doses before age 12 months	
Pneumococcal[6]	6 weeks	4 weeks if first dose administered at younger than age 12 months 8 weeks (as final dose for healthy children) if first dose administered at age 12 months or older or current age 24 through 59 months No further doses needed for healthy children if first dose administered at age 24 months or older	4 weeks if current age is younger than 12 months 8 weeks (as final dose for healthy children) if current age is 12 months or older No further doses needed for healthy children if previous dose administered at age 24 months or older	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age	
Inactivated poliovirus[7]	6 weeks	4 weeks	4 weeks	6 months[7] minimum age 4 years for final dose	
Meningococcal[13]	6 weeks	8 weeks[13]	see footnote 13	see footnote 13	
Measles, mumps, rubella[9]	12 months	4 weeks			
Varicella[10]	12 months	3 months			
Hepatitis A[11]	12 months	6 months			
Persons aged 7 through 18 years					
Tetanus, diphtheria; tetanus, diphtheria, pertussis[4]	7 years[4]	4 weeks	4 weeks if first dose administered at younger than age 12 months 6 months if first dose administered at 12 months or older	6 months if first dose administered at younger than age 12 months	
Human papillomavirus[12]	9 years	Routine dosing intervals are recommended[12]			
Hepatitis A[11]	12 months	6 months			
Hepatitis B[1]	Birth	4 weeks	8 weeks (and at least 16 weeks after first dose)		
Inactivated poliovirus[7]	6 weeks	4 weeks	4 weeks[7]	6 months[7]	
Meningococcal[13]	6 weeks	8 weeks[13]			
Measles, mumps, rubella[9]	12 months	4 weeks			
Varicella[10]	12 months	3 months if person is younger than age 13 years 4 weeks if person is aged 13 years or older			

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Footnotes — Recommended immunization schedule for persons aged 0 through 18 years—United States, 2013

For further guidance on the use of the vaccines mentioned below, see: http://www.cdc.gov/vaccines/pubs/acip-list.htm.

1. **Hepatitis B (HepB) vaccine. (Minimum age: birth)**
   Routine vaccination:
   At birth
   - Administer monovalent HepB vaccine to all newborns before hospital discharge.
   - For infants born to hepatitis B surface antigen (HBsAg)–positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) 1 to 2 months after completion of the HepB series, at age 9 through 18 months (preferably at the next well-child visit).
   - If mother's HBsAg status is unknown, within 12 hours of birth administer HepB vaccine to all infants regardless of birth weight. For infants weighing <2,000 grams, administer HBIG in addition to HepB within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if she is HBsAg-positive, also administer HBIG for infants weighing ≥2,000 grams (no later than age 1 week).

   Doses following the birth dose
   - The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.
   - Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine on a schedule of 0, 1 to 2 months, and 6 months starting as soon as feasible. See Figure 2.
   - The minimum interval between dose 1 and dose 2 is 4 weeks and between dose 2 and 3 is 8 weeks. The final (third or fourth) dose in the HepB vaccine series should be administered no earlier than age 24 weeks, and at least 16 weeks after the first dose.
   - Administration of a total of 4 doses of HepB vaccine is recommended when a combination vaccine containing HepB is administered after the birth dose.

   Catch-up vaccination:
   - Unvaccinated persons should complete a 3-dose series.
   - A 2-dose series (doses separated by at least 4 months) of adult formulation Recombivax HB is licensed for use in children aged 11 through 15 years.
   - For other catch-up issues, see Figure 2.

2. **Rotavirus (RV) vaccines. (Minimum age: 6 weeks for both RV-1 [Rotarix] and RV-5 [RotaTeq]).**
   Routine vaccination:
   - Administer a series of RV vaccine to all infants as follows:
     1. If RV-1 is used, administer a 2-dose series at 2 and 4 months of age.
     2. If RV-5 is used, administer a 3-dose series at ages 2, 4, and 6 months.
     3. If any dose in series was RV-5 or vaccine product is unknown for any dose in the series, a total of 3 doses of RV vaccine should be administered.

   Catch-up vaccination:
   - The maximum age for the first dose in the series is 14 weeks, 6 days.
   - Vaccination should not be initiated for infants aged 15 weeks 0 days or older.
   - The maximum age for the final dose in the series is 8 months, 0 days.
   - If RV-1(Rotarix) is administered for the first and second doses, a third dose is not indicated.
   - For other catch-up issues, see Figure 2.

3. **Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. (Minimum age: 6 weeks)**
   Routine vaccination:
   - Administer a 5-dose series of DTaP vaccine at ages 2, 4, 6, 15–18 months, and 4 through 6 years. The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.

   Catch-up vaccination:
   - The fifth (booster) dose of DTaP vaccine is not necessary if the fourth dose was administered at age 4 years or older.
   - For other catch-up issues, see Figure 2.

4. **Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine. (Minimum age: 10 years for Boostrix, 11 years for Adacel).**
   Routine vaccination:
   - Administer 1 dose of Tdap vaccine to all adolescents aged 11 through 12 years.
   - Tdap can be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.

For further guidance on the use of the vaccines mentioned below, see: http://www.cdc.gov/vaccines/pubs/acip-list.htm.

- Administer one dose of Tdap vaccine to pregnant adolescents during each pregnancy (preferred during 27 through 36 weeks gestation) regardless of number of years from prior Td or Tdap vaccination.

Catch-up vaccination:

- Persons aged 7 through 10 years who are not fully immunized with the childhood DTaP vaccine series, should receive Tdap vaccine as the first dose in the catch-up series; if additional doses are needed, use Td vaccine. For these children, an adolescent Tdap vaccine should not be given.
- Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter.
- An inadvertent dose of DTaP vaccine administered to children aged 7 through 10 years can count as part of the catch-up series. This dose can count as the adolescent Tdap dose, or the child can later receive a Tdap booster dose at age 11–12 years.
- For other catch-up issues, see Figure 2.

5. *Haemophilus influenzae* type b (Hib) conjugate vaccine. (Minimum age: 6 weeks)

Routine vaccination:

- Administer a Hib vaccine primary series and a booster dose to all infants. The primary series doses should be administered at 2, 4, and 6 months of age; however, if PRP-OMP (PedvaxHib or Comvax) is administered at 2 and 4 months of age, a dose at age 6 months is not indicated. One booster dose should be administered at age 12 through15 months.
- Hiberix (PRP-T) should only be used for the booster (final) dose in children aged 12 months through 4 years, who have received at least 1 dose of Hib.

Catch-up vaccination:

- If dose 1 was administered at ages 12-14 months, administer booster (as final dose) at least 8 weeks after dose 1.
- If the first 2 doses were PRP-OMP (PedvaxHIB or Comvax), and were administered at age 11 months or younger, the third (and final) dose should be administered at age 12 through 15 months and at least 8 weeks after the second dose.
- If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a final dose at age 12 through 15 months, regardless of Hib vaccine (PRP-T or PRP-OMP) used for first dose.
- For unvaccinated children aged 15 months or older, administer only 1 dose.
- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- Hib vaccine is not routinely recommended for patients older than 5 years of age. However one dose of Hib vaccine should be administered to unvaccinated or partially vaccinated persons aged 5 years or older who have leukemia, malignant neoplasms, anatomic or functional asplenia (including sickle cell disease), human immunodeficiency virus (HIV) infection, or other immunocompromising conditions.

6a. Pneumococcal conjugate vaccine (PCV). (Minimum age: 6 weeks)

Routine vaccination:

- Administer a series of PCV13 vaccine at ages 2, 4, 6 months with a booster at age 12 through 15 months.
- For children aged 14 through 59 months who have received an age-appropriate series of 7-valent PCV (PCV7), administer a single supplemental dose of 13-valent PCV (PCV13).

Catch-up vaccination:

- Administer 1 dose of PCV13 to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- For children aged 24 through 71 months with certain underlying medical conditions (see footnote 6c), administer 1 dose of PCV13 if 3 doses of PCV were received previously, or administer 2 doses of PCV13 at least 8 weeks apart if fewer than 3 doses of PCV were received previously.
- A single dose of PCV13 may be administered to previously unvaccinated children aged 6 through 18 years who have anatomic or functional asplenia (including sickle cell disease), HIV infection or an immunocompromising condition, cochlear implant or cerebrospinal fluid leak. See MMWR 2010;59 (No. RR-11), available at http://www.cdc.gov/mmwr/pdf/rr/rr5911.pdf.
- Administer PPSV23 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnotes 6b and 6c).

6b. Pneumococcal polysaccharide vaccine (PPSV23). (Minimum age: 2 years)

Vaccination of persons with high-risk conditions:

- Administer PPSV23 at least 8 weeks after the last dose of PCV to children aged 2 years or older with certain underlying medical conditions (see footnote 6c). A single revaccination with PPSV should be administered after 5 years to children with anatomic or functional asplenia (including sickle cell disease) or an immunocompromising condition.

6c. Medical conditions for which PPSV23 is indicated in children aged 2 years and older and for which use of PCV13 is indicated in children aged 24 through 71 months:

- Immunocompetent children with chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy), diabetes mellitus; cerebrospinal fluid leaks; or cochlear implant.
- Children with anatomic or functional asplenia (including sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, or splenic dysfunction);
- Children with immunocompromising conditions: HIV infection, chronic renal failure and nephrotic syndrome, diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas and Hodgkin disease; or solid organ transplantation, congenital immunodeficiency.

7. Inactivated poliovirus vaccine (IPV). (Minimum age: 6 weeks)

Routine vaccination:

- Administer a series of IPV at ages 2, 4, 6–18 months, with a booster at age 4–6 years. The final dose in the series should be administered on or after the fourth birthday and at least 6 months after the previous dose.

Catch-up vaccination:

- In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk for imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
- If 4 or more doses are administered before age 4 years, an additional dose should be administered at age 4 through 6 years.
- A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
- IPV is not routinely recommended for U.S. residents aged 18 years or older.
- For other catch-up issues, see Figure 2.

8. Influenza vaccines. (Minimum age: 6 months for inactivated influenza vaccine [IIV]; 2 years for live, attenuated influenza vaccine [LAIV])

Routine vaccination:

- Administer influenza vaccine annually to all children beginning at age 6 months. For most healthy, nonpregnant persons aged 2 through 49 years, either LAIV or IIV may be used. However, LAIV should NOT be administered to some persons, including 1) those with asthma, 2) children 2 through 4 years who had wheezing in the past 12 months, or 3) those who have any other underlying medical conditions that predispose them to influenza complications. For all other contraindications to use of LAIV see MMWR 2010; 59 (No. RR-8), available at http://www.cdc.gov/mmwr/pdf/rr/rr5908.pdf.

Additional information

- For contraindications and precautions to use of a vaccine and for additional information regarding that vaccine, vaccination providers should consult the relevant ACIP statement available online at http://www.cdc.gov/vaccines/pubs/acip-list.htm.
- For the purposes of calculating intervals between doses, 4 weeks = 28 days. Intervals of 4 months or greater are determined by calendar months.
- Information on travel vaccine requirements and recommendations is available at http://wwwnc.cdc.gov/travel/page/vaccinations.htm.
- For vaccination of persons with primary and secondary immunodeficiencies, see Table 13, "Vaccination of persons with primary and secondary immunodeficiencies," in General Recommendations on Immunization (ACIP), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm; and American Academy of Pediatrics. Passive immunization. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS eds. Red book: 2012 report of the Committee on Infectious Diseases. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics.

- Administer 1 dose to persons aged 9 years and older.

For children aged 6 months through 8 years:

- For the 2012–13 season, administer 2 doses (separated by at least 4 weeks) to children who are receiving influenza vaccine for the first time. For additional guidance, follow dosing guidelines in the 2012 ACIP influenza vaccine recommendations, MMWR 2012; 61: 613–618, available at http://www.cdc.gov/mmwr/pdf/wk/mm6132.pdf.
- For the 2013–14 season, follow dosing guidelines in the 2013 ACIP influenza vaccine recommendations.

9. Measles, mumps, and rubella (MMR) vaccine. (Minimum age: 12 months for routine vaccination)

Routine vaccination:

- Administer the first dose of MMR vaccine at age 12 through 15 months, and the second dose at age 4 through 6 years. The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.
- Administer 1 dose of MMR vaccine to infants aged 6 through 11 months before departure from the United States for international travel. These children should be revaccinated with 2 doses of MMR vaccine, the first at age 12 through 15 months (12 months if the child remains in an area where disease risk is high), and the second dose at least 4 weeks later.
- Administer 2 doses of MMR vaccine to children aged 12 months and older, before departure from the United States for international travel. The first dose should be administered on or after age 12 months and the second dose at least 4 weeks later.

Catch-up vaccination:

- Ensure that all school-aged children and adolescents have had 2 doses of MMR vaccine; the minimum interval between the 2 doses is 4 weeks.

10. Varicella (VAR) vaccine. (Minimum age: 12 months)

Routine vaccination:

- Administer the first dose of VAR vaccine at age 12 through 15 months, and the second dose at age 4 through 6 years. The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose. If the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.

Catch-up vaccination:

- Ensure that all persons aged 7 through 18 years without evidence of immunity (see MMWR 2007;56 [No. RR-4], available at http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have 2 doses of varicella vaccine. For children aged 7 through 12 years the recommended minimum interval between doses is 3 months (if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid); for persons aged 13 years and older, the minimum interval between doses is 4 weeks.

11. Hepatitis A vaccine (HepA). (Minimum age: 12 months)

Routine vaccination:

- Initiate the 2-dose HepA vaccine series for children aged 12 through 23 months; separate the 2 doses by 6 to 18 months.
- Children who have received 1 dose of HepA vaccine before age 24 months, should receive a second dose 6 to 18 months after the first dose.
- For any person aged 2 years and older who has not already received the HepA vaccine series, 2 doses of HepA vaccine separated by 6 to 18 months may be administered if immunity against hepatitis A virus infection is desired.

Catch-up vaccination:

- The minimum interval between the two doses is 6 months.

Special populations:

- Administer 2 doses of Hep A vaccine at least 6 months apart to previously unvaccinated persons who live in areas where vaccination programs target older children, or who are at increased risk for infection.

12. Human papillomavirus (HPV) vaccines. (HPV4 [Gardasil] and HPV2 [Cervarix]). (Minimum age: 9 years)

Routine vaccination:

- Administer a 3-dose series of HPV vaccine on a schedule of 0, 1-2, and 6 months to all adolescents aged 11-12 years. Either HPV4 or HPV2 may be used for females, and only HPV4 may be used for males.
- The vaccine series can be started beginning at age 9 years.
- Administer the second dose 1 to 2 months after the **first** dose and the third dose 6 months after the **first** dose (at least 24 weeks after the first dose).

Catch-up vaccination:

- Administer the vaccine series to females (either HPV2 or HPV4) and males (HPV4) at age 13 through 18 years if not previously vaccinated.
- Use recommended routine dosing intervals (see above) for vaccine series catch-up.

13. Meningococcal conjugate vaccines (MCV). (Minimum age: 6 weeks for Hib-MenCY, 9 months for Menactra [MCV4-D], 2 years for Menveo [MCV4-CRM]).

Routine vaccination:

- Administer MCV4 vaccine at age 11–12 years, with a booster dose at age 16 years.
- Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of MCV4, with at least 8 weeks between doses. See MMWR 2011; 60:1018–1019 available at: http://www.cdc.gov/mmwr/pdf/wk/mm6030.pdf.
- For children aged 9 months through 10 years with high-risk conditions, see below.

Catch-up vaccination:

- Administer MCV4 vaccine at age 13 through 18 years if not previously vaccinated.
- If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks between doses.
- If the first dose is administered at age 16 years or older, a booster dose is not needed.
- For other catch-up issues, see Figure 2.

Vaccination of persons with high-risk conditions:

- For children younger than 19 months of age with anatomic or functional asplenia (including sickle cell disease), administer an infant series of Hib-MenCY at 2, 4, 6, and 12-15 months.
- For children aged 2 through 18 months with persistent complement component deficiency, administer either an infant series of Hib-MenCY at 2, 4, 6, and 12 through 15 months or a 2-dose primary series of MCV4-D starting at 9 months, with at least 8 weeks between doses. For children aged 19 through 23 months with persistent complement component deficiency who have not received a complete series of Hib-MenCY or MCV4-D, administer 2 primary doses of MCV4-D at least 8 weeks apart.
- For children aged 24 months and older with persistent complement component deficiency or anatomic or functional asplenia (including sickle cell disease), who have not received a complete series of Hib-MenCY or MCV4-D, administer 2 primary doses of either MCV4-D or MCV4-CRM. If MCV4-D (Menactra) is administered to a child with asplenia (including sickle cell disease), do not administer MCV4-D until 2 years of age and at least 4 weeks after the completion of all PCV13 doses. See MMWR 2011;60:1391–2, available at http://www.cdc.gov/mmwr/pdf/wk/mm6040.pdf.
- For children aged 9 months and older who are residents of or travelers to countries in the African meningitis belt or to the Hajj, administer an age appropriate formulation and series of MCV4 for protection against serogroups A and W-135. Prior receipt of Hib-MenCY is not sufficient for children traveling to the meningitis belt or the Hajj. See MMWR 2011;60:1391–2, available at http://www.cdc.gov/mmwr/pdf/wk/mm6040.pdf.
- For children who are present during outbreaks caused by a vaccine serogroup, administer or complete an age and formulation-appropriate series of Hib-MenCY or MCV4.
- For booster doses among persons with high-risk conditions refer to http://www.cdc.gov/vaccines/pubs/acip-list.htm#mening.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

ATTACHMENT C

Methods of Notifying and Persons Notified of Request for Comments

Mailed the Request for Comments to all persons who had registered to be on the department's rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a.

Posted the Request for Comment, a fact sheet containing a summary of the proposed changes, and information on the rulemaking process on the department's Immunization Rule web site at http://www.health.state.mn.us/divs/idepc/immunize/immrule/index.html. On the webpage there was also an option for people to "subscribe" to receive an alert when information on the Immunization Rule Revisions webpage is added or updated.

Posted information on the Request for Comments on the department's Facebook page, Twitter feed.

Provided a copy of the Request for Comment, the fact sheet containing a summary of the proposed changes, and a link to the MDH rulemaking website via email directly or through a listserv, to various individuals. The department also requested that these individuals share this information with colleagues, post the information on their website, and send it to their listservs. This list included:

- Health care providers, such as physicians, nurses, physician assistants, infection control practitioners, and hospital personnel. The department has a mailing list of all pediatricians, family practitioners, county public health agencies, hospitals, and other affected health care providers.
- School officials, such as superintendents and school nurses. The department has a mailing list with this information and also worked with the school nurse association to ensure that school nurses received the information.
- All licensed child care providers, both center and family based. The department has a current list of all licensed providers.
- A representative of the Minnesota Natural Health Coalition
- A representative of Vaccine Awareness Minnesota
- A representative of the Minnesota Vaccine Safety Council
- A representative of BEAT

Published information about the Request for Comments and a link to the MDH rulemaking website where people could get further information in publications that reach affected parties. These included:

- The department "Got Your Shots," a newsletter sent to over 6,000 subscribers, which includes nurses, doctors, physician assistants, and other interested parties.
- The Minnesota Medical Association's (MMA) monthly publication, "Minnesota Medicine."

Provided immunization rule information in presentations and at health conferences to health professionals and school personnel.

Provided a copy of the Request for Comments, the fact sheet containing a summary of the proposed changes, and a link to the MDH rulemaking website to members of the Immunization Rulemaking Advisory Committee; and asked them to forward the information to the organization they represent and their colleagues. (See *Attachment E for list of advisory committee members and their organizations*)

ATTACHMENT C

Provided a copy of the Request for Comment, the fact sheet containing a summary of the proposed changes, and a link to the MDH rulemaking website via email, directly or through a listserv, to various organizations. The department also requested that they post this information on their website and send it out to their listserv. This list includes:

- Minnesota Medical Association
- Minnesota Chapter of the Academy of Pediatrics
- Minnesota Chapter of the Academy of Family Physicians
- Minnesota Nurses Association
- Minnesota School Nurse Association
- Minnesota Chapter of the National Association of Pediatric Nurse Practitioners
- Physician Assistant groups
- Early childhood providers, including school readiness, ECFE, and screening coordinators
- Child Care Resource and Referral
- Minnesota Association of Secondary School Principals
- Minnesota Elementary School Principal Association
- March of Dimes
- Minnesota Hospital Association
- Immunization Action Coalition
- Minnesota Council of Health Plans

Notified the Legislature per Minnesota Statutes, section 14.116 and Minnesota Statutes, sections 121A.15, subdivision 12(2)(b) and 135A.14, subdivision 7(d). This include sending a letter with information on the public meetings, a copy of the Request for Comment, and a link to the MDH rulemaking website to the chairs and ranking minority members of the legislative policy and budget committees with jurisdiction over the subject matter.

ATTACHMENT D

Immunization Rulemaking Public Meeting
Video Conference Sites
June 18, 2012

1. Bemidji Office, Minnesota Department of Health
2. Brainerd, Crow Wing County Social Services
3. Crookston, Polk County Public Health
4. Duluth/St. Louis County, Government Service Center
5. Fergus Falls Office, Minnesota Department of Health Office
6. Koochiching County, International Falls
7. Mankato Place, Minnesota Department of Health
8. Marshall Office, Minnesota Department of Health
9. Rochester Office, Minnesota Department of Health
10. Roseau County Social Services, Roseau
11. St. Cloud Office, Minnesota Department of Health
12. Snelling Office Park, Minnesota Department of Health
13. Kandiyohi County Human Services, Willmar

ATTACHMENT E

Immunization Rulemaking Advisory Committee Member List

Name/ Position	Organization/Location Representing
1. DeAnn Besch	Minnesota Child Care Association (MCCA)
2. Amy Buckanaga, Nurse	Tribal Health
3. Katherine Cairns, Executive Director	Minnesota Chapter-American Academy of Pediatrics (MNAAP)
4. Kay Chase	Minnesota Licensed Family Child Care Association (MLFCCA)
5. Carol Diemert, Nurse	Minnesota Nurses Association (MNA)
6. Jennifer Dean Dwyer	Physician Assistant
7. Karen Ernst	Parent
8. Dr. Michael Garvis, Pediatrician	Minnesota Medical Association (MMA)
9. Patty Graham, Health Partners	Minnesota Council of Health Plans
10. Cindy Hiltz, School Nurse Anoka County	School Nurse Organization of Minnesota (SNOM)
11. Dr. Robert Jacobson, President	Minnesota Chapter-American Academy of Pediatrics (MNAAP)
12. Sharon Lynch	Local Public Health Association (LPHA)
13. Dr. Dawn Martin, Chair	Minnesota Immunization Practices Advisory Committee (MIPAC)
14. Kathy Mitchell, Nurse	Children's Hospital Infectious Disease
15. Britta Orr, Director	Local Public Health Association
16. Dr. Sue Park, Family Practice Physician	Minnesota Medical Association (MMA)
17. Jeanne Rancone, Nurse	Adolescent Health
18. Ashley Shelby	Parent
19. Patsy Stinchfield, Nurse	Minnesota Chapter-National Association of Pediatric Nurse Practitioners (MNNAPNAP)
20. Sue Wasland, School Nurse	Greater Minnesota

ATTACHMENT F

Fact Sheet

Advisory Committee on Immunization Practices (ACIP)

The Advisory Committee on Immunization Practices (ACIP)

For more information on vaccines, vaccine-preventable diseases, and vaccine safety:
http://www.cdc.gov/vaccines/conversations

Updated March 2012

- The Centers for Disease Control and Prevention (CDC) sets the U.S. childhood immunization schedule based on recommendations from the Advisory Committee on Immunization Practices (ACIP).
- Before recommending a vaccine the ACIP considers many factors, including the safety and effectiveness of the vaccine.
- Candidates for ACIP membership are screened carefully prior to being selected to join the committee.
- The ACIP develops vaccine recommendations for children and adults. The recommendations include the age(s) when the vaccine should be given, the number of doses needed, the amount of time between doses, and precautions and contraindications.

| questions and answers |

What is the ACIP?

The Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States.

The ACIP consists of 15 experts who are voting members and are responsible for making vaccine recommendations. The Secretary of the U.S. Department of Health and Human Services (DHHS) selects these members after an application, interview, and nomination process. Fourteen of these members have expertise in vaccinology, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health, infectious diseases, and/or preventive medicine. One member is a consumer representative who provides perspectives on the social and community aspects of vaccination.

The ACIP works with 30 professional organizations that are highly regarded in the health field. Examples of these professional organizations with which ACIP develops the annual harmonized childhood schedule are the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP). These members comment on ACIP's recommendations and offer the perspectives of groups that will implement the recommendations.

People with certain vaccine-related interests at the time they apply for the ACIP are not considered for membership. For example, direct employment of a candidate or an immediate family member by a vaccine manufacturer, holding a patent on a vaccine or related product, or serving on a Board of Directors of a vaccine manufacturer, excludes people from ACIP membership. However, because ACIP members are experts in the vaccine field, they may be involved in vaccine studies. Therefore, ACIP members who lead vaccine studies at their respective institutions may become ACIP members but they must abstain from voting on recommendations related to the vaccine they are studying. In addition, they cannot vote on any other vaccines manufactured by the company funding the research or on any vaccines that are similar to the one(s) they are studying.

The Adult Immunization Schedule Adults also need protection against several vaccine-preventable diseases. Therefore, in addition to the childhood immunization schedule, the ACIP makes recommendations for the adult immunization schedule. The ACIP considers many of the same factors for adult immunization recommendations that they consider when making recommendations about the childhood schedule. The professional organizations that work with the ACIP to develop the annual adult schedule include the American College of Obstetricians and Gynecologists (ACOG), the American College of Physicians (ACP), and the American Academy of Family Physicians (AAFP).

How does ACIP make decisions about vaccine recommendations?

The ACIP holds three meetings each year at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia to make vaccine recommendations. Meetings are open to the public and available online via webcast. During these committee meetings, members present findings and discuss vaccine research and scientific data related to vaccine effectiveness and safety, clinical trial results, and manufacturer's labeling or package insert information. Outbreaks of vaccine-preventable disease or changes in vaccine supply, such as vaccine shortages, also are reviewed during these meetings. The recommendations include the age(s) when the vaccine should be given, the number of doses needed, the amount of time between doses, and precautions and contraindications.

In addition to these meetings, ACIP members participate in work groups. These work groups are active all year to stay up-to-date on specific vaccines and vaccine safety information. For example, before a vaccine is even licensed by the U.S. Food and Drug Administration (FDA), an ACIP work group will thoroughly review all available scientific information about the vaccine so that they will be prepared to present information to the ACIP about the vaccine once it is licensed. At this point, the vaccine already has undergone several phases of testing for safety and efficacy with potentially tens of thousands of volunteers. The licensure process could take several years. The work group carefully reviews data available on the vaccine in order to make recommendations to the ACIP,

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but work groups do not vote on the final recommendation. The work group presents its findings to the entire ACIP at several meetings before ACIP members vote on whether to recommend the vaccine and who should receive the vaccine. The committee's recommendations are forwarded to CDC's Director for approval. Once the ACIP recommendations have been approved by the CDC Director, they are published in CDC's Morbidity and Mortality Weekly Report (MMWR) and represent the official CDC recommendations for immunizations in the U.S.

Each year, the ACIP's recommendations result in a single childhood immunization schedule, approved by the CDC, AAP, and AAFP, designed to best protect children in the United States.

Setting the Immunization Recommendations for the Pertussis Vaccine

In the United States, pertussis (whooping cough) still circulates in communities nationwide and is particularly dangerous for young infants. In 2010, whooping cough made more than 27,000 people sick, and 25 babies died. Many of the babies were too young to be fully protected against whooping cough.

Pertussis vaccine is part of the DTaP vaccine, which also protects against diphtheria and tetanus. Infants are recommended to receive four doses—a first dose at 2 months and additional doses at 4 months, 6 months, and 15 through 18 months for best protection. With each dose of the vaccine, they gain more protection against the disease. As disease protection fades over time, a booster dose is recommended for children who are 4 through 6 years old. The ACIP also recommends that mothers, fathers, and other caregivers of infants get a one-time dose of Tdap for added protection against pertussis.

What does the ACIP consider in the vaccine recommendation process?

The information that ACIP reviews for each vaccine always includes the following:

- **The safety and effectiveness of the vaccine when given at specific ages.** Only vaccines licensed by the FDA are recommended, and vaccine manufacturers must conduct rigorous studies to show that a vaccine is safe and effective at specific ages.
- **The severity of the disease.** Vaccines recommended for children prevent diseases that can be serious for them, potentially causing long-term health problems or death.
- **The number of children who get the disease if there is no vaccine.** Vaccines that do not provide benefit to many children may not be recommended for all children.
- **How well a vaccine works for children of different ages.** The immune response from a vaccine can vary depending on the age when the vaccine is given.

What does the ACIP consider when deciding at what age children should receive different vaccines?

The risk of disease and death at different ages is a main factor in deciding the best age to give each vaccine. The ACIP carefully examines data about each vaccine-preventable disease to determine at what ages the rates of the disease peak. Protection against vaccine-preventable disease at the earliest time possible is critical, especially for young children or other high risk groups, for whom a disease can be especially serious. For example, pertussis vaccine is recommended in the United States beginning at 2 months of age to protect infants. That timing saves lives that would otherwise be lost to the disease if vaccines were not given at a very young age.

The immunization schedule also is based on balancing the risk of being exposed to the disease against the added protection of vaccinating at the age that a vaccine works best. Before a vaccine is licensed by the FDA, extensive testing is done to determine the best ages to safely and effectively give the vaccine.

Where can I find ACIP's vaccine recommendations?

All of the ACIP's recommendations are posted on the CDC webpage at *http://www.cdc.gov/vaccines/recs/acip/default.htm.* Once they are reviewed and approved by the CDC's Director and the U.S. Department of Health and Human Services, recommendations are published in the CDC's Morbidity and Mortality Weekly Report (MMWR). The MMWR publication represents the final and official CDC recommendations for immunization of the U.S. population.

How can I learn more about the ACIP?

To learn more about the ACIP and see the schedule of ACIP meetings, review minutes and recommendations from previous meetings, and register for future meetings, visit the ACIP website: *http://www.cdc.gov/vaccines/recs/acip/default.htm.*

| resources |

Immunization Policy Development in the United States: The Role of the Advisory Committee on Immunization Practices by Jean C. Smith et al. Annals of Internal Medicine. January 2009. Vol 150: pages 45-49. *http://www.annals.org/content/150/1/45.full.pdf+html*

The structure, role, and procedures of the U.S. Advisory Committee on Immunization Practices (ACIP). By Jean C.Smith, Vaccine 2010 Vol 28S pages A68–A75. *http://www.cdc.gov/vaccines/recs/ACIP/downloads/article-2010-role-procedures-ACIP-508.pdf*

ACIP Meeting Dates, Meeting Agendas, Meeting Webcast, Minutes, Registration, Presentation Slides. *http://www.cdc.gov/vaccines/recs/acip/meetings.htm*

ACIP Membership List. *http://www.cdc.gov/vaccines/recs/acip/members.htm*

CDC's Morbidity and Mortality Weekly Report (MMWR): 2011 General Recommendations on Immunization. *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm?s_cid=rr6002a1_w*

Immunization Schedules for Children, Adolescents and Teens, and Adults. *http://www.cdc.gov/vaccines/recs/schedules/default.htm*

ATTACHMENT G

Fact Sheet

"Ensuring the Safety of Vaccines in the U.S."

Ensuring the Safety of Vaccines in the United States

For more information on vaccines, vaccine-preventable diseases, and vaccine safety:
http://www.cdc.gov/vaccines/conversations

Last reviewed March 2012

- Currently, the United States has the safest, most effective vaccine supply in its history.
- The United States' long-standing vaccine safety system ensures that vaccines are as safe as possible. As new information and science become available, this system is, and will continue to be, updated and improved.
- The U.S. Food and Drug Administration (FDA) ensures the safety, effectiveness, and availability of vaccines for the United States. Before the FDA licenses (approves) a vaccine, the vaccine is tested extensively by its manufacturer. FDA scientists and medical professionals carefully evaluate all the available information about the vaccine to determine its safety and effectiveness.
- Although most common side effects of a vaccine are identified in studies before the vaccine is licensed, rare adverse events may not be detected in these studies. Therefore, the U.S. vaccine safety system continuously monitors for adverse events (possible side effects) after a vaccine is licensed. When millions of people receive a vaccine, less common side effects that were not identified earlier may show up.

Adverse Events and Side Effects Adverse events reported to the Vaccine Adverse Event Reporting System (VAERS) are not necessarily side effects caused by vaccination. An ***adverse event*** is a health problem that happens after vaccination that may or may not be caused by a vaccine. By definition, a ***side effect*** has been shown to be linked to a vaccine by scientific studies.

Prelicensure: Vaccine Safety Testing

The U.S. Food and Drug Administration (FDA) must license (approve) a vaccine before it can be used in the United States. FDA regulations for the development of vaccines help to ensure their safety, purity, potency, and effectiveness. Before a vaccine is approved by FDA for use by the public, results of studies on safety and effectiveness of the vaccine are evaluated by highly trained FDA scientists and doctors. FDA also inspects the vaccine manufacturing sites to make sure they comply with current Good Manufacturing Practice (cGMP) regulations.

Vaccine Development

Vaccine development begins in the laboratory before any tests in animals or humans are done. If laboratory tests show that a vaccine has potential, it is usually tested in animals. If a vaccine is safe in animals, and studies suggest that it will be safe in people, clinical trials with volunteers are next.

Clinical Trials

Typically, there are three phases of clinical trials. Vaccines that are being developed for children are first tested in adults. FDA sets guidelines for the three phases of clinical trials to ensure the safety of the volunteers.

Phase 1 clinical trials focus on safety and include 20–100 healthy volunteers. In Phase 1, scientists begin to learn how the size of the dose may be related to side effects. If possible at this early stage, scientists also try to learn how effective the vaccine may be.

If no serious side effects are found in Phase 1, next is Phase 2, which involves several hundred volunteers. This phase includes studies that may provide additional information on common short-term side effects and how the size of the dose relates to immune response.

In Phase 3 studies, hundreds or thousands of volunteers participate. Vaccinated people are compared with people who have received a placebo or another vaccine so researchers can learn more about the test vaccine's safety and effectiveness and identify common side effects.

Clinical trials are conducted according to plans that FDA reviews to ensure the highest scientific and ethical standards. The results of the clinical trials are a part of FDA's evaluation to assess the safety and effectiveness of each vaccine. In addition to evaluating the results of the clinical trials, FDA scientists and medical professionals carefully evaluate a wide range of information including results of studies on the vaccine's physical, chemical, and biological properties, as well as how it is manufactured, to ensure that it can be made consistently safe, pure, and potent.

231405D

The trials and all other data must show that the vaccine's benefits outweigh the potential risks for people who will be recommended to receive the vaccine. Only if a vaccine's benefits are found to outweigh its potential risks does the FDA grant a license for the vaccine, allowing it to be used by the public.

| Postlicensure: Vaccine Safety Monitoring |

After vaccines are licensed, they are monitored closely as people begin using them. The purpose of monitoring is to watch for adverse events (possible side effects). Monitoring a vaccine after it is licensed helps ensure that the benefits continue to outweigh the risks for people who receive the vaccine.

Monitoring is essential for two reasons. First, even large clinical trials may not be big enough to reveal side effects that do not happen very often. For example, some side effects may only happen in 1 in 100,000 or 1 in 500,000 people.

Second, vaccine trials may not include groups who might have different types of side effects or who might have a higher risk of side effects than the volunteers who got the vaccine during clinical trials. Examples of these groups include people with chronic medical conditions, pregnant women, and older adults.

If a link is found between a possible side effect and a vaccine, public health officials take appropriate action by first weighing the benefits of the vaccine against its risks to determine if recommendations for using the vaccine should change.

The Advisory Committee on Immunization Practices (ACIP), a group of medical and public health experts, carefully reviews all safety and effectiveness data on vaccines as a part of its work to make recommendations for the use of vaccines. The ACIP modifies recommendations, if needed, based on safety monitoring.

VAERS

Postlicensure monitoring begins with the Vaccine Adverse Event Reporting System (VAERS), a national system used by scientists at FDA and the Centers for Disease Control and Prevention (CDC) to collect reports of adverse events (possible side effects) that happen after vaccination. Health care professionals, vaccine manufacturers, vaccine recipients, and parents or family members of people who have received a vaccine are encouraged to submit reports to VAERS if they experience any adverse events after getting any vaccine.

Scientists monitor VAERS reports to identify adverse events that need to be studied further. All serious reports are reviewed by medical professionals on a daily basis. VAERS data provide medical professionals at CDC and FDA with a signal of a potential adverse event. Experience has shown that VAERS is an excellent tool for detecting potential adverse events. Reports of adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns are followed up with specific studies.

VAERS data alone usually cannot be used to answer the question, "Does a certain vaccine cause a certain side effect?" This is mainly because adverse events reported to VAERS may or may not be caused by vaccines. There are reports in VAERS of common conditions that may occur by chance alone that are found shortly after vaccination. Investigation may find no medical link between vaccination and these conditions.

To know if a vaccine causes a side effect, scientists must know whether the adverse event is occurring after vaccination with a particular vaccine more often than would be expected without vaccination. They also need to consider whether the association between the vaccine and the adverse event is consistent with existing medical knowledge about how vaccines work in the body.

VSD

Scientists use CDC's Vaccine Safety Datalink (VSD) to do studies that help determine if possible side effects identified using VAERS are actually related to vaccination. VSD is a network of 10 managed care organizations across the United States. The combined population of these organizations is more than 9.8 million people.

Scientists can use VSD in two ways. First, scientists can look back in medical records to see if a particular adverse event is more common among people who have received a particular vaccine. Second, instead of looking back, scientists can use Rapid Cycle Analysis (RCA) to continuously look at information coming into VSD to see if the rate of certain health conditions is higher among vaccinated people. This second approach is new, and it allows results to be obtained much more quickly.

Vaccine Manufacturing

Once a vaccine is licensed, FDA regularly inspects vaccine manufacturing facilities to make sure they are following strict regulations. Vaccines are manufactured in batches called lots, and vaccine manufacturers must test all lots of a vaccine to make sure they are safe, pure, and potent. Vaccine lots cannot be distributed until released by FDA.

| the science |

Understanding Vaccine Safety Information from the Vaccine Adverse Event Reporting System by F. Varricchio, et al. *Pediatric Infectious Disease Journal*. April 2004. Vol 23(4): pages 287-294. *http://www.ncbi.nlm.nih.gov/pubmed/15071280*

Vaccine Safety: Current Systems and Recent Findings by Melinda Wharton. *Current Opinion in Pediatrics*. February 2010. Vol 22: pages 88-93. *http://www.cdc.gov/vaccines/spec-grps/hcp/conversations-refs.htm*

The Vaccine Safety Datalink: Immunization Research in Health Maintenance Organizations in the USA by R.T. Chen et al. *Bulletin of the World Health Organization*. 2000. Vol 78: pages 186-194. *http://www.who.int/bulletin/archives/78(2)186.pdf*

Postlicensure Monitoring of Intussusception After RotaTeq Vaccination in the United States, February 1, 2006 to September 25, 2007 by Penina Haber et al. *Pediatrics*. June 2008. Vol 121: pages 1206-1212. *http://pediatrics.aappublications.org/cgi/reprint/121/6/1206?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=Rotateq&andorexactfulltext*

For more information on vaccines call 800-CDC-INFO (800-232-4636) or visit *http://www.cdc.gov/vaccines.*

ATTACHMENT H

Fact Sheet

"Understanding the Vaccine Adverse Events Reporting System (VAERS) in the United States"

Understanding the Vaccine Adverse Event Reporting System (VAERS)

For more information on vaccines, vaccine-preventable diseases, and vaccine safety:
http://www.cdc.gov/vaccines/conversations

Last updated March 2012

- The Vaccine Adverse Event Reporting System (VAERS) is one component of the United States' comprehensive vaccine safety monitoring system.
- VAERS reports are monitored carefully by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).
- Reports of adverse events (possible side effects) after vaccination do not mean that the reported problem was caused by a vaccine. Reports are signals that alert scientists of possible cause-and-effect relationships that need to be investigated.
- Anyone can submit a report to VAERS including health care professionals, vaccine manufacturers, vaccine recipients, and parents or family members of people who have received a vaccine.

questions and answers

What is VAERS?

VAERS is a national vaccine safety surveillance program overseen by CDC and FDA. VAERS collects and analyzes reports of adverse events that happen after vaccination. Each year, VAERS receives around 30,000 reports. Most of these reports describe known, mild side effects such as fever. Scientists at CDC and FDA monitor VAERS reports closely to identify reported adverse events that need to be studied further. Sometimes, it is only after a vaccine has been approved and used broadly that rare side effects can be detected by monitoring systems such as VAERS.

How are the VAERS data used?

VAERS scientists look for unusually high numbers of reports of an adverse event after a particular vaccine or a new pattern of adverse events. If scientists see either of these situations, focused studies in other systems are done to determine if the adverse event is or is not a side effect of the vaccine. Information from VAERS and vaccine safety studies is shared with the public. Throughout the process of monitoring VAERS, conducting studies, and sharing findings, appropriate actions are taken to protect the public's health.

For example, if VAERS identifies a mild adverse event that is verified as a side effect in a focused study, this information is reviewed by CDC, FDA, and vaccine policy makers. In this situation, the vaccine may continue to be recommended if the disease-prevention benefits from vaccination outweigh the risks of a newly found side effect.

Information about newly found side effects is added to the vaccine's package insert that lists safety information. Newly found side effects also are added to the Vaccine Information Statement (VIS) for that vaccine. If serious side effects are found, and if the risks of the vaccine side effect outweigh the benefits, the recommendation to use the vaccine is withdrawn.

Vaccine Information Statements (VISs) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. Federal law requires that VISs be handed out whenever (before each dose) certain vaccinations are given.

Adverse events reported to VAERS are not necessarily side effects caused by vaccination. An ***adverse event*** is a health problem that happens after vaccination that may or may not be caused by a vaccine. These events may require further investigation. By definition, a ***side effect*** has been shown to be linked to a vaccine by scientific studies.

Before the FDA licenses (approves) a vaccine for use, the vaccine must be tested with volunteers during clinical trials to make sure it is safe and effective. Sometimes side effects show up in clinical trials. Most often side effects found in clinical trials are minor, such as possible pain at the injection site, and the vaccine is licensed because the disease-prevention benefits outweigh the risk of getting the side effect.

As part of the United States' comprehensive vaccine safety monitoring system, VAERS detects rare vaccine adverse events, signaling to scientists that focused studies are needed to determine whether the adverse event is a side effect or if there is no medical link.

231405Q

Vaccines are tested before they are used, so why are there possible unknown side effects?

When vaccines are ready for tests in humans, they are tested on thousands to tens of thousands of volunteers. However, even this large number is not always enough to find rare side effects, such as a one-in-a-million side effect. So, VAERS is needed to constantly look for possible side effects that might not have been detected previously.

Are all events reported to VAERS caused by vaccinations?

VAERS data alone usually cannot be used to answer the question, "Does a certain vaccine cause a certain side effect?" This is mainly because adverse events reported to VAERS may or may not be caused by vaccines. There are reports in VAERS of common conditions that are found shortly after vaccination, often related by chance alone, and investigations find no medical link between vaccination and the condition.

To know if a vaccine causes a side effect, scientists must know whether the adverse event is occurring after vaccination with a particular vaccine more often than would be expected without vaccination. They also need to consider whether the association between the vaccine and the adverse event is consistent with existing medical knowledge about how vaccines work in the body.

Who can report to VAERS?

Anyone can submit a report to VAERS including parents, patients, and health care professionals. Vaccine manufacturers who receive reports of adverse events also report the information to VAERS. FDA and CDC encourage anybody who experiences any adverse event after vaccination to report to VAERS. Individuals completing a report can work with a health care professional to make sure they fill out the report form completely. By working together, health care professionals and patients/parents can provide FDA and CDC with data that will be most useful and accurate for examining possible trends.

Why should I report to VAERS?

Reporting to VAERS gives valuable information that helps CDC and FDA ensure that vaccines are very safe. If a previously unknown adverse event does come up, timely reports will help scientists find it and determine how to best address the issue.

How do I report to VAERS?

Reports can be submitted online, by fax, or by mail. To report to VAERS online, go to *https://vaers.hhs.gov/esub/step1* and follow the 5 steps. Or, to print out the form to return it by fax or mail, go to *https://vaers.hhs.gov/resources/vaers_form.pdf*. To request a form by phone, call 1-800-822-7967. Forms may be returned by fax to 1-877-721-0366 or mailed to VAERS, P.O. Box 1100, Rockville, MD 20849-1100. VAERS staff may call for more information.

What events should I report to VAERS?

VAERS encourages the reporting of all adverse events that occur after administration of any vaccine licensed in the United States.

How do I find out if a vaccine adverse event has been reported to VAERS?

VAERS data is available to the public for download at *http://vaers.hhs.gov/data/index*. You may also request information about adverse events reported to VAERS by sending a fax to 301-443-1726, by calling 301-827-6500, or by writing to: Food and Drug Administration, Freedom of Information Staff (HFI-35), 5600 Fishers Lane, Rockville, MD 20857.

Remember, just because an adverse event or condition has been reported does not prove that the adverse event is caused by vaccination. Parents who are concerned about vaccine side effects should talk to their child's health care professional.

| the science |

These articles tell more about VAERS and provide examples of the important role it serves as part of the U.S. vaccine safety monitoring system.

An Overview of the Vaccine Adverse Event Reporting System (VAERS) as a Surveillance System by J.A. Singleton et al. *Vaccine*. July 1999. Vol 17: pages 2908-2917. *http://www.sciencedirect.com/science?_ob=MImg&_imagekey=B6TD4-3WRB2MG-R-9&_cdi=5188&_user=856389&_pii=S0264410X99001322&_origin=search&_coverDate=07%2F16%2F1999&_sk=999829977&view=c&wchp=dGLzVlz-zSkzV&md5=a46c65b0b00e73287cf51d7ed0ec2aa9&ie=/sdarticle.pdf*

Intussusception among Recipients of Rotavirus Vaccine—United States, 1998–1999 in CDC's *MMWR*. July 1999. Vol 48: pages 577-581. *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4827a1.htm*

Intussusception among Infants Given an Oral Rotavirus Vaccine by T.V. Murphy et al. *New England Journal of Medicine*. February 2001. Vol 344: pages 564-572. *http://content.nejm.org/cgi/reprint/344/8/564.pdf*

The Role of the Vaccine Adverse Event Reporting System (VAERS) in Monitoring Vaccine Safety by John Iskander et al. *Pediatric Annals*. September 2004. Vol 33: pages 599-606. *http://www.ncbi.nlm.nih.gov/pubmed/15462575* (abstract only)

Postlicensure Safety Surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine by Barbara Slade et al. *Journal of the American Medical Association*. August 2009. Vol 302: pages 750-757. *http://jama.ama-assn.org/cgi/content/full/302/7/750*

For more information on vaccines call 800-CDC-INFO (800-232-4636) or visit *http://www.cdc.gov/vaccines*.

ATTACHMENT I

Letters of Support

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Minnesota Chapter

Minnesota Chapter of the American Academy of Pediatrics
1043 Grand Ave. #544
St. Paul, MN 55105
Phone: 651-402-2056
Fax: 651-699-7798
www.mnaap.org
cairns@mnaap.org

AAP Headquarters
141 Northwest Point Blvd.
Elk Grove Village, IL 60007
Phone: 847/434-4000
Fax: 846/ 434-8000
www.aap.org

June 14, 2012

Edward Ehlinger, MD, MSPH
Commissioner of Health
Minnesota Department of Health
P.O. BOX 64975
St. Paul, MN 55164-0975

Dear Dr. Ehlinger:

Speaking on behalf of the Minnesota Chapter of the American Academy of Pediatrics, I strongly urge the State of Minnesota to update its School and Daycare Immunization Rules. School and daycare immunization rules work to help families recognize when their children are not up-to-date with recommended vaccines. However, the current rules themselves are not up-to-date. They do not include changes in the recommendations with previous vaccines. They do not include the newest vaccines recommended. As a result, they are confusing and insufficient.

Routine vaccinations save lives. The vaccines we use are safe and effective. Every child in Minnesota should benefit from routine vaccination. For most families who are identified by these rules as "behind in vaccination," the rules work to inform them of what their children need and in turn the parents get the vaccines recommended. When informed by these rules, very few parents claim exemption. Instead, while offering an opportunity for informed declination, the overwhelming majority of parents respond positively to the rules and get their children vaccinated.

Weaker school and daycare rules have been proven to result in lower rates of vaccination and higher rates of vaccine-preventable disease. School and daycare immunization rules not only protect the individual children who are vaccinated, they protect those who cannot get the vaccines because of specific underlying diseases, those who do not respond to the vaccines, and those too young to get the vaccines. They protect those who care for these children and the families of the children who attend school and daycare facilities.

The Minnesota Chapter of the American Academy of Pediatrics recommends that Minnesota's School and Daycare Immunization Rules be brought up to date. We have reviewed and support all of the changes proposed by the Minnesota Department of Health or MDH. These include the following:

- Require that schools submit their Annual Immunization Status Report directly to MDH
- Include all school-based early childhood programs in the school and child care immunization law

- Change the age for the first varicella (chickenpox) immunization from 18 months to 15 months for children enrolling in child care and school-based early childhood programs to match current medically acceptable standards
- Clarify the documentation requirement for history of varicella (chickenpox) disease
- Change the timing of the polio vaccine to match current medically acceptable standards
- Change the timing of the diphtheria-tetanus-acellular pertussis (DTaP) vaccine to match current medically acceptable standards
- Require documentation of hepatitis B, varicella (chickenpox), and MMR vaccines or a legal exemption in all grades - kindergarten through 12th grade
- Require hepatitis B vaccination for a child enrolling in child care or a school-based early childhood program according to medically acceptable standards unless the parent/guardian takes a medical or conscientious exemption.
- Replace the current 7th grade Td requirement with a Tetanus-diphtheria-acellular pertussis (Tdap) requirement
- Require a child enrolling in a secondary school to have a meningococcal vaccination beginning in 7th grade according to medically acceptable standards unless the parent/guardian takes a medical or conscientious exemption for the vaccine
- Require hepatitis A vaccination for a child enrolling in child care or a school-based early childhood program according to medically acceptable standards, unless the parent or guardian takes a medical or conscientious exemption applies.
- The MDH defines current medically acceptable standards as we do, appealing to the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) immunization recommendations.

Again, I strongly urge the State of Minnesota to update its School and Daycare Immunization Rules. The proposed changes make good sense for our patients. They make good sense for Minnesota.

Sincerely,

Robert Jacobson, MD, President-Elect
Minnesota Chapter of the American Academy of Pediatrics

Dawn Martin, MD, Chair Immunization Work Group
Minnesota Chapter of the American Academy of Pediatrics

LOCAL PUBLIC HEALTH ASSOCIATION OF MINNESOTA

June 29, 2012

Dear Ms. Segal Freeman:

On behalf of the Local Public Health Association of Minnesota (LPHA), a voluntary membership organization of all city and county public health departments throughout the state as well as some tribal health departments, I am writing to express support for evidence-based changes to the Minnesota School Immunization Law.

In our Legislative Action Platform, LPHA specifically recognizes that immunization is a key method of keeping our children safe by preventing the spread of deadly communicable diseases. We support maintaining and updating Minnesota's current school and child care immunization requirements and oppose any efforts to weaken these laws. LPHA believes that the school and child care immunization requirements in Minnesota should follow the best available evidence and thus should be updated regularly to align with recommendations from the CDC's Advisory Committee on Immunization Practices (ACIP) which encompass medically acceptable standards.

LPHA appreciates the Department of Health's efforts to update and enhance the immunization laws that keep our children safe from vaccine-preventable diseases. We support the possible changes as specified and request that any additional changes considered also reflect current, evidence-based national immunization recommendations.

Respectfully,

Britta L. Orr

Britta Orr, Executive Director
Local Public Health Association of Minnesota

From: Meningitis Angels

To: Minnesota Department of Health


Ryan died at age 18. Vaccination could have prevented his death.

Ref: Support of Meningococcal Vaccine Requirement for 7th grade entry.

Dear Ms. Freeman,

My name is Frankie Milley. I am the founder and national director of Meningitis Angels. More importantly I am the mother of an only child, Ryan who died from meningococcal meningitis at age 18. Had Ryan had the access or had there been a requirement for the vaccine he would still be with me.

He had just graduated high school, reached his pro-golf status and preparing for college. He became ill on Father's Day with a fever and an earache and 14 hours later he had blood coming from every orifice of his body and death. The medical examiner said, had he lived he would have lost all four extremities, been blind and deaf, had severe brain damage, his kidneys and adrenal glands were ruptured and he would have been in a coma and most likely we would have had to make that horrible decision to remove him from life support.

I would like to commend you and your department's work on protecting kids from deadly diseases through vaccines. It is the best gift all of us can give our children. However unless we make every effort to prevent one of the most debilitating, deadly diseases on earth, we fall short in that effort.

Meningitis Angels works with hundreds of families across the country who have lost children or have children and young adults severely debilitated from this disease. It is unnecessary and preventable. Not one child should suffer.

I encourage you all to make the right decision and commend you on your consideration of requiring this important vaccine.

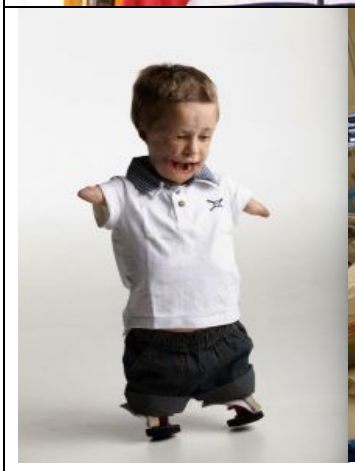
I am enclosing a few of our Angel Stories for you to share with your colleagues as you make these important decisions. Please let me know if I can help in any way.

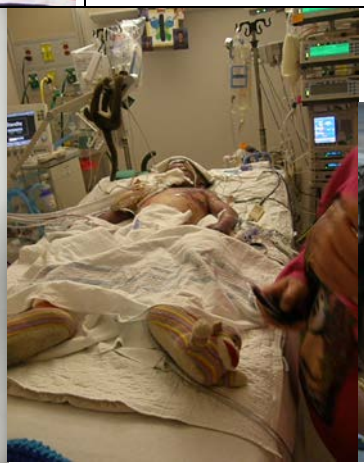
Sincerely, Frankie Milley

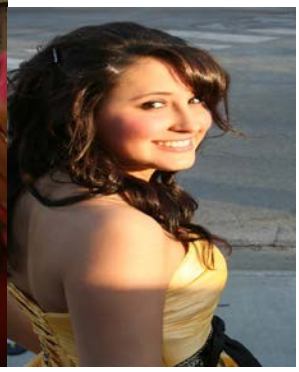
Phone - 713-444-1074 E-Mail fmilley@aol.com Meningitis Angels www.meningitis-angels.org

Meningitis Angels Stories

Dante died at age 14. Vaccination could have prevented his death.







Jeremiah and Karissa were 2 of 7 kids from age 6-19 in the Oklahoma outbreak. Jeremiah lost his face, arms, legs and has internal issues. Karissa had to have her spleen removed. 2 other kids died.

Jessica died at age 15. Vaccination could have prevented her death.

	Erica lost both hands and feet from meningococcal disease at age 19, Vaccination could have prevented this.
	Vincent died at age 16. He had traveled with his brothers out of the country. Within e 2 days he became ill, taken to a clinic and separated from his brothers. He died alone in that clinic in Europe. His parents had to go and make arrangements for his body to be shipped home. Vaccination could have prevented his death.

These are just a few of the thousands of lives affected by meningococcal disease each year in this country.

651-636-1989 or 1-800-652-9704
Fax 651-636-9146

MLFCCA
1821 University Ave West
Suite 324 South
Saint Paul MN 55104
mlfcca.org

10/22/12

Edward Ehlinger, MD, MSPH
Commissioner of Health
Minnesota Department of Health
P.O. BOX 64975 St. Paul, MN 55164-0975

Dear Mr. Ehlinger,

On behalf of the Minnesota Licensed Family Child Care Association (MLFCCA) Board of Directors, I am writing to show our support of Minnesota's Department of Health's (MDH) suggestions for updating immunization rules for schools and child care programs. MLFCCA's mission is to support the highest standard of care for children in Minnesota's diverse licensed family child care homes through recognition, advocacy, professional development and resources. Assuring the health and safety of our children is a prerequisite to any other work we do within our mission. The new rule recommendations solidly fall within that category.

Immunizations save lives and are an inexpensive way to assure the health of our children. MLFCCA fully supports the recommendations MDH is bringing forward in the 2012-13 legislative session.

Sincerely,

Executive Director

MINNESOTA MEDICAL ASSOCIATION

1300 Godward St. NE, Suite 2500
Minneapolis, MN 55413
612-378-1875 • mnmed.org

October 25, 2012

Edward Ehlinger, MD, Commissioner
Minnesota Department of Health
625 N. Robert St.
St. Paul, MN 55155-2538

RE: Proposed Amendments to Minnesota School and Child Care Immunization Law

Dear Commissioner Ehlinger:

On behalf of the Minnesota Medical Association (MMA), I am pleased to offer strong support for the Minnesota Department of Health's (MDH) proposed amendments that will modify the Minnesota School and Child Care Immunization Law, consistent with recommendations set forth by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). The proposed amendments to Minnesota Rules, Chapter 4604, will ensure that Minnesota law reflects the most current, evidence-based recommendations for protecting the health of Minnesota children.

The last revisions to the Minnesota School and Child Care Immunization Law occurred in 2003. There have been many changes to the federal immunization recommendations since that time, including changes to immunization schedules, as well as the addition of new vaccines. The department's proposed amendments will also clarify reporting requirements, and ensure that all school-based early childhood programs are included in Minnesota law. In order for children, schools, child care facilities and immunization providers in Minnesota to be in compliance with federal immunization recommendations, Minnesota law must reflect these changes.

By bringing Minnesota law in line with current federal immunization recommendations, MDH is demonstrating a commitment to reducing the incidence of vaccine-preventable diseases. The steps being taken will help protect the health of all Minnesotans, and the MMA fully supports these efforts.

Sincerely,

Daniel E. Maddox, MD
President

From: Virginia Marso
To: Healtth.immrule@health.state.mn.us
Cc: Lynn Bozof
Subject: Vaccine support request
Date: Friday, June 29, 2012 3:31:54 PM

In conjunction with the MN Department of Health's efforts to support meningococcal vaccination, I have been asked to submit my family's personal story.

My son Andy, then a 22 year old student at the University of Kansas, three weeks from graduating #1 in the KU Journalism school, developed meningococcemia. As is so often the case, it came on with incredible rapidity: He had been working at his parttime job, reporting a high school softball doubleheader. The first game, he felt fine; however, between games, he felt a shiver go up his spine and felt colder than he'd ever been in his life, despite the beautiful 85 degree warmth of that Kansas day and his own history of subzero camping experiences as a Boy Scout growing up in Minnesota. He left and returned to his dorm, thinking he had the flu and that he'd just sleep it off. Early the next morning, about 4 or 5 AM, he trekked down two flights to the kitchen for a glass of juice. He noted, on the return trip, that his feet had that "pins and needles" feeling of numbness, but which never went away; he related his legs felt like blocks of wood. He sent off his stories to the paper and went back to bed. About 11 AM, a friend came to check on him and, seeing purple blotches on his arms and legs, told him he had to get to the Health Service. Andy refused, stating he hurt too much to even stand up. Two friends then carried him down to a waiting car. He was wheeled into the Health Service in a wheelchair, where an astute nurse immediately grabbed a physician, a woman who knew, upon hearing from Andy how quickly the "rash" had developed, that this was very likely bacterial meningitis. She started IV support and had him taken to Lawrence Memorial Hospital via ambulance. Once there, he had a spinal tap. The doctor told my husband, over the phone as he was instructing us to get there as soon as possible if we wanted to see our son alive, that the cloudiness of the sample was confirmation enough for him of the validity of the Health Service doctor's diagnosis. Andy was airlifted to KU Medical Center in Kansas City, where he was met on the helicopter pad by the Chief of Staff, who gave him the first dose of a powerful antibiotic, Xigris. Andy spent 8 days in unstable critical condition, a total of 3 1/2 weeks in critical condition, and then began a round of amputations and skin grafting due to the equivalent of third degree burns over a third of his body. He had all of his fingers amputated, keeping only his right thumb and half of his left. He lost about half of each foot and significant muscle mass in his right calf. He has a great deal of scarring as well. In total, he was at KU Med for over 4 1/2 months and then spent an additional year in rehab. Since then, he has had numerous "tweaking" surgeries, as he calls them, to revise amputations or address infections. He wears prosthetics on both feet, but functions without any on his hands, finding the prosthetic left hand with which he was fitted too cumbersome. Despite what he has experienced, he has obtained a master's degree, works fulltime and functions independently. Others have not been as lucky. Many we know of have died of this disease, often within hours but sometimes only after lengthy illness and even though they have undergone numerous amputations of affected limbs; others we know personally have survived greater degrees of amputation than has Andy, heart attacks, kidney transplants, and more.

I hope our story can serve to save other families, other children from the horrors of what Andy has had to go through, simply by showing the real consequences of a potentially vaccine-preventable disease.

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