

PLAIN TALK ABOUT CHILDHOOD IMMUNIZATION





This edition was developed and edited by the following public and private organizations:

Community Health Plan
Immunization Action Coalition of Washington (WithinReach)
Public Health – Seattle & King County
Snohomish Health District
Washington State Department of Health

We would like to acknowledge receiving support from the following organizations for previous editions of this booklet: Children's Hospital and Regional Medical Center, Junior League of Seattle, National Network for Immunization Information, Program for Appropriate Technology in Health, Rotary International, State of Alaska Immunization Program, U.S. Centers for Disease Control and Prevention, Whatcom County Health & Human Services.

PLAIN TALK ABOUT CHILDHOOD IMMUNIZATION

TABLE OF CONTENTS

Chapter	Page
1. Immunizations Save Lives	5
2. Facts About Vaccine-Preventable Diseases	10
3. How Vaccines Work	13
4. Vaccine Safety	18
5. Vaccine Ingredients	21
6. Compare the Risks	25
7. Q&A About Specific Vaccines	30
8. Legal Requirements	36
9. To Wait or Not to Wait	38
10. Adolescent Health Visit	41
11. Evaluating Immunization Information on the Internet	43
12. Personal Stories	45
13. Glossary	48
14. References	50
15. Resources	53

A MESSAGE TO PARENTS

Dear Parents:

Thank you for your interest in learning more about immunizations. As parents, we must make many important decisions that affect our children. Some of the most difficult ones can be about their health care. Immunizing your child is one of these decisions.

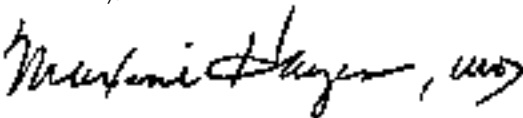
We all want to make good choices and do what's best for our children. As a community, we must also work to protect the public's health. Immunizing your children is one of the most important things you can do to protect them, your family, and the community from diseases that can be prevented by vaccines. We want parents to make informed decisions. Accurate information will help you make the best health decisions for your child.

We designed this booklet in response to requests from parents, health care professionals, school nurses, child care providers, and others. The booklet provides accurate information about immunizations and the diseases they prevent; balances the benefits and risks of immunization to help you make informed decisions; and discusses the safety and effectiveness of vaccines. It also gives you reliable facts about immunizations and vaccine-preventable diseases, setting the record straight about topics that are often misunderstood or reported inaccurately – including the facts on mercury in vaccines.

Each section can be read independently, so it's easy to read a section when you have time. Much of the information is presented in a "question and answer" format, and you may have questions that are not in the booklet. We encourage you to discuss these issues with your doctor, nurse, clinic, or your local health department. The Washington State Department of Health Web site (www.doh.wa.gov/cfh/immunize) also has many resources.

I hope this information will help as you strive to make informed health decisions for your family. Your child's health depends on it.

Sincerely,



Maxine Hayes, MD, MPH
State Health Officer

Immunizations Save Lives

Immunizations are one of the greatest medical success stories in human history because they have saved millions of lives and prevented illness and lifelong disability in millions more. Many serious childhood diseases are preventable by using vaccines routinely recommended for children. Since the introduction of these vaccines, rates of diseases such as meningitis (caused by *Haemophilus influenzae* type b), polio, rubella, and diphtheria have declined by 95 to 100%. Prior to immunization, hundreds of thousands of children were infected and thousands died in the U.S. each year from these diseases. Without immunizations, serious outbreaks of many of the diseases we are now protected from can reoccur.

The following data from Centers for Disease Control and Prevention (CDC) demonstrates dramatic declines in vaccine-preventable diseases since routine childhood vaccination began in the U.S.

Disease	Number of Cases Before Vaccine Was Widely Used	U.S. Reported Cases in 2006	Percent Decrease
Smallpox	48,164	0	100%
Diphtheria	175,885	0	100%
Measles	503,282	55	> 99.9%
Mumps	152,209	6,584	95.7%
Pertussis	147,271	15,632	89.4%
Polio (paralytic)	16,316	0	100%
Rubella	47,745	11	> 99.9%
Congenital Rubella Syndrome	823	1	99.8%
Tetanus	1,314	41	96.9%
Hib (invasive)	20,000	29	99.8%

Source: CDC. *MMWR*, April 12, 1999; 48(12):243-248
 CDC. *MMWR*, March 21, 2008; 55(53):1-94

Immunizations Are Strong Protection

Immunization is the single most important way parents can protect their children against serious diseases. The decision to immunize your child is an important one. Consider the following reasons when making your decision.

Immunize:

- **To prevent common but serious illnesses.** Some diseases, such as pertussis, flu, varicella, and rotavirus are common in the U.S.
- **To prevent diseases that still exist.** Some diseases, such as measles and mumps, still occur in the U.S. at low levels. When fewer people are immunized against these diseases, outbreaks can occur.
- **To prevent diseases that are common in other parts of the world.** Although some diseases, such as polio, are rare or do not exist in the U.S., they are still common in other parts of the world. With the increase in international travel and foreign adoption, serious vaccine-preventable diseases uncommon in the U.S. are literally only a plane ride away.
- **To protect others in your family and community.** By immunizing your child, you also protect those who:
 - have weak immune systems
 - are not fully immunized
 - cannot get shots because of a medical condition
 - are too young or too old to get certain vaccines

Immunizations Complement the Immune System

The immune system is the defense mechanism in each person that helps the body fight disease. Medical science has found that the use of vaccines is an effective way to build immunity. (See also *Chapter 3: How Vaccines Work*)

When you get an infection, your body reacts by producing substances called antibodies. These antibodies fight the invading antigen (virus or bacteria) and help you get over the illness. The antibodies usually stay in your system, even after the disease has gone, and protect you from getting the same disease again. This is called immunity.

Newborn babies often have immunity to some diseases because they have antibodies from their mothers (known as maternal antibodies). **Maternal antibodies are temporary and can only be passed on to the newborn if the mother has immunity herself.** By getting immunized, children can stay immune to many diseases, even after they lose the protection of their mothers' antibodies.

Children who have not been immunized are at far greater risk of becoming infected with serious vaccine-preventable diseases. For example, a study conducted by D. Salmon, et al., showed that children who had not received the measles vaccine were 35 times more likely to get the disease.¹

Alternatives to Immunizations?

There are no effective alternatives to immunization for protection against serious and sometimes deadly diseases. However, parents may hear about breastfeeding and the use of vitamins or herbs in the context of disease prevention.

Despite the known benefits of breastfeeding, such as enhanced protection of the infant against some colds, ear infections, and diarrhea, **breastfeeding does not prevent vaccine-preventable diseases.** Unlike vaccines, breastfeeding does not stimulate the infant's own immune system to produce the antibodies needed to fight very specific diseases. Vaccines do not interfere with the benefits gained from breastfeeding, just as breastfeeding does not hinder the effectiveness of immunization.

The use of vitamins or herbs does not provide specific protection against the many viruses and bacteria that cause vaccine-preventable diseases. Although these substances may have beneficial effects, they cannot replace the protection provided by vaccines.

Immunizations Are a Safe Choice

Vaccines are held to the highest standard of safety. The U.S. currently has the safest, most effective vaccines in history. Years of testing are required by law before vaccines can be licensed. Even after they are licensed and available for use in the general population, vaccines continue to be monitored for safety and efficacy. Immunizations, like any medication, are not risk-free and can cause side effects. Vaccines are not 100% effective. Occasionally, people who receive a vaccine do not respond to it and may still get the illness the vaccine was meant to protect them against.

- In most cases, vaccines cause no side effects, or only mild reactions such as fever or soreness at the injection site.
- Very rarely, people experience more serious side effects, such as allergic reactions. Be sure to tell your health care provider about health problems or known severe, life-threatening allergies to medications or specific foods.
- Severe reactions to vaccines occur so rarely that the risk is difficult to calculate.

The decision not to immunize a child also involves risk. It is a decision to put the child and others at risk of contracting a disease that could be dangerous or deadly. Consider measles. One out of 30 children with measles gets pneumonia. For every 1,000 children who get the disease, one or two will die from it. Thanks to high measles vaccination coverage, there are relatively few cases of measles in the U.S. and most are imported from other countries. The benefits of vaccination are easy to overlook since the effects of disease are rarely seen anymore. (See also *Chapter 4: Vaccine Safety* and *Chapter 6: Compare the Risks*)

Immunizations Prevent the Spread of Disease

Diseases spread through communities by infecting people who are not protected – such as those who are not immunized or not fully immunized. Immunizations help to protect a community from diseases that vaccines can prevent. For some highly contagious diseases, even a small number of unimmunized or underimmunized people can lead to an outbreak of disease. The rates of immunization in a community have a direct effect on outbreaks.

Compare the following two examples:

- In 2006, a multi-state outbreak of mumps occurred in the U.S. Many of the cases occurred among college students, with a total of 6,000 cases reported in 11 Midwestern states. Thousands of additional cases of mumps were likely prevented because of the high mumps vaccination coverage in the U.S., especially in school-age populations. Many of those who contracted mumps were underimmunized because they only received one dose of the vaccine.²
- In the United Kingdom (UK), concerns about the safety of the mumps-containing vaccine led to a marked drop in mumps vaccination coverage in the late 1990s. The mumps outbreak in the UK was longer lasting and more widespread than the U.S. outbreak. Reported cases in the UK show the dramatic correlation between declining vaccination rates and an increase in cases of disease:³
 - 1995 = 1,936 cases
 - 2000 = 2,212 cases
 - 2004 = 16,494 cases
 - 2005 = 18,565 cases



Did You Know?

The effects of a disease-causing bacteria or virus are often more serious in infants than older children.

Vaccines given in the first two years of life represent a fraction of what an infant's immune system successfully encounters and manages every day.

Many of the diseases that vaccines prevent cannot be effectively treated or cured.

Even if a disease is not currently present in a community, the bacteria and viruses that cause it have not gone away. Disease outbreaks can and do occur in families and communities that are not protected by immunization.

The number of recommended immunizations has increased because we are now able to safely protect children from more serious diseases than ever before.

In 2007, about 69% of the children in Washington State were immunized by the age of 2. This remains below the national average of 77%. The national goal for immunization coverage in 2010 is 80% in children 19 to 35 months.

Washington State is a universal state for vaccine funding. This means that all vaccines for children ages birth through 18 years are paid for with public funds and are provided at no cost at most physician offices and clinics. (You may be charged an administration fee, but this may be waived.)

¹ Salmon, D., et al. 1999. Health consequences of religious and philosophical exemptions from immunization laws: Individual and societal risk of measles. *JAMA* 282: 47–53.

² Update: Multi-State Outbreak of Mumps. 2006. *MMWR* 55(20):559-563.

³ Health Protection Agency, Centre for Infections. Available at www.camr.org.uk/infections/topics_az/mumps/data_quarter.htm. Accessed April 15, 2008.

Facts About Vaccine-Preventable Diseases

HEPATITIS B

Hepatitis B virus is passed by contact with infected blood or other body fluids. Most of the time, infected individuals have no symptoms and can spread the virus unknowingly. A mother with hepatitis B can also pass the virus to her newborn baby during childbirth. Hepatitis B causes serious liver infections. People with chronic hepatitis B can develop liver disease and liver cancer, which can be deadly.

ROTAVIRUS

Rotavirus is found in the stool of infected persons. It is easily spread when a person puts something (food, water, hands, or an object) into his or her mouth that has the virus on or in it. Symptoms are high fever and vomiting, followed by diarrhea. These symptoms can cause the child to lose body fluids and become dehydrated, which can lead to hospitalization.

DIPHTHERIA, TETANUS, AND PERTUSSIS

Diphtheria is spread by coughing and sneezing. It causes a sore throat, low-grade fever, and can completely clog a person's airway. Diphtheria can cause breathing and heart problems, coma, paralysis, and death.

Tetanus (lockjaw) is caused when germs enter the body through a deep cut or puncture wound. It is not spread from person to person. It can cause muscle spasms, breathing problems, and death. Since tetanus lives in soil and manure and cannot be removed from the environment, the vaccine will always be needed.

Pertussis (whooping cough) is spread by coughing and sneezing. It causes spells of coughing that make it hard for a child to eat, drink, or even breathe. Pertussis can cause pneumonia, seizures, brain damage, and death. Often, babies with pertussis have to be hospitalized.

HAEMOPHILUS INFLUENZAE TYPE B

***Haemophilus influenzae* type b** (Hib) is spread by coughing and sneezing. It can cause meningitis (swelling of the covering of the brain and spinal cord), brain damage, infections of the joints, skin, and blood, and even death. Hib is most dangerous to children under five years of age.

PNEUMOCOCCAL

Pneumococcal disease is spread by coughing and sneezing. It is the main cause of bacterial meningitis (swelling of the covering of the brain and spinal cord) in young children. It can also cause serious blood infections and pneumonia.

POLIO

Polio is found in the stool and saliva of infected persons. It is easily spread when a person puts something (food, water, hands, or an object) into his or her mouth that has infected feces on or in it. It can cause permanent paralysis and even death. There is no treatment for polio.

INFLUENZA

Influenza (flu) spreads easily by coughing and sneezing. It can cause high fever (usually over 101 degrees F), cough, headache, and muscle aches. This respiratory virus can lead to pneumonia and heart problems. Influenza can be very serious for babies. They often have to be hospitalized. Flu is even more serious for children with chronic illnesses such as asthma, heart disease, or diabetes.

MEASLES, MUMPS, AND RUBELLA

Measles is spread very easily by coughing and sneezing. It causes a high fever, cold-like symptoms, and rash. It can lead to pneumonia, hearing loss, brain damage, and even death. A child who has not been immunized will most likely get measles if exposed.

Mumps is spread by coughing and sneezing. It can cause headache, fever, and swelling of the cheeks, neck, or jaw. Mumps can lead to hearing loss, meningitis (swelling of the covering of the brain and spinal cord), and brain damage.

Rubella is spread by coughing and sneezing. It causes a slight fever and a rash on the face and neck. Pregnant women who get rubella may miscarry or have babies with birth defects such as blindness, deafness, or developmental delays.

VARICELLA

Varicella (chickenpox) is spread by coughing, sneezing, or direct contact with fluid from the blisters caused by the disease. It causes an itchy skin rash (with blisters) and fever. Varicella can be severe and lead to pneumonia, meningitis (swelling of the covering of the brain and spinal cord), and serious skin infections. Exposure to chickenpox during the first 20 weeks of pregnancy may cause serious abnormalities in the fetus if the mother is not immune. If the mother is infected from five days before to two days after delivery, it can result in an overwhelming infection in the newborn with a death rate of 30%.

HEPATITIS A

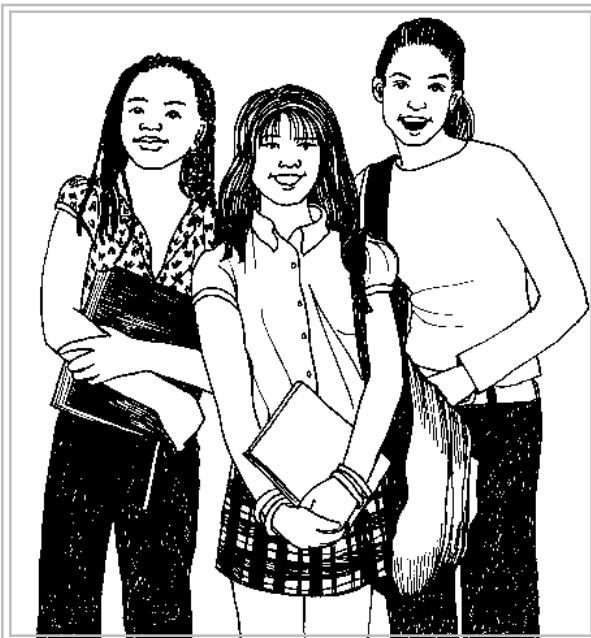
Hepatitis A is found in the stool of infected persons. It is easily spread when a person puts something (food, water, hands, or an object) into his or her mouth that has infected feces on or in it. It can pass easily from one person to another in the same household or child care setting. Hepatitis A can cause liver disease.

MENINGOCOCCAL

Meningococcal disease is spread by direct contact with infected persons by coughing, kissing, or sharing anything by mouth, such as water bottles, eating utensils, or toothbrushes. It can cause pneumonia, bloodstream infection, and meningitis (swelling of the covering of the brain and spinal cord). Severe disease can cause brain damage, loss of hearing or limbs, and death.

HUMAN PAPILLOMAVIRUS

Human papillomavirus (HPV) is a common virus that is primarily spread through sexual contact. Most of the time infected individuals have no symptoms and can spread the virus unknowingly. Almost all cervical cancers and genital warts are caused by HPV.



How Vaccines Work

When you get an infection, your body reacts by producing substances called antibodies. These antibodies fight the invading antigen (virus or bacteria) and help you get over the illness. The antibodies usually stay in your system, even after the disease has gone, and protect you from getting the same disease again. This is called immunity. Vaccines mimic a natural infection and create immunity without the harmful effects of the disease. If a vaccinated child is exposed to the disease in the future, he or she will be protected.

Vaccines are made with viruses and bacteria that are either “live” (but weakened) or “killed” (inactivated). The number of doses needed for protection against a particular disease depends on whether the vaccine is live or killed. Live vaccines, such as MMR (measles, mumps, and rubella) are very effective and usually provide lifelong protection with only one or two doses. However, three or more doses of killed vaccines, such as IPV (inactivated polio) are needed to build immunity. “Boosters” of some vaccines, such as tetanus, diphtheria, and pertussis, are needed throughout life to maintain protection.



QUESTION: Do vaccines decrease the immune system’s natural ability to fight disease?

ANSWER: No. Vaccines strengthen the immune system by preparing it to defend against serious disease-causing bacteria and viruses. Immunity gained from vaccination is similar to natural infection without the risk of natural disease. Dr. Jeff Duchin of Public Health-Seattle & King County described this well: “The immune system is constantly working to protect us from bacteria and viruses in our environment. Immunizations strengthen our immune defenses against a *specific* infection. Immunizations do *not* interfere with our ability to fight off other infections that we are not immunized against.”

Vaccinated children have been shown to suffer fewer infections overall than unvaccinated children. A study conducted in Germany of 496 vaccinated and unvaccinated children found that “...children who received immunizations against diphtheria, pertussis, tetanus, Hib, and polio within the first 3 months of life had fewer infections with vaccine-related and -unrelated [bacteria and viruses] than the non-vaccinated group.”⁴

A 2002 report published by the Institute of Medicine’s (IOM) Immunization Safety Review Committee, revealed a similar conclusion: “...multiple vaccinations *do not* increase the risk of young children developing various infections, ranging from colds and ear infections to pneumonia and meningitis.”⁵ The Immunization Safety Review Committee was a project of the IOM from 2001-2004. This committee reviewed immunization safety concerns and provided independent, non-biased advice to vaccine policy-makers, practitioners, and the public.



QUESTION: I heard that giving several vaccines at the same time “bombards” the immune system, so that it’s better to give them one at a time. Is this true?

ANSWER: No. Receiving more than one immunization at the same time does not harm a child’s immune system. A review of clinical studies by the IOM in 2002 revealed **no association between childhood immunizations and immune system problems.** While there is clearly much more to learn about the immune system, some things we do know. Scientific data show that giving a child several vaccines at the same time has no adverse effect on a healthy immune system. The immune system of a newborn can recognize and respond to hundreds of thousands, if not millions, of different organisms. According to a study published in the January 2002 issue of *Pediatrics*, scientists estimate that a child could receive up to 10,000 vaccines in one day and still not “use up” his or her immune response. A child receiving 11 vaccines in one day would “use up” less than 1% of his or her immune system.⁶

According to Dr. William Atkinson, U.S. Centers for Disease Control and Prevention: “The immune system is an extremely capable system. It can manage and respond to literally millions of antigens (foreign substances) at the same time. Take for example, walking outside on a spring day with flowers and trees in bloom. Through your mouth, nose, and lungs, your immune system will constantly respond to multiple antigens (like pollen and dust) as it does its work in your bloodstream. In the same way, in daily interactions, you may be exposed to multiple cold viruses and your body will respond successfully. But some infections can cause severe illness and death even in persons with healthy immune systems. We can help the immune system ward off the serious infectious diseases that immunizations can prevent.”



QUESTION: Is the method of injecting vaccines harmful for the body?

ANSWER: No. Injecting vaccines is a safe way to get the vaccine into the body. Vaccines are not injected directly into the bloodstream. Most vaccines are injected deep into the muscle or into the fat layer just below the skin. The syringe and needle used for an immunization are sterile and are used only once and then disposed of in a safe manner, so there is no possibility of spreading infection through an injection.

Some vaccines are given orally (by mouth) or intranasally (sprayed into the nose). The method used to administer a vaccine is determined by the manufacturer based on extensive testing for safety and effectiveness. This testing takes several years to complete and is required before the vaccine can be used in the general population.



QUESTION: I have heard that some people get diseases that they have been vaccinated against. Is this true?

ANSWER: Yes. Even though vaccines are extremely effective, they are not perfect. For example, a vaccine that is 90% effective means that 1 in every 10 (10%) people who are vaccinated is not fully protected from the disease. Should disease affect a community, those that are unprotected are more likely to be infected. This includes those who were not vaccinated and the 10% of people who were vaccinated but did not become fully protected. The 10% for whom the vaccine did not work may still have partial immunity; these individuals may experience a milder form of the disease. Because most diseases that vaccines prevent are transmitted from person to person, the more people in a community who are immunized, the less likely that disease will be transmitted and “find” those who are unprotected. Most vaccines require more than one dose to reach protective maximum immunity. Some, like tetanus and diphtheria, require booster doses every 10 years throughout life to maintain protective immunity.



QUESTION: Isn't it true that because of better hygiene and sanitation, vaccine-preventable diseases began to disappear before vaccines were introduced?

ANSWER: No. Many infectious diseases became better controlled as living conditions and hygiene improved. However, they remained serious threats due to periodic outbreaks in vulnerable populations. It wasn't until the introduction of vaccines that there was a dramatic drop in the rates of vaccine-preventable diseases. Vaccine-preventable disease outbreaks still occur because of lack of immunization or an incomplete series of vaccines.

Diseases such as measles and pertussis are highly contagious, regardless of hygiene and living conditions. As stated by Dr. Jeff Duchin of Public Health-Seattle & King County, “Immunizations have led to a dramatic decrease in serious childhood infections, such as Hib disease, that could not have been accomplished through improvement in sanitary conditions alone.”

Two examples of this include:

- The incidence of *Haemophilus influenzae* type b (Hib), measles, and other vaccine-preventable diseases has decreased dramatically due to immunizations. The Hib vaccine was directly responsible for decreasing the rates of Hib disease and Hib meningitis. Once the leading cause of death among young children, Hib disease has dropped more than 95% since the vaccine was introduced.
- Prior to the licensure of measles vaccine in 1963, there were 500,000 cases and 500 deaths from measles in the U.S. per year. In 1999, only about 100 cases were reported and no deaths occurred from measles in the U.S.

According to CDC, the largest outbreaks of measles since 1993 have occurred in populations that refuse vaccination for religious or philosophical reasons.



QUESTION: Is it better to become immune from natural infections rather than through vaccination?

ANSWER: No. Infection from natural disease can be serious and possibly deadly. Diseases can cause permanent disabilities, such as brain damage from measles or pertussis, liver cancer from hepatitis B infection, or paralysis from polio. How a child will react to a disease cannot be predicted based on diet, genetics, overall health, or his or her parent's reaction to the disease. Some vaccines, such as tetanus and Hib, are better at creating immunity than natural infection. Vaccines provide protection from infection without the risk of disease.



QUESTION: Does my baby need vaccinations if I am breastfeeding?

ANSWER: Yes. Breastfed babies need vaccinations because breastfeeding does not prevent vaccine-preventable diseases. Newborn babies do inherit maternal antibodies, although this depends on the immune status of the mother. Breastfeeding does not extend or improve the immunity to vaccine-preventable diseases, except possibly for Hib. The known benefits of breastfeeding include enhanced protection of the infant against some colds, ear infections, and diarrhea. However, unlike vaccines, breastfeeding does not stimulate the infant's own immune system to produce the antibodies needed to fight very specific diseases.

Vaccines do not interfere with the benefits gained from breastfeeding, just as breastfeeding does not hinder the effectiveness of immunization (see *Chapter 1, page 5*). Recommended immunization schedules should be followed for breastfed infants.



QUESTION: Can my premature baby receive vaccines?

ANSWER: Yes. Vaccine schedules for preterm infants should be based on the infant's chronological age. By 1 to 2 months of age, a preterm infant responds as well to vaccines as a baby born full term. Divided or reduced vaccine doses are not recommended or indicated for a premature infant.

In the case of the hepatitis B vaccine, the schedule may be changed for a preterm infant. If the mother has hepatitis B and the baby weighs less than 2,000 grams, the baby's health care provider will determine the best schedule for this vaccine.



QUESTION: Do vaccines cause chronic disease, such as diabetes and cancer?

ANSWER: No. Science-based studies have not found evidence that vaccines cause chronic illness. After decades of vaccine use in the U.S., research shows no reliable evidence proving that vaccines cause chronic illness. Vaccine-safety research, including research into theories linking vaccines to chronic diseases, is ongoing in the U.S. and overseas to ensure that the public is receiving the safest possible vaccines.

Medical conclusions about vaccine safety and the causes of disease must be judged on the quality of the scientific research and evidence. The test of good research is the ability to repeat a study and reach the same conclusion. To date, studies supporting theories about a link between vaccines and chronic illness have not been duplicated. Because no vaccine is without risk, when medical and public health professionals recommend vaccines for infants and children, they must balance the scientific evidence of risks, benefits, and costs. This balance changes as diseases are controlled or eliminated.



⁴ Otto, S., et al. 2000. General non-specific morbidity is reduced after vaccination within the third month of life – the Greifswald Study. *Journal of Infection* 41: 172-175.

⁵ Immunization Safety Review Committee, Institute of Medicine. 2002. *Immunization Safety Review: Multiple Immunizations and Immune Dysfunction*. Washington, D.C.: National Academy Press.

⁶ Offit, P.A., et al. 2002. Addressing parents' concerns: Do multiple vaccines overwhelm or weaken the infant's immune system? *Pediatrics* 109: 124-129.

As a parent, you may have concerns about vaccine safety. Information about how the vaccine licensing process works may help you understand more about vaccine safety. The federal agency responsible for licensing vaccines is the Food and Drug Administration (FDA). FDA has developed scientific criteria for approving vaccines and for monitoring side effects once approval has been given.

Approving Vaccines

The approval process for a biological product such as a vaccine is based on federal regulations and involves clinical trials or studies in three phases. A fourth phase occurs after licensure.

Phase 1: Consists of studies designed to learn more about the safety of the product. This phase involves less than one hundred participants.

Phase 2: Consists of studies designed to demonstrate the ability of a vaccine to induce immunity, as well as to further evaluate side effects and risks. This phase is usually longer and involves a few hundred participants.

Phase 3: Consists of studies designed to verify that a vaccine is effective in preventing a particular disease as well as to gather information on risks versus benefits. Clinical trials in this phase involve several thousand participants and continue for several years before a vaccine is licensed.

After completing this approval process, the manufacturer submits the safety and effectiveness data to FDA in an application for licensure to sell the product. FDA has the responsibility to review the clinical studies data as well as the facilities and methods to be used in the manufacturing of the product for safety and effectiveness. On average, it takes over five years from the time an application for licensure is submitted until FDA approves a product.

Once a vaccine meets FDA approval, a federal vaccine advisory committee, called the Advisory Committee on Immunization Practices (ACIP), presents its findings, has open public meetings, and makes final recommendations for use of the vaccine.

Phase 4: Evaluates the use of a vaccine in the general population, which has a greater range of medical and social conditions. Very rarely, risk for a certain adverse effect is seen that might not have been found in a smaller pre-licensure study. Post-licensure studies also allow for observation of rare side effects that may occur with multiple doses over time.

Monitoring Vaccine Safety

After a product is approved to be licensed (and therefore used), FDA continues to monitor vaccine safety and effectiveness through:

- on-site inspection of the manufacturing facility
- review of manufacturers' safety, potency, and purity testing
- possible duplication of the manufacturers' testing, as a protective measure

Other systems in place to monitor vaccine safety include the Vaccine Safety Datalink Project and the Vaccine Adverse Events Reporting System.

The Vaccine Safety Datalink Project (VSD) was established in 1990 by CDC to study rare side effects associated with vaccines using large, linked databases. Four Health Maintenance Organizations (HMOs) supply CDC with medical and vaccination records of over six million people (all identifying information is removed to protect patient confidentiality). This large amount of medical data enables researchers to conduct planned vaccine-safety studies and examine potential relationships between specific vaccines and adverse events.

The Vaccine Adverse Events Reporting System (VAERS) is another method of gathering safety information on vaccines. VAERS is a national reporting system operated by FDA and CDC, designed to track any adverse reactions following immunizations. The system receives reports from health care providers, patients, parents, or anyone who witnessed or even just heard of a possible adverse reaction that occurred after a vaccine was given. Since 1988, vaccine manufacturers and health care providers who give vaccines are **required by law** to report certain serious adverse events, and may report any reaction or event.

A VAERS report does not mean the vaccine caused the adverse event. It only means that the vaccination preceded the adverse event. VAERS is designed to identify trends or pinpoint the need to investigate further. After vaccines are released for distribution, FDA conducts reviews of the weekly VAERS reports. In addition, CDC closely monitors VAERS reports on a continual basis as it does with any licensed vaccine.

Serious adverse events following the administration of a vaccine should be reported to VAERS in order for the system to work. Information about VAERS can be found on every Vaccine Information Statement (VIS).

To get a VAERS form:

- call 1-800-822-7967
- visit <https://secure.vaers.org/VaersDataEntryintro.htm>
- contact your clinic or health department



QUESTION: Do we know VAERS works?

ANSWER: Yes. We know VAERS works because of the events following licensure of a rotavirus vaccine in 1999, known as Rotashield. Rotavirus is the most common cause of severe diarrhea in infants and children in the U.S. Through VAERS reporting, an increased risk for intussusception (a type of bowel obstruction) following vaccination with Rotashield was observed. This rare side effect occurred in about 1 in 10,000 children and the vaccine was voluntarily withdrawn as a direct result of the data obtained through VAERS.

In February 2006, a new rotavirus vaccine (RotaTeq) was licensed and recommended for routine administration by the ACIP. No evidence of an association between RotaTeq and intussusception was noted in the pre-licensure trial of 70,000 infants. Based on experience with the previous rotavirus vaccine, FDA issued a Public Health Notification on February 13, 2007 to encourage the reporting of intussusception. Results of an outside panel of medical experts concluded that the number of intussusception cases after the administration of RotaTeq was no greater than the number of cases of intussusception in infants who did not receive the vaccine.



QUESTION: I've heard that there are certain vaccine "lots" or batches associated with more adverse events. What does this mean?

ANSWER: Manufacturers produce and distribute vaccines in quantities known as "lots." Lot sizes vary widely between different types of vaccines and different manufacturers. Samples of each lot are sent to FDA for tests of safety, potency, and purity before the lot is allowed to be given to patients.

Vaccine lots range in size from several hundred thousand doses to several million, and some are in distribution much longer than others. Naturally, a larger lot or one that has been in distribution for a longer period of time will be associated with more adverse events simply by chance.

VAERS data can be used to monitor how many adverse events have been reported for each vaccine lot approved for use. However, because vaccine lots are not the same size, differences in the numbers of adverse events reported must be interpreted with great caution. Some people have misinterpreted VAERS data, leading to unsubstantiated media reports about "unsafe lots" of vaccine. If the number and type of adverse event reports for a particular vaccine lot suggested that it was associated with more serious adverse events or deaths than are expected by chance, FDA would immediately recall it for further investigation.

Vaccine Ingredients



QUESTION: Why do vaccines contain additives?

ANSWER: Tiny amounts of three types of substances are added to vaccines to ensure that the vaccines are sterile, effective, and safe. The following ingredients may be used in the preparation of some vaccines:

- **Adjuvants** increase the vaccine's ability to stimulate the body's immune system to fight off disease. Adjuvants also help promote a quicker, more potent, and persistent immune response to disease. Aluminum salts are the only adjuvants currently licensed for use in the U.S. For more information about adjuvants, visit www.chop.edu/consumer/jsp/division/generic.jsp?id=75808.
- **Stabilizers** help maintain the vaccine's effectiveness even when it is exposed to dramatic changes in the environment (such as temperature, light, humidity, etc.). Stabilizers include monosodium glutamate (MSG) and 2-phenoxyethanol.
- **Preservatives** are used to prevent bacteria or fungus from contaminating the vaccine, which could cause serious infections in anyone receiving the vaccine. Antibiotics (such as neomycin and streptomycin), formaldehyde, and thimerosal may be used for this purpose.

If you want specific information on the additives used in a particular vaccine, ask your doctor or nurse for a copy of the vaccine's package insert. Each vaccine comes with an insert listing every ingredient. The insert also lists every known reaction ever reported, regardless of how minor.



QUESTION: What is thimerosal? Why is it used in some vaccines?

ANSWER: Thimerosal is a preservative that is used in very small amounts to prevent vaccines from becoming contaminated with bacteria or fungi. It contains a form of mercury, called **ethylmercury** that is rapidly excreted from the body.⁷ Thimerosal is only necessary as an additive for some vaccines that come in multi-dose vials. A multi-dose vial contains more than one dose of vaccine. These vials contain thimerosal as a preservative because there is a higher risk that the vaccine could become contaminated. Multi-dose vials typically have rubber-like stoppers. Health care workers must puncture the stopper with a needle to withdraw a dose of the vaccine; therefore, the stopper is punctured many times. This can allow bacteria to enter the vial and contaminate the vaccine. If vaccine from a contaminated vial is administered to a patient, it could cause a serious infection. Preservatives are not needed for vaccines in single-dose vials.



QUESTION: Can my child have vaccines that don't contain thimerosal?

ANSWER: Yes. Since 2001, thimerosal has not been used as a preservative in routinely recommended childhood vaccines, with the exception of some influenza and tetanus-diphtheria vaccines in multi-dose vials. Thimerosal has never been used in live vaccines (MMR, varicella, and intranasal flu vaccine).



QUESTION: Why was a recommendation made to remove thimerosal from childhood vaccines?

ANSWER: The recommendation to remove thimerosal from childhood vaccines was made as a precautionary measure in July 1999 by the U.S. Public Health Service, the American Academy of Pediatrics (AAP), and vaccine manufacturers. This decision was influenced by the public health goal to reduce exposure to all sources of mercury in biological products for infants, children, and pregnant women.

The differences between **ethylmercury** and **methylmercury** are important in the context of this decision. **Ethylmercury**, or thimerosal, is the form of mercury found in some vaccines. It is quickly eliminated by the body through the urine.⁸ In contrast, **methylmercury** is found in environmental sources such as pollutants and some fish. **Methylmercury** remains bound to body tissues for longer periods of time.

Studies show that **ethylmercury** and **methylmercury** affect the body differently.⁹ However, the decision to remove thimerosal from childhood vaccines was based on federal guidelines for **methylmercury** exposure and the assumption that the health risks are the same for **methyl** and **ethylmercury**. Removing thimerosal from childhood vaccines eliminates the possibility that some infants who received several vaccines containing **ethylmercury** might exceed the acceptable limits of **methylmercury** set by one federal agency.



QUESTION: Has thimerosal in vaccines been shown to be harmful to children?

ANSWER: No. Studies have not shown any evidence that thimerosal (**ethylmercury**) contained in vaccines causes harm.

The best evidence against the argument that thimerosal causes autism is that removal of thimerosal from vaccines in both the U.S. and other countries has not led to a decrease in the number of new cases of autism. If autism was due to excess infant exposure to thimerosal, then removal of thimerosal would have led to a decrease in autism.

The state of California has been tracking autism and related diagnoses based on services provided by its Department of Developmental Services. The data set is one of the most complete in the country during the period of time before and after removal of thimerosal from vaccines. Researchers reviewed trends in autism diagnoses from January 1995 through March 2007 in children born between the years of 1989 and 2003. They found that even after thimerosal was removed from vaccines, the number of children with autism continued to rise.¹⁰ California will continue to monitor these trends; however, the data should be reassuring to many parents concerned about whether autism was caused by vaccines.

In October 2001, the IOM concluded that the scientific evidence does not support the argument that a child's thimerosal exposure from vaccines given according to the recommended childhood immunization schedule has caused neurodevelopmental disorders. In 2004, the IOM Immunization Safety Review Committee reviewed a large number of scientific studies, including one in Denmark involving 467,450 children. The IOM concluded that: (1) there is no association between autism and vaccines that contain thimerosal as a preservative and (2) there is no evidence for the hypothesis regarding a link between autism and vaccines that contain thimerosal. Visit www.iom.edu/?ID=4705 for more information and to access the full report.

In addition, VSD monitors vaccine safety through analyses of medical data from a large number of people in HMOs. As of November 2003, CDC has not found any evidence from the VSD project that neurodevelopmental disabilities such as autism are caused by vaccines containing thimerosal. This finding is consistent with scientific evidence to date. A follow-up study was published in 2007 to address inconsistent results from the VSD project. The study examined associations between thimerosal exposure and neuropsychological outcomes such as speech and language skills, attention, fine motor coordination, tics, and academic and intellectual functioning. The weight of the evidence in this study does not support a causal association between early mercury exposure from thimerosal-containing vaccines and neuropsychological functioning at ages 7 to 10 years. Visit www.cdc.gov/vaccinesafety/vsd/thimerosal_outcomes/ to access the complete study. *(For more information about MMR and autism see Chapter 7: Q&A About Specific Vaccines)*

For more information on thimerosal, visit CDC's National Immunization Program at www.cdc.gov/vaccines/ or call 1-800-232-4636 (English and Spanish) or 1-888-232-6348 (TTY).



QUESTION: I heard that the federal government compensated the family of Hannah Poling for a vaccine injury case. Doesn't this prove there is a link between vaccines and autism?

ANSWER: No. The legal settlement *does not* establish that vaccines or any of their ingredients cause autism, but that the vaccines may have made an underlying disorder worse. In March 2008, the federal government settled a claim with the Poling family and awarded compensation. Their daughter had a rare underlying mitochondrial disease, a genetic metabolic disorder, and developed symptoms of autism after receiving a series of vaccinations. There is no established link between vaccines, mitochondrial disorders, or autism and it is not known if the underlying disease would have progressed in this way even if the child had not been vaccinated.

As stated by Dr. Anne Schuchat, Director of the National Center for Immunization and Respiratory Disease at CDC, this vaccine injury case “illustrates [that] when it comes to immunizations, child development and specific medical conditions, the best source of guidance is the child’s health care provider.” Given the rare nature of mitochondrial disease, the case does not have broad application, and families can be reassured that having their children vaccinated is still the safer approach.

The federal Vaccine Injury Compensation Program (VICP) was started in 1988 as a way to petition for compensation for injuries from vaccines. Cases are heard in what is called Vaccine Court, a no-fault alternative to the traditional tort system for resolving vaccine injury claims. For more information about VICP visit: www.hrsa.gov/vaccinecompensation/.

⁷ Pichichero, M.E., et al. 2008. Mercury levels in newborns and infants after receipt of thimerosal-containing vaccines. *Pediatrics* 121 (2): e208–e214.

⁸ Ibid.

⁹ U.S. Department of Health and Human Services. 2007 *NIAID Research on Thimerosal*. Available at www.niaid.nih.gov/factsheets/thimerosal.htm. Accessed on March 10, 2008.

¹⁰ Scechter; Grether. 2008. *Arch Gen Psychiatry* 65. As published in CHOP, Parent PACK, January 2008 newsletter.

Compare the Risks

This chapter is designed to compare the risk of disease with the risk of serious reaction from each related vaccine. The probability of a serious vaccine reaction is extremely low. “A one in a million risk means that of the 4.1 million children born in the U.S. every year, four of those children across the country could be affected. The risk of ‘one in a million’ is actually so low that scientists may not be able to tell whether the event was, in fact, caused by the vaccine or not.”¹¹

The data in this table are specific to the U.S. unless otherwise noted.

Risk of disease and related serious complications	Risk of serious reaction from the vaccine
<p>Hepatitis B</p> <p>An estimated 78,000 new infections are reported each year. Nine of 10 infants with the disease were infected at birth and will become lifelong carriers of the disease and 1 of 4 of these infants will ultimately die of liver failure. Up to half of children infected between 1 and 5 years of age will have lifelong infection. Per year:</p> <ul style="list-style-type: none"> • <i>Death:</i> 3,000 – 4,000 of hepatitis B related cirrhosis; 1,000 – 1,500 of hepatitis B related liver cancer 	<p>Hepatitis B vaccine</p> <p>Severe allergic reactions are rare and occur in approximately 1 in 1.1 million doses.</p>
<p>Rotavirus</p> <p>Before the vaccine was available, rotavirus was the most common cause of severe diarrhea in infants and young children. Almost all children have been infected with rotavirus by 5 years of age. Per year:</p> <ul style="list-style-type: none"> • <i>Emergency room visit:</i> 200,000 • <i>Hospitalization:</i> 55,000 – 70,000 • <i>Death:</i> 20 – 60 	<p>Rotavirus vaccine (live)</p> <p>No serious adverse reactions reported.</p> <p>Cases of intussusception following the vaccination are not any higher than would occur without vaccination. (See Chapter 7, page 33)</p>
<p>Diphtheria</p> <p>Before the vaccine was available, approximately 15,000 deaths occurred each year. From 1980-2004, 57 cases were reported. Diphtheria is still seen in other parts of the world; more than 5,000 deaths were reported in the early 1990s in the former Soviet Union.</p> <ul style="list-style-type: none"> • <i>Death:</i> 1 in 10 	<p>DTaP</p> <p>Diphtheria component</p> <p>Severe allergic reactions are rare and occur in approximately 1 in 1 million doses.</p>

Risk of disease and related serious complications

Tetanus

Before the vaccine was available, there were 500 – 600 cases of tetanus and approximately 180 deaths per year. Currently 50 – 100 cases of tetanus are reported annually.

- *Death*: 1 in 10

Pertussis (whooping cough)

Before the vaccine was available, 200,000 cases and 8,000 deaths occurred each year. Over 377 cases in Washington State occurred in 2006. Approximately 1 out of 5 reported cases of pertussis occurred in infants under 1 year of age.

- *Pneumonia*: 1 in 20
- *Seizure*: 1 in 80
- *Death*: 66 in 2004 to 2005, 56 were 3 months of age or younger

Risk of serious reaction from the vaccine

Tetanus component

Severe allergic reactions are rare and occur in approximately 1 in 1 million doses.

Pertussis component

Severe allergic reactions are rare and occur in approximately 1 in 1 million doses.

- *Fever greater than 105°*: 1 in 16,000 doses
 - *Prolonged crying for three hours or more*: 1 in 1,000 doses
 - *Seizure*: 1 in 14,000 doses
- Note: The IOM concluded that there is no evidence that pertussis vaccine causes sudden infant death syndrome (SIDS).

***Haemophilus influenzae* type b (Hib)**

Before the vaccine was available, Hib was the leading cause of bacterial meningitis among children under 5 years of age. 20,000 children under age 5 got severe Hib disease each year. Most cases occur in children younger than 12 months of age.

- *Hearing impairment and neurological damage*: up to 1 in 3 children with invasive Hib disease
- *Death*: 1 in 20 children with invasive Hib disease

Hib vaccine

No known association between Hib vaccine and serious adverse events.

Pneumococcal Disease

Streptococcus pneumoniae is the leading cause of bacterial meningitis. Children under 2 years are at highest risk for serious disease. Before the vaccines were available, per year pneumococcal infection in children under 5 years of age caused:

- *Meningitis*: 700 cases
- *Bacteremia (blood infection)*: 13,000 cases

PCV or PPV

No known association between pneumococcal conjugate or polysaccharide vaccines and serious adverse events.

Risk of disease and related serious complications	Risk of serious reaction from the vaccine
<p>(Pneumococcal continued)</p> <ul style="list-style-type: none"> •<i>Ear infection</i>: 5,000,000 •<i>Death</i>: 200 <p>It can also lead to pneumonia and brain damage.</p>	
<p>Polio</p> <p>Before the vaccine was available, 38,000 cases occurred, including 13,000 – 20,000 cases of paralysis. During the 1970s, there were several outbreaks in nonimmunized populations, none since 1979.</p> <ul style="list-style-type: none"> •<i>Permanent paralysis</i>: 1 in 100 •<i>Death</i>: 1 in 20 children and 1 in 4 adults with paralytic polio 	<p>IPV</p> <p>No known association between inactivated poliovirus and serious vaccine reactions.</p>
<p>Influenza (flu)</p> <p>Four flu pandemics occurred in the 19th century. The 1918–19 pandemic killed an estimated 21 million people worldwide. The most frequent complication of influenza is pneumonia. Others include myocarditis (inflammation of the heart) and death.</p> <p>Per year:</p> <ul style="list-style-type: none"> •<i>Hospitalization</i>: approximately 1 in 200 children 0 – 4 years old •<i>Death</i>: more than 36,000 	<p>LAIV (live) or TIV</p> <p>No known serious vaccine reactions. Severe (anaphylactic) egg allergy is a contraindication for both live attenuated influenza vaccine (intranasal) and trivalent influenza vaccine (injectable).</p>
<p>Measles</p> <p>Before the vaccine was available, there were 500,000 reported cases and 500 deaths per year. During the 1989–91 measles epidemic, there were 55,622 cases due to large numbers of unimmunized children, 45% were less than 5 years old. The epidemic caused 123 deaths, of which 90% were unimmunized.</p> <ul style="list-style-type: none"> •<i>Pneumonia</i>: 1 in 20 •<i>Encephalitis (brain swelling)</i>: 1 in 1,000 •<i>Seizure</i>: 6 to 7 in 1,000 •<i>Death</i>: 1 to 3 in 1,000 	<p>MMR (live)</p> <ul style="list-style-type: none"> •<i>Thrombocytopenia (temporary decrease in blood platelets)</i>: about 1 in 30,000 <p>Measles component</p> <p>Severe allergic reactions are rare.</p>

Risk of disease and related serious complications

Mumps

Before the vaccine was available, 200,000 cases occurred per year. In 2006 there was a multistate outbreak of more than 6,000 cases.

- *Encephalitis (brain swelling)*: 1 in 50,000
- *Testicular swelling*: 1 in 5 males
- *Deafness*: 1 in 20,000
- *Death*: about 1 per year

Rubella

In 1964–65 there were 12.5 million cases, including 2,100 infant deaths, 11,250 fetal deaths, and 20,000 newborns born with congenital rubella syndrome (see below).

- *Arthritis (usually temporary)*: 7 in 10 adult women
- *Thrombocytopenia (low blood platelet count)*: 1 in 3,000
- *Congenital Rubella Syndrome (e.g., deafness, cataracts, mental retardation)*: 4 in 5 newborns whose mothers were infected early in pregnancy

Risk of serious reaction from the vaccine

Mumps component

Severe allergic reactions are rare.

Rubella component

Severe allergic reactions are rare.

- *Arthritis (usually temporary)*: up to 1 in 4, usually teenage or adult women (not children).

Varicella (chickenpox)

Before the vaccine was available, 3–4 million cases occurred per year, with 11,000 hospitalizations. Nine out of 10 people in a household who have not already had chickenpox will catch the virus if exposed to an infected household member. The disease is more severe and complications are more frequent in adolescents and adults, and in those with weakened immune systems. Complications include bacterial infection of skin lesions and scarring, pneumonia, brain inflammation, and reactivation later in life of varicella virus known as Herpes Zoster (shingles).

- *Hospitalization*: 3 in 1,000 cases
- *Death*: 1 per 60,000 cases

Varicella vaccine (live)

Severe allergic reactions are rare.

Risk of disease and related serious complications	Risk of serious reaction from the vaccine
<p>Hepatitis A</p> <p>Before the vaccine was available, 15–20 cases per 100,000 occurred yearly in children 2–18 years of age. In 2004, an estimated 20,000 cases occurred. Prolonged or recurring disease lasting up to six months occurs in 10–15% of cases.</p> <ul style="list-style-type: none"> • <i>Death</i>: Approximately 100 per year 	<p>Hepatitis A vaccine</p> <p>No known association between hepatitis A vaccine and serious adverse events.</p>
<p>Meningococcal</p> <p>There are approximately 2,600 cases reported annually. The rate of invasive disease among 17–20 year olds is twice that of the overall U.S. population. Approximately 3 out of every 10 cases are 12–29 years old.</p> <ul style="list-style-type: none"> • <i>Pneumonia</i>: about 1 in 7 • <i>Sepsis (bloodstream infection)</i>: up to 1 in 5 • <i>Permanent disability (hearing loss, brain damage, loss of limb)</i>: 1 in 5 • <i>Death</i>: 1 in 10 	<p>MCV or MPSV</p> <p>Severe allergic reactions are rare.</p> <p>It is unknown whether meningococcal conjugate vaccine (MCV) increases the risk of Guillain-Barré syndrome (GBS). (See also Chapter 7, page 33)</p>
<p>Human Papillomavirus</p> <p>Up to 75% of HPV infections occur among people 15–24 years old. As of 2007, an estimated 20 million people were infected. Annually, 6.2 million new infections occur.</p> <ul style="list-style-type: none"> • <i>Genital warts</i>: no specific data is available because it is not a reportable infection • <i>Cervical cancer</i>: approximately 9,700 new cases in 2006 • <i>Death</i>: estimated 3,700 cervical cancer deaths in 2006 	<p>HPV</p> <p>No serious adverse reactions reported with the human papillomavirus vaccine.</p>

¹¹ Myers, Martin G., and Diego Pineda. 2008. *Do Vaccines Cause That?! A Guide For Evaluating Vaccine Safety Concerns*. Galveston, TX. Immunizations For Public Health.

(See also Chapter 6: Compare the Risks)

HEPATITIS A (Hep A)



QUESTION: How do you get hepatitis A and how does it spread?

ANSWER: The virus that causes hepatitis A is found mainly in the stool of an infected person. It is easily spread when a person puts something (food, water, hands, or an object) into his or her mouth that has infected feces on or in it. People transmit hepatitis A virus one to two weeks before they even begin to feel sick. Children often do not show any symptoms of illness, so they can unknowingly spread the virus.

The hepatitis A virus can spread in child care settings from an infected baby to another baby if caregivers do not wash their hands between diaper changes. Hand washing after using the bathroom or changing diapers is an excellent preventive measure, although it is not 100% effective.

HEPATITIS B (Hep B)



QUESTION: I know that most people who get hepatitis B are adults. Why is it recommended that the hepatitis B vaccine series be given to infants?

ANSWER: National immunization recommendations call for the routine immunization of all infants against hepatitis B because:

- It is impossible to predict who will be exposed to hepatitis B in the future. Approximately 30% of those who become infected with hepatitis B do not know how they got the disease. Infection can occur as a result of bites, scratches, or contact with blood from an infected playmate or family member.
- Infants and children are much more likely to develop severe and often fatal consequences of hepatitis B virus infection if they become infected when they are very young.
- The earlier in life a child is exposed to the disease, the more likely he or she will become a chronic (lifelong) carrier. Approximately 1 in 4 chronically infected children die prematurely from cirrhosis or liver cancer.
- Adding hepatitis B to the already established immunization schedule helps to ensure people are protected before they are exposed to the virus.



QUESTION: Does hepatitis B vaccine cause multiple sclerosis (MS)?

ANSWER: No. Analyses by the World Health Organization (WHO), IOM, and the Medical Advisory Board of the National Multiple Sclerosis Society conclude that there is no evidence that the hepatitis B vaccine causes MS or other neurological diseases in otherwise healthy individuals.

MS is an autoimmune disorder in which a person's antibodies attack the body's own myelin (a sheath that covers the nerves). MS is a lifelong illness that fluctuates through periods of exacerbation (symptoms worsen) and remission (symptoms subside). The cause of MS is unknown, but most medical experts believe that patients are genetically at risk for the disease and environmental factors can "trigger" its onset.

In May 2002, the IOM's Immunization Safety Review Committee published a report of its findings regarding the possible association between hepatitis B vaccine and multiple sclerosis and related disorders. Following a thorough analysis of the studies of hepatitis B vaccine–exposed populations compared to unvaccinated patients with MS, the committee concluded that the evidence did not support a causal relationship between hepatitis B vaccine and multiple sclerosis. For a copy of the full IOM report, visit www.iom.edu/?ID=4705.



QUESTION: Does hepatitis B vaccine cause sudden infant death syndrome (SIDS)?

ANSWER: No. Since 1991, infants have been receiving hepatitis B vaccine starting as early as the first day of life. If SIDS were somehow related to hepatitis B vaccination, we would expect to see an increase in SIDS deaths since that time. This is not the case. In fact, there has been a steady decrease in the number of newborn deaths, even as the number of hepatitis B vaccinations has increased.

DIPHTHERIA, TETANUS, AND ACCELLULAR PERTUSSIS (DTaP)



QUESTION: What are the side effects of the DTaP vaccine?

ANSWER: Most children who receive the DTaP vaccine will experience only minor discomfort. The most common reactions are soreness, swelling, and redness at the injection site. These reactions are more common following the fourth and fifth doses of the vaccine. Usually these reactions last one to two days. Serious reactions are reported rarely with the acellular pertussis vaccine. Acellular means that the pertussis part of the vaccine contains only parts of the pertussis bacterium, not the whole cell.

The older version of this vaccine, called whole cell DTP, was associated with a higher frequency of local reactions (such as redness, swelling, pain at the injection site) and fever. DTP is no longer used in the U.S. (See also *Chapter 6: Compare the Risks*)



QUESTION: How effective is the DTaP vaccine?

ANSWER: A full series of five shots protects approximately 80 of 100 children from getting severe pertussis. Approximately 95 of 100 children will be protected from diphtheria, and virtually 100% of children will be protected from tetanus after the full DTaP series is given. Each dose of the five dose series increases your baby's protection against these diseases.

Children vaccinated with DTaP who do become ill with pertussis almost always have a milder illness than if they had not been vaccinated. A full primary series of four DTaP shots by age 18 months is recommended, with a booster dose given between 4 to 6 years of age. Consider these DTaP facts:

- Because it is so contagious, the possibility of a child getting severe pertussis when exposed is far greater than the chances of experiencing a severe adverse reaction from the vaccine.
- Children who catch pertussis (especially young infants) often become critically ill.
- Incompletely immunized children contribute to higher rates of pertussis disease in a community.
- Most individuals who have had a full series of DTaP vaccine are protected from diphtheria, tetanus, and severe pertussis for many years. An adolescent and adult booster dose, called Tdap, is recommended for continued protection.

MEASLES, MUMPS, AND RUBELLA (MMR)



QUESTION: Is there any evidence to indicate an association between the MMR vaccine and autism?

ANSWER: No. The best available science indicates that the development of autism is unrelated to use of MMR or any other vaccine. Experts in behavioral and developmental disorders agree that autism is most likely a genetic disorder, although research continues on its exact cause.

Typically, symptoms of autism first appear in children from 18 to 30 months of age. MMR vaccine is usually given to children 12 to 15 months of age. Although autism may be detected during the weeks or months following MMR vaccination, this does not mean that the disorder was caused by the vaccine.

One small review of 12 children conducted in England in 1998 by Wakefield and colleagues seemed to suggest such a link. However, in 2004, 10 of the 13 authors of the study retracted the paper's interpretation, stating now that there was not enough data to establish a link between MMR vaccine and autism.¹²

In 2008, a team of researchers tried and failed to replicate these earlier findings.¹³ This study adds weight to a growing body of epidemiological studies and reviews that refute a connection between MMR and autism. To see a list of these articles, visit www.immunize.org/mmrautism/.



QUESTION: Is it safer to give measles, mumps, and rubella as separate shots instead of the combined MMR vaccine?

ANSWER: No. By giving the vaccines separately, protection is delayed and children are unnecessarily vulnerable to the serious diseases the MMR vaccine prevents. Delaying the rubella vaccine increases the risk of preventable cases of congenital rubella syndrome (CRS) when infected children transmit the disease to susceptible pregnant women.

POLIO



QUESTION: Is it still necessary to be immunized against polio?

ANSWER: Yes. Although wild polio disease was eliminated from the U.S. in 1979, it still exists in other countries. Efforts are underway to eliminate polio worldwide. However, as long as polio exists in the world, our children need protection. Because international travel is common, diseases from other parts of the world are literally only a plane ride away.



QUESTION: What is the difference between oral polio vaccine (OPV) and inactivated polio vaccine (IPV)?

ANSWER: OPV, a live vaccine, was the vaccine of choice for routine immunization of most children in the U.S. from 1963 to the mid-1990s. It is highly effective at preventing polio and convenient to administer orally. However, OPV is associated with a very rare occurrence of paralysis in people who receive the vaccine and in those with whom they have had contact. Approximately eight cases of vaccine-associated paralytic polio (VAPP) occurred in the U.S. each year when OPV was the primary vaccine in use. This represented about one case per 2.5 million doses administered.

In contrast, the injectable IPV cannot and does not cause VAPP because it does not contain live polio virus. The old form of IPV was not as effective as the newer version currently in use. Because wild polio virus has been eliminated from the U.S. and other countries in the western hemisphere, an all-IPV schedule has been used in the U.S. since January 2000.

CHICKENPOX (Varicella)



QUESTION: If chickenpox (varicella) isn't a very serious disease, why vaccinate?

ANSWER: It is important to vaccinate against chickenpox due to possible life-threatening complications from varicella disease. Pneumonia and encephalitis, "flesh-eating" bacterial infection, and death can and do occur in children and adults as a consequence of chickenpox disease. Before chickenpox vaccine became available in 1995 in the U.S., 7,200 children were hospitalized and 100 children died each year. Most of the hospitalizations and deaths

occurred in previously healthy children. Since 1996, hospitalizations and deaths from varicella disease have decreased more than 90%. Vaccinating against the illness during childhood will help reduce the incidence of the disease (and related complications) in later years.



QUESTION: Does my child need a second dose of varicella vaccine?

ANSWER: Yes. A two-dose series is recommended for all healthy children starting at age 12 to 15 months for the best protection. For most people receiving the vaccine, immunity appears to be long lasting. It is 95 to 100% effective against severe disease and 70 to 90% effective against any varicella disease. Even if an immunized person develops chickenpox after being exposed to the disease, the illness will be much milder and shorter in duration than if he or she had never been vaccinated.

PNEUMOCOCCAL (PCV, PPV)



QUESTION: Are there different pneumococcal vaccines for children?

ANSWER: Yes. The pneumococcal polysaccharide vaccine (PPV), which has been used in the U.S. since 1983, is not recommended for children under 2 years of age because it is ineffective in this age group.

A pneumococcal conjugate vaccine (PCV) that can be used in children under 2 years of age became available in 2000. This vaccine targets the seven most common types of pneumococcus that cause the majority of invasive disease in this age group. In the past, pneumococcal infections could be treated effectively with certain antibiotics. However, many of these infections are becoming resistant to antibiotics. For this reason, preventing pneumococcal infection through vaccination is even more important.

INFLUENZA (TIV, LAIV)



QUESTION: Does my baby need influenza (flu) vaccine?

ANSWER: Yes. The ACIP recommends all children beginning at 6 months of age get influenza vaccine. Infants and children younger than 5 years old are more likely to have serious illness and complications, including hospitalization. It is recommended that household contacts and caregivers of children (especially those under 6 months of age) get influenza vaccine each year. Your infant or child will need two doses of influenza vaccine the first season in which he or she is vaccinated. For more information about influenza recommendations visit www.cdc.gov/vaccines.



QUESTION: Are there different types of influenza vaccine?

ANSWER: Yes. Two types of flu vaccine are available, an injectable form and a nasal spray. The shot contains inactivated (killed) viruses and can be given to anyone 6 months and older. The nasal spray is a live-attenuated (weakened) vaccine that was licensed in 2003 and is sprayed into both nostrils. Currently, it is approved for use in healthy children and adults who are 2 to 49 years of age.

ROTAVIRUS (Rota)



QUESTION: Is there a vaccine to prevent rotavirus?

ANSWER: Yes. An oral vaccine licensed in 2006, is given in three doses at 2, 4, and 6 months. The vaccine is 94% effective against severe rotavirus disease and 74% effective against all rotavirus disease. In 2008 a second vaccine was licensed and is a two dose oral series.



QUESTION: What is intussusception? Is there a risk for this condition with the rotavirus vaccine?

ANSWER: Intussusception is an uncommon bowel obstruction that causes one part of the intestine to slide into the next, much like the pieces of a telescope. Current studies have not shown an increased risk of intussusception in infants getting the vaccine compared to infants who have not been vaccinated. (See also Chapter 4, page 18)

MENINGOCOCCAL (MCV, MPSV)



QUESTION: Are there different meningococcal vaccines?

ANSWER: Yes. There are two meningococcal vaccines. Meningococcal conjugate vaccine (MCV) is recommended for people 11 to 55 years of age when at increased risk of invasive meningococcal disease. It is now routinely recommended for 11 to 12 year olds, students entering high school, and college-age freshmen living in a dormitory. Meningococcal polysaccharide vaccine (MPSV) is not routinely recommended for children.



QUESTION: Is there an increased risk for getting Guillain-Barré Syndrome (GBS) with the meningococcal vaccine?

ANSWER: No. However, GBS has been reported among some people following MCV vaccine. GBS occurs so rarely that there is not enough evidence to tell if it is caused by the vaccine. CDC carefully monitors for GBS cases. Currently, CDC recommends vaccination with MCV for those at higher risk for meningococcal disease.

¹² Murch, S.H., et al. 2004. Retraction of an Interpretation. *Lancet* 363: 750.

¹³ Hornig M, et al. 2008 Lack of Association between Measles Virus Vaccine and Autism with Enteropathy: A Case-Control Study. *PLoS ONE* 3(9): e3140 doi:10.1371/journal.pone.0003140

Legal Requirements



QUESTION: What are the legal requirements for immunizing children?

ANSWER: Federal law requires that before immunizations are given, parents or guardians must have:

- information in writing (Vaccine Information Statement) about the risks and benefits of vaccination
- an opportunity to ask questions and obtain additional information about vaccinations from their health care provider

All states require vaccination because they have a responsibility to protect the health of the public and individuals. Requirements vary from state to state. Each state determines which vaccines are required by law for child care, preschool, and school attendance. In Washington State, the requirements for childhood immunizations are defined in the Revised Code of Washington (RCW) 28A.210 and explained in the Washington Administrative Code (WAC) 246-100-166. For more information, visit www.doh.wa.gov/cfh/immunize/schools/default.htm.

Washington State law requires parents or guardians to complete a Certificate of Immunization Status (CIS) for each child before attending licensed child care, preschool, and school. A CIS is available from child care facilities, schools, health departments, and online at www.doh.wa.gov/cfh/immunize. To attend child care, preschool, or school, a child's CIS must document:

- full immunization for his or her age or
- a plan for catching up on late or missed immunizations or
- a signed Certificate of Exemption indicating exemption from vaccination for medical, religious, or personal reasons.

A child who is not fully immunized (due to late/missed immunizations or an exemption) may be excluded from attending child care, preschool, or school during outbreaks of vaccine-preventable diseases.

Be sure to keep a record of your child's immunizations. A Washington State Lifetime Immunization Record card can be ordered free of charge from the Family Health Hotline at 1-800-322-2588 or online at <https://fortress.wa.gov/prt/printwa/wsprt/default.asp>.



QUESTION: Why don't the vaccine requirements for school entry match the current vaccines listed in the Recommended Childhood Immunization Schedule?

ANSWER: School vaccine requirements are the minimum number of immunizations necessary to prevent disease outbreak, while the ACIP

Recommended Childhood Immunization Schedule provides a vaccine schedule for the best protection from vaccine-preventable diseases. In addition, some vaccines protect against diseases that are most serious to infants and toddlers, like *Haemophilus influenzae* type b and rotavirus. These diseases do not pose as great a threat to school-age children and therefore are not required for school entry.

To protect babies and young children against diseases that are most common before they start school, following the recommended immunization schedule is best.



To Wait or Not to Wait

Parents frequently ask why immunizations are given so early in life. You may wonder if you can wait until your child is entering school to get the required immunizations. You may also wonder about the risk if your child does not receive all recommended immunizations.



QUESTION: Who determines the Recommended Immunization Schedules?

ANSWER: The Advisory Committee on Immunization Practices (ACIP) develops written recommendations for the scheduling and appropriate use of childhood, adolescent, and adult vaccines. These recommendations become the Recommended Childhood, Adolescent, and Adult Immunization Schedules with collaborative approval by ACIP, AAP, and the American Academy of Family Physicians (AAFP).

The ACIP is comprised of 15 immunization experts who are selected by the Secretary of the U.S. Department of Health and Human Services (HHS). The goal of ACIP is to provide advice and guidance to HHS and CDC in reducing the incidence of vaccine-preventable diseases through vaccination.

Individual states determine which recommended vaccines are required for entry into child care, preschool, and school. (See also Chapter 8: *Legal Requirements*)



QUESTION: What happens if I wait to immunize my child until he or she is ready to start school?

ANSWER: Waiting puts your child at increased risk for serious diseases. Many vaccine-preventable diseases are more severe and pose the greatest risk for complications in infants and very young children. Delaying immunizations until kindergarten or even until after the first birthday can put your child at unnecessary risk when he or she is most vulnerable. Any protection the baby received through maternal antibodies wanes during the first year, which usually coincides with the child being more frequently exposed to other children and adults who may be infected with these diseases.



QUESTION: Can my child catch up if he or she is behind on getting immunized?

ANSWER: Yes. If a child is behind on the immunization schedule, a catch-up schedule can be determined by the child's doctor, nurse, or clinic. An interruption in the schedule **does not** require a child to start the series over for any vaccine. However, until the entire vaccine series is received, the

child will not have the maximum protection against the disease.

Some vaccines, such as rotavirus, PCV, and Hib, cannot be given if they are not started or completed by a certain age. It is best to follow the recommended schedule as closely as possible.



QUESTION: Can my child get immunizations even if he or she has a minor illness?

ANSWER: Yes. Immunizations can be given and requested during any visit to your doctor or nurse, even if your child has a minor illness, such as mild fever, a cold, diarrhea, or is taking antibiotics. The vaccine will still be effective. It will not make your child's illness worse. Receiving all immunizations when they are due is an important way to complete each vaccine series on time and avoid extra visits.



QUESTION: Are there times that vaccines should NOT be given?

ANSWER: Yes. Sometimes there are medical reasons for not giving a vaccine or for delaying it. These are referred to as "contraindications" and "precautions." In general, a child should not receive an immunization if he or she:

- Has a medical condition that could be made more severe, or even life-threatening if the vaccine were given. For example: A child has a severe allergy to a vaccine component (e.g., neomycin, gelatin) that would cause a serious reaction, such as difficulty breathing, low blood pressure, or shock if the vaccine were given.
- Has a medical condition that could reduce the ability of the vaccine to produce the desired immunity. For example: A child has recently received blood products (such as immune globulin or a blood transfusion), and the antibodies in the blood could damage a live vaccine, such as measles vaccine.

In most instances, vaccines may be given if a child is breastfed, has an ear infection, is taking antibiotics, has mild diarrhea, or has a milk allergy. Infants or children living in a household with a pregnant woman may receive all vaccines, including live vaccines (such as MMR and varicella). Check with your health care provider if you have specific questions regarding these or other circumstances.



QUESTION: I am concerned about specific vaccines and the number of vaccines recommended for my 2-month-old. Although his doctor would prefer to follow the routinely recommended schedule, she has agreed to adjust the schedule for our family. What do I need to consider and what should I do next?

ANSWER: Here are some considerations and next steps before you make your decision.

Considerations:

- Using combination vaccines reduces the number of shots given at one time.
- Vaccines for children under 3 are preservative-free. (See *Chapter 5: Vaccine Ingredients*)
- Some diseases are more serious for infants than older children.
- Adjusting the schedule may lead to more visits to your health care provider and repeated discomfort for your child.

Next steps:

- Educate yourself about the diseases. (See *Chapter 6: Compare the Risks*)
- Prioritize the vaccines according to disease risk.
- Protect your unimmunized baby by encouraging everyone who spends time with your baby (including you) to be immunized.
- Continue to discuss your decision with your health care provider at each visit.



Infant and child immunization programs in the U.S. have greatly decreased the occurrence of many childhood diseases. However, vaccine-preventable diseases such as hepatitis A and B, pertussis, and measles continue to affect many adolescents and young adults. Low immunization coverage in this population increases the spread of disease to vulnerable people such as infants and the elderly.

In order to protect adolescents and young adults from serious vaccine-preventable diseases, ACIP, AAP, and AAFP all strongly recommend an **adolescent health visit at 11 to 12 years of age**. This visit allows parents to discuss the recommended vaccines with their health care provider; decide which immunizations their teen needs, and receive other preventative care. Parents can help prepare their adolescents for a healthy adulthood by taking them to the adolescent health visit and being sure their immunizations are up-to-date.



QUESTION: Which vaccines are recommended for my adolescent?

ANSWER: ACIP currently recommends the following vaccines beginning at age 11 to 12:

- Tetanus, diphtheria, and acellular pertussis vaccine (Tdap)
- Meningococcal vaccine (MCV)
- Human papillomavirus (HPV) vaccine series
- Influenza (yearly)

Adolescents should get the following vaccinations if they did not receive **all** recommended doses when younger:

- Hepatitis A series
- Hepatitis B series
- Polio series
- Measles, mumps, and rubella (MMR) series
- Varicella (chickenpox) series

Adolescents with chronic medical conditions may need additional vaccines. Check with your health care provider.

Adolescent health visits build a lifelong commitment to good health. Ask your health care provider about immunizations at every visit including sports physicals, injury, and illness visits.



Evaluating Immunization Information on the Internet



QUESTION: How do I know if the vaccine information I find on the Internet is accurate?

ANSWER: The Internet can be a valuable resource to find health information. However, the quality of health information on the Internet is extremely variable and difficult to assess. Remember that medical information changes rapidly, so it is a good idea to check more than one place for information.

Consider the following 10 tips to help you determine whether the information you find is accurate and trustworthy.

- 1. The ownership of the site should be clear.** Is the name of the organization or individual posting the information in clear view? Look for highlighted text that tells you more about the author of the site. On some sites, the ownership can be found by clicking "View" and then "Document Source" or "Document Information."
- 2. The information provided should be based on sound scientific study.** Scientists discover truth by testing their findings repeatedly, to be sure that their thinking and methods are not flawed, influenced by their own assumptions, or marred by special circumstances. Studies with hundreds of participants or cases bear more weight than descriptions of a single case. The most useful studies compare the findings in one group of people or cases with the findings in another group (control groups). A mark of sound scientific study is that the findings are peer reviewed and endorsed by groups or institutions dedicated to science, such as professional associations or universities.
- 3. The site should carefully weigh the evidence and acknowledge the limitations of the work.** Think: What does the weight of the evidence indicate? If conclusion #1 is found in three studies, but conclusion #2 is found in 30 studies, which is more likely to point to the truth? Be wary of people or sites proclaiming that they, and only they, have discovered the "hidden truth." The scientific approach takes time, and often answers are slow in coming or don't come at all. This can be very frustrating if the answers will have an impact on our own or our children's health and well-being. Solid researchers, however, are not afraid to address the weaknesses as well as the strengths of their findings, to say that the findings were inconclusive, or to say that additional research is needed before any conclusions can be drawn. A scientifically sound Web site will reflect these circumstances.

4. Beware of “junk science” and suggestions of “conspiracies.” The hallmarks of junk science are hasty, and often sensational, claims that other scientists have not seen, reviewed, or verified. Media attention does not necessarily mean a claim is true. “Conspiracy” theories often offer a quick and exciting answer to a puzzle. Think: If I take apart the pieces of “evidence,” do they really fit together again?

5. The individuals or group providing the information should be qualified to address the subject matter. Beware of information attributed to unnamed “noted researchers” or “world-renowned scientists.” A researcher who has done good, solid work would insist that his or her name be attached to that work, even if it's controversial. Who stands behind the information? What educational background do they have that relates to the health topic area? What other work have they published, and where was it published?

6. Arguments should be based on facts, not conjecture. Beware of sites that mix fact with guesses, without distinguishing between the two. As with junk science, the resulting “theories” can be sensational but are not scientifically sound.

7. The motives of the site should be clear. Is the site a sales and promotional device? There is nothing wrong with selling books and tapes, or enlisting you in a cause, but motives should be clear.

8. The information provided should make sense. Is it too good to be true (“Lose 50 pounds in two days!”)? Or too awful to be true (“Thousands abducted by UFOs!”)? If so, then it probably isn't true.

9. A scientifically sound site should have references from and to recognized peer reviewed publications.

10. You should be able to obtain additional information if you need it. Is an e-mail, postal address, or telephone number provided for further information? Is a reading list or source list provided? Is the reading available through a public library, or is the list a source of income for the site owner? If government documents or publications are referenced, remember that they are usually available free or at low cost through the publishing agency or the Superintendent, Government Printing Office, in Washington, D.C. To inquire, call toll-free 1-888-293-6498 or fax 202-512-1262.



QUESTION: Is there any regulation or standardization of information on the Internet?

ANSWER: No. There is little regulation of the information on the Internet. The following resources can provide some guidelines to consider:

- **The Federal Trade Commission (FTC)**
Law-enforcement efforts of the FTC focus on deceptive and unproven claims. The federal agency monitors the Internet for fraud and deception, and it can act against a company if it sees a pattern of law violations. To help make consumers aware of Web sites that promote fraudulent products, the FTC launched the campaign “Operation Cure All” in June 1999, www.ftc.gov/cureall.
- **The World Health Organization (WHO)**
The WHO has established guidelines for Web sites providing information about vaccine safety. It features a list of Web sites that meet its expectations, www.who.int/vaccine_safety/good_vs_sites/en/.
- **Healthfinder**
The Healthfinder Web site at www.healthfinder.gov is the federal government’s gateway for reliable information from U.S. government agencies and other organizations. The site displays selected resources of consumer health and human services information. These sources have been reviewed and found reliable and credible.

Chapter sources:

- Tips on Evaluating Immunization Information on the Internet excerpted from U.S. Department of Health and Human Services; National Vaccine Program Office (2008) [Electronic version]. Available at www.hhs.gov/nvpo/tips.htm. Accessed May 5, 2008.
- National Network for Immunization Information. Available at www.immunizationinfo.org. Accessed March 10, 2008.

The Personal Side of Vaccine-Preventable Disease in Washington State

Chickenpox Is Not a Nice Party Gift

Neil Kaneshiro, MD, Past President, Washington Chapter AAP

In 2004, I saw Michael*, a 3 year-old with chickenpox. Michael was about five days into his illness and his mom was worried because he was still having high fevers and the spots seemed to be getting bigger. In addition, he seemed tired and refused to drink and eat. He sounded sicker than most, so I agreed to see him in the office. I noted that his mom had previously declined the immunization for chickenpox.

Michael had hundreds of vesicles of varying stages of healing on his face, trunk, and extremities. He had more than a few lesions the size of silver dollars that were swollen, red, and draining pus. He was definitely not happy. Mom seemed anxious, which I thought was appropriate given the extent of the illness.

I discussed with her the severity of Michael's illness. It was serious and he needed IV fluids and antibiotics. When I saw him the next day, his fever was down and his skin infection seemed to be improving. However, his mother still seemed anxious and she asked if there would be any permanent damage. Fortunately, he had no evidence of encephalitis or neurological involvement, and the skin infection appeared to be resolving nicely. I said that he might have scars from the bigger lesions, but he should be fine.

Most patients would have been happy simply to see their child improve, so I asked her why she was so worried. She told me that she had taken Michael to a "chickenpox party" and exposed him to a child known to have had chickenpox recently. She believed that it was better for him "to get the illness now and get it over with." I explained to her that although many kids have no problem with the chickenpox, we know that it can make some people quite ill, and in fact does cause permanent damage and death in some cases. That is why the vaccine was developed and is recommended. Exposing a child on purpose to chickenpox is never a good idea for this very reason. The party gift of chickenpox can be life threatening, so don't give it.

*Names have been changed to protect patient privacy

A Father Speaks Up About Influenza

On Valentine's Day 2007, my oldest daughter suddenly and unexpectedly passed away at the age of 8. She had been suffering from influenza for a few days before her death, but the cause of her death was a complication known as viral myocarditis (inflammation of the heart). It was triggered by the influenza virus and infected the tissue of her heart, causing it to fail. Viral myocarditis is very difficult for even experienced health professionals to diagnose. In many cases, the symptoms are simply masked by symptoms more commonly associated with the flu. By the time we began to suspect that our daughter was suffering from something other than just ordinary flu, it was far too late.

The influenza strain responsible for the infection was apparently a particularly virulent strain that had rampaged through the community in the previous days and weeks. The week prior to her death, a local high school canceled classes for two days due to one-third of the student body being out sick with influenza. The week of my daughter's death, over 50% of her second grade class was absent from school with the flu. Ten days before her death, another local girl had died from influenza-related viral myocarditis.

The influenza complication responsible for my daughter's death is still relatively rare. However, please remember that the influenza vaccine not only prevents illness, but it also prevents complications which result in death.

Pertussis: One Mother's Experience

As an infant, my son Cole had pertussis. It was a frightening experience. Watching him suffer convinced me that it is extremely important for parents to be sure their children's immunizations are up-to-date.

When my son was 4 weeks old, he got a persistent cough that continued to worsen. He coughed almost 24 hours a day, often turning purple. It sounded like he was choking on fluids. The initial examination at the local hospital, which included a test for pertussis, found nothing to indicate my baby had anything more than a routine cough.

After a month of watching Cole suffer and spend almost every waking hour of every day struggling to breathe, we took him to the emergency room. He was admitted and three days into his hospitalization was retested for pertussis. This time, the test came back positive. He was put on antibiotics. We were told that after five days of treatment, he would no longer be able to spread the disease to others. Little by little, he improved, but it took time for the coughing to finally stop. I was so relieved. However, I was also upset that what many think is an ordinary and harmless disease was such a threat to my son and that this disease had gone unrecognized for more than a month.

My baby was infected by the mother of three middle school aged boys, before he was old enough to get the vaccine. People must be aware that this disease is out there and serious. I urge caregivers to be sure they, and the children they care for, are up-to-date on their immunizations. Keeping your child immunized on time will help protect babies and others who are most vulnerable.

Your decisions about immunizations don't just affect your children. They impact your family, your neighbor's children, and the whole community.



VACCINES

DTaP	Diphtheria, tetanus, and acellular pertussis
Flu	Influenza
Hep A	Hepatitis A
Hep B	Hepatitis B
Hib	<i>Haemophilus influenzae</i> type b
HPV	Human papillomavirus
IPV	Inactivated poliovirus
LAIV	Live, attenuated influenza vaccine
MMR	Measles, mumps, and rubella
MCV	Meningococcal conjugate vaccine
MPSV	Meningococcal polysaccharide vaccine
OPV	Oral poliovirus
PCV	Pneumococcal conjugate vaccine
PPV	Pneumococcal polysaccharide vaccine
Rota	Rotavirus
Td	Tetanus, diphtheria
Tdap	Tetanus, diphtheria, and acellular pertussis
TIV	Trivalent inactivated influenza vaccine
Var	Varicella (chickenpox)

TERMS

CIS	Certificate of Immunization Status
CRS	Congenital Rubella Syndrome
GBS	Guillain-Barré Syndrome
HMO	Health Management Organization
MS	Multiple Sclerosis
SIDS	Sudden Infant Death Syndrome
VAERS	Vaccine Adverse Event Reporting System
VAPP	Vaccine Associated Paralytic Polio
VIS	Vaccine Information Statement
VSD	Vaccine Safety Datalink Project

ORGANIZATIONS

AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ACIP	Advisory Committee on Immunization Practices
CDC	Centers for Disease Control and Prevention
CHOP	Children's Hospital of Philadelphia
DOH	Washington State Department of Health
FDA	Food and Drug Administration
FTC	Federal Trade Commission
HHS	U.S. Department of Health and Human Services
IOM	Institute of Medicine
NIH	National Institutes of Health
VICP	National Vaccine Injury Compensation Program
WHO	World Health Organization



References

- 2006 Red Book, Report of the Committee on Infectious Diseases. 27th Edition Elk Grove Village, IL: American Academy of Pediatrics.
- Armstrong, G., E. Mast, M. Wojczynski, H.S. Margolis. 2001. Childhood hepatitis B virus infections in the United States before hepatitis B immunization. *Pediatrics* 108: 1123–1128.
- Centers for Disease Control and Prevention. 2007. *Epidemiology and Prevention of Vaccine-Preventable Diseases* (The Pink Book), 10th Edition. U.S. Department of Health and Human Services.
- CDC officials help physicians answer DTP safety questions. 1995. *American Academy of Pediatrics News*, March: 9–10.
- Dales, L., S.J. Hammer, N.J. Smith. 2001. Time trends in autism and MMR immunization coverage in California. *Journal of the American Medical Association* 285: 1183–1185.
- Decline in *Haemophilus influenzae* Type b Meningitis—Seattle & King County, Washington, 1984–89. 1990. *MMWR* 39(8).
- Donald, A., and V. Muthu. 2002. Measles. Clinical Evidence. BMJ Publishing. Available at www.clinicalevidence.com. Accessed July 10, 2002.
- *Epi-Log*, Seattle-King County Department of Public Health, vol. 2, no. 4.
- Evans, Alfred S. 1989. *Viral Infections of Humans*, Third Edition. New York: Plenum Publishing.
- Evans, Alfred S., and Philip S. Brachman. 1991. *Bacterial Infections of Humans*, Second Edition. New York: Plenum Publishing.
- Health Protection Agency, Centre for Infections. Available at www.camr.org.uk/infections/topics_az/mumps/data_quarter.htm. Accessed April 15, 2008.
- Hornig M, Briese T, Buie T, Bauman ML, Lauwers G, et al. 2008 Lack of Association between Measles Virus Vaccine and Autism with Enteropathy: A Case-Control Study. *PLoS ONE* 3(9): e3140 doi:10.1371/journal.pone.0003140
- Humiston, Sharon G., and Cynthia Good. 2003. *Vaccinating Your Child: Questions and Answers for the Concerned Parent*. Atlanta: Peachtree Publishers.
- Immunization Safety Review Committee, Institute of Medicine. 2002. *Immunization Safety Review: Hepatitis B Vaccine and Demyelinating Neurological Disorders*. Washington, D.C.: National Academy Press. Available at www.nap.edu/catalog.php?record_id=10393. Accessed July 29, 2008.
- Immunization Safety Review Committee, Institute of Medicine. 2001. *Immunization Safety Review: Measles-Mumps-Rubella Vaccine and Autism*. Washington, D.C.: National Academy Press. Available at www.nap.edu/catalog.php?record_id=10101. Accessed July 29, 2008.
- Immunization Safety Review Committee, Institute of Medicine. 2002. *Immunization Safety Review: Multiple Immunizations and Immune Dysfunction*. Washington, D.C.: National Academy Press. Available at www.nap.edu/catalog.php?record_id=10306. Accessed July 29, 2008.

- Immunization Safety Review Committee, Institute of Medicine. 2001. *Immunization Safety Review: Thimerosal - Containing Vaccines and Neurodevelopmental Disorders*. Washington, D.C.: National Academy Press. Available at www.nap.edu/catalog.php?record_id=10208. Accessed July 29, 2008.
- Margolis, Harold. 1990. *The Road Ahead: Future Policy for the Elimination of Hepatitis B Transmission in the United States*. 24th National Immunization Conference Proceedings, May 21–25.
- Murch, S.H., A. Anthony, D. Casson, M. Malik, M. Berelowitz, A. Dhillon, M. Thomson, A. Valentine, S. Davies, J. Walker-Smith. 2004. Retraction of an Interpretation. *Lancet* 363: 750.
- Murkoff, Heidi and Sharon Mazel. 2008. *What to Expect Guide To Immunizations*. New York: The What to Expect Foundation.
- Myers, Martin G., and Diego Pineda. 2008. *Do Vaccines Cause That?! A Guide For Evaluating Vaccine Safety Concerns*. Galveston, TX. Immunizations For Public Health.
- National Network for Immunization Information. Available at www.immunizationinfo.org. Accessed March 10, 2008.
- Offit, Paul A. 2006. *Vaccines and autism*. Vaccine Education Center, Children's Hospital of Philadelphia. Available at www.immunize.org/catg.d/p2065.htm. Accessed March 10, 2008.
- Offit, Paul A., and Louis A. Bell. 2003. *What Every Parent Should Know About Vaccines*. New Jersey: John Wiley & Sons, Inc.
- Offit, P.A., J. Quarles, M.A. Gerber, C.J. Hackett, E.K. Marcuse, T.R. Kollman, B.G. Gellin, S. Landry. 2002. Addressing parents' concerns: Do multiple vaccines overwhelm or weaken the infant's immune system? *Pediatrics* 109: 124–129. Available at www.aap.org/family/multivaccines.htm. Accessed March 10, 2008.
- Otto, S., B. Mahner, I. Kadow, J. F. Beck, S. K.W. Wiersbitzky, R. Bruns. 2000. General non-specific morbidity is reduced after vaccination within the third month of life—the Greifswald study. *Journal of Infectious Disease* 41:172–175.
- Outbreak of Poliomyelitis – Dominican Republic and Haiti. 2000. *MMWR* 49(48): 1094.
- Parents of Kids with Infectious Diseases. Available at www.pkids.org. Accessed March 10, 2008.
- Pertussis Deaths – United States. 2000. *MMWR* 51(28): 616–618.
- Pichichero, M.E., A. Gentile, N. Giglio, V. Umido, T. Clarkson, E. Cernichiaro, G. Zareba, C. Gotelli, M. Gotelli, L. Yan, J. Treanor. 2008. Mercury levels in newborns and infants after receipt of thimerosal-containing vaccines. *Pediatrics* 121(2): e208–e214.
- Plotkin, Stanley A., Walter P. Orenstein, Paul A. Offit. 2008. *Vaccines*, Fifth Edition. Philadelphia: W.B. Saunders.

- Priven, J. 1997. The Biological Basis of Autism. *Current Opinion in Neurobiology* 7: 708–12.
- Rodier, P.M. and S.L. Hyman. 1998. Early environmental factors in autism. *MRDD Research Reviews* 4: 121–128.
- *Research Strategies for Assessing Adverse Events Associated with Vaccines: A Workshop Summary*. 1994. Institute of Medicine. National Academy Press.
- Rivara, Frederick P. 1994. Epidemiology & Prevention of Pediatric Traumatic Brain Injury. *Pediatric Annals* 23(1).
- Salmon, D., M. Haber, E.J. Gangarosa, L. Phillips, N.J. Smith, R.T. Chen. 1999. Health consequences of religious and philosophical exemptions from immunization laws: Individual and societal risk of measles. *JAMA* 282: 47–53.
- Sanford, Jay P. 1995. Tetanus: Forgotten but Not Gone. *The New England Journal of Medicine* 332(12): 812–813.
- Scechter, Grether. 2008. *Arch Gen Psychiatry* 65. As published in CHOP, Parent PACK, January 2008 newsletter.
- *Standards for Pediatric Immunization Practices*. 1996. U.S. Department of Health and Human Services, Public Health Service.
- Taylor, B., E. Miller, C.P. Farrington, M.C. Petropoulos, I. Favot-Mayaud, J. Li, P.A. Waight. 1999. Autism and measles, mumps, and rubella vaccine: No epidemiological evidence for a causal association. *Lancet* 353: 2026–2029.
- *Tips on Evaluating Immunization Information on the Internet* excerpted from U.S. Department of Health and Human Services; National Vaccine Program Office (2008) [Electronic version]. Available at www.hhs.gov/nvpo/tips.htm. Accessed May 5, 2008.
- U.S. Centers for Disease Control and Prevention. *Six common misconceptions about vaccination*. 2002. Available at www.cdc.gov/nip/publications/6mishome.htm. Accessed March 10, 2008.
- U.S. Centers for Disease Control and Prevention, National Immunization Program. *Vaccine Information Statements*. 2008. Available at www.cdc.gov/vaccines/pubs/vis/. Accessed March 10, 2008.
- U.S. Centers for Disease Control and Prevention. 2007. *Parents Guide to Childhood Immunization*. U.S. Government Printing Office.
- U.S. Department of Health and Human Services. *NIAID Research on Thimerosal*. 2007. Available at www.niaid.nih.gov/factsheets/thimerosal.htm. Accessed March 10, 2008.
- Update: Multi-State Outbreak of Mumps. 2006. *MMWR* 55(20):559-563.
- Vaccine Education Center at The Children's Hospital of Philadelphia. Available at www.vaccine.chop.edu. Accessed March 10, 2008.
- Wakefield, A.J., et al. 1998. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet* 351: 637–641.
- *What Parents Need to Know About Vaccination and Childhood Disease: Guidelines for Parents*. 1994. American Academy of Pediatrics.
- Wolfe R.M., L.K. Sharp, M.S. Lipsky. 2002. Content and design attributes of anti-vaccination web sites. *Journal of American Medical Association* 287: 3245–3248.

Chapter 15

Resources

Washington State Resources

Washington State Department of Health Immunization Program CHILD Profile

www.doh.wa.gov/cfh/immunize
360-236-3595 or 1-800-397-0337

CHILD Profile

Washington State's Health Promotion
and Immunization Registry
www.childprofile.org

Local Public Health Agencies

www.doh.wa.gov/LHJMap/LHJMap.htm

WithinReach

Family Health Hotline 1-800-322-2588
(services available in many languages)
www.immunizewa.org
www.parenthelp123.org

National Resources

American Academy of Pediatrics

www.aap.org/family/parents/vaccine.htm

American Academy of Family Physicians

www.aafp.org

Allied Vaccine Group

www.vaccine.org

Bill and Melinda Gates Children's Vaccine Program

www.childredivaccine.org

Children's Hospital of Philadelphia

www.vaccine.chop.edu

Food and Drug Administration (FDA)

vaccine safety and regulations
www.fda.gov/cber

Immunization Action Coalition

www.immunize.org

Institute for Vaccine Safety at Johns Hopkins

www.vaccinesafety.edu

National Network for Immunization Information

www.immunizationinfo.org

U.S. Centers for Disease Control and Prevention

National Immunization Program Web site:

www.cdc.gov/vaccines/

National Immunization Program Hotlines, English & Spanish:

1-800-232-4636, TTY: 1-888-232-6348

NOTES: _____

We're fully immunized,
fully protected,
and ready to go!



Do you have questions about...

delaying immunizations? see page 36

multiple vaccines and
the immune system? see page 12

how vaccines work? see page 11

thimerosal and other
vaccine ingredients? see page 19

vaccines for adolescents? see page 39

weighing the risks of
disease vs. immunizations? see page 23

Check with your doctor, nurse, or clinic if you have more questions or concerns about immunizations. If you need help finding an immunization clinic, contact the Family Health Hotline:

- 1-800-322-2588 (voice)
- 1-800-833-6388 (TTY relay)
- www.parenthelp123.org

For a copy of this free booklet you can download a pdf version at www.doh.wa.gov/cfh/immunize or order a printed copy by calling 1-800-322-2588.



Sixth Edition © 2008
Washington State
Department of Health
DOH pub# 348-080