Chapter 4

IMMUNIZATIONS

Immunization Requirements

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Immunization Requirements

The American Academy of Pediatrics' (AAP) policy on immunizations recommends universal immunization of all children against nine communicable diseases including diphtheria, pertussis, tetanus, poliomyelitis, *Haemophilus influenzae* type b, measles, mumps, rubella and hepatitis B.[1] The AAP recognizes that multiple barriers jeopardize the implementation of this policy. The AAP is committed to "promoting access to comprehensive health care and to all recommended vaccines for all children regardless of their social, religious or financial status" and "ensuring access to immunizations for all children by removing economic barriers to immunization and encouraging appropriate reimbursement from third-party payers, or through local, state, or national subsidization of vaccines."[2] School health programs can offer immunizations to those children who may otherwise be unable to access them. The following section presents Texas laws and requirements for immunizations. A brief discussion of immunization administration is also included.

Background Information*

Vaccines are responsible for the control of many infectious diseases that were once common in this country. Vaccines have reduced, and in some cases, eliminated, many diseases that routinely killed or harmed many infants, children, and adults. However, the viruses and bacteria that cause vaccine-preventable disease and death still exist and can be passed on to people who are not protected by vaccines. Vaccine-preventable diseases have a costly impact, resulting in doctor's visits, hospitalizations, and premature deaths. Sick children can also cause parents to lose time from work.

Polio

Polio virus causes acute paralysis that can lead to permanent physical disability and even death. Before polio vaccine was available, 13,000 to 20,000 cases of paralytic polio were

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reported each year in the United States. These annual epidemics of polio often left thousands of victims—mostly children--in braces, crutches, wheelchairs, and iron lungs.

Development of polio vaccines and implementation of polio immunization programs have eliminated paralytic polio caused by wild polio viruses in the U.S. and the entire Western hemisphere. In 1999, as a result of global immunization efforts to eradicate the disease, there were about 5,000 documented cases of polio in the world. In 1994, wild polio virus was imported to Canada from India, but high vaccination levels prevented it from spreading in the population.

Measles

Before measles immunizations were available, nearly everyone in the U.S. got measles. There were approximately 3-4 million measles cases each year. An average of 450 measles-associated deaths were reported each year between 1953 and 1963.
In industrialized countries, up to 20% of persons with measles are hospitalized, and 7% to 9% suffer from complications such as pneumonia, diarrhea, or ear infections. Although less common, some persons with measles develop encephalitis, resulting in brain damage. It is estimated that as many as one of every 1,000 persons with measles will die.

Measles is one of the most infectious diseases in the world and is frequently imported into the U.S. In 1998, most cases were associated with international visitors or U.S. residents who were exposed to the measles virus while traveling abroad. More than 90% of people who are not immune will get measles if they are exposed to the virus.

According to the World Health Organization, nearly 900,000 deaths occurred among persons in developing countries in 1998. In populations that are not immune to measles, measles spreads rapidly. If vaccinations were stopped, 2.7 million measles deaths worldwide could be expected. In the U.S., widespread use of measles vaccine has led to a greater than 99% reduction in measles compared with the pre-vaccine era.

Haemophilus Influenzae Type b (Hib) (Meningitis)

Before Hib vaccine became available, Hib was the most common cause of bacterial meningitis in U.S. infants and children. Before the vaccine was developed, there were approximately 20,000 invasive Hib cases annually. Approximately two thirds of the 20,000 cases were meningitis, and one-third were other life-threatening invasive Hib

diseases such as bacteria in the blood, pneumonia, or inflammation of the epiglottis. About one of every 200 U.S. children under 5 years of age got an invasive Hib disease. Hib meningitis killed 600 children each year, and left many survivors with deafness, seizures, or mental retardation.

Since introduction of conjugate Hib vaccine in December 1987, the incidence of Hib has declined by 98 percent. From 1994-1998, fewer than 10 fatal cases of invasive Hib disease were reported each year. This preventable disease was a common, devastating illness as recently as 1990; now, most pediatricians who are just finishing training have never seen a case.

Pertussis (Whooping Cough)

Since the early 1980s, reported pertussis cases have been increasing, with peaks every 3-4 years; however, the number of reported cases remains much lower than levels seen in the pre-vaccine era. Compared with pertussis cases in other age groups, infants who are 6 months old or younger with pertussis experience the highest rate of hospitalization, pneumonia, seizures, encephalopathy (a degenerative disease of the brain) and death. From 1990 to 1996, 57 persons died from pertussis; 49 of these were aged <6 months. Before pertussis immunizations were available, nearly all children developed whooping cough. In the U.S., prior to pertussis immunization, between 150,000 and 260,000 cases of pertussis were reported each year, with up to 9,000 pertussis-related deaths.

Pertussis can be a severe illness, resulting in prolonged coughing spells that can last for many weeks. These spells can make it difficult for a child to eat, drink, and breathe. Because vomiting often occurs after a coughing spell, infants may lose weight and become dehydrated. In infants, it can also cause pneumonia and lead to brain damage, seizures, and mental retardation.

A newer pertussis vaccine (acellular or DTaP) has been available for use in the United States since 1991. These vaccines are effective and associated with fewer mild and moderate adverse reactions when compared with the older (whole-cell DTP) vaccine. During the 1970s, widespread concerns about the safety of pertussis immunization led to a rapid fall in immunization levels in the United Kingdom. More than 100,000 cases and 36 deaths due to pertussis were reported during an epidemic in the mid 1970s.

In Japan, pertussis vaccination coverage fell from 80 percent in 1974 to 20 percent in 1979. An epidemic occurred in 1979, resulted in more than 13,000 cases and 41 deaths.

Rubella (German Measles)

While rubella is usually mild in children and adults, up to 90 percent of infants born to mothers infected with rubella during the first trimester of pregnancy will develop congenital rubella syndrome (CRS), resulting in heart defects, cataracts, mental retardation, and deafness. In 1964-1965, before rubella immunization was used routinely in the U.S., there was an epidemic of rubella that resulted in an estimated 20,000 infants born with CRS, with 2,100 neonatal deaths and 11,250 miscarriages. Of the 20,000 infants born with CRS, 11,600 were deaf, 3,580 were blind, and 1,800 were mentally retarded.

Many developing countries do not include rubella in the childhood immunization schedule. Since 1996, greater than 50% of the reported rubella cases have been among adults. Sites of exposure for several outbreaks have included workplaces and communities. In 1998, 12 outbreaks of rubella occurred resulting in 19 pregnant women contracting rubella. Incidence of CRS declined dramatically with widespread use of rubella vaccine.

Varicella (Chickenpox)

Chickenpox is always present in the community and is highly contagious. Prior to the licensing of chicken pox vaccine in 1995, almost all persons in the U.S. had suffered from chickenpox by adulthood. Chicken pox was responsible for an estimated 4 million cases, 11,000 hospitalizations, and 100 deaths each year.

Chicken pox is usually mild, but may be severe in some infants, adolescents and adults. Some people who get chicken pox have also suffered from complications such as secondary bacterial infections, loss of fluids (dehydration), pneumonia, and central nervous system involvement. In addition, only persons who have had chicken pox in the past can get shingles (*herpes zoster)*, a painful inflammation of the nerves. There are about 300,000 cases of shingles that occur each year when inactivated chicken pox virus is activated in people who have had chicken pox in the past.

From March of 1995 through August of 1999, a total of 18.5 million doses of chicken pox vaccine were distributed in the United States. Vaccine coverage among children 19-

35 months was 43% in 1998. In 1990 in the U.S., the cost of caring for children who contracted chickenpox was estimated as $918 million annually. Without a vaccine for chicken pox almost every child would miss a week of school (and the parent a week of work), 11,000 people—mostly children—would be hospitalized, and 50-100 varicella related deaths would occur each year, most of them in previously healthy children and adults.

Hepatitis B

More than 2 billion persons worldwide have been infected with the hepatitis B virus at some time in their lives. Of these, 350 million are life-long carriers of the disease and are able to transmit the virus to others. One million of these people die each year from liver disease and liver cancer. National studies have shown that five percent of Americans—1.25 million people—have been infected with hepatitis B virus. In addition, these studies have shown that about 300,000 people have been infected with hepatitis B virus each year for the two decades prior to 1990. Currently, there are about 1.25 million people who have life-long hepatitis B virus infection. Each year about 4,000-5,000 of these people die from related liver disease resulting in over $700 million of medical and work-loss costs.

Infants and children who become infected with hepatitis B virus are at highest risk of developing lifelong infection, which often leads to death from liver disease (cirrhosis) and liver cancer. Approximately 25% of children who become infected with life-long hepatitis B virus would be expected to die of related liver disease as adults.

The Centers for Disease Control and Prevention (CDC) estimates that one-third of the life-long hepatitis B virus infections in the United States resulted from infections occurring in infants and young children. About 16,000 - 20,000 hepatitis B antigen infected women give birth each year in the United States. It is estimated that 12,000 children born to hepatitis B virus infected mothers were infected each year before implementation of infant immunization programs. In addition, approximately 33,000 children (10 years of age and younger) of mothers who are not infected with hepatitis B virus were infected each year before routine childhood hepatitis B vaccination was recommended.

Diphtheria

Diphtheria is a serious disease caused by poison produced from bacteria. It frequently causes heart and nerve problems. The death rate is 5%-10%, with higher death rates (up to 20%) in the very young and the elderly.

In the 1920's, diphtheria was a major cause of illness and death for children in the U.S. In 1921, a total of 206,000 cases and 15,520 deaths were reported. With vaccine development in 1923, new cases of diphtheria began to fall in the U.S., until in 1998 only one case was reported.

Although diphtheria is rare in the U.S., it appears that the bacteria continues to get passed among people. In 1996, 10 isolates of the bacteria were obtained from persons in a Native American community in South Dakota, none of whom had classic diphtheria disease. There has been one death reported in 1999 from clinical diphtheria caused by a related bacteria. There are high rates of susceptibility among adults. Screening tests conducted since 1977 have shown that 41%-84% of adults 60 and over lack protective levels of circulating antitoxin against diphtheria.

Although diphtheria is rare in the U.S., it is still a threat. Diphtheria is common in other parts of the world and with the increase in international travel, diphtheria and other infectious diseases are only a plane ride away. With the breakdown of the public health services in the former USSR, diphtheria epidemics began in 1990, fueled primarily by persons who were not properly vaccinated. From 1990-1998, more than 150,000 cases and 5,000 deaths were reported.

Tetanus (Lock Jaw)

Tetanus is a severe, often fatal disease. The bacteria that cause tetanus are widely distributed in soil and street dust, are found in the waste of many animals, and are very resistant to heat and germ-killing cleaners. From 1922-1926, there were an estimated 1,314 cases of tetanus per year in the US. In the late 1940's, the tetanus vaccine was introduced, and tetanus became a disease that was officially counted and tracked by public health officials. In 1998, only 45 cases of tetanus were reported in the U.S.

People who get tetanus suffer from stiffness and spasms of the muscles. The larynx (throat) can close causing breathing and eating difficulties, muscles spasms can cause

fractures (breaks) of the spine and long bones. Some people go into a coma, and die. Approximately 30% of reported cases end in death.

Tetanus in the U.S. is primarily a disease of adults. From 1995-1997, 35% of reported cases of tetanus occurred among persons 60 years of age or older, 60% occurred in patients 20-59 years of age. The National Health Interview Survey found that in 1995, only 36% of adults 65 or older had received a tetanus vaccination during the preceding 10 years.

Worldwide, tetanus in newborn infants continues to be a huge problem. Every year tetanus kills 300,000 newborns and 30,000 birth mothers who were not properly vaccinated. Very recently, an increased number of tetanus cases in younger persons has been observed in the U.S. among intravenous drug users, particularly heroin users. Tetanus is infectious (not contagious); unlike other vaccine-preventable diseases, immunization by members of the community will not protect others from the disease. Because tetanus bacteria is widespread in the environment, tetanus can only be prevented by immunization.

Mumps

Before the mumps vaccine was introduced, mumps was a major cause of deafness in children; it occurred frequently reported cases of the disease. Mumps is usually a mild viral disease. However, rare conditions such as swelling of the brain, nerves and spinal cord can lead to serious side effects such as paralysis, seizures, and fluid in the brain.

Serious side effects of mumps are more common among adults than children. Swelling of the testes is the most common side effect in males past the age of puberty, occurring in up to 20-50% of men who contract mumps. An increase in spontaneous abortions has been found among women who develop mumps during the first trimester of pregnancy.

An estimated 212,000 cases of mumps occurred in the U.S. in 1964. After vaccine licensure in 1967, reports of mumps decreased rapidly. In 1986 and 1987, there was a resurgence of mumps with 12,848 cases reported in 1987. Since 1989, the incidence of mumps has declined, with a total of 606 cases in 1998. This recent decrease is probably due to the fact that children have received a second dose of mumps vaccine (part of the two-dose schedule for measles, mumps, rubella or MMR) and the eventual development of immunity in those who did not gain protection after the first mumps vaccination.

Ask the Experts: General Vaccine Questions, VISs, Thimerosal*

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The "Ask the Experts" questions and answers that follow have appeared in *NEEDLE TIPS & the Hepatitis B Coalition News*. Some have been revised to reflect new recommendations and some out-of-date questions have been removed. For this reason, you should not use older sets of these questions and answers. If you have additional questions about immunization or hepatitis B that would interest our readers, please send them to us.

Editor's note: The Coalition thanks William L. Atkinson, MD, MPH, of the Centers for Disease Control and Prevention for answering the following questions for our readers:

General Vaccine Questions

by William L. Atkinson, MD, MPH

If a patient is on steroids, when should vaccines be withheld?
Steroid therapies that are short term (<2 weeks); alternate-day; physiologic replacement; topical (skin or eyes); aerosol; or given by intra-articular, bursal, or tendon injection are not considered contraindications to the use of live virus vaccines. The immunosuppressive effects of corticosteroid treatment vary, but many clinicians consider a dose equivalent to either 2 mg/kg of body weight or a total of 20 mg per day of prednisone for ≥2 weeks as sufficiently immunosuppressive to raise concern about the safety of vaccination with live virus vaccines (MMR, varicella, yellow fever). Providers should wait at least 1 month after discontinuation of therapy or reduction of dose before administering a live virus vaccine to patients who have received high systemically absorbed doses of corticosteroids for 2 weeks or more. Inactivated vaccines and toxoids can be administered to all immunocompromised patients, although the response to these vaccines may be suboptimal. All inactivated vaccines are recommended for immunocompromised persons in usual doses and schedules. (4/01)

A 3-year-old who was otherwise on schedule received some of her 15-month vaccinations (MMR, DTaP, IPV) twice due to a change in health plans. Can these doses be counted toward kindergarten vaccinations?
Whether these doses count as part of the child's series depends on the intervals between these doses and the ones that preceded them. If the doses of MMR and IPV were separated from the previous ones by at least 4 weeks, they can be counted as the second MMR and fourth IPV. No additional doses are required. (Exception: some states require a dose of polio vaccine on or after the fourth birthday for school entry. In this case, the child would need a fifth dose of IPV on or after her fourth birthday.) The fifth dose of DTaP should not be given earlier than 4 years of age. Assuming this dose of DTaP was the fifth the child received, it was given much too early and should not be counted. The DTaP should be repeated on or after the child's fourth birthday. (4/01)

Which vaccines should be given before one becomes pregnant? Which vaccines may be given during pregnancy?
Women who intend to become pregnant should have documentation of immunity (either vaccination or serology) to tetanus, diphtheria, measles, mumps, rubella, and varicella. A history

of chickenpox is considered adequate evidence of varicella immunity. Hepatitis B immunity is also recommended for women with occupational or behavioral ask factors for hepatitis B virus infection. Verification of rubella immunity is particularly important for women born outside the U.S. where rubella vaccine may not be part of routine childhood immunization. Live virus vaccines should not be given to a woman known to be pregnant or planning to become pregnant in the next 1-3 months, although yellow fever vaccine may be considered under some travel circumstances. Inactivated vaccines and toxoids may be administered to pregnant women for whom the vaccines are indicated. Influenza vaccine is recommended for women who will be in the second or third trimester of pregnancy during influenza season. (4/01)

What vaccinations are recommended for new immigrants to the United States?
In 1996 Congress amended the Immigration and Nationality Act and added vaccination requirements for any person who is applying for permanent resident status in the U.S. Children and adults must have evidence of having received (or at least having started the series of) the same vaccines recommended for an American citizen of the same age. Children must be vaccinated according to the current U.S. childhood schedule. Adults 18 years of age and older must have evidence of vaccination for tetanus and diphtheria. People born after 1956 must have evidence of immunity (vaccination or serology) for measles, mumps, and rubella. All persons 12 months of age and older must have evidence of varicella immunity (vaccination or history of chickenpox). Children adopted from outside the U.S. and political refugees are exempt from these requirements. Persons entering the U.S. as visitors are not required to provide proof of vaccination regardless of the length of stay. (4/01)

What should one do when the vaccine package insert does not agree with the ACIP recommendations?
ACIP recommendations occasionally differ from those on the manufacturer's package insert. Usually, package insert information is somewhat more conservative than ACIP recommendations. The FDA has very strict requirements for information the manufacturer may include on the package insert. ACIP sometimes makes recommendations based on expert opinion and public health considerations. Published recommendations of national advisory groups (such as ACIP or AAP's Committee on Infectious Diseases) should be considered equally as authoritative as those on the package insert. (4/01)

For patients undergoing bone marrow transplantation, are there special vaccine recommendations?
In Oct. 2000, CDC, the Infectious Diseases Society of America, and the American Society of Blood and Marrow Transplantation jointly published comprehensive guidelines for the prevention of opportunistic infections among recipients of hematopoietic stem cell (HSC) transplants, which includes bone marrow transplants. *(MMWR* 2000; 49 [RR-10]). These guidelines include vaccination recommendations (see CDC's website at **www.cdc.gov/nip/publications/HSCTrecs.pdf**). In short, all HSC transplant recipients should be revaccinated. Influenza vaccination should begin ≥6 months following the transplant and annually thereafter. Inactivated vaccines and toxoids (diphtheria, tetanus, Hib, polio for all persons; pertussis included for children <7 years) should begin 12 months after the transplant. Immunocompetent persons should receive MMR 24 months after transplant. Varicella and pneumococcal conjugate vaccines are not currently recommended for HSC transplant recipients. (4/01)

Is there a recommended period of time a person should wait in the clinic or pharmacy following an immunization?
The rationale for a "waiting period" after vaccination is, presumably, that if an allergic reaction

to the vaccine were to occur, the person would still be in the facility. With appropriate screening, the likelihood of a serious allergic reaction is extremely low. Accordingly, the Advisory Committee on Immunization Practices (ACIP) has never recommended a specific waiting period after vaccination. Potentially life-threatening allergic reactions occur in a matter of minutes. Even without a waiting period, it is likely that the person would still be in the facility should a life-threatening reaction occur. (7/00)

With what frequency should splenectomized patients receive Hib, pneumococcal, and meningococcal vaccines?
Persons with functional or anatomic asplenia should receive two doses of pneumococcal polysaccharide vaccine separated by 3-5 years, depending on age. They should also receive at least one dose of meningococcal polysaccharide vaccine. The need for additional doses is uncertain. Adults--even those without spleens--are at very low risk of invasive Hib disease. ACIP recommends that a single pediatric dose of Hib conjugate vaccine "be considered" for asplenic persons. (7/00)

What length of needle should be used to give infants IM injections? One of our clinical coordinators says a 1" needle and another says a 5/8" needle.
ACIP recommends that a 7/8" to 1" needle be used to administer intramuscular injections to infants. (8/99)

A patient of mine inadvertently received MMR vaccine two weeks after receiving varicella vaccine? What is recommended now?
ACIP recommends that, whenever possible, injected live virus vaccines, like MMR and varicella vaccines, be separated by 30 days because of possible interference of the vaccine given first with the vaccine given second. There is no evidence that this interference actually occurs with vaccines currently in use. ACIP does not have a recommendation to repeat live injected vaccines that are separated by less than 4 weeks. (8/99)

Should you administer vaccine to a child who is taking antibiotics?
Treatment with antibiotics alone is not a valid reason to defer vaccination. If the child or adult is otherwise well, or has only a minor illness, vaccines should be administered. But if the person has a moderate or severe acute illness, regardless of antibiotic use, one should defer vaccination until the person's condition has improved. (8/99)

Who is responsible for reporting cases of vaccine-preventable diseases to the state? Which cases are reportable?
Reporting requirements vary from state to state but, in general, the responsibility for submitting a disease report is with the provider who diagnoses the disease. Most states prefer to receive reports of suspected as well as confirmed diseases, particularly for diseases in which prompt containment activities are needed to prevent further spread of the disease (e.g., measles, pertussis). While some diseases (e.g., measles, pertussis) are reportable in all states, some diseases are not. Your state health department can supply a list of reportable diseases and specific reporting procedures. (8/99)

Why do ACIP recommendations not always agree with package inserts?
There is usually very close agreement between vaccine package inserts and ACIP statements. The Food and Drug Administration must approve the package insert, and requires documentation for all claims and recommendations made in the insert. Occasionally, ACIP may use different data to formulate its recommendations, or try to add flexibility to its recommendations, which results in wording different than on the insert. (3/99)

If my state has a registry, do I still need to give patients vaccine record cards?
Yes. Patient-held cards are an extremely important part of a person's medical history. The person may move to an area without a registry, and the personal record may be the only vaccination record available. In addition, even within a state, all health care providers may not participate in the registry, and the personal record card would be needed. (3/99)

An 11-year old with no immunization record recently immigrated to the USA. What do I do?
An attempt should be made to locate an immunization record. If no record can be located, the person should be revaccinated as indicated for his or her age. You should never assume that anyone was vaccinated without documentation. The child will need the following vaccines: Td, IPV, hepatitis B, MMR, and varicella (or a reliable history of the disease). (3/99)

Can influenza and pneumococcal vaccine be put together in the same syringe?
Absolutely not. No vaccines should ever be mixed in the same syringe unless the combination has been specifically approved by the FDA. At present, only Aventis Pasteur's DTaP and Hib vaccines (as TriHIBit) have been approved for mixing in the same syringe but only for the fourth dose. (3/99)

After a blood transfusion, which vaccines are contraindicated and for how long?
Measles, mumps, and rubella vaccines should not be given for at least 6 months following a transfusion of whole blood. A table in the 1998 MMR ACIP statement (*MMWR* 1998;47[RR-8]) lists the recommended delay following other antibody-containing blood products. Varicella vaccine should be delayed for at least 5 months after a transfusion of whole blood. Inactivated vaccines (DTaP, Hib, etc.) and live oral vaccines (OPV, oral typhoid) may be given at any time before or after receipt of blood products. (3/99)

What vaccines can a child with severe combined immunodeficiency syndrome (SCIDS) receive?
Children with SCIDS may be given inactivated vaccines (i.e., DTaP, Hib, hepatitis B, IPV, influenza, and, if indicated, pneumococcal and hepatitis A). They should not be given live vaccines (MMR, oral polio, and varicella). (3/99)

When the expiration date of a vaccine indicates a month and year, does the vaccine expire on the first or last day of the month?
Vaccine may be used through the last day of the month indicated on the expiration date. (10/98)

Should multidose vials of vaccine (DTaP, Td, Hib, etc.) be disposed of after they have been opened for 30 days?
No. These vaccines contain a bacteriostatic agent and may be used until the expiration date unless they become contaminated. (10/98)

Is it "legal" to draw up vaccines at the beginning of the shift? If it isn't, how much in advance can this be done?
The Advisory Committee on Immunization Practices (ACIP) recommends against pre-drawing vaccine into syringes, primarily because of the increased possibility of administration and dosing errors. Many vaccines look alike after drawing into a syringe. In addition, some vaccines have a very limited shelf life after reconstitution. In particular, varicella vaccine must be administered within 30 minutes of reconstitution, and MMR must be administered within 8 hours. If you decide to pre-draw syringes, I would strongly suggest that you draw up only inactivated vaccines (hepatitis B, DTaP, IPV, Hib), and only enough for a single day's use. Make sure the syringes are clearly marked to avoid administration errors. Pre-drawn doses

should be kept refrigerated. Live injected vaccines (MMR and varicella) should not be pre-drawn. (10/98)

When giving two IM injections in the same limb, what is the minimum spacing between the two injection sites?
The vaccines should be separated by at least one inch in the body of the muscle so that any local reactions are unlikely to overlap. (10/98)

Is it safe to give a vaccine directly into an area where there is a tattoo?
Both intramuscular and subcutaneous vaccines may be given through a tattoo. (10/98)

Do patients with sickle cell disease or functional asplenia have any special vaccination recommendations?
Sickle cell disease often causes spleen damage. Persons two years of age and older with sickle cell disease should receive pneumococcal vaccine. A second dose of pneumococcal vaccine is recommended for this group (and other persons without a functional spleen) 5 years after the first dose. Persons without a functional spleen (including persons with sickle cell disease) should also receive a single dose of meningococcal vaccine, and a single dose of Hib vaccine, if they have not already been vaccinated against Hib. (10/98)

Some doctors do not vaccinate children with minor illnesses. Are minor illnesses a contraindication to vaccination?
No. The ACIP, the AAP, and the AAFP recommend that children with minor illnesses, with or without low-grade fever, should be vaccinated. Minor illness would include upper respiratory infections, most cases of otitis media, colds, and diarrhea. There is no consistent evidence that these minor illnesses interfere with response to the vaccine, or increase adverse events. Children with more serious illnesses should be vaccinated as soon as they improve. (10/98)

What length of needle is recommended for subcutaneous and intramuscular vaccines given to children and adults?
In both children and adults, subcutaneous injections (MMR, varicella, IPV) should be given with a 5/8- to 3/4-inch, 23- to 25-gauge needle. For intramuscular injections in infants and children, a minimum needle length of 7/8-inch should be used for anterolateral thigh injections, and a minimum of 5/8-inch for deltoid intramuscular injections is recommended. For adults, a 1- to 1 ½- inch needle is recommended, depending on muscle mass. (10/98)

How do I obtain ACIP statements?
ACIP statements are published in the *Morbidity and Mortality Weekly Report (MMWR)*. To obtain any of the ACIP statements try any of the following: **1)** Download them from CDC's website at **www.cdc.gov/epo/mmwr/mmwr.html**. You can also request a free electronic subscription to *MMWR* at this site. **2)** Call CDC's Immunization Hotline at (800) 232-2522. **3)** E-mail your request to **nipinfo@cdc.gov** **4)** Call your state immunization program. **5)** Request them from your medical library. Note: if you want new ACIP recommendations as soon as they are released, CDC's website is the place to go! (4/98)

Why do some vaccination rules say months and some say weeks for minimum intervals?
The choice of using week or month terminology is based on the preference of the person writing the statement, or the way the interval was described in prior statements. It does not appear to be based on science. Until recently, there has been no clear guidance on the appropriate unit of measurement. However, the ACIP statement on measles, mumps, and rubella vaccines (*MMWR*, 1998;47:No.RR-8) is the first to operationally define a month as 28 days. (4/98)

If a 2-month old was vaccinated with DTaP, IPV, Hib, and Hep B, then received a second set of the same shots 3 weeks later, will the child need these doses repeated at 4 months of age?
The minimum interval between doses of these vaccines is either 4 weeks (DTaP and IPV) or a month (Hib). The "General Recommendations on Immunization" (*MMWR,* 1994;43:No.RR-1) state that doses given at less than the minimum interval should not be counted as part of the series. These doses should be repeated at 4 months of age. (4/98)

For a child under two years of age traveling outside of the U.S., can I give varicella vaccine, MMR, and at the same time give immune globulin (IG) to prevent hepatitis A?
No. The antibody in IG will inactivate the live attenuated vaccine viruses in MMR and varicella vaccines. The vaccines should be given 2 weeks prior to administration of IG. If the IG has already been given, MMR should be delayed for 3 months and varicella vaccine for 5 months. (4/98)

Does IG given for hepatitis A prophylaxis to infants interfere with DTaP, polio, hepatitis B, or Hib vaccines?
Inactivated vaccines, such as DTaP, Hib, IPV, and hepatitis B, may be given at any time before or after IG. Response to the vaccines will not be affected. Oral polio and yellow fever vaccines are also not affected by IG, even though they are live virus vaccines. (4/98)

If a patient has a bleeding disorder, what injection route should I use for administering vaccinations?
This issue is discussed in the "General Recommendations on Immunization" (*MMWR,* 1994; 43:No. RR-1). Briefly, vaccines should be given by the same route as in a person without a bleeding disorder. Intramuscular vaccines should be given with a fine needle (23 gauge or smaller), and firm pressure should be applied over the site for at least 2 minutes. If possible, schedule the IM injections shortly after antihemophilia or similar therapy to minimize the risk of a hematoma. (4/98)

I've heard you're never supposed to start a vaccination series over again. Is there a document that supports this recommendation?
It is not necessary to restart the series of any vaccine due to an extended interval between doses (the only exception is oral typhoid vaccine). This issue is discussed in the *1994 General Recommendations on Immunization*, and in the 2000 *AAP Red Book* (p.27). (10/97, updated 5/01)

Which vaccinations can be given to a pregnant health care worker?
Inactivated vaccines (Td, hepatitis B, influenza, IPV) may be given to pregnant women if indicated. Pneumococcal vaccine should be administered prior to pregnancy. Live vaccines (MMR, varicella) should not be given to a pregnant woman or one who is trying to become pregnant. (10/97)

Why are some vaccinations given subcutaneously while others must be given intramuscularly?
In general, inactivated vaccines are administered intramuscularly (IM), and live virus vaccines are given subcutaneously (SC). Inactivated polio and pneumococcal vaccines may be given either SC or IM. Vaccines intended to be given IM may cause local reactions (such as irritation, induration, skin discoloration, inflammation, and granuloma formation) if injected into subcutaneous tissue. Response to the vaccine may also be reduced if not given by the recommended route. (10/97)

If I give a pneumococcal polysaccharide vaccine to my patient now, how long must I wait before giving the influenza or Td vaccine?
Influenza vaccine and Td may be given at the same time or at any time before or after a dose of pneumococcal polysaccharide vaccine. There are no minimum interval requirements between the doses of any inactivated vaccines. (10/97)

Where can I get the most up-to-date information on vaccination recommendations for my patients who travel outside the U.S.?
Check with your local and/or state health departments because many of them receive up-to-date vaccination recommendations for international travelers from CDC. You may also receive travel recommendations from CDC by phone [(877) FYI-TRIP{394-8747}], by fax [(888) 232-3299], or from the CDC travel website **http://www.cdc.gov/travel** "Health Information for International Travel," a biannual publication of the Division of Quarantine at CDC, is available on the CDC travel website, or from the Government Printing Office [(202) 512-1800]. In addition to these sources, there are a number of private companies which sell computer programs and books designed to assist with vaccine recommendations for international travelers. (10/97)

Which vaccines can be given if the patient is taking steroids?
If the patient is receiving immunosuppressive doses of steroids (i.e., more than 2 mg/kg/day or more than 20 mg of prednisone per day), live vaccines (MMR, OPV, varicella) should not be given. All vaccines may be administered if lower doses of steroids are being taken. Examples of nonimmunosuppressive doses of steroids include inhalers, topical preparations, short rapidly-tapering courses, and alternate day schedules. (10/97)

Which childhood vaccines may be given simultaneously?
All vaccines used for routine childhood vaccination in the United States may be given simultaneously. There is no evidence that simultaneous administration of vaccines either reduces vaccine effectiveness or increases the risk of adverse events. The only vaccines which should NOT be given simultaneously are cholera and yellow fever vaccines. (2/97)

Which vaccines are contraindicated if a child is breast-feeding?
Breast-feeding is not a contraindication to the administration of any vaccine, either to the mother or to the child. (2/97)

Which vaccines are contraindicated if a child's mother or other household contact is pregnant?
A pregnant household member, including the child's mother, is not a contraindication to administration of any vaccine. (2/97)

What is the Vaccine Adverse Event Reporting System (VAERS)?
As the name implies, VAERS is a nationwide system for monitoring adverse events following vaccination. VAERS is operated jointly by the Food and Drug Administration and the Centers for Disease Control and Prevention, and became fully operational in November 1990. (9/96)

How do I report an adverse event to VAERS?
A standardized form is used to report to VAERS. The report forms and instructions, or a copy of the Vaccine Injury Table, may be obtained directly from VAERS by calling (800) 822-7967. The forms may also be obtained from your state immunization program, the *FDA Drug Bulletin,* the AAP's *Red Book*, and the *Physician's Desk Reference*. (9/96)

Following vaccination with a live virus such as varicella or MMR, must a person wait a

certain period of time before donating blood?
ACIP has not addressed this issue. However, it is the policy of the American Red Cross that an interval of 28 days is required between receipt of any live attenuated vaccine and blood donation. (9/96)

Why aren't people in the United States vaccinated with BCG?
BCG vaccine is used in countries of high endemicity to help prevent tuberculosis disease. A more effective strategy for the prevention of tuberculosis in countries where the endemicity is low, is to identify infected persons using a Mantoux (PPD) skin test, and eliminate the infection with antituberculous drugs. This is the strategy used in the United States. (9/96)

What is the Vaccines For Children (VFC) Program?
VFC is a program designed to reduce or eliminate vaccine cost as a barrier to childhood vaccination. The program purchases vaccines from manufacturers and provides them at no cost to participating public and private health care providers for use in children ages 0 through 18 years who are eligible for Medicaid, are without health insurance, or are American Indian. Children with health insurance who are served by federally qualified health centers are also able to receive free vaccine if their insurance does not cover vaccination. If you are interested in becoming a VFC provider, you should contact your state immunization program. (9/96)

Our new patient's mother lost her child's vaccination record, but says the child has had all his shots. What should I do?
An attempt should be made to locate the missing record, or to verify what vaccines have been received. Ask the child's mother to recheck at home. You can also try to locate a record by contacting the child's previous doctor or clinic. If a record cannot be located after a reasonable search, the child should be considered unimmunized, and revaccinated as appropriate for the child's age. (1/96)

Please give me a schedule for how to "catch-up" children who have fallen behind on their vaccinations. What are the minimum spacing intervals of the vaccines?
Infants or children who are more than one month or one dose behind schedule should be accelerated, which means the intervals between doses should be reduced to the minimum allowable. Both an accelerated schedule (Table 4) and the minimum intervals between doses (Table 10) can be found in the 1994 General Recommendations on Immunization. Copies of this document may be obtained from the National Immunization Program at (800) 232-2522. (1/96)

*Editor's note: Also, the Coalition distributes "Summary of Rules for Childhood Immunization." This handy two-sided reference includes schedules for "catching-up" children who have fallen behind on immunizations. Click **here** to view a web version of this reference tool.*

What should be the interval between MMR and varicella vaccine if not given simultaneously?
If not given simultaneously, MMR and varicella vaccines should be separated by 4 weeks. (5/95)

VISs

by William L. Atkinson, MD, MPH

By law, when vaccinating adults or children, when and to whom is it required to give Vaccine Information Statements (VISs)?
The National Childhood Vaccine Injury Act requires that a VIS must be given to parents/guardians or adult patients before administering a vaccine containing diphtheria, tetanus,

pertussis, hepatitis B, measles, mumps, rubella, varicella, Hib, polio, or pneumococcal conjugate. A VIS must be provided prior to each dose, not just the first. Providers should be sure they are using the most current version of each VIS. Current VISs and their dates are available from the National Immunization Program website at **www.cdc.gov/nip/publications/vis** and from IAC's website at **www.immunize.org/vis** (4/01)

Where can I get instructions on how, why, and when to use the federally mandated VISs?
Instructions on the use of VISs are available from the National Immunization Program at **www.cdc.gov/nip/publications/vis/default.htm** or you can call your state immunization program. (8/99)

Where can I get foreign language VISs?
Foreign language VISs are available on the Immunization Action Coalition's website at: **www.immunize.org/vis** or you can call your state immunization program. (8/99)

Thimerosal

by William L. Atkinson, MD, MPH

What is thimerosal and why has it been in the news recently?
Thimerosal is an effective preservative that contains ethyl mercury. It has been used in small amounts to reduce the chance of bacterial growth in vaccines and other products since the 1930s. On July 9, 1999, the U.S. Public Health Service (USPHS) and the American Academy of Pediatrics (AAP) released a joint statement urging vaccine manufacturers to eliminate or reduce the mercury content of their vaccines as expeditiously as possible. (8/99)

Does the presence of thimerosal in vaccines present any danger to children?
From 1990 through 1998, 45 reports alleging adverse reactions due to thimerosal were received by the Vaccine Adverse Events Reporting System (VAERS). Most of these reports concerned allergic reactions. Although thimerosal contains ethyl mercury, there is no evidence that mercury received through vaccines is harmful to a child. (8/99)

Are vaccines available that do not contain thimerosal?
Yes. For routine childhood vaccines there is at least one brand of each vaccine that does not contain thimerosal. USPHS agencies including the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) and the AAP are working with vaccine manufacturers to reduce or eliminate the use of thimerosal in vaccines. (8/99)

If we don't have a thimerosal-free brand of vaccine in stock, should we defer vaccination of the child?
Absolutely not. It is critical that children continue to be vaccinated on time, even if a thimerosal-free vaccine is not immediately available. There is no evidence that thimerosal in vaccine is harmful to children. If vaccines are deferred, coverage levels could drop which could result in outbreaks. (8/99)

Minimum Requirements

Children and Students Included in Requirements. 25 Texas Administrative Code §97.61.[3]

- At a minimum, the immunizations required in this section are required for all children in the State of Texas, including children admitted, detained, or committed in Texas Department of Criminal Justice, Texas Mental Health and Mental Retardation, and Texas Youth Commission facilities.
- The immunization requirements also apply to all children and students entering, attending, enrolled in, and/or transferring to child-care facilities, public schools, private schools, nonpublic schools, or parochial schools.

Sec. 38.001, Education Code, requires:

- Each student shall be fully immunized against diphtheria, rubeola, rubella, mumps, tetanus, and poliomyelitis.
- The Texas Board of Health may modify or delete any of the immunizations in Subsection (a) or may require immunizations against additional diseases as a requirement for admission to any elementary or secondary school.[4]

For School Entry

Requirements for Enrollment. Sec. 25.002, Education Code[5]: When a child is enrolled in school, the parent or guardian, or the previous school attended, has 30 days to furnish the school with the child's birth certificate or other proof of identity, and a record of required immunizations or exemption from immunizations.[6]

Provisional Enrollment. 25 Texas Administrative Code §97.71[7]: A student may be admitted provisionally if he or she has begun the required immunizations and if he or she continues to receive the immunizations as rapidly as is medically feasible. The school granting the enrollment must ensure that the immunizations are received on schedule.

By Age

These requirements are summarized from 25 Texas Administrative Code §§97.61-97.77.[8] Consult the Texas Administrative Code for complete requirements, exceptions, and explanations.

1. Children 15 months of age but not yet five years:

   a. **Polio: 3 doses.**

   b. **DTP/DTaP: 4 doses of DTP/DTaP** (Fourth dose not required until 18 months.)

   c. **MMR: 1 dose of MMR** received on or after the first birthday.

   d. **HibCV: 1 dose of Hib on or after 15 months** of age is required unless a schedule for a primary series and booster was completed prior to or at 15 months of age.

   e. **Varicella: 1 dose** of varicella vaccine is required and must have been received on or after the first birthday.

   f. **Hepatitis A: 1 dose** of hepatitis A vaccine administered on or within 30 days of their second birthday for children two years of age but not yet three. Children three years of age but not yet four are required to have **2 doses** of hepatitis A vaccine administered on or after their second birthday. Children attending school in the following counties must comply with this requirement: Brewster, Brooks, Cameron, Crockett, Culberson, Dimmit, Duval, Edwards, El Paso, Frio, Hidalgo, Hudspeth, Jeff Davis, Jim Hogg, Kenedy, Kinney, La Salle, Maverick, McMullen, Pecos, Presidio, Real, Reeves, Starr, Sutton, Terrell, Uvalde, Val Verde, Webb, Willacy, Zapata, and Zavala.

2. Children 5 years of age and over:

   a. **Polio: 3 doses** including one received on or after the fourth birthday.

b. **DTP/DTaP: 4 doses** including one received on or after the fourth birthday. Proof of pertussis vaccination not required for children five years of age and older.

c. **MMR: 2 doses** including one received on or after the first birthday and one additional dose of measles vaccine (may be received as part of a second MMR.)

d. **Hepatitis B: 3 doses**

e. **Hepatitis A: 2 doses** if attending school in the above-mentioned counties.

f. **Varicella: 1 dose** on or after the first birthday for children born on or after September 2, 1994. Children born between September 2, 1988, and September 1, 1994 (inclusive), must have one dose of varicella received on or after the first birthday, within 30 days after the 12th birthday. If the first dose is received after age 13, two doses are required.

Pneumococcal Conjugate Vaccine

Though not required by law in Texas, the CDC's Advisory Committee on Immunization Practices (ACIP) has added the heptavalent pneumococcal conjugate vaccine (PCV) to the 2001 Recommended Childhood Immunization Schedule. PCV should be given to all children 2-23 months of age. They should receive **4 doses**, intramuscularly at 2, 4, 6, and 12-15 months. ACIP also recommends **1 dose** of the vaccine for children aged 24-59 months old who are at increased risk for pneumococcal disease.[9]

Texas Vaccines for Children Program©[10]

The Texas Vaccines for Children Program (TVFC) began on October 1, 1994, and offers to improve vaccine availability by providing vaccines free of charge to eligible children through public and private providers statewide. This program is a combination of federal

and state funds, all with the single purpose of increasing the immunization level among Texas' children. School nurses can be TVFC providers.

Children who are eligible for Texas Vaccines for Children Program include:

- Those enrolled in Medicaid;
- Uninsured;
- American Indian or Alaskan Native; or
- Underinsured (children whose insurance does not cover immunizations).

Benefits to children:

- Eliminates vaccine cost as a barrier to immunizations; and
- Children can obtain vaccines in their medical homes.

Benefits to health care providers:

- Provides vaccine at no charge to public and private providers;
- Reduces the practice of referring children for immunizations; and
- Covers new vaccines as they become available.

For more information call 1-800-252-9152.

Exemptions

Serologic Confirmation of Immunity (or Serologic Proof of Infection)

25 Texas Administrative Code §97.63 & 97.67[11]:

- Serologic confirmation of immunity to measles, rubella, mumps, hepatitis A, or hepatitis B is acceptable in lieu of vaccine against the serologically confirmed disease.
- Evidence of measles, rubella, mumps, hepatitis A, or hepatitis B illnesses must consist of a laboratory report indicating confirmation of immunity or confirmation of infection.
- The school shall accurately record the results of any serologic tests supplied as proof of immunity. The original should be returned to the child or the child's parent or guardian.

- All histories of varicella illness must be supported by a written statement from a physician or the child's parent or guardian containing wording such as: "This is to verify that (name of student) had varicella disease (chickenpox) on or about (date) and does not need varicella vaccine," or by serologic confirmation of varicella immunity. School nurses may also write this statement to document cases of chickenpox that they observe.
- The school shall accurately record the existence of any statements attesting to previous varicella illness as proof of immunity. The original should be returned to the child or the child's parent or guardian.

Medical Contraindications

Excerpt from 25 Texas Administrative Code §97.62:[12] The child or student must present an affidavit or certificate signed by a physician duly registered and licensed to practice medicine in the United States, in which it is stated that, in the physician's opinion, the immunization required would be injurious to the health and well-being of the applicant or any member of his or her family or household. Unless a lifelong condition is specified, the affidavit or certificate is valid for only one year from the date signed by the physician and must be renewed every year for the exclusion to remain in effect.

Exemptions for Religious Conflicts

25 Texas Administrative Code §97.62:[13] The law allows for exemption from vaccination requirements in cases where vaccination conflicts with a family's religious beliefs or practices. Texas law does not, however, currently allow for exemption based on personal or philosophical beliefs.

A signed affidavit must be presented by the child's parents or guardian stating that the immunization conflicts with the tenets and practices of a recognized religious organization of which the applicant is an adherent or member. This exemption does not apply in times of emergency or outbreak declared by the Commissioner of Health or local health authority.

Exemptions for Service in Armed Forces

25 Texas Administrative Code §97.62:[14] Persons actively serving in the armed forces are exempt from the above immunization requirements. This exemption does NOT apply to children of persons serving in the military.

Authorization/Consent

Sec. 32.101, Family Code[15]

In addition to parents, persons authorized to consent to immunization of a child include a guardian of the child and any person authorized under the law of another state or by a court order to consent for the child. If neither parents nor guardians are available, consent may be given by a grandparent, an adult brother or sister, an adult aunt or uncle or a stepparent unless they have knowledge that a parent or guardian has refused to give consent for immunization, has been told not to consent for the child, or has withdrawn a prior authorization for the person to consent.

Authorization

In order to assist the health department with ensuring full immunization of children in the community, a school or district may elect to provide immunizations on campus. Often, the health department will supply schools with immunizations if the school wishes to provide them. Immunizations may also be procured from the Texas Vaccines for Children program. All legal guidelines for consent, documentation, and liability as discussed in this chapter apply. It is recommended that each site where immunizations are given have a protocol in place for anaphylaxis or other emergencies associated with vaccine administration. The district school health nurse practitioner or physician should oversee any immunization programs and emergency protocols. Both Chapters 5 and 9 of this manual further address the issue of an anaphylaxis protocol.

Liability

Sec. 161.001, Health and Safety Code[16]:

- A person who administers or authorizes the administration of a vaccine or immunizing agent is not liable for an injury caused by the vaccine or

immunizing agent if the immunization is required by the Board of Health or is otherwise required by law or rule.

- A person who administers or authorizes the administration of a vaccine or immunizing agent is not liable or responsible for the failure to immunize a child because of the failure or refusal of a parent…or guardian to consent to the vaccination or immunization…
- This section does not apply to a negligent act in administering the vaccine or immunizing agent.

Procedure

General Administration Procedures

- Subcutaneous (SQ) injections should be given in the thigh of infants, and in the deltoid area of older children with a 5/8-3/4 inch, 23-25 gauge needle.
- Intramuscular (IM) injections should be given in the anterolateral aspect of the upper thigh for infants and toddlers, and in the deltoid muscle for children and adults.

Vaccine Information Statements (VISs) should be given to parents/guardians of every immunization recipient. Original VISs and the addendums containing consent forms are included at the end of this chapter. They may also be obtained from the Texas Department of Health (TDH) or downloaded from the following website: www.tdh.state.tx.us/immunize/vischart.htm.

Adverse Events Reporting

The Vaccine Adverse Event Reporting System (VAERS) is a national program designed to collect and analyze reports of adverse events related to vaccine administration and form a database of such reports. The purpose of this database is to allow the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) to monitor trends and associations between vaccines and adverse events that were not discovered during clinical trials.

Reports can be submitted by anyone. All reportable events occurring within the specified time frame listed in the vaccine drug insert and any event listed in the insert as a contraindication to subsequent doses must be reported. Exhibit 2, adapted from the VAERS web site (www.fda.gov/cber/vaers/eventtab.htm), lists reportable adverse events and their timeframes. See Exhibit 3 for the Vaccine Adverse Event Reporting System report form and instructions for completing the form.

Adverse events following vaccination with a vaccine purchased with public funds such as Vaccines for Children should be reported through the following agencies:

- **Texas:** 1-800-252-9152
- **Bexar County:** 1-210-207-2087 (for Bexar County residents)
- **Houston:** 1-713-794-9267 (for City of Houston residents)

Events associated with privately purchased vaccines should be reported directly to VAERS. Call 1-800-VAC-RXNS for information. It is important to have the vaccine manufacturer and lot number available when reporting.

Documentation

School Records

25 Texas Administrative Code, §97.72[17]: All schools are required to maintain records of the immunization status of individual students during their period of attendance at the school. Records must be made available for inspection by representatives of the Texas Education Agency, the Texas Department of Health, or local health departments/districts.

Acceptable Documents of Immunizations

25 Texas Administrative Code, §97.73[18]: Any validated document of immunization presented by a student is acceptable, provided it shows the month, day, and year when each immunization was received. It must also show the address where the vaccine was given, the manufacturer and lot number of the vaccine, and the date of publication of the CDC Vaccine Information Statement (VIS) provided. It is recommended that the site and

route of administration also be included. The Texas Department of Health requires that at a minimum, the month, day, year, vaccine given, and clinic validation be documented.[19]

The Texas Department of Health and local health departments/districts will provide record-keeping cards free of charge for maintaining school immunization files. Commercially or locally produced immunization cards may be used.

Vaccine Registry

ImmTrac is the statewide immunization registry developed by the Texas Department of Health (TDH). It is part of a TDH initiative to increase vaccination coverage for Texas children. With consent of the parents or guardians, immunization information about children from around the state is compiled and made available to schools, child care centers, health departments, and public/private health care providers. More information about ImmTrac, including registration forms, can be found at www.tdh.state.tx.us/immunize/immtrac.htm.

According to Section161.007 of the Health and Safety Code,[20] health care providers who administer immunizations to persons younger than 18 years of age must provide immunization history on those persons to the state registry unless the immunization history is submitted to an insurance company, health maintenance organization or other organization that pays or reimburses the claim for immunizations. In that case, the organization to which the claim was submitted must provide the registry with the information.

Exhibit 1:

Minimum Age for Initial Vaccination and Minimum Interval Between Vaccination Doses, by Type of Vaccine©[21]

Vaccine	Minimum age for first dose	Minimum interval from dose 1 to 2	Minimum interval from dose 2 to 3	Minimum interval from dose 3 to 4
Hepatitis B (HBV)	birth	1 month	2 months[a]	
DTaP	6 weeks	1month	1 month	6 months
Hib (primary series)	6 weeks	1 month	1 month[b]	-----[c]
IPV	6 weeks	1 month	1 month	
MMR	12 months[d]	1 month		
Varicella	12 months			
Hepatitis A	24 months	6 months		

[a] A minimum of 4 months should elapse between doses 1 and 3 of this series. Thus, if only 1 month elapsed between dose 1 and 2, the minimum interval between dose 2 and 3 would be 3 months. Infants who are being vaccinated at recommended ages should not complete the series before six months of age.

[b] Not all brands of Hib vaccine require this dose. All brands do require a booster dose, after 12 months of age, and at least 2 months after the previous dose.

[c] The booster dose of Hib vaccine which is recommended following the primary vaccination series should be administered no earlier than 12 months of age and at least 2 months after the previous dose of Hib vaccine.

[d] Although children may be appropriately vaccinated against measles as young as 6 months in outbreak areas, children initially vaccinated before the first birthday should be revaccinated after 12 months of age. An additional dose of measles-containing vaccine should be administered at school entry, or according to local policy. Doses of MMR or other measles-containing vaccine should be separated at least 30 days.

Exhibit 2: Summary of Rules for Childhood Immunizations*

Adapted from ACIP, AAP, and AAFP by the Immunization Action Coalition, March 2001

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The newer combination vaccines are not listed on this table but may be used whenever administration of any component is indicated and none is contraindicated. Read package inserts. For detailed information, see the ACIP statements which are published in the MMWR. To obtain, visit www.cdc.gov/nip/publications/ACIP-list.htm or visit the Immunization Action Coalition's (IAC) website at www.immunize.org/acip For recommendations of American Academy of Pediatrics (AAP), consult AAP's *2000 Red Book* and the journal *Pediatrics*, www.aap.org

Vaccine	Ages usually given and other guidelines	If child falls behind (minimum intervals)	Contraindications (Remember: mild illness is not a contraindication
DTaP (Diphtheria, tetanus, acellular pertussis) Give IM	• DTaP (not DTP) is recommended for all doses in the series. • Give at 2m, 4m, 6m, 15– 18m, 4– 6yrs of age. • May give #1 as early as 6wks of age. • May give #4 as early as 12m of age if 6m have elapsed since #3 and the child is unlikely to return at age 15– 18m. • If started with DTP, complete the series with DTaP. • Do not give DTaP to children _ 7yrs of age (give Td). • May give with all other vaccines but as a separate injection. • It is preferable but not mandatory to use the same DTaP product for all doses	• #2 & #3 may be given 4wks after previous dose. • #4 may be given 6m after #3. • If #4 is given before 4th birthday, wait at least 6m for #5 (4– 6yrs of age). • If #4 is given after 4th birthday, #5 is not needed. • DO NOT restart series, no matter how long since previous dose.	• Anaphylactic reaction to a prior dose or to any vaccine component. • Moderate or severe acute illness. Don't postpone for mild illness. • Previous encephalopathy within 7d after DTP/ DTaP. **Precautions for DTP/ DTaP:** The following are precautions, not contraindications. Generally when these conditions are present, the vaccine shouldn't be given. But in situations when the benefit outweighs the risk (e. g., community pertussis outbreak), vaccination should be considered. • T _ 105 (F (40.5 (C) within 48hrs after previous dose. • Continuous crying lasting _ 3hrs within 48hrs after previous dose. • Previous convulsion within 3d after immunization. • Pale or limp episode or collapse within 48hrs after previous dose. • Unstable progressive neurologic problem (defer until stable).
DT Give IM	• Give to children <7yrs of age if child had a serious reaction to "P" in DTaP/ DTP or if parents refuse the pertussis component. • May give with all other vaccines but as a separate injection.		
Td Give IM	• Use for persons > 7yrs of age. • A booster dose is recommended for children 11– 12yrs of age if 5yrs have elapsed since last dose. Then boost every 10yrs. • May give with all other vaccines but as a separate injection.	For those never vaccinated or with an unknown vaccination history: dose#1 is given now, dose #2 is given 4wks later, dose #3 is given 6m after #2, then give booster dose every 10yrs. If the series is incomplete, continue from where you left off. DO NOT restart the series.	• Anaphylactic reaction to a prior dose or to any vaccine component. • Moderate or severe acute illness. Don't postpone for minor illness.

Vaccine	Ages usually given and other guidelines	If child falls behind (minimum intervals)	Contraindications (Remember: mild illness is not a contraindication
MMR (Measles, mumps, rubella) Give SC	• Give #1 at 12– 15m of age. Give #2 at 4– 6yrs of age. • Make sure that all children (and teens) over 4– 6yrs of age have received both doses of MMR. • If a dose was given before 12m of age it doesn't count as the first dose, so give #1 at 12– 15m of age with a minimum interval of 4wks between these doses. • If MMR and Var (and/ or yellow fever vaccine) are not given on the same day, space them > 28d apart. • May give with all other vaccines but as a separate injection.	• 2 doses of MMR are recommended for all children < 18yrs of age. • Dose should be given whenever it is noted that a child is behind. Exception: If MMR and Var (and/ or yellow fever vaccine) are not given on the same day, space them > 28d apart. • There should be a minimum interval of 28d between MMR #1 and MMR #2. • Dose #2 can be given at any time if at least 28d have elapsed since dose #1 and both doses are administered after 1yr of age. • DO NOT restart the series, no matter how long since previous dose.	• Anaphylactic reaction to a prior dose or to any vaccine component. • Pregnancy or possible pregnancy within next 3m (use contraception). • Moderate or severe acute illness. Don't postpone for minor illness. • If blood, plasma, or immune globulin were given in past 11m, see ACIP recommendations or *2000 Red Book* (p. 390) re: time to wait before vaccinating. • HIV is NOT a contraindication unless severely imunocompromised. • Immunocompromised persons (e. g., because of cancer, leukemia, lymphoma). **Note:** For patients on high- dose immunosuppressive therapy, consult ACIP recommendations regarding delay time. **Note:** MMR is not contraindicated if a PPD test was recently applied. If PPD and MMR weren't given on same day, delay PPD for 4– 6wks after MMR.
Varicella (Var) (Chickenpox) Give SC	• Routinely give at 12– 18m of age. • Vaccinate all children _ 12m of age including all adolescents who have not had chickenpox. • May use as postexposure prophylaxis if given within 3– 5d. • If Var and MMR (and/ or yellow fever vaccine) are not given on the same day, space them _ 28d apart. • May give with all other vaccines but as a separate injection.	• Do not give to children <12m of age. • Susceptible children <13yrs of age receive 1 dose. • Susceptible persons > 13yrs of age receive 2 doses 4-8 wks apart. • DO NOT restart series, no matter how long since previous dose.	• Anaphylactic reaction to a prior dose or to any vaccine component. • Moderate or severe acute illness. Don't postpone for minor illness. • Pregnancy or possibility of pregnancy within 1m. • If blood, plasma, or immune globulin (IG or VZIG) were given in past 5m, see ACIP recommendations or AAP's *2000 Red Book* (p. 390) re: time to wait before vaccinating. • Persons immunocompromised due to high doses of systemic steroids, cancer, leukemia, lymphoma or or immunodeficiency. **Note:** For patients with humoral immunodeficiency, HIV infection, or leukemia, or for patients on high doses of systemic steroids, consult ACIP recommendations. • For use in children taking salicylates, consult ACIP recommendations.

Vaccine	Ages usually given and other guidelines	If child falls behind (minimum intervals)	Contraindications (Remember: mild illness is not a contraindication
Polio (IPV) Give SC or IM	• Give at 2m, 4m, 6– 18m, and 4– 6yrs of age. • May give #1 as early as 6wks of age. • Not routinely recommended for those _ 18yrs of age (except certain travelers). • May give with all other vaccines but as a separate injection.	• All doses should be separated by at least 4wks. • #4 is given at 4– 6yrs of age. • If #3 of an all- IPV or all- OPV series is given at _ 4yrs of age, dose #4 is not needed. • Those who receive a combination of IPV and OPV doses must receive all 4 doses. • DO NOT restart series, no matter how long since previous dose.	• Anaphylactic reaction to a prior dose or to any vaccine component. • Moderate or severe acute illness. Don't postpone for minor illness.
Hib Give IM	• HibTITER (HbOC) & ActHib or OmniHib (PRP - T): give at 2m, 4m, 6m, 12-15m. • PedvaxHIB (PRP - OMP): give at 2m, 4m, 12– 15m. • Dose #1 of Hib vaccine may be given as early as 6wks of age but no earlier. • May give with all other vaccines but as a separate injection. • Hib vaccines are interchangeable. • Any Hib vaccine may be used for the booster dose. • Hib is not routinely given to children >5yrs of age.	**Rules for all Hib vaccines:** • The last dose (booster dose) is given no earlier than 12m of age and a minimum of 2m after the previous dose. • For children _ 15m and <5yrs of age who have never received Hib vaccine, give only 1 dose. • DO NOT restart series, no matter how long since previous dose. **Rules for HbOC (HibTITER) & PRP- T (ActHib, OmniHib) only:** • #2 and #3 may be given 4 wks after previous dose. • If #1 was given at 7– 11m, only 3 doses are needed; #2 is given 4– 8wks after #1, then boost at 12-15m • If #1 was given at 12– 14m, give a booster dose in 2m. **Rules for PRP- OMP (PedvaxHiB) only:** • #2 may be given 4wks after dose #1. • If #1 was given at 12– 14m, boost 8wks later.	• Anaphylactic reaction to a prior dose or to any vaccine component. • Moderate or severe acute illness. Don't postpne for minor illness.

Vaccine	Ages usually given and other guidelines	If child falls behind (minimum intervals)	Contraindications (Remember: mild illness is not a contraindication
Hep- B Give IM	• Vaccinate all infants at 0– 2m, 1– 4m, 6– 18m of age. • Vaccinate all children 0 through 18yrs of age. • For older children/ teens, spacing options include: 0, 1, 6m; 0, 2, 4m; or 0, 1, 4m. • Children born (or whose parents were born) in countries of high HBV endemicity or who have other risk factors should be vaccinated ASAP. • **If mother is HBsAg positive:** give HBIG and hep B #1 within 12hrs of birth, #2 at 1- 2m, and #3 at 6m of age. • **If mother's HBsAg status is unknown:** give hep B #1 within 12hrs of birth, #2 at 1– 2m, and #3 at 6m of age. If mother is later found to be HbsAg positive, her infant should receive HBIG within 7d of birth. • May give with all other vaccines but as a separate injection.	• DO NOT restart series, no matter how long since previous dose. • 3- dose series can be started at any age. • Minimum spacing for children and teens: 4wks between #1 & #2, and 8wks between #2 & #3. Overall there must be > 16wks between #1 & #3. • Dose #3 should not be given earlier than 6m of age. **Dosing of hepatitis B vaccines:** Vaccine brands are interchangeable for 3- dose schedule. For Engerix- B, use 10mcg for 0 through 19yrs of age. For Recombivax HB, use 5mcg for 0 through 19yrs of age. **Alternative dosing schedule for adolescents aged 11 through 15yrs:** For Recombivax HB *only*, use 10mcg (adult dose) in two doses spaced 4– 6m apart. May only be given to adolescents 11 through 15yrs of age.	• Anaphylactic reaction to a prior dose or to any vaccine component. • Moderate or severe acute illness. Don't postpone for minor illness.
Hep- A Give IM	• Vaccinate children _ 2yrs old who live in areas with consistently elevated rates of hepatits A, as well as children who have specific risk factors. (See ACIP statement and column 2 of this table for details.) • Children who travel outside of the U. S. (except Western Europe, New Zealand, Australia, Canada, or Japan). • Give dose #2 a minimum of 6m after dose #1. • Dose #1 may not be given earlier than 2yrs of age. • May give with all other vaccines but as a separate injection.	• DO NOT restart series, no matter how long since previous dose. • The minimum interval between dose #1 and #2 is 6m. • Hepatitis A vaccine brands are interchangeable. • Consult your local or state public health authority for information regarding your city, county, or state hepatitis A rates. States with consistently elevated rates (average > 10 cases per 100,000 population from 1987- 1997) include the following: AL, AZ, AK, CA, CO, ID, MO, MT, NV, NM, OK, OR, SD, TX, UT, WA, and WY.	• Anaphylactic reaction to a prior dose or to any vaccine component. • Moderate or severe acute illness. Don't postpone for minor illness.
Pneumo- coccal conjugate (PCV7) Give IM	• Give at 2m, 4m, 6m and 12– 15m of age. • For children age 24– 59m of age, give 2 doses to high - risk children, and consider 1 dose for moderate- - risk children. (See box below for list of high- and moderate-risk children).	• Minimum interval for infants _ 12m of age is 4wks, for >12m of age is 8wks. • For infants 7– 11m of age: If unvaccinated, give dose #1 now, give dose #2 4– 8wks later, and boost at 12-15m. If infant has had 1 or 2 previous doses, give next dose now, and boost at 12-15m.	• Anaphylactic reaction to a prior dose or to any vaccine component. • Moderate or severe acute illness. Don't postpone for minor illness.

	• If both PCV7 and PPV23 are indicated, PPV23 is given > 8wks after PCV7. • May give 1 dose to unvaccinated healthy children 24– 59m. • PCV7 not routinely given to children >5 years of age. • May give with all other vaccines but as a separate injection.	• For infants 12– 23 months: If not previously vaccinated or only one previous dose before 12m, give 2 doses > 8 wks apart. If infant previously had 2 doses, give booster dose >8 wks after previous dose. • DO NOT restart series, no matter how long since previous dose.	
	High- risk children: Those with sickle cell disease; anatomic or functional asplenia; chronic cardiac, pulmonary, or renal disease; diabetes mellitus; CSF leak; HIV infection; or immunosuppression. **Moderate- risk children:** Children aged 24– 35m; children aged 24– 59m who attend group daycare centers or are of Alaska Native, American Indian, or African American descent.		
PPV23 Give IM or SC	There are children > 2yrs of age for whom pneumococcal polysaccharide vaccine (PPV23) is recommended. Give IM or SC. Consult the ACIP statement *Prevention of Pneumococcal Disease* (4/ 4/ 97) for details.		
Influenza Give IM	There are children > 6m of age for whom influenza vaccine is recommended. Give IM. Consult the current year's ACIP statement *Prevention and Control of Influenza* for details.		
Lyme Give IM	There are teenagers (>15yrs of age) for whom Lyme disease vaccine is recommended. Give IM. Consult the ACIP statement *Recommendations for the Use of Lyme Disease Vaccine* (6/ 4/ 99) for details.		
Mening. Give SC	Meningococcal disease risk and vaccine availability should be discussed with college students. Give SC. Consult the ACIP statement *Meningococcal Disease and College Students* (6/ 30/ 00) for details.		

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Exhibit 3: VAERS Reportable Events

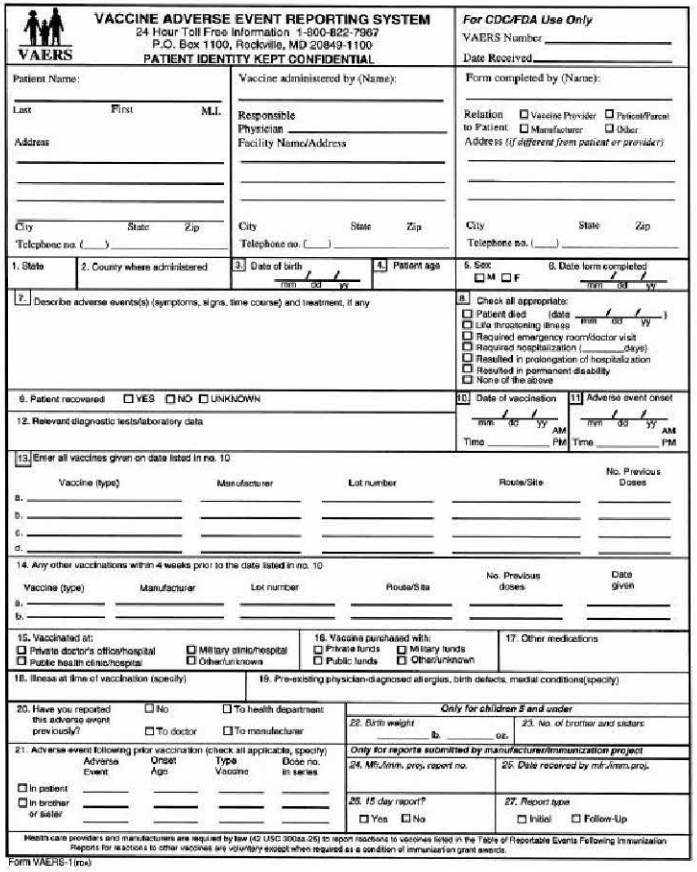
Vaccine Adverse Event Report System (VAERS)

Table of Reportable Events Following Vaccination

Vaccine / Toxoid	Event	Onset Interval
Tetanus in any combination; DTaP, DTP, DTP-HiB, DT, Td, TT	A. Anaphylaxis or anaphylactic shock B. Brachial Neuritis C. Any sequela (including death) of above events D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	7 days 28 days No limit see package insert
Pertussis in any combination; DTaP, DTP-HiB, P	A. Anaphylaxis or anaphylactic shock B. Encephalopathy (or encephalitis) C. Any sequela (including death) of above events D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	7 days 7 days No limit see package insert
Measles, mumps and rubella in any combination; MMR	A. Anaphylaxis or anaphylactic shock B. Encephalopathy (or encephalitis) C. Any sequela (including death) of above events D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	7 days 15 days No limit see package insert
Rubella in any combination; MMR, MR,R	A. Chronic arthritis B. Any sequela (including death) of above events C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	42 days No limit see package insert
Measles in any combination; MMR, MR,M	A. Thrombocytopenic purpura B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient C. Any sequela (including death) of above events D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	30 days 6 months No limit see package insert
Oral Polio (OPV)	A. Paralytic polio --in a non-immunodeficient recipient --in an immunodeficient recipient --in a vaccine-associated community case	 30 days 6 months No limit

	B. Vaccine-Strain Polio Viral Infection --in a non-immunodeficient recipient --in an immunodeficient recipient --in a vaccine-associated community case C. Any sequela (including death) of above events D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	30 days 6 months No limit No limit see package insert
Inactivated Polio(IPV)	A. Anaphylaxis or anaphylactic shock B. Any sequela (including death) of above events C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	7 days No limit see package insert
Hepatitis B	A. Anaphylaxis or anaphylactic shock B. Any sequela (including death) of above events C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	7 days No limit see package insert
Hemophilus influenzae type b	A. Early-onset Hib disease B. Any sequela (including death) of above events C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	7 days No limit see package insert
Varicella	A. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	see package insert

Exhibit 4: VAERS Report Form



VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

VAERS

For CDC/FDA Use Only
VAERS Number
Date Received

Patient Name: Last First M.I.
Address
City State Zip
Telephone no. ( )

Vaccine administered by (Name):
Responsible Physician
Facility Name/Address
City State Zip
Telephone no. ( )

Form completed by (Name):
Relation to Patient: ☐ Vaccine Provider ☐ Private/Parent ☐ Manufacturer ☐ Other
Address (if different from patient or provider)
City State Zip
Telephone no. ( )

1. State | 2. County where administered | 3. Date of birth mm dd yy | 4. Patient age | 5. Sex ☐ M ☐ F | 6. Date form completed mm dd yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
☐ Patient died (date mm dd yy)
☐ Life threatening illness
☐ Required emergency room/doctor visit
☐ Required hospitalization (_____days)
☐ Resulted in prolongation of hospitalization
☐ Resulted in permanent disability
☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm dd yy AM Time PM

11. Adverse event onset mm dd yy AM Time PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
☐ Private doctor's office/hospital ☐ Military clinic/hospital
☐ Public health clinic/hospital ☐ Other/unknown

16. Vaccine purchased with:
☐ Private funds ☐ Military funds
☐ Public funds ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions(specify)

20. Have you reported this adverse event previously? ☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under
22. Birth weight lb. oz.
23. No. of brother and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/immunization project
24. Mfr./imm. proj. report no.
25. Date received by mfr./imm.proj.

26. 15 day report? ☐ Yes ☐ No
27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

Form VAERS-1 (rev)

"Fold in thirds, tape & mail - DO NOT STAPLE FORM"

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD
POSTAGE WILL BE PAID BY ADDRESSEE

VAERS
P.O. Box 1100
Rockville MD 20849-1100

DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed)

GENERAL

Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine orthat person's legal representativewill not be made available tothe public, but may be available to the vaccinee or legal representative.
Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms diagnosis, treatment and recovery should be noted.
Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.
Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please
Item 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.
Item 13: List ONLY those vaccines given on the day listed in Item 10.
Item 14: List any other vaccines that the patient received within 4 weeks prior to the data listed in Item 10.
Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.
Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.
Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.
Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one priorvaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.
Item 26: This space is for manufacturers' use only.

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