Appendix D

Questions and Answers on General Administration of Vaccines, General Contraindications and Precautions, and Specific Vaccines for Civil Surgeons

The following general information is based on both U.S. and World Health Organization (WHO) experience with immunization programs. This information reflects the recommendations of the U.S. Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and WHO's worldwide Expanded Programme on Immunization (EPI).

The guidance on vaccines found in Section III is based on U.S. vaccines and standards, but also reflects global vaccine information published by WHO and the United Nations Children's Fund (UNICEF) in 1996 in the document entitled State of the World's Vaccines and Immunizations.

Civil surgeons should use this information to inform potential applicants receiving vaccines regarding the benefits, contraindications, and precautions related to vaccinations. Civil surgeons must provide oral and written information about the benefits and risks of vaccines, and their administration.

I. General Administration

1. What can be considered proof of valid immunizations?

Written documentation is necessary and sufficient as evidence of prior immunization. In general, written immunization records may be considered valid if the vaccine, date of administration, interval between doses, and age of the patient at the time of vaccination would be appropriate for a comparable vaccine produced in the United States. Self-reported doses of vaccines without written documentation are not acceptable.

2. Is the storage and handling of vaccines important?

Yes, because failure to adhere to recommended specifications for storage and handling of vaccines can weaken these products or make them ineffective. Recommendations included in a product's package inserts, including reconstitution of vaccines, should be followed closely to ensure maximum potency of vaccines. Vaccine quality is the shared responsibility of all parties from the time the vaccine is manufactured until it is administered. Vaccines should be stored at recommended temperatures immediately upon receipt.

The following vaccines are very sensitive to increased temperature:

- Oral polio vaccine (OPV)
- Varicella

The following vaccines are sensitive to freezing:

- Diphtheria and tetanus toxoids and pertussis vaccine (DTP)
- Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP)
- Diphtheria and tetanus toxoids for pediatric use (DT)
- Tetanus and diphtheria toxoids for adult use (Td)
- Inactivated poliovirus vaccine (IPV)
- *Haemophilus influenzae* type b conjugate vaccine (Hib)
- Hepatitis B vaccine (HepB)
- Pneumococcal vaccine
- Influenza vaccine

3. What if a required vaccine is not immediately available through the civil surgeon?

Normally, the civil surgeon should refer the applicant to a facility where the vaccine is available. It is the civil surgeon's responsibility to verify the potency of a vaccine, such as assessing and ensuring the cold chain is maintained at other facilities to which he or she is referring an applicant.

4. What if the civil surgeon does not know the age of a child?

In the extremely rare event that neither the applicant's caretaker nor the civil surgeon knows the age of a child presenting for immunization, the civil surgeon should follow good medical practice. If the child does not present any contraindications and has no proof of prior immunization, the child should receive the first dose of a series of vaccines appropriate for the estimated age of the child.

5. Are children from other countries being adopted by U.S. citizens required to have vaccinations?

Children 10 years of age or younger who are adopted from other countries are exempt from vaccination requirements if a parent who has sponsored the child signs an affidavit stating that he or she will ensure that the child receives the required vaccinations within 30 days after the child's arrival into the United States.

6. Can a child or person with poorly documented medical history receive vaccines?

Yes, anyone needing to receive a vaccine must do so at the time of his or her medical examination when applying for adjustment of status or permanent resident status in the United States. Every effort should be made to vaccinate unless a contraindication exists, in which case a waiver may be necessary. A child with an HIV-infected parent must be tested for the infection before receiving live vaccines.

7. Is it an acceptable practice to administer several of the required vaccines simultaneously?

Yes, studies and extensive clinical experience have strengthened the scientific basis for administering certain vaccines simultaneously. Many of the commonly used vaccines can safely and effectively be administered simultaneously (that is, on the same day, not at the same anatomical site). The simultaneous administration of the most widely used live and inactivated vaccines, including varicella, has not resulted in impaired antibody responses or increased rates of adverse reactions.

8. If vaccines are administered simultaneously, how and where on the body should they be administered?

Vaccinators should be familiar with the structural anatomy of the area into which they are injecting a vaccine. An individual decision on needle size and site of injection must be made for each person based on age, the volume of the material to be administered, the size of the muscle, and the depth below the muscle surface into which the material is to be injected. Depending on the age of the recipient, needle length may vary from 5/8-inch (1.6 centimeters) to 1.5 inches (3.8 centimeters). A 22- to 25-gauge needle is appropriate for most intramuscular vaccines. For subcutaneous injections, a 23- or 25-gauge needle, 5/8-inch (1.6 centimeters) to 3/4-inch (1.9 centimeters) long is recommended. The deltoid muscle is recommended for routine intramuscular vaccination among adults.

The following vaccines are given intramuscularly:

- DTP
- DTaP
- DT
- Td
- Hib
- HepB
- IPV (can be given subcutaneously)
- Pneumococcal conjugate
- Pneumococcal polysaccharide (can be given subcutaneously)
- Influenza

The following vaccines are given subcutaneously:

- Measles-mumps-rubella (MMR)
- Varicella

With regards to an ideal distance between injection sites for multiple vaccinations in the same arm, the following is recommended:

- If more than one vaccine preparation is administered simultaneously, it is preferable to administer each at a different anatomic site.
- It is preferable to avoid administering two intramuscular injections in the same limb, especially if DTP is one of the products administered.

- If more than one injection must be administered in a single limb, the thigh is usually the preferred site because of the greater muscle mass; the injections should be sufficiently separated (1 to 2 inches [2.5 to 5.1 centimeters] apart) so that any local reactions are unlikely to overlap.

II. General Information on Contraindications and Precautions

1. What are some examples of when vaccines may not be medically appropriate?

Conditions when vaccines may not be medically appropriate are when the recipient:

- Has had a neurologic or severe hypersensitivity reaction to a prior dose of DTP or DTaP.

- Has an anaphylactic allergy to neomycin or streptomycin contained in polio, measles, mumps, and rubella vaccines; allergy to yeast in hepatitis vaccine or to eggs in influenza vaccine.

- Is pregnant. Td and HepB are the only vaccines routinely indicated for susceptible pregnant women. Polio, measles, mumps, rubella, and varicella vaccines should not be routinely administered to pregnant women.

- Is an immunocompromised child. Special consideration needs to be given to immunocompromised children, such as those with congenital immuno-deficiencies, human immunodeficiency virus infection, malignancy, or recipients of immunosuppressive therapy. Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses), can reduce the immune response to vaccines. Medical waivers for live virus vaccines, such as oral polio, measles, mumps, rubella, and varicella vaccine, should be granted in these cases and vaccines not administered. If immunosuppressive therapy will be discontinued shortly, it is reasonable to defer vaccination with inactivated vaccines, such as pertussis, diphtheria, typhoid and IPV, until the person has been off therapy for 1 month. Otherwise, the person should be vaccinated with these vaccines while still on immunosuppressive therapy.

- Is experiencing moderate to severe vomiting. The person should wait until he or she recovers before receiving the vaccine.

Fever *per se* is not a contraindication to immunization. For the child with an acute, febrile ($\geq$38 ^{o} Celsius [C]; $\geq$100.4^{o} Fahrenheit [F]) illness, guidelines for immunization are based on the physician's assessment of the child's illness and the specific vaccines the child is scheduled to receive. However, if fever or other manifestations suggest a moderate or serious illness, the child should not be vaccinated until he or she has recovered.

2. When should people with moderate or severe febrile illnesses be vaccinated?

These people can be vaccinated as soon as they have recovered from the acute phase of the illness. This wait avoids superimposing adverse effects of vaccination on the underlying illness or mistakenly attributing a manifestation of the underlying illness to the vaccine.

3. What is the difference between a contraindication and a precaution?

A contraindication is a condition in a recipient that greatly increases the chance of serious adverse reaction. A precaution is a condition in a recipient that may increase the chance of a serious adverse reaction, or a condition that may compromise the ability of the vaccine to produce immunity, such as administering measles vaccine to a person with passive immunity to measles from a blood transfusion. When faced with precautions, some providers may elect to administer a vaccine if they believe that the benefits outweigh the risks for the patient. For example, caution should be exercised in vaccinating a child with DTP who within 48 hours of receipt of a prior dose of DTP developed:

- Fever $\geq 40.5^{o}$ C (105^{o} F).
- Persistent, inconsolable crying for 3 hours or more.
- Shock-like state.
- Seizure within 3 days of receiving the previous dose of DTP.

These signs are not contraindications *per se*.

The major **contraindications** to vaccination include:

- An immediate anaphylactic reaction.
- Encephalopathy (not due to another identifiable cause) relating only to pertussis-containing vaccines.
- Pregnancy for receiving live attenuated vaccines (measles-mumps-rubella [MMR] and varicella), and IPV.

Some **precautions** to vaccination (relating only to pertussis-containing vaccines) include:

- Fever $\geq 40.5^{o}$ C ($\geq 105^{o}$ F) that is not attributed to another identifiable cause occurring within 48 hours after vaccination.
- Collapse or shock-like state (that is, a hypotonic-hyporesponsive episode) occurring within 48 hours after vaccination.
- Persistent, inconsolable crying lasting 3 hours or more and occurring within 48 hours after vaccination.

- Convulsions with or without fever occurring within 3 days after vaccination.

4. What are some of the safety considerations when administering vaccines?

People administering vaccines should take the precautions necessary to minimize risk for spreading disease. Hands must be washed before each new patient is seen. Syringes and needles used for injections must be sterile and preferably disposable to minimize the risk of contamination. ***A separate needle and syringe must be used for each injection***. Different vaccines should not be mixed in the same syringe unless specifically licensed for such use. Disposable needles and syringes should be discarded in labeled, puncture-proof containers to prevent inadvertent needle stick injury or reuse. Long-term disposal should be by incineration or autoclaving.

III. Information on Specific Vaccines

1. What are the different types of vaccines and what are the expected side effects from these vaccines?

There are two basic types of vaccines: live attenuated and inactivated. Live attenuated vaccines are produced by modifying a disease-producing (wild) virus or bacteria in a laboratory. The resulting vaccine organism retains the ability to replicate (grow) and produce immunity, but usually does not cause illness. Adverse events following live attenuated vaccines are similar to a mild form of the natural illness. For example, measles disease is characterized by rash and fever; the most common adverse events following measles vaccine are rash and fever. Adverse events following live vaccines occur after one incubation period of the vaccine virus (except allergic reactions, which occur in minutes or hours). For example, the peak occurrence of fever and rash after measles vaccine is 7 to 10 days after vaccination. Live attenuated vaccines include oral polio, measles, mumps, rubella, and varicella vaccines.

Inactivated vaccines can be composed of either whole or partial (fraction or subunits) bacteria or viruses. Inactivated vaccines do not replicate, so adverse events are not similar to the natural disease. Since a large amount of killed bacteria or virus is given in the injection, the most common adverse events are local at the site of injection, such as pain, swelling, and redness. Fever can occur, often as a manifestation of inflammation at the site of injection. Local reactions to inactivated vaccines generally increase with increasing numbers of doses of the vaccine. Mild systemic symptoms can also occur. Adverse events from inactivated vaccines generally occur within 1 to 3 days of the dose of the vaccine (that is, unrelated to the incubation period of the disease). Inactivated vaccines include diphtheria and tetanus toxoids and pertussis (whole cell or acellular), *Haemophilus influenzae* type b, hepatitis B, pneumococcal, and influenza vaccines.

2. What are the benefits and risks associated with the diphtheria, tetanus, and pertussis vaccines?

About the Disease

To understand why the vaccines for diphtheria, tetanus, and pertussis are used, one must first understand the diseases caused by these bacteria.

a. Diphtheria

Diphtheria is an infectious disease caused by the bacteria *Corynebacterium diphtheriae*, and is spread by coughing and sneezing or through contact with skin infections. It can affect the tonsils, upper respiratory tract, and heart. Although the disease can be treated with diphtheria antitoxin and antibiotics, even with appropriate treatment up to 10% of cases are fatal. Serious complications from the spread of diphtheria can occur, involving the heart (myocarditis), central nervous system, and various other organs.

Diphtheria was a dreaded childhood illness in the pre-vaccine era and is reemerging today in epidemics mainly involving adults and nonimmunized children.

b. Tetanus

Tetanus is an acute, often fatal, disease caused by a toxin produced by the bacteria *Clostridium tetani* that is commonly found in soil or feces. It is characterized by generalized increased rigidity and convulsive spasms of skeletal muscles. The muscle stiffness usually involves the jaw (lockjaw) and neck first, and later becomes generalized. It is often fatal.

c. Pertussis

Pertussis (whooping cough) is an infectious disease caused by the bacteria *Bordetella pertussis*. In 1994, there were an estimated 40 million cases of pertussis worldwide and 360,000 deaths. Every year nearly 5 million children suffer from bronchopneumonia as a result of pertussis infection, while 50,000 children develop long-term neurological complications, including permanent brain damage. In developing countries, the death rate can exceed 15%, but is usually not so high. In the industrialized countries, it is much lower, with 4 deaths out of every 10,000 infected children.

About the Vaccine

Children younger than 7 years of age should receive either combination diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) or pediatric diphtheria and tetanus vaccine (DT) if a there is a contraindication to pertussis vaccine. Combination diphtheria and tetanus toxoids and whole-cell pertussis vaccine (DTP) are available, but are no longer recommended in the United States. Pediatric formulations (DT and DTaP) contain a similar amount of tetanus toxoid as the adult

tetanus and diphtheria vaccine (Td), but contain three to four times as much as diphtheria toxoid. Td is the vaccine of choice for children 7 years of age or older, and for adults.

What are the benefits of the vaccines for diphtheria, tetanus, and pertussis?
Vaccination is the most effective method of preventing these diseases and their serious complications, including death. Because it is not possible to eradicate the organism that causes tetanus, vaccination is the only method to prevent the disease.

What are the risks of the vaccines for diphtheria, tetanus, and pertussis?
As with most inactivated vaccines, local reactions (such as pain, redness, and swelling at the injection site) are the most common adverse events observed. Fever and mild systemic reactions also occur frequently, usually starting within several hours of vaccination and lasting 1 to 2 days. Arthus-type hypersensitivity reactions, characterized by severe local reactions, can occur, particularly in people who have had multiple prior boosters. Rarely, severe systemic reactions such as generalized urticaria, anaphylaxis, or neurologic complications have been reported. Other reactions that can occur after pertussis vaccine are prolonged or unusual crying, high fever, seizure, and a shock-collapse reaction (infant becomes pale, limp, and less alert). No long-term consequences of these reactions have been found. Very rarely, some children can have prolonged seizure activity or encephalopathy following the vaccine.

3. What are the benefits and risks associated with the polio vaccine?

About the Disease
To understand why the polio vaccine is used, one must first understand the disease caused by this virus. Polio is a viral infection of the nervous system. It most often affects children and can cause lifelong paralysis, respiratory distress, and sometimes death. Up to 95% of all polio infections are inapparent, but infected persons without symptoms shed virus in the stool and are able to transmit the virus to others. Although polio is incurable, it can be prevented by immunization.

About the Vaccine
Two vaccines are available: an injectable inactivated polio vaccine (IPV) and a live attenuated oral polio vaccine (OPV). Both vaccines are highly effective against all three serotypes of poliovirus, but there are significant differences in the way each vaccine works.

OPV is the vaccine of choice for use in most countries of the world. It is cheaper and easier to administer than the injectable vaccine. It also multiplies and induces immunity in the gut, the key site where wild poliovirus multiplies. Although OPV is safe and effective, in about 2 in every 5 million doses of the vaccine, the live attenuated virus can cause paralysis, either in the vaccinated child or in people with close contact to the vaccinated child.

IPV is only available for routine polio vaccine the United States. A polio vaccination schedule begun with OPV should be completed with IPV. IPV provides individual protection against polio paralysis, but it induces only very low immunity in the gut. Because of this, IPV cannot prevent the spread of wild poliovirus and cannot be used to eradicate polio in the world. However, IPV does not carry the risk of paralysis associated with OPV.

What are the benefits of the polio vaccine?
Polio vaccine prevents polio. Before polio vaccine, hundreds of thousands of children acquired polio each year.

OPV: No injection. OPV provides individual protection and increases the protection for communities from polio outbreaks.

IPV: IPV provides individual protection from polio. It can be given to immuno-compromised people or to people living in a household with immunocompromised people. It does not cause paralysis.

What are the risks of the polio vaccine?
OPV: From 1980 through 1999, a total of 152 confirmed cases of paralytic poliomyelitis were reported in the United States, an average of 8 cases per year. Six cases were acquired outside of the United States and imported. The remaining 144 (95%) cases were vaccine-associated paralytic polio caused by OPV. In response to mounting public concern, the U.S. Advisory Committee on Immunization Practices (ACIP) decided in June 1995 to draw up new guidelines on polio immunization. In October 1995, the ACIP recommended the introduction of a combined IPV/OPV schedule in the United States: an initial two doses of IPV to be followed by two doses of OPV. To further the goal of complete elimination of paralytic polio in the United States, the ACIP recommended in July 1999 that IPV be used exclusively and emphasized that the schedule applies only to the United States; however, the ACIP has strongly endorsed WHO's global eradication strategy. OPV cannot be given to immunocompromised people or people living in households with immuno-compromised people.

IPV: Mild soreness at the site of injection can occur.

4. What are the benefits and risks associated with the vaccines for measles, mumps, and rubella (measles or MR or MMR)?

About the Disease
To understand why the vaccines for measles, mumps, and rubella are used, one must first understand the diseases caused by these viruses.

1. Measles
   Measles remains one of the major childhood killers, accounting for more child deaths than from all the other vaccine-preventable diseases combined. WHO

estimates that about 40 million cases of measles occur each year, but less than 5% are ever reported. The disease thrives in cities, especially in deprived urban areas where overcrowding, poor sanitation, and pockets of low immunization ensure the continued circulation of measles and other diseases.

Ninety-eight percent of measles deaths occur in developing countries. Globally, the disease accounts for over 10% of deaths among children younger than 5 years of age and for 50% of deaths among those younger than 1 year of age. Measles can lead to lifelong disabilities, including brain damage, blindness, and deafness, especially in developing countries. Other complications include pneumonia, diarrhea, ear infections, and seizures.

2. Mumps
   Mumps infection can cause fever, headache, lymphadenopathy, aseptic meningitis, deafness, and orchitis and oophoritis (which can lead to male and female sterility, respectively.) Infrequently, pancreatitis can occur.

3. Rubella
   Rubella (German measles) is a mild rash disease that affects mostly children. However, if the disease is contracted by a woman during the first 3 months of pregnancy, the consequences for the developing fetus can be devastating. There is a 50% increase in spontaneous abortions. In up to 70% of cases, the baby is born with permanent disabilities, including blindness, deafness, brain damage, and heart defects. In developing countries, it is estimated that a quarter of a million babies are born with congenital rubella syndrome (CRS) annually. In an epidemic year, there is likely to be a tenfold increase in the incidence of CRS in individual countries.

About the Vaccine

Measles, mumps, and rubella vaccines are live attenuated viral vaccines. They are widely used in the industrialized world, although immunization schedules vary from one country to another. Although measles, mumps and rubella vaccines are available as a single antigen preparation, the U.S. ACIP recommends that combined measles-mumps-rubella (MMR) vaccine be used when anyone of the individual components is indicated.

What are the benefits of the vaccines for measles, mumps,and rubella?
Vaccination is the best way to protect against measles, mumps, rubella, and the complications from those diseases, including CRS.

What are the risks of the vaccines for measles, mumps, and rubella?
The adverse events following administration of measles, mumps, and rubella vaccines represent replication of the viruses with subsequent mild illness. Allergic reactions occur within minutes to hours following the vaccine administration. Soon after the vaccination, there might be soreness, redness, or swelling at the injection site. One to two weeks after the vaccination, there might be rash; fever;

lymphadenopathy; or, infrequently, a seizure.

Adverse events related to the measles component of the vaccine occur 5 to 12 days post-vaccination. The most common adverse events are fever and rash. Information from Sweden and Finland indicates that a decrease in the platelet count (thrombocytopenia) can occur once in 30,000 to 40,000 doses of vaccine. Thrombocytopenia is usually not clinically apparent, although a few cases of thrombocytopenic purpura have been reported. Parotitis and fever have been reported rarely following mumps vaccine. In countries that use the Urabe strain of mumps vaccine virus, there is a slight risk of aseptic meningitis (one per several thousand doses). One to three weeks following the vaccination, there may be arthralgia or arthritis in one or more joints, lasting up to 3 days. This is believed to be the result of the rubella component of the vaccine. The joint complaints are more frequent in post-pubertal women.

Pregnant women should not receive MMR vaccine or any of its components. Pregnancy should be avoided for 1 month after receiving the measles vaccine and MMR vaccine. Close contact with pregnant women is **NOT** a contraindication to MMR vaccination of the contact. Breastfeeding is **NOT** a contraindication to vaccination of either the woman or the breastfeeding child.

5. What are the benefits and risks associated with the *Haemophilus influenzae* type b (Hib) vaccine?

About the Disease

To understand why the *Haemophilus influenzae* type b (Hib) vaccine is used, one must first understand the disease caused by the bacteria. Hib is a leading cause of acute lower respiratory tract infection among young children, especially in developing countries. While it is difficult to assess the global burden of Hib disease, it is estimated that approximately 400,000 children a year die from Hib pneumonia. Hib is also one of the leading causes of nonepidemic meningitis, which can lead to brain damage and acquired deafness. It is estimated that approximately 100,000 children die from Hib meningitis every year worldwide. The disease affects mainly children younger than 5 years of age (90% of all cases), with peak incidence at 6 to 11 months of age.

About the Vaccine

Since 1990, Hib conjugate vaccines (vaccines which are made more potent by linking the cell wall of inactivated bacteria with a protein carrier) have been licensed for use in infants and children in the United States. Three manufacturers currently have Hib vaccines licensed for use in the United States. Invasive Hib disease in U.S. children has been reduced by approximately 99% due to widespread use of Hib vaccines. Many other countries have seen equally dramatic reductions in Hib disease with high vaccine coverage.

What are the benefits of the Hib vaccine?
Vaccination is the best way to protect against Hib disease. Many children would die or suffer lifelong complication from Hib disease
severe Hib disease, with possible lifelong complications, without the vaccine.

What are the risks of the Hib vaccine?
Hib vaccines are among the safest of all vaccines. Adverse events following Hib vaccine are uncommon. As with any medicine, there is a very small risk that serious problems, even death, could occur after receiving a vaccination. However, the disease is much more likely to cause serious illness than the vaccine. Pain, redness, and/or swelling at the injection site have been seen in 5-30% of recipients, and these mild reactions usually resolve within 24 hours. Systemic reactions such as fever or irritability are infrequent.

6. What are the benefits and risks associated with the hepatitis B vaccine?

About the Disease
To understand why the vaccine for hepatitis B is used, one must first understand the disease and disease complications caused by the virus. More than 2 billion people today have at some time in their lives been infected with the hepatitis B virus. Of these, about 350 million remain chronically infected (carriers), developing cirrhosis of the liver, or liver cancer. Chronically infected persons are able to transmit the disease for many years. Every year there are over 4 million acute clinical cases of hepatitis B and approximately 1 million deaths. Primary liver cancer caused by hepatitis B is now one of the principal causes of cancer death in many parts of Africa, Asia, and the Pacific basin.

Globally, child-to-child and mother-to-child transmissions account for the majority of infections and carriers. Young children rarely develop acute clinical disease, but approximately 25% of children infected before 7 years of age become chronically infected. No more than 10% of older children and adults become chronically infected. However, about 40% of older children and adults who are infected develop acute clinical hepatitis B with jaundice. The disease can also be transmitted through the use of unsterile needles or other medical equipment and through cultural practices that involve skin piercing or cutting.

In areas where there is low incidence of the disease (Western Europe, North America, much of Latin America, and Australia) mother-to-child and child-to-child transmissions are less common. Most infections occur in adults through sexual activity; needle sharing among injecting drug users; and, less frequently, among medical workers exposed to blood products.

About the Vaccine
The first hepatitis vaccine to be developed was an inactivated vaccine from the plasma of HBV-positive donors. Although it was safe and effective, it was removed from the U.S. market in 1992 because of fears of transmission of live HBV and other

blood-borne pathogens. The second vaccine, available since 1986, is a genetically engineered recombinant vaccine. It is equally as safe and effective as the plasma-derived alternative.

What are the benefits of the hepatitis B vaccine?
Vaccination is the most effective way to prevent hepatitis B infection and the serious complications and sequelae.

What are the risks of the hepatitis B vaccine?
The most frequent adverse events following hepatitis B vaccine are pain at the site of injection and mild to moderate fever. Fatigue, headache, and irritability have also been reported. Serious allergic reactions have been reported rarely.

7. What are the benefits and risks associated with the varicella vaccine?

About the Disease
To understand why the varicella vaccine is used, one must first understand the disease and disease complications caused by the virus. Chickenpox is a common childhood disease affecting millions of children each year. Although the disease is usually mild in otherwise healthy young children, it can be serious when contracted by older children or adults. It causes a rash, itching, malaise, and fever. It can lead to pneumonia, brain damage, or death. People who have had chickenpox can develop herpes zoster (shingles) later in life.

About the Vaccine
The chickenpox vaccine is a live attenuated vaccine. It was licensed for use in the United States in March 1995.

What are the benefits of the varicella vaccine?
Varicella vaccine is the most effective way to prevent chickenpox and its complications. People who develop chickenpox after receiving the vaccine develop a milder case. Herpes zoster has been reported to occur four to five times less often following the vaccine than following the natural disease.

What are the risks of the varicella vaccine?
Local reactions such as soreness, redness, or swelling at the site of injection can occur. A mild rash and fever can also occur approximately 2 weeks after the vaccination. Rarely, febrile seizures have been reported.

8. What are the benefits and risks associated with the vaccine for pneumococcal disease?

About the Disease
To understand why the pneumococcal vaccine is used, one must first understand the disease caused by the bacteria. Every year in developing countries, more than a million children younger than 5 year of age die from pneumonia caused by

Streptococcus pneumoniae. This form of bacterial pneumonia is the biggest killer among the acute respiratory infections, which together claim the lives of over 4 million children a year in the developing world. *S. pneumoniae* is also responsible for pneumococcal meningitis, which has a fatality rate approximately as high as other forms of meningitis and often leads to hearing loss or brain damage in children who survive.

Pneumococcal pneumonia is the most common clinical presentation of invasive pneumococcal disease among adults. An estimated 175,000 hospitalized cases of pneumococcal pneumonia occur annually in the United States. It is a common bacterial complication of influenza and measles. Bacteremia occurs in about 25% to 30% of those with pneumococcal pneumonia. The case fatality rate of pneumococcal bacteremia is about 20%, but may be up to 60% among the elderly. *S. pneumoniae* cause 13% to 19% of all cases of bacterial meningitis in the United States, with a case fatality rate of up to 80% in the elderly.

While early treatment with antibiotics saves many lives, there is increasing evidence that the misuse of antibiotics has led to the appearance of drug-resistant strains of the bacteria in many countries.

About the Vaccine

The pneumococcal polysaccharide vaccine is composed of purified preparations of pneumococcal cell wall. One of the major problems in developing a successful vaccine against *S. pneumoniae* is the large number of different serotypes involved. More than 83 serotypes of the bacterium are known to cause disease; about 10 of these account for up to 70% of disease in young children. The frequency of the serotypes can vary from year to year, from one age group to another, and from one geographical area to another.

Pneumococcal polysaccharide vaccines (PPV23) are available that protect against 23 of the known serotypes. It is the vaccine that should be administered routinely to all adults 65 years of age and older and people 2 years of age and older with chronic illnesses, including cardiovascular disease, pulmonary disease, diabetes, or cirrhosis. Polysaccharide vaccines are not effective in children younger than 2 years of age, the age at which children are most vulnerable to the disease.

Pneumococcal conjugate vaccine (PCV7), which was licensed in the United States in 2000 for children younger than 2 years of age. It is composed of purified preparations of the pneumococcal cell wall of 7 serotypes conjugated to a nontoxic diphtheria toxin.

What are the benefits of the pneumococcal vaccine?

PPV23 is 60% to 70% effective in preventing invasive disease. The vaccine may be less effective in pneumococcal infection in some groups, particularly those with significant underlying illness. However, it is still recommended for such people because they are at high risk for developing severe disease.

What are the benefits of the pneumococcal conjugate vaccine?
PCV7 is effective in preventing bacteremia and meningitis in children younger than 2 years of age. It is 97% effective in preventing invasive disease caused by vaccine serotypes, and 89% effective against disease caused by all serotypes, including those not in the vaccine.

What are the risks of the pneumococcal polysaccharide vaccine?
About half of those who are given pneumococcal vaccine have very mild side effects, such as redness and pain at the injection site. Infrequently, some people can develop fever, muscle aches, and severe local reactions. All reactions subside within 1 week after vaccination.

What are the risks of the pneumococcal conjugate vaccine?
Local reactions, such as redness, swelling and tenderness at the injections site, occur in 10% to 20% of children. Fever >38^{o}C (100.4^{o}F) within 48 hours was reported in 15% to 24% of children.

9. What are the benefits and risks associated with the influenza vaccine?

About the Disease
To understand why the influenza vaccine is used, one must first understand the disease caused by the influenza virus. Influenza is a highly infectious viral illness. Influenza disease is characterized by the abrupt onset of fever, muscle aches, sore throat, and nonproductive cough. The symptoms usually last from 2 to 3 days. The most frequent complication of influenza is pneumonia, usually secondary bacterial pneumonia. Primary influenza viral pneumonia is an uncommon complication, but has a high fatality rate. Other complications of influenza include myocarditis, worsening of chronic pulmonary diseases, and death.

About the Vaccine
The influenza vaccine that is used in most countries is composed of inactivated influenza virus. Because it is an inactivated vaccine, it cannot cause the "flu".
In June 2003, a nasal spray influenza vaccine was approved for healthy people age 5 to 49 years. The nasal spray influenza vaccine uses a live but weakened virus administered to help develop immunity.

The influenza vaccine should be administered for all adults 50 years of age and older, regardless of the presence of chronic illness, and people >6 months of age with chronic illnesses, including pulmonary disease, cardiovascular disease, diabetes, renal dysfunction, hemoglobinopathies, or immunosuppression. Other groups targeted for influenza vaccine include people residents of long-term care facilities, pregnant women, and persons 6 months to 18 years of age receiving chronic aspirin therapy. Healthy children aged 6-23 months and household contacts and other caregivers of children <24 months of age are encouraged to receive influenza vaccine.

What are the benefits of the influenza vaccine?
Inactivated influenza vaccine: The vaccine is effective in preventing disease in up to 90% of healthy young adults. Although the vaccine is only 30% to 40% effective in preventing disease in frail elderly people, it is 50% to 60% effective in preventing hospitalization in the elderly, and 80% effective in preventing death.

Live intranasal influenza vaccine: In a clinical trials with health children and adults, the vaccine was 85%-87% effective in preventing influenza.

What are the risks of the influenza vaccine?
Inactivated influenza vaccine: Local reactions (soreness, erythema, and induration at the injection site) are the most common adverse events following vaccination with the. These reactions usually last 1 to 2 days. Mild systemic symptoms, such as fever, chills, fatigue, and muscle aches are reported in fewer than 1% of vaccine recipients. These reactions begin 6 to12 hours after vaccination and last for 1 to 2 days. They occur most often in people with no prior exposure to the influenza virus or vaccine. Rare allergic reactions have occurred, and they likely were a result of residual egg protein in the vaccine. Unlike the 1976 swine influenza vaccine, subsequent vaccines prepared from other virus strains have not been clearly associated with an increased risk of Guillain-Barré syndrome.

Live intranasal influenza vaccine: The most common adverse events included runny nose, cough, irritability, headache, sore throat and muscle aches.