VACCINE HEALTH AND SAFETY MANUAL

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INTRODUCTION

Important Information About CDC-Recommended Vaccines, Vaccine Health, and Vaccine Side Effects and Injuries

Currently, the Centers for Disease Control and Prevention (CDC) recommend that children and adults receive regularly-scheduled vaccinations to protect against 17 specific illnesses. The CDC also recommends certain additional vaccinations for individuals who are traveling and who are particularly at risk for contracting certain types of diseases.

While the CDC advises that recommended vaccinations are generally safe for administration to most people, it is generally understood that like any medical treatment or therapy, vaccinations can carry risks for certain types of illnesses and injuries. Health care providers, parents, and all other vaccine recipients should all be aware of these risks and coordinate with their physicians prior to administering or seeking a vaccination. In this Vaccine Health and Safety Manual, you will find information about:

- The most-common CDC-recommended vaccinations
- The potential benefits and risks associated with CDC-recommended vaccines
- The differences between routine versus unusual side effects associated with recommended vaccinations
- · Examples of vaccine-related illnesses and injuries and their respective symptoms
- Steps that should be taken by parents and adult vaccine recipients alike should they experience signs or symptoms of a vaccine adverse event



1. WHAT ARE SOME OF THE MOST COMMON VACCINES?

In the United States, the most-common vaccines are those listed on the CDC's Recommended Vaccine Schedules for children, teens and adults. Beginning at birth, the CDC recommends vaccination against 17 common preventable illnesses, and all of these vaccines are readily available from hospitals, clinics, doctor's offices, and pharmacies across the country. As of 2019, the <u>CDC</u> recommends vaccination against the following diseases:

- Diphtheria
- Haemophilus influenzae type b disease (Hib)
- Hepatitis A
- Hepatitis B
- Human papilloma virus (HPV)
- Influenza (flu)
- Measles
- Meningococcal

- Mumps
- Pertussis
- Polio
- Pneumococcal
- Rotavirus
- Rubella
- Tetanus
- Varicella (chickenpox)
- Zoster (shingles)

Additional common vaccines not included on the CDC's recommended vaccination schedules are the immunizations for:

- adenovirus
- anthrax
- cholera
- J. encephalitis

- malaria
- rabies
- typhoid
- yellow fever

Limitations on the CDC's Vaccine Recommendations

While the CDC recommends these vaccinations generally, the presence of certain risk factors may make it inadvisable for some individuals to get vaccinated. These risk factors vary from one vaccine to the next; and, as a result, all individuals should consult with their doctors prior to getting vaccinated.

Some examples of the more-common risk factors for CDC-recommended immunizations include:

- Having a prior adverse reaction to an immunization
- Having a fever
- Having a weakened immune system
- Being diagnosed with lung, heart or kidney disease
- Pregnancy
- Suffering from allergies
- Suffering from seizures
- Taking certain medications

For individuals who have questions about the CDC's vaccine recommendations, further information can be obtained from tables outlining the CDC's recommendations which can be found online. The CDC publishes separate tables for children through age six, pre-teens and teens, and adults ages 19 and older. A sample chart below is provided by The Children's Health Defense (childrenshealthdefense.org).

Ch			mmendec chedule: 1		19
1986 ⇒	12 shots 25 antigens 8 diseases		201 9 ⇒	54 shots 70 antigens 16 diseases	
DTP (2 Months)	MMR (15 Months)	DTP (4 Years)	Hep B (1 day)	Influenza (7 Months)	Influenza (5 years)
Polio (2 Months)	DTP (18 Months)	Polio (4 Years)	Hep B (1 Month)	MMR (12 Months)	Influenza (6 Years)
DTP (4 Months)	Polio (18 Months)	Td (14 Years)	DTaP (2 Months)	Varicella (12 Months)	Influenza (7 Years)
Polio (4 Months)	Hib (2 Years)		Polio (2 Months)	Hib (12 Months)	Influenza (8 Years)
DTP (6 Months)			Hib (2 Months)	Hep A (12 Months)	Influenza (9 Years)
			PCV 13 (2 Months)	PCV 13 (12 Months)	Influenza (10 Years)
			Rotavirus (2 Months)	DTaP (15 Months)	HPV (11 Years)
			DTaP (4 Months) Polio (4 Months) Hib (4 Months) PCV 13 (4 Months) Rotavirus (4 Months) DTaP (6 Months)	Hep A (18 Months) Influenza (18 Months) Influenza (2 Years) Influenza (3 Years) DTaP (4 Years) MMR (4 Years)	Meningococcal ACWY (11 Years) Tdap (11 Years) Influenza (11 Years) HPV (11.5 Years) Influenza (12 years) Influenza (13 Years)
			Polio (6 Months) Hep B (6 months)	Polio (4 Years)	Influenza (14 Years) Influenza (15 Years)
C1:11			Hib (6 Months)	Varicella (4 Years)	Meningococcal ACWY (16 Years)
Childr Health D	en s MM		PCV 13 (6 Months)		Influenza (16 years)
Health D	efense		Rotavirus (6 Months)		Influenza (17 Years)
			Influenza (6 Months)		Influenza (18 years)

Note: DTP, DTaP, Tdap and MMR vaccines contain three antigens each.

50URCE: CDC Recommended Childhood Vaccine Schedule, Birth to 18

2. WHY SHOULD MY CHILD AND I GET THESE VACCINES?

For many people, understanding that the CDC recommends vaccination is not enough. They also want to know the reasons for *why* certain vaccinations are recommended. As with any medical treatment or therapy, it is important to make informed decisions about whether or not to receive a vaccination, and anyone who has questions should discuss the benefits of vaccination with their doctor before making that decision.

Being vaccinated reduces the risk of contracting preventable diseases and can lessen the likelihood of ones experiencing the severe (and, in some cases, potentially fatal) complications that can arise as a result. Widespread vaccination also helps to ensure that preventable diseases are not spread throughout the population. As a result, being vaccinated not only protects the vaccine recipient, but also protects the members of his or her family, the community, and society at large.

Since 2003, the CDC has been working with researchers at universities and hospitals to estimate how successful certain vaccinations are at combatting illness. While no vaccine is 100 percent effective, the level of effectiveness for all CDC-recommended vaccines, also known as the vaccine effectiveness rating (or "VE") has been scientifically proven to be sufficient to make vaccination worthwhile. Each year, vaccines protect millions of people across the United States. In an effort to address many of the common concerns surrounding the decision of whether or not to vaccinate, the CDC discusses how vaccinations work to prevent illness and further explains:

"Statistically, the chances of your child getting diseases such as measles, pertussis, or another vaccine-preventable disease might be low, and your child might never need the protection vaccines offer. However, you don't want them to be lacking the protection vaccines provide if they ever do need it. . . . Think of it this way: You always make sure to buckle your child in his car seat even though you don't expect to be in an accident."

In other words, even if the risk of contracting a particular disease or illness may be low, the fact that there is *any risk at all* means that it is well worth the modest time and effort required to get vaccinated. Likewise, even if a particular vaccine is not rated as 100% effective, getting vaccinated (such as receiving the flu shot, or other vaccinations) can still significantly reduce the risk of you or your child missing time from school or work due to contracting an illness or disease that could easily have been prevented.

3. FACTS ABOUT THE FLU SHOT

Among all CDC-recommended vaccinations, no vaccine is administered to more people than the annual flu shot. For the 2019-2020 flu season, the CDC estimates that as many as 169 million Americans will receive influenza vaccinations. During the 2017-2018 flu season, the CDC estimates that the flu shot, "prevented an estimated 7.1 million influenza illnesses, 3.7 million influenza-associated medical visits, and 109,000 influenza-associated hospitalizations, and 8,000 influenza-associated deaths."

The specific formulation of the flu shot varies from year to year based on recommendations issued by the World Health Organization (WHO). In the United States, the U.S. Food and Drug Administration (FDA) has the final say on what specific formula will be used that year. All flu shots used in the U.S. are FDA-approved, and the CDC considers all formulations of the flu shot to carry relatively few risks for administration to the general population.

Some other notable facts about the annual flu shot include:

- The annual flu shot's vaccine effectiveness (VE) rating can vary significantly from one year to the next. It can also vary within a single year for recipients in different age groups. From 2009 through 2019, the annual flu shot had its lowest VE during the 2014-2015 flu season (19 percent), and the annual flu shot's overall VE peaked at 60 percent for 2010-2011.
- Some, but not all, flu shot formulations contain egg proteins. Egg allergies are among the mostcommon causes of anaphylactic reactions to immunizations. Adults and parents of children with egg allergies should request approved egg-free formulations, which may vary from year to year.
- Aside from giving due consideration to the risk of an allergic reaction and other potential adverse reactions to particular flu shot formulations, the CDC generally does not recommend one formulation of the flu shot over any other in any given year. The CDC encourages vaccination with, "any licensed age-appropriate influenza vaccine including inactivated influenza vaccine (IIV), recombinant influenza vaccine (RIV4) or live attenuated influenza vaccine (LAIV4)."

What Is Guillain-Barre Syndrome (GBS), and Can It Develop After Receiving A Flu Vaccine?

Along with the risk of an allergic reaction, one of the primary risks associated with the annual flu shot is the risk of developing Guillain-Barre Syndrome (GBS). GBS is an autoimmune disorder that causes the immune system to attack the nerve cells in the body, which can potentially lead to severe complications. Although rare, GBS (and its variants, such as chronic inflammatory demyelinating polyneuropathy (CIDP)) is a risk worth considering, and anyone who experiences symptoms of GBS following a flu shot should see a doctor promptly.

4. WHAT IS THE MMR VACCINE AND WHAT SHOULD I KNOW?

The measles, mumps and rubella (MMR) vaccine is a combination vaccine that the CDC recommends children receive by six years of age. Teens and adults who have not yet received two doses of the MMR vaccine should receive "catch-up" vaccines, according to the CDC. A relatively-new alternative to the MMR vaccine is the MMRV vaccine, which also protects against varicella (chickenpox). In the United States, MMR and MMRV vaccines are sold under the brand names M-M-R® II and ProQuad®, respectively.

For young children, the CDC recommends administration of the MMR vaccine in two doses, with the first dose being administered at age 12 to 15 months and the second dose being administered at four to six years of age. The CDC advises that parents and other adults should consult with their doctors prior to getting themselves or the children immunized with the MMR (or MMRV) vaccine if any of the following risk factors apply:

- Severe allergic reaction to a prior dose of the vaccine
- Pregnancy
- Weakened immune system due to a disease or medical treatment
- Family history of immune system problems
- Bruising or bleeding easily
- Recent receipt of a blood transfusion
- Tuberculosis
- Moderate illness

The CDC also states that individuals should wait at least four weeks after receiving any other vaccine before getting immunized against measles, mumps and rubella.

The MMR Vaccine and the Risk of ITP

One of the greatest risks associated with the measles, mumps, and rubella vaccination is the risk of developing idiopathic thrombocytopenic purpura, which is more commonly known as ITP. ITP is a rare blood disorder where blood platelet counts become very low which results in issues with blood clotting and can potentially lead to symptoms such as;

- Easy or excessive bruising
- Superficial bleeding (typically on the lower legs)
- Nose bleeds
- Blood in the stool or urine
- Unusually-heavy menstrual flow

Bleeding gums

Typical recovery time after receiving an MMR vaccine is four to five months; however, some individuals may experience chronic symptoms or relapses that can result after periods of having been asymptomatic.

5. AN OVERVIEW OF THE CHICKENPOX VACCINE

Approved by the FDA in 1995, the chickenpox vaccine has been extremely effective in reducing the number of children diagnosed with this potentially-dangerous disease. While chickenpox is most well-known for causing red blister-like rashes on the skin, it can have potentially-serious complications; and, as a result, fighting the disease through vaccination is extremely important. The CDC estimates that vaccination prevents approximately 3.5 million cases of chickenpox in the United States each year.

According to the CDC, two doses of the chickenpox vaccine are "more than 90% effective" in preventing the disease among vaccine recipients. Similar to MMR, the CDC recommends that children receive their first dose between the ages of 12 and 15 months and their second dose between the ages of four to six years. Older children and adults who have not received two doses of the vaccine can still be immunized; and, according to the CDC, "[t]he risk of getting chickenpox after two doses of chickenpox vaccine is lower than after only one dose of chickenpox vaccine."

The chickenpox vaccine is sold in the U.S. under the brand name Varivax® (or as the combination MMRV vaccine under the brand name ProQuad®). Adolescents and adults who are receiving "catch-up" chickenpox vaccines should receive two doses a minimum of four weeks apart; and, ideally, should receive their second dose within eight weeks of the first. Contradictions (risk factors) that may warrant not receiving the chickenpox vaccine include:

- Allergic reaction to gelatin or any other vaccine ingredient
- Blood dyscrasias, leukemia, lymphomas, or malignant neoplasms
- Primary or acquired immunodeficiency
- Prolonged, high-dose systemic immunosuppressive therapy
- Moderate to severe illness
- Receipt of whole blood, plasma or immune globulin within the previous three to 11 months
- Family history of immunodeficiency
- Pregnancy

Once again, these contradictions may or may not make it inadvisable to receive the vaccine, and anyone with questions about whether it is safe to receive the chickenpox vaccine should discuss the matter with their treating physician.



6. IDENTIFYING ROUTINE VS. UNUSUAL SIDE EFFECTS FROM VACCINES

Although considered safe for administration to the population at large, many vaccinations that are recommended by the CDC are associated with well-known side effects. In most cases, these side effects are minor, and should last no more than a couple of days (and in many cases no more than a couple of hours). However, some individuals who receive vaccinations will experience unusual side effects, and these side effects may be symptomatic of an illness or injury triggered by the vaccine.

As a result, understanding the common side effects of vaccines is important, and anyone who experiences unusual side effects should seek medical attention promptly.

What are Common Vaccine Side Effects?

Similar to the risk factors discussed in Chapter 1, the side effects of immunization vary from one vaccine to the next. A list of specific vaccine side effects can be found on the CDC's website. Some examples of potential side effects that are common among multiple CDC-recommended vaccines include:

• Minor pain at the injection sight

- Vomiting
- Redness or swelling at the injection site
- Slight fever

- Headaches
- Sore muscles, joints or body aches

Fatigue

Severe pain, severe swelling or bleeding, a fever above 102 degrees Fahrenheit, difficulty breathing, and seizures are rare, but are also among the more-common serious side effects that may signify the need for prompt medical attention.

What is Shoulder Injury Related to Vaccine Administration (SIRVA) and How Can I Avoid It?

For many individuals who receive vaccines, severe shoulder pain and limited mobility are signs of shoulder injury related to vaccine administration (SIRVA). SIRVA refers to traumatic physical injuries caused by errors that can occur during vaccine administration, such as use of an incorrect needle size, injecting a needle too high up on the shoulder, or inserting the needle at an incorrect depth or angle. SIRVA is often diagnosed as:

- Adhesive capsulitis (frozen shoulder)
- Brachial neuritis
- Shoulder bursitis
- Tendonitis

As a vaccine recipient, there are certain steps you can take to reduce your risk of developing SIRVA. These include exposing your entire shoulder rather than pulling down the collar of your shirt to receive the vaccine. Asking your vaccine provider if he or she is aware of the risks of SIRVA is recommended. You may also avoid SIRVA injuries by making sure that you and the vaccine administrator are at the same level during vaccination by ensuring that both parties are either standing or sitting. Ultimately, it is your provider's responsibility to administer your vaccine appropriately. Once the needle has been inserted, it may already be too late to prevent a potentially serious injury.

What Steps Should I Take If I Have Been Injured by a Vaccine?

If you have been injured by a vaccine, the most important step you can take is to see a doctor right away. SIRVA, GBS, and other common vaccine-related injuries and illnesses require prompt treatment, and any delay in seeking a diagnosis may prolong your recovery and increase your risk of complications.

In addition to seeing a doctor, it is also recommended that you speak with a vaccine attorney, as you may be entitled to financial compensation under the National Vaccine Injury Compensation Program (VICP).



7. WHAT ARE MY LEGAL RIGHTS REGARDING VACCINES?

The National Vaccine Injury Compensation Program (VICP) is a federal government program that provides no-fault compensation to individuals who have been diagnosed with vaccine-related illness or injuries. Eligible claimants can recover compensation for their medical expenses, loss of income, and pain and suffering.

While many types of vaccine-related illnesses such as SIRVA and GBS, are specifically listed as eligible medical conditions on the Vaccine Injury Compensation Program's Vaccine Injury Table , these are *not* the only conditions for which compensation is available. Although there are less steps involved in recovering compensation for so-called "on-table" injuries, it is often possible to recover compensation for "off-table" injuries as well.

Timeframes for Filing a VICP Claim

For individuals who believe they may be entitled to financial compensation under the VICP, there are two timeframes of which to be aware. The first is the amount of time that has occurred between an individual's receipt of the vaccination and the first onset of symptoms of their illness or injury. If symptoms do not onset within the timeframe prescribed by the Vaccine Injury Table, then the condition is not considered an "on-table" injury, which means that it may be more difficult (but certainly not impossible) to file a successful claim.

The second timeframe is the VICP's statute of limitations. In order to preserve one's eligibility for compensation, vaccine recipients must initiate their claims within three years of the first onset of symptoms. However, while vaccine recipients have up to three years to file a claim, upon being diagnosed with a vaccine-related illness or injury, it is generally advisable to begin working on your claim as soon as possible.

Proving Your Claim in the Vaccine Court

Although the VICP provides no-fault compensation for vaccine injuries, claimants must still prove their right to compensation in the U.S. Court of Federal Claims (which is also commonly known as the Vaccine Court). While this *may* mean going to trial, most successful claims are resolved via settlement negotiations between the claimant's attorney and attorneys from the U.S. Department of Justice who represent the Department of Health and Human Services which administers the Vaccine Program. Due to the complex substantive and procedural issues involved, it is highly recommended that VICP claimants hire a lawyer.

8. FREQUENTLY ASKED QUESTIONS (FAQS) ABOUT COMMON VACCINES

Q: Can all types of vaccines cause shoulder injury related to vaccine administration (SIRVA)?

Yes. Since SIRVA injuries result from errors that occur during administration of a vaccine, the specific vaccination being injected has no bearing on the vaccine recipient's risk of being injured.

Q: Can all types of vaccines cause Guillain-Barre Syndrome (GBS)?

To date, GBS has only been linked to the annual flu shot and vaccinations containing <u>tetanus</u> (DT, DTaP, DTP, Td and Tdap). Regarding the flu shot, no specific ingredients have been conclusively linked to GBS, and there have been reported cases of influenza-related GBS in each of the past several years.

Q: What are some examples of "on-table" injuries under the VICP?

Under the VICP, certain medical conditions are listed as "on-table" injuries for specific types of vaccines. Some examples of the most-common vaccine-related injuries listed on the Vaccine Injury Table include:

- GBS resulting from the flu shot
- Chronic arthritis resulting from the MMR or MMRV vaccine
- ITP resulting from the MMR or MMRV vaccine
- Encephalopathy, encephalitis and <u>ADEM</u> resulting from pertussis, measles, mumps and rubella vaccines
- Intussusception resulting from the rotavirus vaccine
- SIRVA which results following the receipt of any covered vaccine

Additionally, <u>anaphylaxis</u>, SIRVA and vasovagal syncope (sudden drop in heart rate and blood pressure) are listed as "on-table" injuries for many of the most-common CDC-recommended vaccines.

Q: Where Can I Learn More?

Visit the websites below for more information on vaccinations.

- FDA: <u>https://www.fda.gov/vaccines-blood-biologics/vaccines</u>
- CDC: <u>https://www.cdc.gov/vaccines/</u>
- Vaccine Glossary: <u>https://www.vaccines.gov/resources/glossary</u>
- Tear Free Vaccination Tips: <u>https://www.healthychildren.org/English/safety-</u> prevention/immunizations/Pages/Tear-Free-Vaccination-Tips.aspx
- IAC Vaccine Information: <u>https://vaccineinformation.org/</u>