A REPORT FROM
THE AMERICAN ACADEMY
OF MICROBIOLOGY

ADULT VACCINES: A GROWN UP THING TO DO

FAQ

AMERICAN
SOCIETY FOR
MICROBIOLOGY

FAQ

ABOUT ASM FAQs

The American Academy of Microbiology is the honorific branch of the American Society for Microbiology, a non-profit scientific society with almost 40,000 members. Fellows of the AAM have been elected by their peers in recognition of their outstanding contributions to the field of microbiology. Through its colloquium program, the AAM draws on the expertise of these fellows to address critical issues in microbiology.

FAQ reports are based on the deliberations of 15-20 expert scientists who gather for a day to develop science-based answers to questions the public might have about topics in microbiology. The reports are reviewed by all participants, and by outside experts, and every effort is made to ensure that the information is accurate and complete. However, the report is not intended to advocate any particular position or action, nor to replace the advice of an individual's health care provider.

The AAM does not offer medical advice and encourages consumers to be educated and informed when making medical decisions.

Contents of the report may be distributed further so long as the authorship of the AAM is acknowledged and this disclaimer is included.

1752 N Street, NW
Washington, DC 20036
www.asm.org

STEERING COMMITTEE:

Nicola Klein, M.D., Ph.D.
Kaiser Permanente, Vaccine Study Center

Michael N. Oxman, M.D.
Veterans Administration Medical Center

Stanley A. Plotkin, M.D.
Vaxconsult, LLC

Gregory A. Poland, M.D.
Mayo Clinic College of Medicine

Ann Reid
American Academy of Microbiology

Michael Ingerson-Mahar, Ph.D.
American Academy of Microbiology

PARTICIPANTS:

Roger Baxter, M.D.
Kaiser Permanente Vaccine Study Center

Michael D. Decker, M.D., Ph.D.
Sanofi Pasteur

Leonard Friedland, M.D.
GlaxoSmithKline

Stanley A. Gall, M.D.
University of Louisville, Department of Obstetrics, Gynecology and Women's Health

Hayley Gans, M.D.
Stanford University Medical Center

Pierce Gardner, M.D.
Stony Brook University School of Medicine

Kevin P. High, M.D.
Wake Forest University, Division of Infectious Disease

Wendy Keitel, M.D.
Baylor College of Medicine

Martin G. Myers, M.D.
Emeritus, University of Texas Medical Branch

Alison Naleway, Ph.D.
Kaiser Permanente Northwest, The Center for Health Research

Kristin L. Nichol, M.D.
University of Minnesota, Research Service (151)

Saad B. Omer, Ph.D.
Emory University, Schools of Public Health & Medicine and Emory Vaccine Center

Jason L. Schwartz, M.B.E., A.M.
University of Pennsylvania

Jonathan L. Temte, M.D., Ph.D.
University of Wisconsin School of Medicine and Public Health, Department of Family Medicine

Written by
Michael Ingerson-Mahar
and Ann Reid

The world around us is filled with tiny microorganisms called microbes. Most of them are harmless and many are even beneficial to us, but some microbes—called pathogens—are capable of making us sick. Our skin and mucous membranes keep a lot of these pathogens out while our immune system is responsible for fighting off those that get inside us. The human immune system has been ridding our bodies of pathogens for millions of years, but only in the last century have scientists learned enough to help give us an additional edge. Modern medicine has given us tools to aid our immune system in the fight against pathogens. Drugs like antibiotics help eliminate pathogens after they make us sick, but only vaccines are able to prepare our immune system so that many pathogens never make us sick in the first place. Despite their benefits, many people do not know how vaccines work, making some people uncomfortable and even mistrustful of vaccination. Also, many people may not realize that vaccines are not just for children; adults can benefit too! This document will tell you more about how vaccines work, why they are important, and how they can protect adults. Take some time and look it over—your immune system will thank you.

1. What are vaccines and how do they protect against disease?

A vaccine is a substance that teaches your immune system to recognize a pathogen, protecting you against a specific disease. To understand how this is possible, it is important to know a little bit about how the immune system works. The immune system can be summarized as a defense network inside the body that reacts to invasion by pathogens, microscopic organisms that can make us sick. Our immune system protects us by recognizing pathogens and creating special tools to attack and eliminate them. The next time you encounter that same pathogen, your immune system will remember it and fight it off more quickly. You may experience either very mild symptoms or none at all.

In essence, vaccines mimic that initial attack. They trick your immune system into thinking that you have been infected by a pathogen. Included in every vaccine is a component that "looks" like a specific pathogen to your immune system. The immune system analyzes the pathogen look-alike and learns to develop the tools needed to combat it. In most cases, special memory cells that are able to produce those tools persist in the body for a long time, sometimes even for life. If an exposure to the pathogen occurs after vaccination, the immune system already has, or knows how to build, the tools needed to fight it and can do so quickly. With a blueprint for fighting the pathogen in place, many pathogens will be killed or rendered harmless before they have a chance to make us sick. Vaccines protect against disease by preparing the immune system for a pathogen ahead of time. In this respect, vaccines are very "natural", because they simply educate the body's own infection fighting system.

BOX 1: The "parts list" of a vaccine

Vaccines are not magic concoctions. They are made up of only a few basic ingredients that each has a specific purpose or reason for inclusion.

Antigens

The primary component in any vaccine is called the antigen. The antigen is the "pathogen look-alike" that trains your immune system to develop tools to protect against that particular disease. You can think of the antigen as the "active ingredient" of the vaccine. There are two main types of vaccines defined by what type of material is used as the antigen: "live" vaccines and "not live" vaccines.

Live vaccines employ a live pathogen that has been weakened (or "attenuated") as an antigen. To prepare these types of antigens scientists isolate a pathogen and tame it in the laboratory to the **point** that it is no longer capable of causing disease. The weakened pathogen is then introduced to the body by way of the vaccine. In its weakened state the pathogen poses little threat to our body, but instead acts like a training dummy to teach the immune system how to fight the full-strength version of the pathogen.

Unlike live vaccines, "not live" vaccines employ either an entire killed pathogen or a small part of it as an antigen. Either way, it cannot cause disease on its own. When this antigen is introduced into the body by the vaccine, the immune system develops tools to recognize and destroy it. If, in the future, the body is exposed to the whole pathogen, the immune tools designed against the small part will recognize the little piece of the pathogen it was exposed to before and aggressively attack it, eliminating the whole pathogen. Some "not live" vaccines use a different strategy – they prepare the immune system to recognize the pathogen's worst weapons. Many pathogens produce powerful poisons, called toxins, that make us sick. Scientists can isolate these toxins and render them inactive in a laboratory. When these inactivated toxins are introduced into our body in a vaccine, the immune system creates tools to fight them. After vaccination, if the pathogen invades our body and produces that toxin, the immune system will already have the tools to fight the toxin and the pathogen will be without its primary weapon. Although these vaccines use slightly different tactics to boost the immune system they are all considered "not live" vaccines because they do not contain any live pathogen. "Not live" vaccines may also be referred to as "inactivated" vaccines, but don't be misled by the name; they are excellent at protecting against disease.

Adjuvants

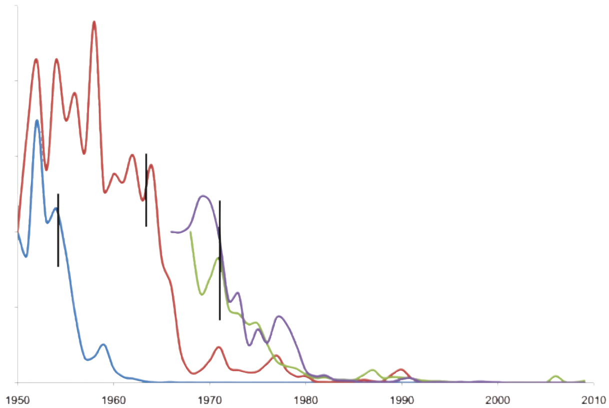
In some vaccines the antigen may be accompanied by another component called an adjuvant. Adjuvants are materials that increase the immune system's response to a vaccine. Sometimes the inclusion of adjuvants in a vaccine allows manufacturers to decrease the amount of antigen needed in each dose of the vaccine. Adjuvants like aluminum salts have been used in vaccines for over 70 years.

Preservatives

Vaccines may also contain preservatives, sometimes called stabilizers, to ensure that the vaccine remains effective and safe until it is ready to be used. Preservatives keep unwanted microbes out of vaccines. Most people are familiar with antibiotics, one commonly used preservative. Antibiotics help keep unwanted bacteria out of vaccines. Formaldehyde may also be used as a preservative in some vaccines. Low levels of formaldehyde are poisonous to microbes but safe for humans. In fact, small amounts of formaldehyde are produced and metabolized naturally by our bodies. Regulatory agencies carefully monitor the levels of formaldehyde in vaccines to be certain that they do not reach higher, harmful levels. Thimerosal (sometimes called thiomersal) was used as a preservative from the 1930's until 1999, when it was removed from almost all vaccines. Thimerosal contains mercury, and its inclusion in vaccines sparked fear among some members of the public. Although scientific studies by many independent groups showed that thimerosal was safe in the levels used in vaccines, its use was discontinued out of concern that fear of thimerosal would make people reluctant to get vaccinations. Compounds called stabilizers are also sometimes added to protect vaccines from the rigors of transport and make sure that vaccine components don't break down before the vaccine can be administered. Many stabilizers are sugars or amino acids, compounds that are part of our everyday diet. Glycine is one example of a stabilizer. It protects vaccines from damage from light, heat, and humidity.

Trace materials and fluids

Vaccines also contain trace amounts of residual compounds. These are mainly leftover ingredients from the manufacturing process. For example, the weakened pathogens used in some vaccines are grown in chicken eggs, so it is not uncommon to find trace amounts of egg protein in these vaccines. Any residual compound used in the production of the vaccine must be listed on the ingredients of a vaccine, even if the compound is below detectable levels. Fluids are added to vaccines so they can be given by injection or inhalation. Generally, vaccine ingredients are suspended in a mixture of water and salt, called saline.



Prevalence of polio (blue), measles (red), mumps (green), and rubella (purple) in the US from 1950-2009, the black lines indicate the introduction of a vaccine to protect against each disease.

BOX 2: Edward Jenner the "Father of Immunology" and the first vaccine

Edward Jenner was born in Gloucestershire, England in 1749, a time when smallpox still claimed the lives of millions of people in periodic epidemics and left millions more with characteristic scars, or pock-marks. As a young doctor Jenner became obsessed with finding a way to prevent the horrible disease. Strangely, the answer to his dilemma came from an unusual expression of the time—"smooth as a milkmaid's skin"—and the hands of a woman named Sarah Nelmes.

Nelmes claimed that she was immune to smallpox because she had contracted cowpox while working as a milkmaid. Normally a disease of cattle, cowpox could spread to humans that handled infected udders when milking cows. Human infections were usually very mild and confined to the hands, the area that was in contact with infected udders. In 1796, Jenner set out to test Nelmes' claim and determine if cowpox infection could protect against smallpox. He took material from a cowpox sore on Nelmes' hand and introduced it into the body of an eight year old boy, James Phipps. A few months later Jenner exposed Phipps to material taken from a fresh smallpox scab. Nelmes was right! Normally exposing the boy to smallpox would result in a reaction, if not the development of full-blown disease, but Phipps remained healthy, protected from the pathogen that caused smallpox.

While vaccine development has certainly come a long way since Jenner's time, many of the principles are unchanged. We know now that the pathogen that causes cowpox is very similar to the pathogen that causes smallpox in humans. When Jenner introduced the cowpox pathogen into Phipps his immune system developed tools to fight it. So the cowpox virus acted as the antigen in the vaccine. Because of the similarity between the cowpox and smallpox viruses, when Phipps was later exposed to the smallpox pathogen his immune system already had tools to fight it off.

Jenner's process was used to protect multitudes of people against smallpox, saving millions of lives around the world, and jump-starting the field of immunology. In fact, the name "vaccine" dates back to Jenner's discovery. In Jenner's honor, Louis Pasteur coined the term vaccine from *vaccinia*, the name of the pathogen that causes cowpox. Interestingly, Jenner's discovery explained why milkmaids' skin was so smooth – their on-the-job exposure to *vaccinia* protected them from smallpox, so milkmaids rarely suffered pockmark scars from smallpox infections!

2. Why do we need vaccines?

Disease	Average U.S. Cases (per year 20th century) Pre-vaccine	2010	% Decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	0	100%
Whooping cough	200,752	21,291	89%
Tetanus	580	8	99%
Polio	16,316	0	100%
Measles	530,217	61	>99%
Mumps	162,344	2,528	98%
Rubella (German Measles)	47,745	6	>99%

If you are younger than 50, you never had to worry about polio or smallpox. Because these diseases and others like them have been effectively eliminated from the United States, we often take our increased life-span and relatively epidemic-free world for granted. The world without vaccination was very different. The past offers insight into the harsh reality of a world without vaccines. Parents watched helplessly as their children were paralyzed by polio. Smallpox killed millions and left millions more with grotesquely disfiguring smallpox scars. Diphtheria and whooping cough were major causes of death among children. These diseases and others like them were horrific but unavoidable before vaccines were introduced.

Vaccines give our immune system the opportunity to develop the tools to fight off a pathogen without having to suffer the disease caused by the pathogen itself. In this way vaccines are incredibly important to every individual's health. There are still diseases, like polio or measles, for which we have few treatment options. In these cases the vaccine is the best, and sometimes only, option for dealing with the disease.

Vaccines also save us money. Every year illness imposes substantial costs in the form of doctors' visits, prescription drugs, and hospitalizations. Caring for ailing individuals can place significant demands on their families and friends. When illness is prevented by vaccination, it saves money and the burden of sick days and days spent at home caring for loved ones.

The benefits of vaccination are not limited to your own health, but extend to those around you. Infectious diseases are transmitted from one person to another, so individuals are like links in a chain. Every vaccination breaks another link, helping to protect those who cannot be vaccinated themselves. In this way vaccination of one person protects those around them from

BOX 3: The eradication of smallpox: a vaccine triumph

Smallpox was a devastating disease caused by the viruses *Variola major* and *Variola minor* that plagued humans for thousands of years; indeed smallpox scars were found on an Egyptian mummy dating back to 10,000 BC. Characterized by the formation of raised pustules all over the body, the disease was as deadly as it was grotesque; *Variola major* killed about 30% of those that it infected.[1] Those that survived infection were often left scarred and sometimes even blinded. The loss of life exacted by smallpox was astronomical; the World Health Organization (WHO) estimated that smallpox was responsible for the deaths of nearly 500 million people in the 20th century alone. Edward Jenner developed his smallpox vaccine in 1796, but even in the mid-1900's vaccination levels were not high enough to halt the spread of the viruses and there was no effective treatment for smallpox once contracted. Doctors in the mid-20th century were nearly as powerless to halt an infection as the ancient Egyptians.

The *Variola* viruses had one critical weakness—they could only reproduce in humans. If enough people were immune to the viruses, they would have no home, no way to replicate and smallpox would disappear forever. With the goal of eradication in mind, public health officials from the WHO and other public health organizations spearheaded massive worldwide smallpox vaccination programs in the mid 1900's. The last naturally occurring case of smallpox was recorded on October 26, 1977. The protective power of the vaccine and the diligence of public health workers had paid off; the 12,000 year reign of smallpox was finally ended. The greatest triumph of vaccination, the global eradication of smallpox, was announced by the scientific community in 1979. Since that time people have lived free of the fear of the devastating disease.

disease, including their loved ones, co-workers, and their community. No vaccine offers perfect protection. The more often you are exposed to in infectious disease, the more likely you are to become infected. When others around you are vaccinated, you are less likely to be exposed. This indirect protection, known as herd protection, relies on high vaccination rates and is particularly important for the very young and very old. Even though they are the most vulnerable to disease, these people often cannot receive recommended vaccines because they have a weakened or immature immune system. Their protection depends on others. Another important aspect of herd protection is that unlike the U.S., some parts of the world do not have the resources to vaccinate; in these countries the diseases of our past are still the diseases of their present. Terrible infectious diseases like diphtheria, measles, and polio are only a short plane flight away from the U.S. These diseases are not gone from the world; they are simply prevented from spreading in the U.S. by high vaccination rates. There have been many studies showing that if vaccines were discontinued, pre-vaccine conditions would quickly return. Choosing not to be vaccinated also affects those around you. Even if you have no symptoms you can still act as a carrier of a disease and can infect others around you. This puts the elderly, people with weakened immune systems, and very young infants at risk and is why medical personnel and care givers are so strongly encouraged to be vaccinated. Many doctors' offices, especially those that treat infants, are now asking parents before office or emergency room visits to inform them about their child's immunization status, in order to protect their other vulnerable patients from potential exposure to the pathogens that unvaccinated people could be carrying.

3. Aren't vaccines only for children? How about adults? Is it too late to get vaccinated?

Vaccines are for everyone, not just children. In fact, there are some vaccines that are specifically recommended for adults. These "adult" vaccines protect against diseases that are more common in adults than children.

For example, shingles is a disease caused by the same pathogen as chickenpox. The pathogen hides in nerve cells for years and can reemerge in older adults to cause shingles, so anyone who has ever had chickenpox is at risk. However, because shingles is rare in children the vaccine is generally only recommended for adults. Some vaccines protect against diseases that can be more serious when contracted by adults. Adults who develop chickenpox are more likely to suffer from serious complications, including pneumonia. Arthritis and inflammation of the brain are rare complications of measles in children, but for unknown reasons are much more common in adults suffering from measles. So if you were not vaccinated against measles in childhood, it is important to get the vaccine as an adult. Other adult vaccines may actually be boosters of vaccines that you received as a child. Although the immune system uses memory cells to "remember" how to build the tools to fight a pathogen, over time this memory can fade. Booster vaccines "refresh" the immune system's memory, so that it can continue to provide protection against the disease.

The influenza vaccine (flu vaccine) is available for both adults and children and is recommended to be given once a year. In this case, it's not that our immune system forgets how to fight the influenza virus; rather, the virus can change from year to year so we have to retrain our immune system to fight it. Each year's influenza vaccine may contain different antigens from the previous year's vaccine. The new antigens are specially customized to train the immune system to fight this year's influenza viruses.

BOX 4: Is there anyone that should not receive vaccines?

The benefits of vaccines vastly outweigh the risks for almost everyone. But there are a few notable exceptions. Anyone who is allergic to any component of a vaccine, or has had a serious adverse reaction after vaccination or anyone that is immune compromised should speak with a physician before being vaccinated.

Pregnancy is a particularly important time for vaccination; however women who are pregnant should not receive "live" vaccines, but may receive "non-live" vaccines. Two vaccines, influenza and combination tetanus with whooping cough vaccine are specifically recommended for pregnant women. Other "non-live" vaccines such as pneumococcal vaccine and hepatitis vaccines can be recommended if certain risk indications are present. Pregnant women should consult with a physician regarding these vaccines.

Keeping up-to-date on vaccinations as an adult can help you avoid contracting many of these diseases to begin with. No one likes suffering from influenza, and it can be very serious especially for the elderly, but it is just one disease that adult vaccines can protect against. Shingles and whooping cough vaccines are two other examples of vaccines that can save you a lot of misery. Shingles is characterized by an extremely painful rash, particularly in older people. Severe cases of shingles can result in permanent nerve damage, pain, and even blindness. Whooping cough has been described as the "hundred day cough" and sometimes can cause coughing fits so powerful that they result in broken ribs. Getting vaccinated reduces your risk of getting shingles, measles, whooping cough, or influenza. To put

BOX 5: Scientists play "Cat and Mouse" with influenza

The influenza vaccine stands out from other adult vaccines as it is recommended to be given annually. But what makes it special? The answer actually lies not in the vaccine, but in the nature of the pathogen that causes the "flu"—the influenza virus.

Influenza is not a single virus; there is a whole family of influenza viruses. Although all the influenza viruses are closely related, they look very different to our immune system, and the tools that it builds to defeat one type of influenza virus may not work against another. To make matters worse individual members of the influenza virus family change how they appear over time, so the tools developed against one member of the influenza virus family may not work against it the following year. Most flu seasons there are one or two main types of influenza virus causing infections in the U.S., but because vaccine production takes a few months, scientists must guess ahead of time which viruses will dominate each year. Most of the time the scientists are right and the vaccine for the year protects well against influenza, other times the virus changes in unexpected ways and the vaccine is less effective. This is why the influenza vaccine offers better protection some years than others.

Health professionals agree that even partial protection from influenza through vaccination is far better than no protection at all. Although many people think of influenza as just a nuisance, it can be far more serious. Most years, 5,000 to 40,000 people, generally older adults, die of influenza.[2] Some years are far worse; the infamous 1918 influenza outbreak killed over 50 million people worldwide.[3] While scientists generally think that a recurrence of such a deadly influenza is unlikely (due to better nutrition and health, availability of antibiotics to treat complications, and greater understanding of the virus), the annual vaccine still represents your best chance at dodging influenza. Flu shots, and the influenza vaccine delivered by nasal spray, are widely available, and scientists agree that the benefits, even if they are uncertain in any given year, far outweigh the risks.

So will this game of cat and mouse ever end? As scientists learn more about the influenza virus they are becoming better at correctly predicting which types will emerge each year. New vaccine production techniques are reducing the amount of time it takes to make a new vaccine so that the prediction of what influenza virus will be circulating doesn't have to be made so early. Scientists are also working on new vaccines that will better protect against more, or even all, types of influenza viruses. While scientists differ in their opinion on whether there will ever be a "universal" influenza vaccine that protects against all types of influenza, we can still hope that one day the yearly cat and mouse game we play with influenza will be put to rest.

that risk in perspective, every year in the United States over 40,000 adults die from diseases against which they could have been vaccinated.

This number is particularly saddening because adult vaccines are so effective in protecting against these diseases. It's true that some vaccines are more effective than others. The type of vaccine, the age of the recipient, and other factors can all alter the effectiveness of a vaccine. But even if a vaccine is not 100% effective at protecting you from contracting the disease, it is likely to lessen the severity of the symptoms associated with the disease. The shingles vaccine is an excellent example; although some adults who have been immunized against shingles may still develop the disease, their symptoms are typically milder than those who were not vaccinated.

Although it is generally never too late to be vaccinated, most vaccines are designed to be given at specific times. The Centers for Disease Control and Prevention (CDC) maintains an adult immunization schedule with vaccine recommendations for adults based on age, occupation, and other risk factors. New vaccines are constantly being developed. The CDC adult immunization schedule website (http://www.cdc.gov/vaccines/recs/schedules/downloads/adult/mmwr-adult-schedule.pdf) and your doctor are great references to stay up-to-date on what vaccines are available for adults and when they are recommended.

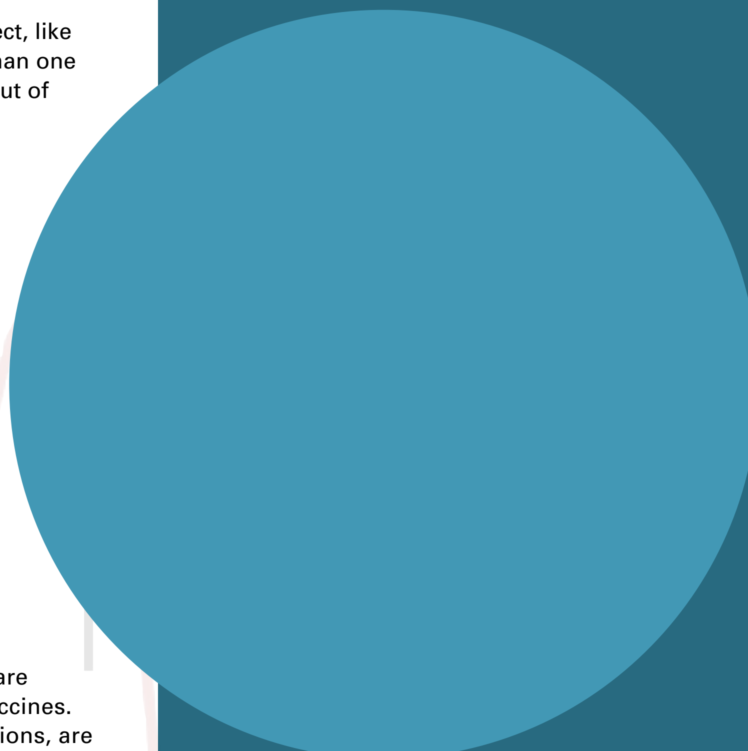
4. Are vaccines safe? How do we know this?

In short, vaccines are extremely safe.

The chance of experiencing a serious side effect, like an allergic reaction, after vaccination is less than one in a million. That means that 999,999 people out of a 1,000,000 do not suffer any serious adverse effects after vaccination.[4] To put this into perspective, it is nearly as likely for someone to suffer a severe allergic reaction to aspirin as to a vaccine.[5, 6]

Vaccines are always safer than contracting the diseases that they are designed to protect against, but to say that vaccines are completely harmless is not true. Everything in life carries some risk, even ordinary daily activities. For example, in the U.S. each year 350 people die from shower or bathtub related injuries, 200 choke to death while eating, and 100 are struck and killed by lightning while outside during a storm.[7] Vaccines can cause side effects, but most are short-lived and result in only very mild discomfort. Redness and some swelling around the injection site are some of the more common side effects of vaccines. Serious side effects, like severe allergic reactions, are exceedingly rare, far less common than serious slips and falls in the shower.

So why do some people cringe at the thought of vaccination and not at showering? The answer lies in how we perceive risk. People are less comfortable accepting risks with unfamiliar benefits—even if those benefits are great. The benefits of showering are very familiar and well worth the risk of a fall. The benefits of protection against a disease that most people have not experienced or even observed first hand are less familiar. In this regard vaccines can be thought of as a victim of their own success. Because vaccines protect us from these diseases, many people are not familiar with how horrific the diseases truly are.



If the blue circle represents everyone who received a vaccine, then the black point in the center represents the people that would experience a severe allergic reaction to the vaccine. Can't see the black point? It's actually too small to print, but even if it could be printed you would need a very powerful microscope to see it.

BOX 6: How VAERS works – your role in monitoring vaccine safety

Ensuring the safety of vaccines is a group effort. Public and private researchers and scientists, the FDA, and the CDC are just a few of the groups that work to make sure vaccines are safe. The **Vaccine Adverse Event Reporting System (VAERS)** allows you to play a role in the process too. Researchers use VAERS to track adverse health events experienced by individuals after vaccination. These adverse events may be caused by the vaccine (vaccine side effects) or they just may be events that happened by coincidence around the same time as the vaccine was given. If you experience an adverse event following a vaccination you should report it to VAERS (http://vaers.hhs.gov/index). Each report, called an anecdote, is reviewed by VAERS researchers. Because side effects after vaccination are so rare, separating chance events from vaccine side effects requires review of many, many anecdotes and, often the conducting of additional studies. Every report logged in the system gives researchers a little more information and allows them to make better decisions on the safety of vaccines.

FROM CONCEPT TO LICENSING – THE LIFE HISTORY OF A VACCINE

That vaccines are so safe is no accident. To understand this, it is helpful to consider the path a potential vaccine must take to be approved for use.

From their beginning as a twinkle in a researcher's eye to being stocked in your local physician's office, vaccines may be the most heavily scrutinized of all manmade goods. A new vaccine's first challenge is the manufacturers' own in-house tests. New vaccines must pass laboratory and animal tests meant to demonstrate their safety and effectiveness. If these tests are a success the company can submit a request to the Food and Drug Administration (FDA) to begin human testing.

The FDA carefully reviews all the preliminary data submitted by the drug company and if those data are satisfactory authorizes human clinical trials of a vaccine in three phases. Phase I trials typically include 20-100 volunteers and test the vaccine for any serious side effects; phase II trials involve hundreds of volunteers to optimize vaccine dosing; finally phase III trials consist of anywhere from hundreds to many thousands of volunteers who test the vaccine for safety and effectiveness. During the final phases of clinical trials, FDA employees also inspect the manufacturing process and production facilities for the vaccine. Additional periodic inspections are conducted by the FDA even after a vaccine is licensed to ensure that the manufacturing process has remained the same. The three phases of clinical trials and inspection can take many years to complete, and if at any point in the trials the safety or effectiveness of the vaccine is called into question the FDA can halt testing.

If a vaccine successfully makes it through all three human trial stages, the manufacturer can submit an application for a license for the vaccine. At this stage, a diverse group of experts from the FDA reviews all the data collected. The FDA may also ask a group of non-FDA experts to review the data. During this time the results of the clinical trials are also published and made available for review by the entire scientific and medical communities. Finally, the FDA will decide whether to license the vaccine, request that more studies be done, or deny the license. Because of this

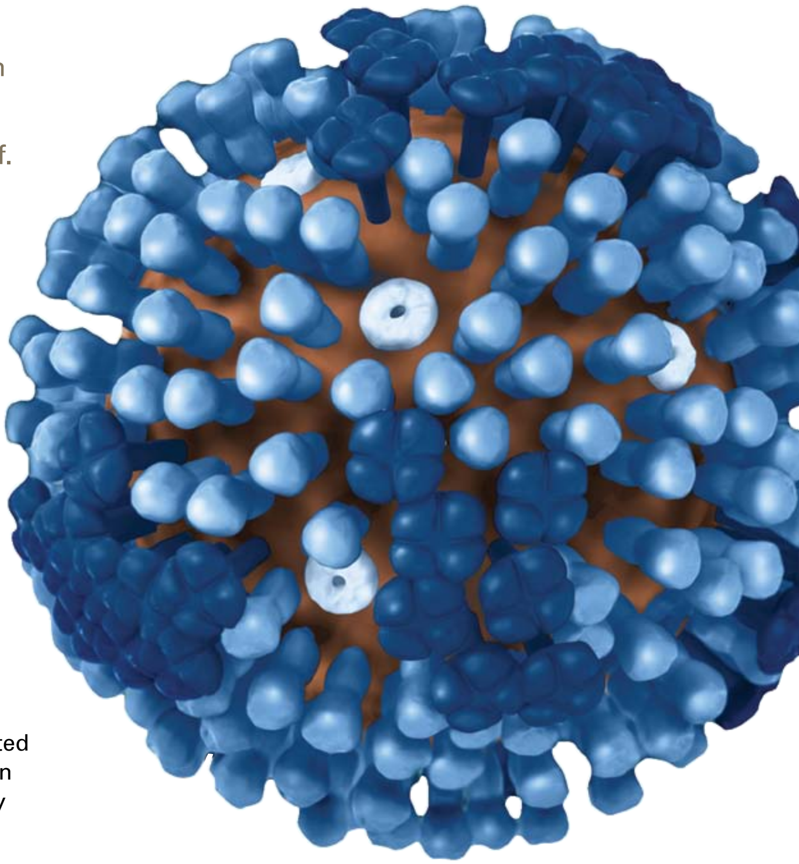
rigorous process of review only the safest and most effective vaccines are approved.

Even after it has been licensed, a vaccine continues to be closely scrutinized. In the U.S. there are a number of parallel systems in place to monitor the safety and effectiveness of vaccines. The CDC and the FDA both monitor vaccine safety through the Vaccine Adverse Event Reporting System (VAERS). VAERS is a tool that physicians, patients, and caregivers can use to report adverse events that occur after a person is vaccinated. The system captures all adverse events that are reported to it, and the CDC and FDA monitor the reports for any suspicious trends that might point to a rare but serious vaccine side effect. Other vaccine safety monitoring services include the Vaccine Safety Datalink (VSD) project and the Clinical Immunization Safety Assessment (CISA) network. The VSD project is a collaboration among ten large health care providers. The Datalink tracks health records on over 9 million individuals and provides this information to the CDC, FDA, and scientists to compare health risks between vaccinated and unvaccinated individuals. The Clinical Immunization Safety Assessment (CISA) network is a group of six academic medical centers that specialize in evaluating the safety and efficacy of vaccines. CISA conducts clinical research to monitor for and study any adverse effects after vaccination.

RECOMMENDING A VACCINE FOR USE

The CDC maintains recommended vaccination schedules for both adults and children. Only after a vaccine has gone through the lengthy licensure process can it become eligible to be included in the recommended schedule of vaccines. The CDC is advised on vaccine recommendation decisions by the Advisory Committee on Immunization Practices (ACIP), a diverse group of physicians, scientists, public health officials, and consumer advocates. The ACIP was established in 1964 by the U.S. Surgeon General to consider the large number of vaccines that were being developed at the time and it has been in service ever since. It is made up of 15 voting members and 30 nonvoting liaisons from different government agencies and professional associations like the American Medical Association and the American Academy of Family Physicians. Voting members are experts in their fields who are free of conflicting ties to vaccine manufacturers or individual vaccines. Despite their extensive expertise ACIP voting members work on a volunteer basis; they are not paid nor do they receive any financial benefits for their work on the committee. In an effort to be transparent, all of the meetings of the committee are open to the public and available for viewing live in real time on the internet. After each meeting the minutes are also made available online. ACIP recommendations are the cornerstone of the CDC's recommended immunization schedules.

5. Can vaccines give you the disease that they are designed to protect against?



Sometimes, so called "live vaccines" contain a weakened pathogen and can cause you to develop a very mild form of the disease itself. This is an intended part of the vaccination process. The yellow fever, varicella (chickenpox), smallpox, typhoid, and measles-mumps-rubella (MMR) vaccines are examples of live vaccines that may cause an extremely mild form of the disease. In these cases, it is worth a little discomfort to train your immune system to fight the pathogens responsible for these diseases because the benefits far outweigh the temporary inconvenience.

Very rarely, when administered to someone whose immune system is severely weakened, the attenuated pathogen contained in the live vaccine can cause an infection similar to the natural infection. This is why anyone with a weakened immune system should consult a physician before receiving any vaccine.

"Not live" vaccines will never cause the disease, even a mild case, because they do not contain live disease-causing pathogen. For example, the inactivated influenza shot is a "not live" vaccine and thus cannot give you influenza. So why do some people come down with flu-like symptoms after vaccination? Influenza vaccines are generally given during "flu season" which is prime time for all sorts of viruses that cause upper respiratory infections. Influenza vaccines only protect you from the influenza virus, not the dozens of other viruses that can cause similar, but generally much milder symptoms. So, there's a reasonable chance of getting a cold or some other "flu-like" illness soon after getting the influenza vaccine. It doesn't help that we call so many illnesses "the flu" that aren't caused by the influenza virus. For example, there is absolutely no relationship between what most of us call the "stomach flu" and influenza virus. Intestinal upsets are caused by an entirely different set of viruses, so the influenza vaccine will not protect you against "stomach flu".

One additional point to note is that mild side effects of the vaccine should not be confused with symptoms of a disease. It is not uncommon to experience a slight fever, fatigue, and aches after receiving a vaccine. These side effects are an indication that the immune system is responding to the vaccine, not symptoms of the disease itself. Vaccines have protected people well enough that many people have not seen first-hand symptoms of many of these diseases so the confusion is understandable. In almost every case these side effects of the vaccine pale in comparison to the symptoms of the disease itself.

Getting vaccinated is a very safe and effective choice that any adult can make to help ensure his or her health and the health of those around them. Vaccine recommendations are based on the best science regarding safety, personal health, and the health of the public. Vaccines have saved millions of lives and are perhaps the single greatest development in the war against disease since the separation of sewage from drinking water. While the diseases that they protect against may not be familiar to us in the U.S., they are still present, often only a short plane ride away. Vaccines offer the best, and sometimes only, line of protection from these diseases. The fact that we do not worry about these diseases is a testament to the tremendous success of vaccine in the past. The future of vaccines is bright; each year scientists formulate more innovative and effective vaccines. There are already vaccines that can help protect against certain types of cancer and more are under development now. Scientists are also working on new vaccines that could in time protect against killers like malaria, tuberculosis, and HIV. Their efforts will help ensure that vaccines will save millions more lives in the future.

Learning more about adult vaccination

This document is meant to be a primer to understanding how vaccines work and why they are important, but there is much more to learn. The best information on vaccination comes from the experts studying them. If you would like to learn more about vaccines you can turn to any of the sources listed below. They will provide reliable information, checked by scientists and researchers for accuracy.

Centers for Disease Control and Prevention (CDC)
www.cdc.gov/vaccines

CDC Adult Immunization Schedule
www.cdc.gov/vaccines/recs/schedules/downloads/adult/mmwr-adult-schedule.pdf

National Network of Immunization Information (NNii)
www.immunizationinfo.org

The Immunization Action Coalition (IAC)
www.immunize.org

The College of Physicians of Philadelphia
offers information about vaccine concepts and history
www.historyofvaccines.org

Johns Hopkins Institute for Vaccine Safety
www.vaccinesafety.edu

References

[1] Behbehani AM. The smallpox story: life and death of an old disease. *Microbiol Rev* 1983; 47 (4): 455–509.

[2] Centers for Disease Control and Prevention. MMWR. 08/08/2008.

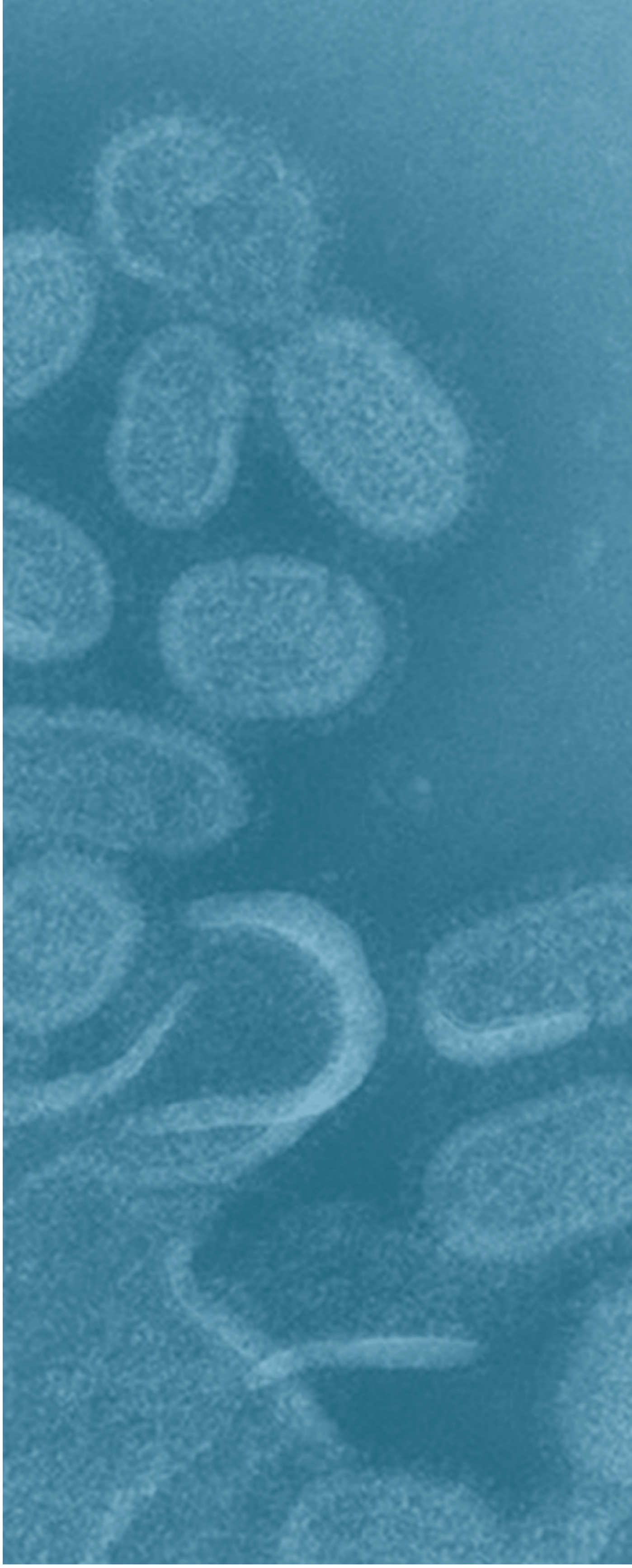
[3] Taubenberger JK and Morens DM. 1918 Influenza: the Mother of All Pandemics. CDC. 2006.

[4] Myers M. and Pineda D. Do Vaccines Cause That?!: A Guide for Evaluating Vaccine Safety Concerns. Immunizations for Public Health 2008; 18–19.

[5] Kemp SF, Lockey RF, Wolf BL, Lieberman P. Anaphylaxis. A review of 266 cases. *Arch Intern Med.* 1995; 155: 1749–1754.

[6] Simons FE, *et al.* "World Allergy Organization survey on global availability of essentials for the assessment and management of anaphylaxis by allergy-immunology specialists in health care settings". *Annals of allergy, asthma & immunology* 2010; 104 (5): 405–412.

[7] Statistics derived from National Safety Council's Data on Accidents in the year 2000. Accessed at: http://danger.mongabay.com/injury_odds.htm.



FAQ

THIS REPORT WAS DESIGNED BY
PENSARÉ DESIGN GROUP
WWW.PENSAREDESIGN.COM