
Understanding Vaccine Safety



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Understanding Vaccine Safety

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Understanding Vaccine Safety

Immunization Remains Our Best Defense Against Deadly Disease by Michelle Meadows

Smallpox and polio have been wiped out in the United States. Cases of measles, mumps, tetanus, whooping cough (pertussis) and other life-threatening illnesses have been reduced by more than 95 percent. Immunization against influenza and pneumonia prevent tens of thousands of deaths annually among elderly persons and those who are chronically ill. As a result, millions of lives have been saved. But don't let the success of vaccines fool you into thinking we no longer need them. Most vaccine-preventable diseases aren't gone.

Steve Berman, M.D., president of the American Academy of Pediatrics and a pediatrician in Denver, says he and his colleagues were devastated to recently see an infant die of whooping cough. "This was a case where the family thought the risks of vaccination outweighed the benefits," Dr. Berman says. The baby was exposed to the disease by two older brothers who hadn't been vaccinated.



Vaccines contain a weakened (attenuated) or killed (inactivated) form of disease-causing bacteria or viruses, or components of these microorganisms, that trigger a response by our body's immune system. For example, vaccines stimulate our bodies to make antibodies--proteins that specifically recognize and target the bacteria and viruses against which the vaccines are designed, and that help eliminate them from the body when we encounter them.

Without vaccine protection, we can easily contract and transmit infectious diseases. It may only take one person, whether it's a family member, a neighbor, or a visitor from another country, to start the spread of a disease.

And

even immunized individuals can be at risk because no vaccine is ever 100 percent effective for everyone.

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- Do I Have Arthritis
- Questions and Answers About Juvenile Rheumatoid Arthritis
- Stories of Depression

Recommended Childhood Immunization Schedule United States, January-December 2001												
Vaccine	Birth	1 Month	2 Months	4 Months	5 Months	12 Months	15 Months	18 Months	24 Months	4-6 Years	11-12 Years	14-18 Years
Hepatitis B		1st dose	2nd dose			3rd dose					Catch up	
Diphtheria Tetanus Pertussis			1st dose	2nd dose	3rd dose		4th dose	4th dose		5th dose	Tetanus + Diphtheria	
H. Influenza type b			1st dose	2nd dose	3rd dose	4th dose						
Inactivated Polio			1st dose	2nd dose		3rd dose				4th dose		
Pneumococcal Conjugate			1st dose	2nd dose	3rd dose	4th dose						
Measles Mumps Rubella						1st dose				2nd dose	Catch up	
Varicella Chickenpox						1 dose					Catch up	
Hepatitis A										1 dose [In selected areas]		

Source: The Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP).



(See "Recommended Childhood Immunization Schedule, United States, January-December 2001.)

Most parents believe in the benefits of vaccination, as evidenced by record high childhood vaccination rates, and more and more adults are getting vaccinated against influenza, pneumococcal disease, and tetanus. But some people who need vaccines don't get them for a variety of reasons, including fear of side effects. Lately, a surge of negative publicity focusing on the risks of vaccines--some of which are unproven or inaccurate--has some wondering whether they do more harm than good. But vaccine experts and the overwhelming majority of health-care providers caution consumers against skipping important vaccinations because of an evening news report or a posting on the Internet.

Sometimes such reports contain unsubstantiated or inaccurate information and don't reflect a balanced view of the risks and benefits of a particular vaccine.

The Food and Drug Administration recommends that consumers arm themselves with the facts about the

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- Rheumatoid Arthritis
- Over-the-Counter Medicines: What's Right for You?
- Facts About Anxiety Disorders
- Arthritis: Timely Treatments for an Ageless Disease
- Think It Through: A Guide to Managing the Benefits and Risks of Medicines
- Questions & Answers About Arthritis and Exercise
- Bone Marrow Transplants Come of Age
- Facts About Breast Cancer and Mammograms
- Vision Correction: Taking a Look at What's New
- Boning Up on Osteoporosis
- Questions and Answers About Arthritis and Rheumatic Diseases



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- Losing Weight: More Than Counting Calories
 - Atopic Dermatitis
 - Controlling Asthma
 - Do I Have Lupus?
 - Questions & Answers About Acne
 - Questions & Answers About Rosacea
 - Questions & Answers About Reactive Arthritis
 - Prostate Cancer: No One Answer for Testing or Treatment
 - Osteoarthritis
 - Taking Charge of Menopause
 - Questions and Answers About Scoliosis in Children and Adolescents
 - New Over-the-Counter Medicine Label...Take a Look!
 - Questions & Answers About Gout

benefits and risks of vaccines, along with the potential consequences of not vaccinating themselves against certain diseases. According to a Washington state-based organization called **Parents of Kids with Infectious Diseases (PKIDS)**, some parents are shocked to learn that children can die of chickenpox and other vaccine-preventable diseases they hadn't considered a threat.

The FDA's Center for Biologics Evaluation and Research (CBER) regulates vaccines in the United States, and works with several other agencies, including the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), to study and monitor vaccine safety and effectiveness. New vaccines are licensed only after the FDA thoroughly reviews the results of extensive laboratory studies and clinical trials performed by scientists, physicians, and manufacturers.

For vaccines intended for wide use in healthy populations such as children, clinical testing with careful safety monitoring typically involves thousands of patients before a vaccine is ever licensed. And after a vaccine hits the market, the safety monitoring continues, as does FDA oversight to assure the highest levels of quality control in the vaccine production process.



"We are always monitoring for evidence that might suggest possible problems with vaccines," says Karen Midthun, M.D., director of CBER's office of vaccine research and review. CBER scientists also conduct research to better ensure vaccine safety and to better understand vaccine-related side effects.

A Commitment to Safety

On the surface, it may seem that approaching vaccine safety as a continuous process--always looking into problems and potential problems--implies that vaccines are unsafe, "but it's actually a reflection of our ongoing commitment to safety, and assures the prevention of potentially lethal infectious diseases," says Jesse Goodman, M.D., M.P.H., deputy director for medicine at CBER. "It's also the nature of science to seek and implement improvements which make for safer and more effective medical products."

Since 1996, for example, CBER has licensed several acellular pertussis vaccines. Acellular pertussis vaccines use only parts of the disease-causing bacteria and are

- Understanding Vaccine Safety
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- Aspirin for Reducing Your Risk of Heart Attack and Stroke: Know the Facts
- Breathing Better: Action Plans Keep Asthma in Check
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- Questions & Answers About Arthritis Pain
- Fitness and Exercise
- Medications and Older Adults
- Take Time to Care...About Diabetes
- What to Do When a Friend is Depressed
- Keeping an Eye on Contact Lenses
- My Medicines



Available Publications

- An Aspirin A Day...Just Another Cliche?
- Beat the Winter Bugs: How to Hold Your Own Against Colds and Flu
- Brain Basics: Preventing Strokes
- Emerging Trends in Medical Device Technology: Home Is Where the Heart Monitor Is
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- Let's Talk About Depression
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- Your Rights After a Mastectomy
- Protect Your Drinking Water
- Catch the Spirit

associated with fewer side effects than the whole cell pertussis vaccines that had been in use. In 1997, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended a switch from using the whole cell pertussis component of the diphtheria, tetanus, pertussis (DTP) vaccine to using acellular pertussis vaccines for all five doses in the childhood schedule (see "Recommended Childhood Immunization Schedule").

The National Institute of Allergy and Infectious Diseases (NIAID) sponsored clinical trials for some of the experimental acellular vaccines. "We set out to develop an improved vaccine that would be as effective as the standard whole cell vaccine but cause less extended crying, fevers, and other side effects," says Carole Heilman, Ph.D., director of NIAID's division of microbiology and infectious diseases. CBER scientists also played a critical role by developing methods to evaluate the acellular vaccines, which helped them get to clinical trials faster.

There have been other recent policy changes to improve vaccine safety, including ACIP's 1999 recommendation to change from the use of oral polio vaccine (OPV) to the inactivated polio virus (IPV). OPV had



been highly effective in controlling naturally occurring polio outbreaks, preventing thousands of cases of paralysis a year. But as a live virus, it mutated in extremely rare cases to cause polio itself. Continued use of OPV resulted in about 10 cases of paralytic polio each year among millions vaccinated and their contacts, according to William Egan, Ph.D., deputy director of CBER's office of vaccine research and review. Switching to the use of IPV eliminated this risk and was appropriate once epidemic polio was controlled.

"There are times when we also take action even when there is just the theoretical potential for harm," Goodman says. Thimerosal, a mercury-containing compound, had been the most widely used preservative in vaccines. Its use in minute amounts helped to prevent bacteria from contaminating multi-dose vials of vaccines and other medicines, protecting against potentially serious infections. But thimerosal has been nearly eliminated from vaccines because of legitimate and growing scientific concerns about the possible effects of mercury on the nervous system, Goodman says.

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"In addition, as the numbers of vaccines used in children have increased, small infants who received every recommended vaccine could be exposed to cumulative doses of mercury that exceeded some, but not all, federal guidelines," Goodman explains.

Even though there are no convincing data that show the harm of including thimerosal in vaccines, the U.S. Public Health Service recommended moving rapidly to vaccines that are thimerosal-free. The FDA encouraged manufacturers to comply and set the highest priority for its reviews of such products, Goodman says. As a result, all recommended pediatric vaccines available are now thimerosal-free or have greatly-reduced thimerosal contents. In March 2001, the FDA approved a newly formulated version of Tripedia, a diphtheria and tetanus toxoids and acellular pertussis (DTAP) vaccine with only a trace amount of thimerosal.



A Thorough Process

The most common components of vaccines are weakened microbes (disease-causing microorganisms), killed microbes, and inactivated toxins. In addition, sub-unit vaccines, which only use a part of the bacterium or virus, are increasingly being used.

Manufacturers conduct stringent tests to make sure that cell lines used for producing viral vaccines do not contain adventitious agents (unwanted viruses), such as simian virus 40 (SV40), which was found in some early polio vaccines. These vaccines had been manufactured in kidney cells from simians (monkeys) that harbored SV40. Following its discovery, SV40 was removed from vaccines, and vaccines have been free of the virus since the early 1960s. CBER scientists are developing potentially better methods to detect such infectious agents.

Developing vaccines is a thorough and rigorous process, Egan says. Vaccines are tested for safety on animals first, and then in humans during several phases of clinical trials. The most important clinical trial for the

For More Information

The National Vaccine Program Office

<http://www.cdc.gov/od/nvpo>

FDA's Vaccine Adverse Event Reporting System

<http://www.fda.gov/cber/vaers/vaers.htm>

Centers for Disease Control and Prevention National Immunization Program

Home page: [http:// www.cdc.gov/nip](http://www.cdc.gov/nip)

National Immunization Hotline:

1-800-232-2522 (English) or

1-800-232-0233 (Spanish)



Steps to Take When You Vaccinate

1. Review the vaccine information sheets that explain the potential risks of each vaccine. Health practitioners are required by law to provide them.
2. Talk to your doctor about whether certain reactions to vaccines can be controlled. For example, fever may be prevented or reduced by taking acetaminophen before or after a vaccination.
3. Tell your doctor if you, your child, or a sibling has ever had a bad reaction to a vaccine.
4. Ask your doctor about conditions under which you or your child should not be vaccinated. This might include being sick or having a history of certain allergic or other adverse reactions to previous vaccinations or their components, such as allergies to eggs, which are used to grow influenza vaccines.
5. Report unexpected events after vaccinations to your doctor and to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967.

recently-licensed vaccine Prevnar involved nearly 40,000 people, equally divided between those who received the vaccine and those who did not. Prevnar was approved to prevent invasive pneumococcal diseases such as meningitis.

A group of FDA scientists reviews data and the proposed labeling of the vaccine, which includes directions for use and information about potential side effects. The committee also reviews manufacturing protocols, conducts its own tests, and inspects the manufacturing facility. The FDA's Vaccines and Related Biological Products Advisory Committee, which includes scientific experts and consumer representatives, can be consulted at any time to review data and recommend action to the agency.

After a vaccine is licensed, the FDA generally requires that manufacturers use validated methods to test samples from each vaccine lot for safety, potency, and purity, prior to its release for public use. The FDA also tests selected lots and products to help assure the accuracy of tests conducted by the manufacturers.



Common Concerns

"Most vaccines cause some side effects, but they are usually minor and short-lived, like low-grade fever and soreness at the injection site," Midthun says. Serious vaccine reactions--causing disability, hospitalization, or death--are extremely rare but they can happen.

Like any medicine, vaccines carry a small risk of serious harm, such as severe allergic reaction. But experts point out that the risk of being harmed by a vaccine is much lower than the risk that comes with infectious diseases.

For example, in 1976, the swine influenza (flu) vaccine was associated with a severe paralytic illness called Guillain-Barré Syndrome (GBS). According to the CDC's vaccine information sheet on the influenza vaccine, "if there is a risk of GBS from current influenza vaccines, it is estimated at 1 or 2 cases per million persons vaccinated, much less than the risk of severe influenza, which can be prevented by vaccination." Each year, the flu causes tens of thousands of deaths, mostly among older people. Most

National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program became effective in 1988. The program is a federal "no-fault" system designed to compensate those individuals, or families of individuals, who have been injured by childhood vaccines. A claim may be made for any injury or death thought to be the result of a vaccine covered under the program. The program is administered jointly by the U.S. Department of Health and Human Services, the U.S. Court of Federal Claims, and the U.S. Department of Justice. For more information, call 1-800-338-2382, or visit <http://www.bhpr.hrsa.gov/vicp>.



"It's important that policy decisions about vaccine safety be based on science," says Martin G. Myers, M.D., director of the U.S. Department of Health and Human Service's National Vaccine Program Office. As vaccine safety research continues, Myers says, we can't afford to lose sight of what life was like before immunization. Vaccination is the reason we don't see the suffering, disability, and death from whooping cough, measles, polio and other infectious diseases, like we used to.

"Vaccines are very safe," Myers adds, "but nothing is without risk." Not vaccinating against certain diseases means choosing another type of risk, he says. Myers recalls treating an infant with seizures from tetanus so strong they shook the baby's whole body. These types of seizures and many deaths are preventable by vaccination. And Myers still has an audiotape from the early eighties of a child hacking and gasping for air because of whooping cough. "The child's mother asked me to play it for parents who might be undecided about getting vaccinated." He's also played the tape for medical students and residents. "It doesn't take long before somebody in the room asks me to please turn it off."

people who get the influenza vaccine have no serious problem from it.

And though some people worry about it, you can't get the flu from the flu vaccine, Midthun says. "Just as there are no vaccines that are 100 percent safe, there are also none that are 100 percent effective," she says. "So you may get the flu soon after you received the vaccine, before it could be expected to protect you. It does not mean the shot gave you the flu," she says.

Some live virus vaccines, such as the chickenpox vaccine, can cause mild versions of the disease they protect against, says Goodman, "but this is usually only a serious problem if the patient has a severely compromised immune system." And vaccines are generally not advised for such people. It's important to talk with your doctor about the benefits and risks of vaccines, and any concerns you may have, specifically as it relates to you and your family (see "Steps to Take When You Vaccinate"). If you or your child has previously had a significant reaction to a vaccine, that may affect the risk/benefit ratio for the individual and whether that vaccine should be recommended again.



How Reactions Are Evaluated

Before a vaccine is put into standard medical practice, it must be studied in clinical trials of thousands of people, which allow for evaluation of relatively common side effects. For example, a common side effect might occur in one or more of several hundred vaccine recipients. But rare events (fewer than one case in several thousand recipients) aren't usually evident in clinical trials. "Unless you've studied something in a million or more people, you might never see the very rare event or be able to know whether it occurred due to vaccination or simply by chance," Goodman says.

Through the Vaccine Adverse Event Reporting System (VAERS), jointly operated by the FDA and the CDC to monitor the safety of licensed vaccines, experts look for patterns and any unusual trends that may raise questions about a vaccine's safety once it is used more widely in the population. The FDA continuously reviews and evaluates individual reports, in addition to monitoring overall reporting patterns. The FDA also monitors reporting trends for

measles, mumps, and rubella (MMR) vaccines and autism, a hypothesis that has received considerable publicity over the last year.

The CDC and the NIH recently contracted with the Institute of Medicine, part of the National Academy of Sciences, to establish the Immunization Safety Review Committee. The independent committee is charged with evaluating nine vaccine safety topics over a three-year span. The possible association of the MMR vaccine and autism was the first topic.

On April 23, 2001, the Immunization Safety Review Committee reported its finding that the current evidence does not favor the hypothesis that there is a link between MMR and autism, and that no changes should be made in the current policy of administering the MMR vaccine. The committee could not rule out the possibility that the MMR vaccine might be linked to autism in some sub-population, and recommended that targeted research in this area be conducted. To date, there is no indication as to whether there is any such sub-population, or what the genetic makeup or other characteristics of such a subpopulation would be, Egan says.



information in VAERS and permits more rigorous evaluation of possible safety concerns. For example, the system allows researchers to compare how often an adverse event occurs in people recently vaccinated with those not recently vaccinated, to evaluate the likelihood that the vaccine caused the adverse event.

Alleged Associations

Some have looked to vaccines to explain a host of serious conditions that we don't fully understand, including sudden infant death syndrome (SIDS), multiple sclerosis, diabetes, and autism. While there have been a number of epidemiological studies of these possible associations, experts say there is no good scientific evidence at this time showing that vaccines cause these diseases or conditions.

"Physicians give vaccines to children at multiple time points during their development and a lot can happen during that time," says Midthun. She stresses that both the FDA and the CDC take concerns of parents seriously. After careful review of all available information, neither agency has found that existing data support any link between the

individual vaccine lots. Most reports come from health-care providers, but anyone can report an unexpected event after vaccination to VAERS. (See "Steps to Take When You Vaccinate" for the VAERS toll-free number.)

VAERS receives 800 to 1,000 reports each month. Because it often can't be determined whether an adverse event occurring after vaccination was actually caused by the vaccination, health-care providers and consumers are encouraged to report any event that might be attributable to a vaccine.

"You don't have to be sure," says Susan Ellenberg, Ph.D., director of CBER's office of biostatistics and epidemiology. "Reporting possible reactions will help identify adverse events that might be truly associated with vaccinations and need further study." But this approach to reporting means that one can't assume that all VAERS reports describe true vaccination reactions.

VAERS is a passive, voluntary reporting system, which means not all adverse events get reported. It also means that many reports are incomplete or even contain inaccurate information because the forms are not filled out



by trained personnel. Another problem with interpreting VAERS data is the lack of information on the total number of individuals who received a particular vaccine, making it impossible to estimate the incidence of reported adverse events. It's also often the case that multiple vaccines are given at the same time, further complicating the interpretation of what might have caused the event, Ellenberg says.

Despite these problems, VAERS does contribute in important ways to understanding vaccine safety. VAERS data may suggest the need for more research on certain vaccines. "In this sense, VAERS is a signal generator," Egan says. Recently, VAERS data were instrumental in evaluating RotaShield, a vaccine licensed to protect against rotavirus infection. Rotavirus is the most common cause of gastroenteritis in children younger than five and can result in severe diarrhea, dehydration, and death. This virus is an especially serious problem in developing nations, where it kills hundreds of thousands of children every year.

Following the vaccine's licensure, VAERS started to

receive reports of bowel obstruction in a number of infants who had received RotaShield. Careful review of these reports revealed that the bowel obstruction occurred most often in the first two weeks after RotaShield was administered. As a result, the CDC recommended postponing any further distribution or administration of RotaShield until more data could be collected and evaluated.

The FDA discussed the concerns with the manufacturer, which decided to voluntarily withdraw the product from use. In November 1999, ACIP withdrew its previous recommendation for universal use of the vaccine. At this time, the FDA, NIH, and CDC are still studying the bowel obstruction and RotaShield-associated cases, Egan says. "We continue to look into mechanisms for any serious adverse events. We want to understand why they happen so that we can prevent them from occurring in the future."

The CDC's Vaccine Safety DataLink, which links computerized histories of vaccination to hospitalization records and other medical information for members of eight large managed care organizations, supplements the