The Value of Vaccination
a conversation

VACCINES

Disease prevention requires deliberate actions, such as getting adequate sleep and exercise, dressing appropriately, and washing our hands.

It also requires an occasional vaccination.

Vaccines stop disease, and this is their biggest value.

They have dramatically altered our quality of life and have prevented millions of deaths and untold suffering here and around the world from diseases such as hepatitis B, measles, and rubella.

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Questions and Answers

The Immune System vs. Germs

Without any conscious effort on our part, or medical intervention, the body can create its own defense against some infectious agents.

For example, when the virus that causes influenza invades a body, the immune system creates antibodies (a substance created by the body when it detects a potentially harmful invader called an antigen) that bind to the virus and neutralize or inactivate it.

While this is going on, memory B cells are produced and remain ready—often for a lifetime—to mount a quick, protective immune response against subsequent infection of that specific strain of the influenza virus.

So even though the number of antibodies created to fight the influenza virus subside, the memory B cells remain, forever on guard for that specific strain of the virus.

A vaccine causes a similar immune response. It is made from an antigen (a foreign substance that the body's immune system identifies as potentially harmful) from the influenza virus.

The vaccine is injected and then absorbed into the blood stream. The memory B cells in the blood stream respond to the vaccine antigen by producing antibodies.

As happens after an actual infection, the memory B cells remain ready to mount a quick protective immune response against subsequent infection by the influenza virus.

Why Aren't There Vaccines For All Infections?

Vaccines exist for all sorts of diseases, both viral and bacterial.

But not all diseases can be prevented by a vaccine (at least, not yet).

For example, to date, scientists have been unable to develop vaccines against the viruses that cause the common cold, hepatitis C, or HIV.

Efforts to create a vaccine against the common cold have failed because there are so many viruses that cause colds, and they are capable of mutating or changing so rapidly, antibodies that form to fight one cold virus don't recognize the new or mutated virus and can't fight it.

The hepatitis C virus and the human immunodeficiency virus (HIV) remain challenges because they change ever so slightly every time they make copies of themselves.

Developing a vaccine to fight one version of the hepatitis C virus would not work with the versions that have been slightly altered by replication. The same goes for the human immunodeficiency virus.

Perhaps one day scientists will be able to design vaccines that go after the common genetic material in each virus, so that no matter what the slight variations are in each version, there will be some identifiers that won't change and will, therefore, be susceptible to vaccines.

Why is There a Different Influenza Vaccine Each Year?

Influenza vaccines are specific for certain strains of the virus. For a vaccine to be effective against a flu epidemic, it must be designed for that specific influenza strain. That is why a new vaccine is developed for each flu season.

If you are exposed to a different flu virus from the one you are vaccinated for, you will still catch the flu.

How Are Vaccines Made and Why Do They Work?

In their book Vaccines: What Every Parent Should Know*, Dr. Paul Offit and Dr. Louis Bell take the complex question of how vaccines are made and answer it in a way we can all understand:*

Vaccines are made by taking viruses or bacteria and weakening them so that they can't reproduce (or replicate) themselves very well or so that they can't replicate at all.

Children given vaccines are exposed to enough of the virus or bacteria to develop immunity, but not enough to make them sick. There are four ways

that viruses and bacteria are weakened to make vaccines:

Change the virus blueprint (or genes) so that the virus replicates poorly.

This is how the measles, mumps, rubella, and varicella vaccines are made.

The virus blueprint is changed by a technique called cell culture adaptation [adapting a virus to grow in specialized cells grown in the lab instead of the cells it normally grows in].

Because viruses can still, to some extent, make copies of themselves after cell culture adaptation (and therefore are still alive), they are often referred to as live, attenuated (or weakened) viruses.

Destroy the virus blueprint (or genes) so that the virus can't replicate at all.

This is how the "killed" polio vaccine (or polio shot) is made.

Vaccine virus is made by treating polio virus with the chemical formaldehyde. This treatment permanently destroys the polio genes so that the virus can no longer replicate.

Use only a part of the virus or bacteria.

This is how, for example, the Hib, hepatitis B, and (in part) pertussis vaccines are made.

Because the viral or bacterial genes are not present in the vaccine, the viruses or bacteria can't replicate.

Take the toxin that is released from the bacteria, purify it, and kill it so it can't do any harm.

Some bacteria cause disease not by replicating but by manufacturing harmful proteins called toxins.

For example, bacteria like diphtheria, tetanus, and pertussis (whooping cough) all cause disease by producing toxins. To make vaccines against these bacteria, toxins are purified and killed with chemicals (such as formaldehyde).

Again, because bacterial genes are not part of the vaccine, bacteria can't replicate.

Vaccine Boosters

Because the immune response from some vaccines may decrease over time, some vaccines require an additional dose or "booster" to maintain a protective immune response against that particular germ.

Tetanus boosters, for example, are recommended every 10 years starting at age 10 or 11.

Passive Immunity

In addition to natural or "vaccine-induced" immunity to diseases, there is also "passive" immunity. Passive immunity occurs when someone is injected directly with antibodies that are ready to immediately fight a specific virus or bacteria.

These antibodies go to work immediately against any antigen or pathogen. There is no waiting period, as is needed by some vaccines, before sufficient antibodies are produced.

However, protection from these antibody injections is temporary. Once the antibodies are cleared from the body, no new antibodies are made.

Doctors use this approach to treat people who have been recently exposed, for example, to hepatitis B, hepatitis A and rabies. Babies born to mothers with hepatitis B are immediately treated with hepatitis B antibodies (called HBIG or hepatitis B immune globulin) and simultaneously immunized against hepatitis B to prevent any infection that might have occurred during the birth process.

Monitoring Vaccines for Safety

Vaccines in the US are licensed by the Food and Drug Administration (FDA) and recommended for use by the Centers for Disease Control and Prevention (CDC) and professional medical associations. Prior to licensing, the vaccines go through years of clinical trials to make sure they provide immunity and don't cause serious side effects, and that the benefits of the vaccines are greater than the risks.

However, there is a system to monitor the safety of vaccines after they are licensed and recommended. The goals of these safety monitoring programs are to identify and evaluate safety issues that may have been too rare to be picked up in clinical trials, or that take a long time to develop, or that may occur among subpopulations (a part of the larger population—for instance only men, or only teenage girls, or only children under five years of age).

These systems are designed to detect potential problems, evaluate potential problems to see if the vaccine is the cause, and if the vaccine is the cause, to understand who is being affected and how frequently.

These safety monitoring programs are conducted by health agencies in the federal government, managed care organizations and health insurance companies, and researchers in

universities.

Detecting Potential Problems

In 1990, the FDA and the CDC established the Vaccine Adverse Events Reporting System (VAERS) to detect potential safety problems related to vaccines.

Anyone can make a report to VAERS. Healthcare providers are required to report certain adverse health events that occur after a child is vaccinated.

The adverse event may have been caused by something other than the vaccine, such as an infection, an illness the child had before he or she was vaccinated, or an injury, but there is a small chance that the event was caused by a vaccine.

Parents of those vaccinated, or individuals being vaccinated themselves can make reports to VAERS. The system is designed to capture health issues that are unexpected, and because of this design will often pick up issues that are not actually caused by the vaccine.

Approximately 30,000 VAERS reports are filed annually. Around 85-90% of the reports describe mild events such as fever, local reactions, episodes of crying or mild irritability. The remaining reports reflect serious adverse events involving life-threatening conditions, hospitalization, permanent disability, or death, which may or may not have been caused by an immunization.

Doctors and scientists at the CDC and the FDA carefully review VAERS reports, looking for unusual or unexpected health events that may be related to the vaccine and require additional, more rigorous studies.

Some VAERS reports are also reviewed by specialists at universities that are a part of the Clinical Immunization Safety Assessment (CISA) Project funded by the CDC. The CISA network will try to determine if and how the vaccine caused the health outcome in that individual person, if there are some characteristics of the person that make them more likely to have an adverse reaction to the vaccine, and if there are specific questions that need to be researched further.

VAERS receives reports of many events that occur after immunization. Some of these events may occur coincidentally following vaccination, while others may truly be caused by vaccination. Studies help determine if there is more than a temporal (time) association between immunization and adverse events. There are several systems in place to conduct these large studies to determine if the vaccine is causing the adverse event.

VAERS Contact Information
Phone: 1-800-822-7967
Web: http://vaers.hhs.gov
Email: info@vaers.org

Vaccine Safety Datalink Project

Large healthcare databases are a part of the vaccine safety monitoring program. They allow research scientists to have access to the complete medical records of millions of people who receive vaccines. (Patient identity is not released).

The Vaccine Safety Datalink (VSD), initiated by the CDC in 1990, combines anonymous data from nine managed care organizations (MCOs) that provide care for about 10 million people.

Each participating managed care organization routinely collects information on vaccination (vaccine type, date of vaccination, other vaccines given at the same time), medical outcomes (outpatient visits, inpatient visits, urgent care visits), birth data, and census data.

These records are important because they allow for the careful study of vaccinated and unvaccinated people to determine if the vaccine is associated with the health outcome being explored.

The VSD has conducted hundreds of vaccine safety studies over the past 25 years. Most of these studies have found that the vaccine was not causing the health outcome being investigated.

Some of these studies have found that the vaccine is causing the health outcome. These studies are shared with other scientists and the public, and can result in changes to vaccine recommendations, including in rare instances removal of recommendations to use the vaccine.

While the VSD is very large, there are circumstances where it is not large enough to quickly answer important questions. Several other healthcare databases are also used to investigate vaccine safety issues.

Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Program

The PRISM Program was established to monitor the safety of the 2009 H1N1 vaccine, and continues to be used by the FDA to investigate vaccine safety issues.

PRISM covers about 40 million persons, linking health information from three large health insurance companies with immunization data from eight state immunization registries.

Often PRISM researchers will pull anonymous medical records and have them reviewed by medical specialists to obtain additional information about the patient and the health outcome being explored.

In comparison to the VSD, PRISM, because of its large size, can study some issues faster, is better able to look at subpopulations, and is more representative of the US population.

Other Large Healthcare Databases

In addition to the VSD and PRISM, there are other large healthcare databases that are used to monitor the safety of vaccines in special populations. For instance:

- The Centers for Medicare and Medicaid Services provides healthcare for about 45 million Americans, primarily people 65 years and older.
- The Indian Health Services provides healthcare to Native Americans.
- The Department of Defense provides healthcare to the military and their dependents.
- The Department of Veterans Affairs provides healthcare to our veterans.

Put all together, the safety monitoring program is able to conduct studies among about a third of the US population. All of these safety programs have systems in place to ensure the confidentiality and privacy of patients.

Often, studies will be conducted within one of these programs based upon the vaccine being studied and the population or subpopulation of interest. But at times, studies have been conducted across the many different programs allowing data to be combined to study very rare health outcomes.

This system enables rapid and thorough studies of potential safety problems that arise from VAERS or the medical literature, and to study changes to the vaccine schedule, including new vaccines that are added to the routine schedule.

Independent Review of Safety Issues by the Institute of Medicine

The Institute of Medicine—a medical research organization funded by Congress to provide objective, timely, authoritative information and advice concerning health to government, the corporate sector, the professions, and the public—has conducted many vaccine safety reviews to consider the available scientific information and determine if a vaccine is causing an adverse health outcome and, if so, how frequently and among whom.

These reports are known for their comprehensiveness and objectivity. Summaries of the reports and ordering information can be found on the IOM website.

National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (NVICP) compensates people who have been determined to have been injured by vaccines.

Established in 1988, it's a federal "no-fault" program that covers all routinely recommended childhood vaccinations.

It is "no-fault" because people who file claims are not required to prove negligence on the part of the healthcare provider or the manufacturer. Serious injuries that are likely to be caused by certain vaccines are included in the vaccine injury table.

People who apply to the program can be compensated for other health outcomes if they can show that the vaccine was more likely to cause the health outcome than not. This vaccine injury table is updated as medical research uncovers more information on the side effects of vaccines.

You may file a claim if you received a vaccine covered by the NVICP and believe that you have been injured by the vaccine.

You may also file a claim if you are a parent or legal guardian of a child or disabled adult who received a vaccine covered by the VICP and believe that the person was injured by this vaccine.

You may file a claim if you are the legal representative of the estate of a deceased person who received a vaccine covered by the VICP and believe that the person's death resulted from the vaccine injury.

You may file a claim if you are not a United States citizen.

Some people who receive vaccines

outside of the U.S. may be eligible for compensation.

In addition, to be eligible to file a claim, the effects of the person's injury must have:

- lasted for more than 6 months after the vaccine was given; or
- resulted in a hospital stay and surgery; or
- resulted in death.

Funds accumulated from a tax on each dose of a vaccine purchased are used for the compensation awards.

If a vaccine or combination of vaccines is not listed above, call 1-800-338-2382 to determine if it is covered under the Program.

NVICP Contact Information
Phone: 1-800-338-2382
Web: http://www.hrsa.gov/vaccinecompensation/

Why Are Vaccines Mandated?

Why do states mandate that millions of children and adolescents receive certain immunizations for school entry?

The more people in a community who are vaccinated, the healthier that community is. Here is how Dr. Samuel Katz, a renowned vaccine expert, explained it before Congress in 1999.

"We know too well that the level of [immunization] protection that we have now established in our children and our communities is a fragile one that depends on what we refer to as community or 'herd' immunity. From the standpoint of effectiveness, modern childhood vaccines are approximately 90 to 95 percent effective. What that means is that for every 20 children who are vaccinated one or two may not develop a sufficient immune response [or antibodies to fight an infection].

"It cannot be assured that these children will be protected from the virus or bacteria should they encounter it at school, at a playground, at a shopping mall, or at their church daycare. However, if sufficient numbers of children in a community are immunized, the vaccinated ones protect the unprotected by effectively stopping the chain of transmission in its tracks and drastically lowering the probability that the susceptible child will encounter the bacteria or virus.

"*As long as the great majority of children receive their vaccines, we will be able to maintain our current level of disease control*," Katz explained. "*However, should the level of community protection drop to the point where the viruses and bacteria travel unimpeded from person- to-person, from school-to-school, and from community-to-community, we instantly return to a past era when epidemics were an accepted part of life*."

America experienced such an outbreak in 1989-91 with the resurgence of measles. There were 55,622 reported cases mainly in children less than 5 years of age, more than 11,000 hospitalizations and 125 deaths.

Some states do allow personal exemptions, so parents can choose not to vaccinate their children, but those exemptions carry risk to the child and to the public's health, emphasizing the importance of community immunity.

It was found that, on average, those children who were exempted from immunizations ran a 35-fold greater risk of contracting measles compared to those who were vaccinated.

Exemptors have also been found to be at increased risk of pertussis, Hib, and pneumococal disease compared to vaccinated children

Not only are these children at greater risk of disease, their infections can be the spark that ignites a disease outbreak in a community.

"*States without school immunization requirements had incidence rates for measles significantly higher than states with these requirements*," noted Dr. Katz.

"*Recognizing these data, other states (not the federal government), quickly adopted similar requirements.*

"*The results are striking*," he added. "*Before we had a measles vaccine, an estimated 500,000 cases of measles were reported each year. In 1998, there were 89 cases of measles in the United States with no measles-associated deaths. Most counties in the United States were free of measles. However, we have learned that nearly all of the cases of measles that did occur in the United States were imported from other countries. This would not have been possible without the "school exclusion" statutes that now exist in every state. While we hear dramatic stories of exotic diseases that are just a plane ride away, the importation of vaccine preventable diseases into a susceptible population is much more frightening. Should we allow our community immunity to wane, we will negate all the progress we have made and allow our communities to be at risk from threats that are easily prevented*."

Compulsory vaccination laws in the United States have repeatedly been upheld as a reasonable exercise of the state's compelling interest even in the absence of an epidemic or a single case.

The Supreme Court makes clear that:

"…the liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. [Liberty] is only freedom from restraint under conditions essential to the equal enjoyment of the same right by others."

If There Are No Diseases, Why Are Some Vaccines Still Necessary?

There hasn't been a single case of wild-virus polio in the United States since 1979, so why do we need to be immunized against it? While the United States has escaped polio for decades, other regions of the world have not been so lucky.

Travelers can unknowingly bring these diseases into the United States, and if the public is not protected by vaccinations, these diseases will quickly spread throughout the population causing epidemics.

Vaccinations are necessary to protect ourselves, even if we think our chances of getting any of these diseases are small. The diseases still exist and can still infect anyone who is not protected. A few years ago, in California, a child who had just entered school caught diphtheria and died. He was the only unvaccinated pupil in his class.

Another reason to get vaccinated is to protect those around us. There is a small number of people who cannot be vaccinated (because of severe allergies to vaccine components, for example), and a small percentage of people don't respond to vaccines. These people are susceptible to disease, and their only hope of protection is that people around them are immune and cannot pass disease along to them.

The CDC explains why, from a disease control and prevention perspective, we should vaccinate:

Diseases are becoming rare due to vaccinations

It's true, some diseases (e.g., polio and diphtheria) are becoming very rare in the U.S. Of course, they are becoming rare largely because we have been vaccinating against them. But it is still reasonable to ask whether it's really worthwhile to keep vaccinating.

It is like bailing out a boat with a slow leak. When we started bailing, the boat was filled with water. But we have been bailing fast and hard, and now it is almost dry. We could say, "Good. The boat is dry now, so we can throw away the bucket and relax." But the leak hasn't stopped. Before long we'd notice a little water seeping in, and soon it might be back up to the same level as when we started.

Keep immunizing until disease is eliminated

Unless we can "stop the leak" (i.e., eliminate the disease), it is important to keep immunizing. Even if there are only a few cases of disease today, if we take away the protection given by vaccination, more and more people will get infected and spread disease to others, and soon we will have undone the progress we made over the years.

Example case in Japan

In 1974, Japan had a successful pertussis (whopping cough) vaccination program, with nearly 80 percent of their children vaccinated. There were only 393 cases of pertussis that year in the entire country and no deaths. But then rumors began to spread that pertussis vaccination was no longer needed and that the vaccine was not safe. By 1976, only 10 percent of infants were getting vaccinated. In 1979, Japan suffered a major pertussis epidemic with more than 13,000 cases of whopping cough and 41 deaths. In 1981, the government began vaccinating with the acellular pertussis vaccine, and the number of pertussis cases dropped again.

Similar situations occurred around the same time in the UK, Sweden and other countries.

What if we stopped vaccinating?

So what would happen if we stopped vaccinating here? Before long we would see epidemics of diseases that are nearly under control today. More children would get sick and more would die.

We vaccinate to protect our future

We don't vaccinate just to protect our children. We also vaccinate to protect our grandchildren and their grandchildren. With one disease—smallpox—we "stopped the leak" in the boat by eradicating the disease. Our children don't have to get smallpox shots anymore because the disease no longer exists. If we keep vaccinating now, parents in the future might be able to look back at the "old days" when we had diseases like polio and measles, for which children had to get vaccinated.