VACCINE

SAFETY



When it comes to immunization, your baby sees the world through your eyes.

answers you seek

A PARENT'S GUIDE

TO CHILDHOOD IMMUNITY

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Brought to you by Sanofi Pasteur Inc.







A message to mome and dads

Your child looks to you to do what's best.

As a parent, your primary goal is to keep your little one safe. So when it comes to decisions like buying that very first car seat, you probably do so only after careful research.

Making the choice to immunize your child against infectious diseases is one of the most important decisions you can make.

We know there's a lot of confusing information today about immunizations. We also know you need the facts, which is why you can look to ImmYounity. The ImmYounity program is dedicated to providing helpful, truthful information about vaccines. This booklet is brought to you by Sanofi Pasteur and is written by moms, dads, and health care professionals. It is based on science. It is a helpful tool to give you the answers you seek on vaccinations.

Please take some time to read this booklet, and learn how to help keep your child safe from vaccine-preventable diseases.

Because when it comes to immunization, your baby sees the world through your eyes.

Having the facts can help you make the choice to vaccinate

Why should my child be vaccinated?

Vaccines are life savers. In fact, they prevent the deaths of an estimated 3 million children each year worldwide.¹

Because of vaccines, people living in the United States today don't see some of the serious diseases, such as polio and diphtheria, that used to harm or kill many children in this country. However, some of our parents or grandparents may well remember these feared diseases.^{2,3}

> Although some vaccine-preventable diseases may not be obvious today in the United States, they still exist. Once you weigh the evidence, you can see that the best way to protect your child is through immunization.

I thought babies were born with immunity. Isn't that right?

Babies may be born with immunity that has been passed on from their mothers. Unfortunately, this protection doesn't last as long as moms might expect.⁴

A mother can pass on immunity only if she herself has been immunized or had a disease.⁵ This immunity, passed through the placenta and from breast milk, may possibly last only a month to about a year.^{5,6}

Immunity against certain diseases, such as whooping cough, wears off over time. What's more, protection passed from a mother to her newborn is often not strong enough to fight off an infection during the first few months of an infant's life.⁶ Immunization has been called one of the 10 greatest public health achievements. It has saved millions of lives over the years and prevented hundreds of millions of cases of disease.⁷

-Centers for Disease Control and Prevention (CDC)

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Vaccines, on the other hand, provide immunity that is like the immunity someone develops when they have an infection or a disease. This kind of immunity gives infants longer-lasting protection against potentially life-threatening disease.⁴

As your infant grows, the protection from some vaccines may begin to wear off, and an additional dose (a booster dose) may be recommended to continue to provide protection against certain diseases.⁸

Aren't the diseases we vaccinate against essentially gone in the United States?

Many vaccine-preventable diseases may be largely unseen in this country, but they are certainly not gone. Outbreaks of chickenpox, whooping cough, influenza, and measles still send otherwise healthy children to the hospital and even cause their deaths every year.^{3,9}

Whooping cough (known medically as pertussis) may sound like an old-fashioned disease, but it's very much a modern-day problem. Cases of whooping cough occur across the country every week.¹⁰ Babies usually suffer the most.¹¹ In fact, 92% of whooping cough deaths have occurred in infants younger than 4 months of age, who are too young to be fully immunized.¹¹

A real worry is that babies often catch whooping cough from the people who love them the most, including their parents. Researchers have found that up to 80% of babies caught the disease from family members, so it's important for all members of your family to be vaccinated.¹²



Babies can catch whooping cough from those who love them the most.

REMINDERS THAT INFECTIOUS VACCINE-PREVENTABLE DISEASES ARE STILL WITH US:

The California Department of Public Health officially declared a whooping cough epidemic in 2010—89% of the cases were among infants under 6 months of age.^{13,14}

Scientists are asking if polio could come back. From 2009 to 2010, 23 countries that had previously been certified "polio-free" were reinfected due to imported cases of the disease.¹⁵

MEASLES IN THE UNITED STATES

The United States has a highly vaccinated population of children, which helps shield them from invading germs.¹⁶ But pockets of unvaccinated people provide the opening infectious diseases need to take hold, leading to outbreaks.¹⁷



GLOBAL STATISTICS

Measles affects more than 20 million people worldwide each year. It remains one of the leading causes of vaccine-preventable deaths among young children.²⁰



Why vaccinate against diseases that other countries have, but the United States doesn't have?

Because we live in a global society, diseases we thought were gone remain a threat in the United States. People and goods cross borders every day, and with them comes another kind of frequent flyer: infectious disease germs.

You don't need to be a world traveler to be at risk. Someone you know could go on an overseas trip and bring a disease back home. Or, someone from outside the United States could visit your community and bring a disease with them.

Smallpox is the only disease that has been wiped out worldwide as the result of vaccination.¹

In 2008, 140 confirmed measles cases were reported in the United States.¹⁸ Then in 2011, 222 measles cases were reported—including 17 outbreaks.²² In both instances, at least **89% of cases were brought into the United States, or associated with imported cases from other countries—particularly countries in Europe, where there were measles outbreaks.**^{18,22} Many of the cases occurred among unvaccinated school-aged children.^{18,22}



Answers you seek about the making of vaccines



How do vaccines work?

Vaccines teach our immune systems how to recognize and fight bacteria and viruses before an infection happens.⁶ In this way, they work a lot like natural infection.

When a person is exposed to a disease-causing germ, the immune system mounts a defense, producing substances known as antibodies to fight it.⁶ A vaccine creates a similar immune response by giving the body a small sample or part of the germ, so people develop resistance to the harmful bacteria or virus without actually getting the disease.⁶

The immune system has a memory, so the next time the immunized person comes in contact with that germ, their immune system recognizes it and the antibodies work to fight it off.⁶

Over time, the protection provided from some vaccines may begin to wear off.⁸ An additional dose of a vaccine, given as a booster, helps remind the immune system to stay on alert against certain diseases.⁸

How are vaccines made?

It's only natural to want to know about the ingredients of a vaccine. You check food labels, so why shouldn't you be curious about what goes into a vaccine?

For starters, vaccines are made from viruses or bacteria, so people get protection, or immunity, from the disease, without getting the disease.²³

VACCINES ARE MADE IN DIFFERENT WAYS:

- WEAK
- Live viruses are weakened so they cannot cause disease. These include mumps, German measles (rubella), and chickenpox (varicella).²³
- X X
- Bacteria or viruses are killed or inactivated. The polio vaccine is made this way.²³



• Vaccines are also made by using only part of the virus or bacteria. The hepatitis B (Hep B) vaccine is an example.²³

Why are additives put in vaccines?

Ingredients are added to vaccines to help extend shelf life or effectiveness and are only used in very tiny amounts. The amount of chemical additives in today's vaccines is very small.²⁴

Here are some ingredients you may have questions about:

Aluminum is used in some vaccines to allow for a better immune response.²⁵ Infants are constantly exposed to aluminum in a number of ways. It's present in air, water, food, even in breast milk.²⁵ The amount used in vaccines, though, is a tiny fraction of the amount a baby would receive through breast milk or infant formula in the first 6 months of life.²⁵

That small amount is eliminated quickly from a baby's body.²⁵

- Antibiotics are used to prevent the growth of bacteria during production and storage and rarely cause allergic reactions^{24,25}
- Thimerosal is a preservative that is added in very small amounts to multidose vials of vaccines to prevent bacteria from contaminating the vaccine.²⁴ It is no longer in most children's vaccines, which are supplied as single doses.²⁶ (You can read more about thimerosal on the following pages.)

If you have any concerns about what ingredients are in a specific vaccine, be sure to talk to your child's health care professional.

Vaccine safety, a parent's primary concern

Are vaccines safe?

This is the big question on every parent's mind. It may be reassuring to know that vaccines are constantly studied and monitored to make sure they are safe. Safety testing continues long after vaccines are licensed.27

No medical intervention is 100% safe; however, the risk of serious side effects from vaccines, such as severe allergic reactions, is extremely small.²⁸

What side effects could my child have?

Vaccines usually cause redness or soreness at the injection site. Another typical side effect is fever.²⁸ If your child develops a high fever or appears to be in severe pain, seek medical attention right away.

> To learn more facts about immunization, visit www.lmmYounity.com

RELATIVE RISK OF VACCINE SIDE EFFECTS

- **1 in 5** Soreness or swelling at injection site after chickenpox (varicella) vaccine²⁸
- **1 in 3000** Seizure caused by fever after measles, mumps, and rubella (MMR) vaccine²⁸
- 1 in 1,000,000 Severe allergic reactions after the MMR and hepatitis B (Hep B) vaccines²⁸

Compare vaccine risks to other risks at www.lmmYounity.com.

When you think about it, everyday life is full of risks. Consider driving, for example. Many of us drive with our children in the car, despite the risk of being on the road. As parents, we do our best to manage the risk by buckling our children into the safest car seats we can find.

Similarly, vaccines allow us to manage the risk of getting an infectious disease. If you consider that a child is far more likely to be seriously injured by an infectious disease than by any vaccine, the benefits of getting your child vaccinated outweigh the risks.

The truth about vaccines and autism

Do vaccines cause autism?

The increase of autism spectrum disorders (ASDs) has made a lot of parents wonder if there is a connection with vaccines.^{29,30} Yet there hasn't been any scientific proof.³⁰

More than 20 published scientific studies have found no link between vaccines and ASDs.³¹

Yet some parents still have questions about a possible link.³⁰ One reason for this is timing: some parents of children with autism say they first noticed signs of it around the time their children received their 12- to 24-month vaccinations.³⁰ Their children may have appeared normal before 1 or 2 years of age, and then they lost the language or social skills they had.²⁹

However, developmental specialists can identify symptoms of autism in an infant's first few months of life, before parents notice something unusual.³⁰ Only carefully controlled studies can prove if vaccines cause autism—and so far, they have not.³⁰ A recent study analyzed the vaccination and medical records of children with and without an ASD. This study found no association between their exposure to vaccines and the risk of developing an ASD.³²

A small study of autistic children in 1998 initially raised the question about a connection between the MMR vaccine and ASDs.^{30,31} Yet in 2004, 10 of the study's original 13 authors retracted the study's conclusions and stated the data did not show a link.³¹ What's more, the scientific journal that published the original findings retracted the article after an investigation found the results to be false.³³

For more information, visit

www.cdc.gov/vaccinesafety/Concerns/ Autism/antigens.html

What about a link between the vaccine preservative thimerosal and autism?

This is another big question parents have, but again, no link has been found.

During the past few years, a series of studies has shown the concern about a potential link between thimerosal and autism to be unfounded.³⁴

> A study in 2007 of more than 1000 children found that receiving thimerosal-containing vaccines did not cause harm.

In that study, researchers measured many different abilities, including language, behavior, memory, and intelligence to reach that conclusion.³⁵

Thimerosal is a mercury-containing preservative. It was used in small amounts for more than 50 years in multidose vials of vaccines to prevent them from being contaminated by bacteria.^{24,26} The mercury that was used (ethylmercury) is different from the environmental mercury (methylmercury) that people are exposed to when they eat some types of fish and shellfish.²⁶

Unlike the kind that can make its way into the food chain, the mercury used in vaccines is broken down and passed from the body much faster.²⁶

All recommended pediatric vaccines used in the United States are available with no thimerosal or only trace amounts.²⁴

Is thimerosal still used in vaccines given to children?

As a precaution, thimerosal has been removed from or reduced to trace amounts in vaccines for children 6 years of age and younger, with the exception of multidose inactivated influenza vaccines.²⁶

For infants and children, a single-dose, preservativefree version of the inactivated influenza vaccine is also available.²⁶

Even though thimerosal was removed from vaccines, more people than ever

before are being diagnosed with ASDs.^{36,37} For many people, this is the most convincing evidence that thimerosal could not be linked to autism.

Experts say there are indeed more people being diagnosed with ASDs. The increase in diagnoses is due in part to ASDs being more broadly defined and better recognized and diagnosed.²⁹

The exact cause of autism is still being studied. Most scientists agree that genetics plays a role.²⁹

Recommended US Childhood

Immunization Schedule^{38,39,b} 2 Months 6 Months Hepatitis **B** Hep B 3 doses Hep B (Hep B) 2 or 3 **Rotavirus** RV RV RV (RV) doses Diphtheria. Tetanus, Pertussis 5 doses DTaP DTaP DTaP (DTaP) Haemophilus 3 or 4 Hib Hib Hib influenzae type b doses^d (Hib) Pneumococcal 4 doses PCV PCV PCV (PCV) Inactivated IPV IPV 4 doses Poliovirus (IPV) 1 or 2 Influenza dosese Measles, Mumps, 2 doses Rubella (MMR) Varicella 2 doses Hepatitis A 2 doses^f (Hep A)

^b There is additional flexibility in the schedule. For the complete CDC recommended US childhood

immunization schedule, go to http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-schedule.pdf.

^c Depending on the rotavirus vaccine used, your child may need 2 or 3 doses.

^d Depending on the Hib vaccine used, your child may need 3 or 4 doses.

^e Two doses given at least four weeks apart are recommended for children 6 months through 8 years of age who are getting a flu shot for the first time.

VACCINE Schedule



^f Two doses of Hep A are needed for lasting protection. The first dose of Hep A vaccine should be given between 12 and 23 months of age. The second dose should be given 6 to 18 months later.

If your child has missed any doses of a vaccine, has a medical condition that puts him or her at risk for infection, or is traveling outside the United States, consult your health care professional.

VACCINE

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Understanding your child's vacaines and schedules

Which childhood vaccinations are recommended?

Current recommendations call for immunization against 15 vaccine-preventable diseases before 6 years of age.³⁸ That may sound like a lot, but remember, vaccines use up only a tiny part of a healthy baby's immune system—yet they offer broader protection against many serious diseases than ever before.⁹

Young children should receive 1 vaccine (Hep B) shortly after birth. The rest of the schedule continues at 1 to 2 months of age through the time children enter kindergarten.³⁸

No federal vaccination laws exist, but all 50 states require certain vaccinations for children entering schools or day care. Depending on the state, children must be vaccinated against some or all of the following diseases: mumps, measles, rubella, diphtheria, pertussis, tetanus, polio, Hep B, and Hib.^{40,41}

You can search for your state vaccine requirements at:

www.immunizationinfo.org/vaccines/state-requirements



Who approves and recommends vaccines?

After successful testing in thousands of people, a vaccine is approved (licensed) for use in the United States by the US Food and Drug Administration.⁴²

Even after licensing, monitoring of a vaccine continues.⁴² The vaccine is then recommended for use in specific age groups by the CDC Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians.³⁷

A lot of thought goes into developing the vaccination schedule. Each year, the schedule is re-evaluated based on the most recent scientific data available.⁴³ This helps make sure that children get the most protection against serious, vaccine-preventable diseases.

Is it dangerous for babies to receive several vaccines during the same medical visit?

This is an understandable worry for a parent. But there is a lot of reassuring evidence that multiple vaccinations at the same time do not overload a healthy baby's immune system.⁹

Vaccines routinely recommended for children use only a small portion of the immune system's memory.⁹ In fact, only tiny fragments of viruses or bacteria are in vaccines compared with the large amounts of germs children come in contact with every day.⁹

Parents who are worried about the increasing number of recommended vaccines also may take comfort in knowing that vaccines today expose children to fewer bacterial or viral parts than in the past, yet protect against more diseases.⁹

A study published in March 2013 confirmed that there is no relationship between the number of vaccines a child receives at one time and the risk of autism.³²

What's a combination vaccine?

Combination vaccines contain more than 1 type of vaccine in a single injection. Practically speaking, they help reduce the number of injections your child would need to get, and they may help parents stay on track with the recommended immunization schedule.⁴⁴

Most important, combination vaccines are given to protect vulnerable children against infectious diseases during their early months, when they're most at risk.⁴⁴ The CDC, which recommends the immunization schedule, generally prefers the use of a combination vaccine over separate injections.⁴⁴

Studies have shown that the recommended vaccines are as effective in combination as they are in a single injection, and that they carry no greater risk for serious side effects—which, of course, is a parent's priority.⁴⁴

Can I spread out the vaccination schedule for my child so there is more time between each shot?

Some flexibility is built into the vaccination schedule with age ranges for individual vaccines. For example, the chickenpox vaccine may be given at any point from 12 to 15 months of age.³⁸

The schedule is designed to work best with a child's immune system at certain ages and at specific times, and at the time when the child is at higher risk for most diseases.⁴³ For these reasons, it is not advised to change the recommended schedule.

Spreading out shots can leave your child unprotected and open to getting serious diseases.⁴³ It has also been shown that not sticking to the schedule can result in outbreaks of disease.⁴³ Because you may not know the vaccination status of other children, you can at least make sure your own child is protected by having him or her immunized.

Some children should not receive certain vaccines for medical reasons. For example, they may be allergic to certain ingredients (though allergic reactions are rare) or have a weakened immune system due to illness. In those cases, sometimes a vaccine may be delayed or skipped altogether.^{28,43}

For children who should not receive certain vaccines, their only protection from infectious disease is the immunity of people around them.⁷





| | What it is | What it can cause | Some facts |
|---|--|---|--|
| Hepatitis B (Hep B) | A serious liver disease transmitted at birth if a baby's mother is infected, or through a cut, wound, or contact with an infected person. ¹⁸ | Hep B can lead to liver damage and liver cancer. ¹⁸ | Of children infected with Hep B between 1 and 5 years of age, 30% to 50% have chronic or lifelong Hep B infection that can cause serious health complications. ¹⁸ |
| Rotavirus (RV) | An extremely contagious intestinal viral disease. Children can get it from contact with other children who are infected. ¹⁸ | Rotavirus can cause severe dehydrating diarrhea with fever and vomiting. | It's the leading cause of severe diarrhea in infants and young children in the United States. ¹⁸ |
| Diphtheria | A contagious disease caused by bacteria. You can get it from contact with an infected person. ¹⁸ | Diphtheria can lead to breathing problems, heart failure, and death. ¹⁸ | Before the vaccine, diphtheria caused up to 15,000 deaths in the United States per year. ¹⁸ |
| Tetanus | A bacterial disease you can get from a cut or wound. Tetanus is not contagious. ¹⁸ | Tetanus can lead to stiffness of muscles, including the jaw, so the person can't open his or her mouth or swallow. It's often called "lockjaw" for this reason. ¹⁸ | Almost all reported cases of tetanus are in people who have either never been vaccinated, or who have not had a booster in 10 years. ¹⁸ |
| Pertussis (whooping cough) | A highly contagious, bacterial disease. ¹⁸ | Pertussis can cause violent coughing spells. ¹⁸ | Pertussis is on the rise in the United States. ¹⁸ Infants may not be fully protected against pertussis until they have received at least 3 doses of the infant pertussis vaccine. ^{11,18} |
| <i>Haemophilus influenzae</i> type b (Hib) | Before vaccines, this was the leading cause of bacterial meningitis (infection of the brain and spinal cord coverings) in children under 5 years of age. It may be spread through close contact with an infected person, such as through coughing or sneezing. ¹⁸ | Hib can lead to meningitis, pneumonia, brain damage, deafness, and death. ¹⁸ | Cases of Hib have decreased by 99% since the use of the Hib vaccine. Recent cases of Hib disease were in unvaccinated or incompletely vaccinated children. ¹⁸ |

VACCINE-Preventable Diseases

| | What it is | What it can cause | Some facts |
|--------------------------------|---|---|---|
| Pneumococcal disease | A bacterial infection transmitted from an infected person. ¹⁸ | Pneumococcal disease can lead to pneumonia and meningitis. | Before the vaccine was available, about 188 of every 100,000 children younger than 2 years of age in the United States developed invasive pneumococcal disease. ⁴⁵ |
| Polio | A disease caused by a virus that is spread person-to-person. Up to 72% of people who are infected have no symptoms. However, they can still spread the disease to others. ² | Polio can lead to paralysis or death. ³ | Before the vaccine, 13,000 to 20,000 cases of polio were reported each year in the United States. ³ |
| Influenza | A serious respiratory illness, particularly for people with certain medical conditions, including asthma, diabetes, and heart disease. ⁴⁶ | Influenza can result in serious complications and even death. ⁴⁶ | Each year, an average of 20,000 children under 5 years of age are hospitalized because of flu complications. Flu seasons vary, but some children die from the flu each year. In 2009, more than 340 children died from the swine flu (H1N1). ⁴⁷ |
| Measles | Measles is one of the most infectious viral diseases in the world. ³ | Measles can lead to fever, cough, runny nose, red eyes, and generalized rash. It can also lead to ear infections, pneumonia, brain damage, and even death. ^{3,18} | Before the vaccine, nearly everyone in the United States got the measles. ³ Today, measles still occur. There were 17 outbreaks in 2011. ²² |
| Mumps | A viral disease that causes swollen glands in the neck and jaw area. ^{3,17} | Mumps can lead to deafness, paralysis, seizure, and fluid in the brain. ³ | Before the vaccine was available, mumps was a major cause of deafness in children. ³ |
| Rubella (German measles) | Rubella is a viral infection that can cause a mild rash. ¹⁸ | Rubella can cause miscarriages and premature birth in pregnant women. It can also cause birth defects, such as deafness, blindness, and mental retardation. ³ | Before routine use of the vaccine, 20,000 infants were born with birth defects as the result of rubella from 1964 to 1965. ³ |

| | What it is | What it can cause | Some facts |
|---------------------------|--|--|---|
| Varicella (chickenpox) | A disease that causes a rash on the body with many red spots and blisters. ⁴⁸ | You may think of chickenpox as a normal part of childhood, but it can be dangerous. Before the vaccine, chickenpox caused 100-150 deaths each year in the United States. ³ | Cases of chickenpox have decreased nearly 90% in some areas as a result of the vaccine. ³ |
| Hepatitis A (Hep A) | A virus you can get from eating contaminated food or drinking contaminated water. Some infected children do not show symptoms—a factor that plays a role in the spread of the disease. ¹⁸ | Hep A can lead to relapses and hospitalization. ¹⁸ | A total of 1987 cases of Hep A was reported in the United States in 2009. ¹⁸ |
| Meningococcal disease | A severe bacterial infection spread through contact with an infected person's respiratory and throat secretions. This can occur through coughing, kissing, and sneezing. ¹⁸ | Meningococcal disease can affect the brain (meningitis) and blood, and lead to deafness and other serious, life-long complications. ⁴⁹ | Each year, an estimated 1000 cases of meningococcal disease occur in the United States, most frequently in infants. ⁴⁹ |



Not necessarily. It's best to talk with your health care professional about any past infectious disease your child has had.



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Look to ImmYounity for answers you seek.

Don't let your journey for more information about vaccines stop here.

Learn more facts about immunization and share what you've learned on our website.

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