

### **Childhood Vaccinations**

## Top 12 questions answered with the nuance you're looking for

### Are childhood vaccines safer than the diseases themselves?



Yes, the **benefits continue to outweigh the risks** for routine vaccine-preventable diseases. For example, the risks of side effects from a measles-mumps-rubella (MMR) vaccination are vanishingly small, especially compared to the devastating effects of measles, as shown below.

### Complications from 10,000 children getting measles infections:

- 2,000 hospitalizations
  - 10 cases of brain swelling
  - 10-30 child deaths
- 1,000 ear infections with potential permanent hearing loss
- 500 cases of pneumonia

### Complications from 10,000 children getting the MMR vaccine:

- 3 fever-related seizures
- 0-1 cases of abnormal blood clotting
- 0.035 allergic reactions

### Do children *really* need vaccinations, even if the disease is not still around?



Although many diseases, like measles, are no longer widespread in most U.S. communities, children still need vaccines to maintain their immunity. These diseases are still alive and well in other parts of the world. In the U.S., we have cases of rubella, for example, but only from international travelers.

Think of population immunity like a water dam built to prevent flooding. Once it's built, we won't have flooding anymore. But if the next generation comes along and says, "Hey, there's no flooding anymore—do we really need this dam?" and decides to get rid of it, the flooding would return quickly. Your probability of encountering measles or polio is low because so many people around you are vaccinated.

Protecting against flooding is most important for people who can't save themselves—babies, the elderly, and the sick. When adults and kids are vaccinated against common diseases, it helps protect people whose immune system isn't fully functioning or who haven't been able to be vaccinated yet.

#### How do we know vaccines are safe? Are they ever taken off of the market?

Cal trials living

Rigorous, ongoing scrutiny of vaccine safety continues long after clinical trials conclude. This is important because even among the largest trials involving tens of thousands of volunteers, scientists may not detect a very rare safety concern that may emerge only after millions of doses.

The U.S. has a few monitoring systems to watch for the ongoing safety of vaccines:

- Anyone can submit a report to the Vaccine Adverse Event Reporting System (VAERS), which
  requires careful follow-up and additional study to figure out what if any, role vaccines played in
  the reported medical conditions. VAERS reports are frequently misrepresented as proof of
  vaccine safety issues, but they are unconfirmed reports that provide potential directions. If
  enough reports are submitted, the U.S. does a far more rigorous follow-up study using VSD (see
  next bullet).
- Vaccine Safety Datalink (VSD) is a national network of medical records from healthcare
  organizations and insurers that allows us to examine whether there is a link between
  vaccinations and safety signals.
- V-safe is a new program that started during the COVID-19 pandemic in which people text CDC more actively after a vaccine about how they feel and follow up weeks and months afterward. This allows CDC to watch for safety signals proactively.

Other monitoring systems exist, including **FDA BEST**. We also don't rely solely on U.S. data. The same vaccines are used worldwide, and other countries can flag potential safety issues that we can interrogate.

**Example of catching a safety signal quickly**: In 1999, an approved vaccine against rotavirus, a common cause of severe gastrointestinal illness in children, was found to be associated with a potentially fatal intestinal blockage. Within months of the vaccine's approval in 1998, reports to VAERS suggested a possible association. The vaccine was halted while the issue was investigated, and following confirmation of a link, the CDC withdrew its recommendation that infants receive the vaccine. It was never used again.

**Example of how sensitive our systems are:** During the COVID-19 pandemic, these systems also contributed to rapidly identifying blood clots associated with the Johnson & Johnson COVID-19 vaccine, ultimately leading to recommendations against its use and eventual withdrawal from the U.S. market. This safety signal was detected after 6 cases (out of 6.8 million doses given).

### Children receive so many more vaccines these days. Why? Is this okay?

This is true; Children born before the 1990s received far fewer vaccines than today's kids. However, **over the years, we have gotten better at developing vaccines in two ways.** 



#### 1983

Children under 2 received vaccines against **7 diseases.** 

These vaccine formulas were safe and effective but complex, targeting more than **3,000 antigens.** 

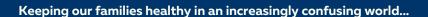
#### **TODAY**

Children under 2 receive vaccines against **15 diseases.** 

These vaccine formulas target **180 antigens** and therefore ask 'less' of the immune system.

This is one way scientists and physicians know that the number of childhood vaccines cannot 'overwhelm' immune systems. Also, this number of antigens is far less than the germs our immune systems marshal a response to every day, almost always without us even knowing it. That's the immune system doing its job!

**Advances in medical research** have also led to many new vaccines that have further reduced childhood illnesses. For example, a safe and effective Haemophilus influenza type b ("HiB") vaccine was developed in the late 1980s. It has dramatically lowered rates of childhood meningitis (brain infections), pneumonia, and epiglottitis (infection of the epiglottis that prevents kids from breathing). The same can be said for vaccines against varicella, pneumonia, rotavirus, and others capable of causing severe illness and deaths of children.



# Do we need to be reinfected to keep the immune system active? What about boosters?

Contrary to rumors, we don't need to get reinfected over and over for our immune systems to be ready to respond. Everything in our life—our house, pets, our own body—is filled with microbes. Although most of these microbes aren't harmful, they keep our immune systems active and ready to defend against dangerous foreign invaders.

That said, to stay protected from certain diseases (like pertussis, aka "whooping cough", or tetanus, aka "lockjaw"), you may need a vaccine booster. This is for a few reasons:

- 1. Catching these diseases usually acts as a natural booster but would also put you and your family at risk.
- 2. **Even if you got infected, boosters can help.** For example, a tetanus infection will not give you any immunity—the dose of toxin is too low to activate an antibody response; you have no protection from getting tetanus a second time if you are infected. A vaccine can help.
- 3. Some diseases need annual booster shots because viruses change quickly. For example, the flu virus changes from year to year, so each year's shot targets a different version of the virus. Scientists are hard at work figuring out the details of how to make current vaccines work better, but until those mysteries are unraveled, boosters it is.

### Why can't pharmaceutical companies be sued for vaccine injury?

This varies by country. In the U.S., you cannot immediately sue the pharmaceutical company. **You have to go through the NCVIA first.** 

The National Childhood Vaccine Injury Act (NCVIA) was enacted in 1986, after parent activists who believed their children were harmed by vaccines engaged in a series of lawsuits against pharmaceutical companies seeking compensation for damages. While there weren't any major wins on the part of these groups, the cost of these trials eventually reached a point where it was more than what vaccine manufacturers were earning from their products. Consequently, many vaccine manufacturers stopped making vaccines; it didn't make financial sense for them to do so-and the handful that remained were contemplating doing the same.

At that point, Congress stepped in with the National Childhood Vaccine Injury Act (NCVIA), which created the **National Vaccine Injury Compensation Program.** This act granted pharmaceutical companies certain legal protections and established a no-fault compensation system operated by the Department of Health and Human Services with a reduced burden of proof for petitioners who felt they had been harmed by vaccines. The system is paid for by an excise tax on each vaccine dose. The program also established a table of known vaccine-related adverse events-all of them quite rare-for which compensation is provided expeditiously.

This act also established a number of important oversights, including the previously mentioned Vaccine Adverse Effects Reporting System and a non-governmental committee to determine vaccine safety.

This system is imperfect, but it ensures that people harmed by vaccines have a path to compensation and that we still have access to lifesaving vaccines.

### Why does the U.S. have different recommendations than other countries?

Country-to-country differences tend to be pretty minor overall. When there are differences, they reflect (a) differences in manufacturing capabilities, (b) differences in the patterns of disease, and (c) differences in the payment and distribution systems. Here are a few examples:

- **Behavioral**: Universal vaccination recommendations work better than targeted vaccinations because of convenience and education. The U.S. used to have targeted hepatitis B vaccine recommendations, but uptake was poor. After a universal recommendation, there was a big decline in disease, and many lives (and livers) were saved. The same happened with the flu vaccine; universal recommendations increased uptake among high-risk groups.
- Financial: Most countries' governments pay for vaccines through national healthcare systems with fixed budgets, so the cost-benefit analysis is a big consideration when making policy decisions—for some countries, it would be too expensive for the government to vaccinate everyone, so they try to find where the money will have the biggest impact. Sometimes, this can have unexpected results. For example, modeling data suggests that when resources are constrained, prioritizing school-aged children for flu vaccination has the greatest benefit in minimizing flu deaths, even though the majority of deaths occur in the elderly (because this would have the biggest effect on transmission). The U.S. is fortunate in that, rather than having to pick and choose from a place of limited resources, it can offer the vaccine to everyone.
- **Safety net:** The U.S. has much less wiggle room because of worse healthcare access, social support, healthcare capacity, and health. Casting a larger net through universal vaccine recommendations is more critical than in other countries.
- Availability and accessibility: Some countries use the oral polio vaccine instead of the inactivated polio vaccine because the oral kind is easier to administer (you don't need people trained in giving injections), cheaper, and stops transmission better. The oral polio vaccine has a different number and timing of doses than the inactivated polio vaccine. However, because the oral vaccine contains actual poliovirus and can revert to paralytic polio if it circulates in the environment, use of the oral vaccine is considered only in places where there is a lot of polio (although even this is being reconsidered).
- **Epidemiological**: Though the diseases themselves are the same, their behavior within a particular country might differ. For example, meningitis caused by meningococcal B tends to occur in adolescents and young adults (and in particular in congregant living settings like college dorms), but throughout Europe, invasive meningococcal disease due to these bacteria is more common among infants. For this reason, many European countries have a recommendation for a meningococcal B vaccination in infancy, whereas the U.S. does not.

Physicians do not get paid by pharmaceutical companies for vaccinations. Vaccination is often billed to insurance companies. But these administration fees are rarely worth it. Surveys of pediatricians report that **most break even or even lose money from vaccination**—because the costs of vaccine storage, handling, and the doses themselves are so high. Some insurers have regional programs offering small financial incentives to pediatric practices for maintaining a certain level of vaccine uptake in their practices, but these programs are not universal, and the incentives are indeed small. The cost of vaccinating kids has gotten so high that some pediatric practices have stopped offering recommended vaccines.

### How do we know that the rise in autism is not linked to vaccines?



First, it's important to note that a lot of research is still needed to evaluate the cause of autism. The data we do have suggests that it is primarily the result of genetics.

What is clear is that vaccines, particularly MMR vaccines, do not cause autism. We know this because of a few reasons:

- 1. This rumor became prominent in the mid-1990s after a fraudulent scientific study was published by a scientist with conflicts of interest (trying to make his own measles vaccine) who eventually lost his medical license.
- 2. Huge, robust studies (spanning millions of children across many countries) have not found a link between autism and vaccines.
- 3. Scientists have learned that the hallmark of autism is dysregulation of brain development starting in the prenatal period before childhood vaccines are introduced.
- 4. Autism rates have increased over time. This increase is partially explained by factors like changes in diagnosis. Scientists continue to explore the data behind this trend.

## Why do babies need the hepatitis B vaccine if they aren't high-risk?

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The highest risk factor for hepatitis B (or HBV) is a history of sexually transmitted infections or multiple sex partners. So, if you've only had one partner for a decade, is this even applicable to your baby?

Yes, because the hepatitis B virus is a tricky booger:

- 1. The majority of people with HBV globally are unaware they have it. Many who do have it don't know how they contracted it. If we only give it to people who believe they are highrisk, we will miss many cases. Remember: it can take decades from the time you contract hepatitis B virus before symptoms become apparent.
- 2. **Hepatitis B virus requires only a very tiny dose to cause infections,** which means that even though it is bloodborne and sexually transmitted, it can be spread casually, like through sharing a toothbrush or even through being bitten by an infected person (such as at daycare).
- 3. **It's very stable in the environment,** capable of remaining infectious for weeks and even months on surfaces.
- 4. **The outcomes can be severe.** Mother-to-baby transmission at birth is the most common cause of chronic HBV infection, which can lead to liver cancer, liver failure, and death. If babies contract hepatitis B disease near birth, 95% develop the chronic form.

The HBV vaccine induces protective immune responses in nearly everyone (80-100%). The vaccine risks are extremely low—the only safety signal found is rare allergic reactions (one severe allergic reaction for every 2-3 million doses).

### Are there any long-term studies on whether the HPV vaccine impacts fertility?



Some of these concerns stemmed from a case series that was published in 2012, describing six girls who developed primary ovarian insufficiency (POI) from 8 months to 2 years after they received the first human papilloma virus (HPV) vaccine dose. This stirred public concern that the HPV vaccine could cause infertility.

However, case series often generate more questions than answers because they can't assess causality (correlation doesn't equal causation). Fortunately, **no rigorous lab or epidemiological follow-up studies have found a link:** 

- No effect of HPV vaccination on fertility has been found in 3 studies in rodents.
- A strong study in North America followed women planning on getting pregnant. Some of the women (and their partners) had their HPV vaccines, some of them didn't. The scientists found no difference in infertility. In fact, in some groups, vaccinated women had higher fertility.
- Another large study found that 120 of 199,078 female patients at hospitals had POI.
   There was no difference between those with the HPV vaccine and those without.

It is also critical to note that **being infected by the HPV virus can harm fertility** because of the procedures involved in treating HPV-related cancers. Some evidence has also suggested that HPV itself may reduce male fertility.

### Why do some children still get sick with a disease after being vaccinated?

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Vaccines significantly reduce the likelihood of getting sick from infectious diseases and, in many cases also greatly reduce transmission. For example, since the chickenpox vaccination program began in the United States, there has been an over **97% decrease in chickenpox cases.** For whooping cough, nearly all children (98 in 100) were protected within a year of their last shot and about 7 in 10 children were protected five years after getting the last DTaP shot. Most vaccines, however, do not completely eliminate the risk of becoming infected with the disease.

Upon infection, vaccines can also **lessen the severity of several diseases.** Most recently, this has been demonstrated in a number of COVID-19 vaccine studies, which have found that vaccinated individuals, compared with unvaccinated individuals, are less likely to become severely ill.

For many vaccine-preventable diseases, immunity from an infection can be imperfect- it may still make sense to get vaccinated even after recovering to help prevent serious illness from reinfection and to reduce spread.

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### Why do some children still get sick with a disease after being vaccinated?

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