Q&A THE FACTS ABOUT VACCINE SAFETY: WHAT YOU SHOULD KNOW

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Q. Are vaccines safe?

A. Because vaccines are given to people who are not sick, they are held to the highest standards of safety. As a result, they are among the safest things we put into our bodies.

How does one define the word safe? If safe is defined as "free from any negative effects," then vaccines aren't 100% safe. All vaccines have possible side effects. Most side effects are mild, such as fever, or tenderness and swelling where the shot is given. But some side effects from vaccines can be severe. For example, the pertussis vaccine is a very rare cause of persistent, inconsolable crying, high fever or seizures with fever. Although these reactions do not cause permanent harm, they can be quite frightening.

If vaccines cause side effects, wouldn't it be "safer" to just avoid them? Unfortunately, choosing to avoid vaccines is not a risk-free choice — it is a choice to take a different and much more serious risk. One example is the COVID-19 mRNA vaccine. While the vaccine includes a low risk of developing myocarditis (an inflammation of the heart), having a COVID-19 infection includes a much greater risk of developing myocarditis. Further, myocarditis caused by infection has been more severe than that following vaccination. So, avoiding the COVID-19 vaccine does not decrease, but rather increases, the risk for this serious condition.

Other examples abound. For example, discontinuing the pertussis vaccine in countries like Japan and England led to a tenfold increase in hospitalizations and deaths from pertussis. And declines in the number of children receiving measles vaccine in the United Kingdom and the United States have led to increases in cases of measles.

When you consider the risk of vaccines and the risk of diseases, vaccines are the safer choice.

Q. Are vaccines still necessary?

A. Although several of the diseases that vaccines prevent have been dramatically reduced or eliminated, vaccines are still necessary:

- ***To prevent common infections.*** Some diseases are so common that a choice not to get a vaccine is a choice to get infected. For example, choosing not to get the pertussis (whooping cough) vaccine is a choice to risk a serious and occasionally fatal infection.

- ***To prevent infections that could easily reemerge.*** Some diseases can easily reemerge with relatively small decreases in immunization rates (for example, measles, mumps and *Haemophilus influenzae* type b, or Hib). We have seen this with measles and mumps. Unvaccinated people are more likely to be infected.

- ***To prevent infections that are common in other parts of the world.*** Although some diseases have been completely eliminated (polio) or virtually eliminated (diphtheria) from this country, they still occur commonly in other parts of the world. Children are still paralyzed by polio and sickened by diphtheria in other areas of the world. Because there is a high rate of international travel, outbreaks of these diseases are only a plane ride away. This was demonstrated in 2022 when an unvaccinated individual in New York was paralyzed by polio.

Q. What is the harm of changing the vaccine schedule?

A. Although the infant vaccine schedule can look intimidating, it's based upon the best scientific information available and is better tested for safety than any alternative schedules. Experts review studies designed to determine whether any changes are safe in the context of the existing schedule (called concomitant use studies).

Separating, spacing out or withholding vaccines causes concern for a few reasons. First, this approach causes infants to be susceptible to diseases for longer periods of time. This is important because the schedule is determined by balancing when the recipient is at highest risk of contracting the disease and when the vaccine will generate the best immune response.

Second, changing the vaccine schedule requires additional doctor visits. Research measuring cortisol, a hormone associated with stress, has determined that children do not experience more stress when receiving two shots as compared with one shot. Therefore, an increased number of visits for individual shots will mean an increase in the number of stressful situations for the child without benefit. Third, because altered schedules are not the norm and often vary by an individual family's wishes, there is an increased potential for administration errors. Finally, more time and travel are needed for appointments; costs may increase, and there is a possibility that the child will never get some vaccines.

Q. Do children get too many shots?

A. Newborns commonly manage many challenges to their immune systems at the same time. Because some children could receive more than 25 vaccine doses by the time they are 2 years old and multiple shots in a single visit to the doctor, some wonder whether it is safe to give children so many vaccines.

Although the womb is free from bacteria and viruses, newborns immediately face a host of different challenges to their immune systems. From the moment of birth, thousands of different bacteria start to live on the surface of the skin and intestines. By quickly making immune responses to these bacteria, babies keep them from invading the bloodstream and causing serious diseases. In fact, babies are capable of responding to millions of different viruses and bacteria because they have billions of immunologic cells circulating in their bodies. Therefore, vaccines given in the first two years of life are a raindrop in the ocean of what an infant's immune system successfully encounters and manages every day.

Q. Do vaccines cause autism?

A. Carefully performed studies clearly disprove the notion that vaccines cause autism. Because the signs of autism may appear in the second year of life, at around the same time children receive certain vaccines, and because all causes of autism are unknown, some have wondered whether vaccines might be at fault. These concerns focused on three hypotheses — autism is caused by the measles-mumps-rubella (MMR) vaccine; thimerosal, an ethylmercury-containing preservative used in vaccines; or receipt of too many vaccines too soon.

A large body of medical and scientific evidence strongly refutes all three of these notions. Multiple studies have found that vaccines do not cause autism. These studies included hundreds of thousands of children, occurred in multiple countries, were conducted by multiple investigators, and were well controlled.

To find the most up-to-date information about the causes of autism, visit the Autism Science Foundation website, autismsciencefoundation.org.

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Q&A THE FACTS ABOUT VACCINE SAFETY: WHAT YOU SHOULD KNOW

Q. Do vaccines contain additives?

A. Many vaccines contain trace quantities of antibiotics or stabilizers. Antibiotics are used during the manufacture of vaccines to prevent inadvertent contamination with bacteria or fungi. Trace quantities of antibiotics are present in some vaccines. However, the antibiotics contained in vaccines (neomycin, streptomycin or polymyxin B) are not those commonly given to children. Therefore, children with allergies to antibiotics such as penicillin, amoxicillin, sulfa or cephalosporins can still get vaccines. Adults with medication allergies should check with their healthcare provider before getting vaccinated.

Gelatin is used to stabilize live, weakened viral vaccines and is also contained in many food products. People with known allergies to gelatin contained in foods may have severe allergic reactions to the gelatin contained in vaccines. However, this reaction is extremely rare.

Q. Is the amount of aluminum in vaccines safe?

A. Yes. Aluminum is used as an adjuvant in some vaccines. Adjuvants increase the immune response, often allowing for lower or fewer doses of vaccine. All of us have aluminum in our bodies, and most of us are able to process it effectively. The two main groups of people who cannot process aluminum effectively are severely premature infants, who often receive large quantities of aluminum in intravenous fluids, and people who have long-term kidney failure. They often receive large quantities of aluminum, primarily in antacids. In both cases, the kidneys are not working properly or at all, exposing these individuals to large quantities of aluminum over a long period of time.

The amount of aluminum in vaccines given during the first six months of life is about 4 milligrams, or four-thousandths of a gram. A gram is about the weight of one raisin, so a milligram is about one-thousandth of a raisin. In comparison, breast milk ingested during this period will contain about 10 milligrams of aluminum, and infant formulas will contain about 40 milligrams. Soy-based formulas contain about 120 milligrams of aluminum. These quantities, which are larger than those from vaccines, are still very minor and easily handled by babies, so the aluminum exposure to babies from vaccines and food is safe.

Interestingly, when studies were performed to look at the amount of aluminum injected in vaccines, the levels of aluminum in blood did not detectably change. This indicates that the quantity of aluminum in vaccines is minimal compared with the quantities already found in the blood.

Q. Are vaccines made using fetal cells?

A. Viruses require cells in which to reproduce. This means to make viral vaccines that contain parts of or whole viruses, the vaccine virus must be grown in cells in the laboratory. In a few cases, the types of cells chosen were from pregnancies that were terminated electively. The scientists made this decision for two reasons. First, viruses that infect people reproduce best in cells from people. Second, cells isolated from a fetus are not likely to contain contaminating viruses because the womb is sterile.

The fetal cells used to grow vaccine viruses were isolated from three elective abortions. The two most commonly used cell lines were isolated from procedures that occurred in the early 1960s. The third type, made using retinal cells, was isolated in 1985. This type is only used in the adenovirus-based COVID-19 vaccines (like J&J/Janssen), which are no longer available in the U.S. In all three cases, the cells have been grown in the laboratory since they were isolated, and no additional abortions are needed to make the vaccines that are produced using them.

The vaccines made using the fibroblast cell lines isolated in the 1960s include the chickenpox, rubella (part of MMR), hepatitis A, and rabies (one version) vaccines.

Q. Can vaccines change a person's DNA?

A. No. Vaccines do not change a person's DNA. This concern has risen in two contexts. First, some people have concerns that if a vaccine is made using human cell lines, it could contain remnants of human DNA that would change a person's DNA. This is not possible because the vaccine production process includes steps to remove most manufacturing residuals, and any DNA that remains is too fragmented to cause any changes. Second, the COVID-19 mRNA and adenovirus vaccines deliver genetic material, so some people worry that this material can change their own DNA. This is not possible in the case of either vaccine:

- mRNA vaccines do not deliver DNA, and they do not include the enzymes required to produce DNA from RNA.
- Adenovirus vaccines, which are no longer available in the U.S., deliver DNA, but they do not include the enzymes required for the vaccine-delivered DNA to be added into a person's DNA.

Also, important to consider is that these vaccines are delivered to muscle cells, and they are processed near the injection site. This means that the genetic material delivered by these vaccines is never introduced to, or even located near, cells involved with reproduction, such as sperm or egg cells. For these reasons it is not possible for vaccines to change a person's DNA.

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Q&A VACCINE INGREDIENTS: WHAT YOU SHOULD KNOW

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Some parents are concerned about ingredients in vaccines, such as aluminum, mercury, gelatin and antibiotics. Parents can be reassured by two facts. First, the quantities of each ingredient are minimal. Second, only necessary ingredients are used, and any ingredients present are tested as part of the vaccine during safety studies. This sheet describes some of the ingredients used in vaccines and why they are necessary.

Q. Why is aluminum in vaccines?

A. Aluminum is used in vaccines as an *adjuvant*. Adjuvants enhance the immune response by allowing for lesser quantities of active ingredients and, in some cases, fewer doses. Until recently, aluminum salts were the only class of adjuvants approved for use in the United States.

Aluminum

Aluminum salts have been used as adjuvants in vaccines in the United States since the 1930s. Some people wonder whether aluminum in vaccines is harmful – the facts are reassuring.

First, vaccines are not the only way we are exposed to aluminum. It is present in our environment – in the air we breathe, the water we drink, and the food we eat.

Second, the quantity of aluminum in vaccines is small. For example, in the first six months of life, babies receive about 4 milligrams* of aluminum if they get all of the recommended vaccines. However, during this same period, they will consume about 10 milligrams of aluminum if they are breastfed, 40 milligrams if they are fed regular infant formula, and up to 120 milligrams if they are fed soy-based infant formula. Even though the amounts of aluminum in a baby's food are larger than those from vaccines, these quantities are all very small and, therefore, safe.

Some people wonder about the difference between aluminum injected in vaccines versus aluminum consumed in food. Typically, infants have between 1 and 5 nanograms (billionths of a gram) of aluminum in each milliliter of blood. Researchers have shown that after vaccines are injected, the quantity of aluminum detectable in an infant's blood does not change and that when we are exposed to aluminum, about half is eliminated from the body within one day. In fact, aluminum causes harm only when kidneys are not functioning properly, or at all (so aluminum cannot be effectively eliminated), AND large quantities of aluminum, such as those in antacids, are administered.

Other adjuvants

Monophosphoryl lipid A
Monophosphoryl lipid A was isolated from the surface of bacteria and detoxified so that it cannot cause harm. This adjuvant has been tested for safety in tens of thousands of people and was approved for use in the United States in 2009.

QS21
This soap-based molecule was isolated from the bark of *Quillaja saponaria* trees.

MF59
This substance is a mix of an oil, called squalene, and water. Squalene is found in people, animals and plants.

CpG
This substance is a mix of two nucleic acids that make up DNA, known as cytosine and guanine.

**A milligram is one-thousandth of a gram, and a gram is the weight of about one raisin.*

Q. Why is formaldehyde in vaccines?

A. Formaldehyde is a byproduct of vaccine production. Formaldehyde is used during the manufacture of some vaccines to inactivate viruses (like polio and hepatitis A viruses) or bacterial toxins (like diphtheria and tetanus toxins). While most formaldehyde is purified away, small quantities remain.

Because formaldehyde is associated with the preservation of dead bodies, its presence in vaccines seems inappropriate. However, it is important to realize that formaldehyde is also a byproduct of protein and DNA synthesis, so it is commonly found in the bloodstream. The quantity of formaldehyde found in blood is 10 times greater than that found in any vaccine.

Q. Why is gelatin in vaccines?

A. Gelatin is used in some vaccines as a *stabilizer*. Stabilizers are added to vaccines to protect the active ingredients from degrading during manufacture, transport and storage. Gelatin, which is made from the skin or hooves of pigs, is concerning because some people (about 1 of every 2 million) might have a severe allergic reaction to it.

Also, because religious groups, such as Jews, Muslims and Seventh Day Adventists, follow dietary rules that prohibit pig products, some parents are concerned about using vaccines that contain gelatin. However, all religious groups have approved the use of gelatin-containing vaccines for their followers for several reasons. First, vaccines are injected, not consumed (except the rotavirus vaccine, which does not contain gelatin). Second, gelatin in vaccines has been highly purified and hydrolyzed (broken down by water), so it is much smaller than that found in nature; therefore, religious leaders believe it to be different enough that it does not break the religious dietary laws. Finally, leaders from these religious groups believe that the benefits of receiving vaccines outweigh adherence to religious dietary laws.

Q. Why is mercury in vaccines?

A. Mercury is contained in some multi-dose preparations of influenza vaccine as a *preservative*. Preservatives prevent contamination with bacteria. Early in the 20th century, most vaccines were packaged in vials that contained multiple doses. Doctors and nurses would draw up a single dose and place the remaining vaccine back in the refrigerator. Unfortunately, sometimes bacteria would inadvertently enter the vial, contaminating the remaining doses of vaccine. When another patient received vaccine from that vial, they might also be injected with the contaminant, occasionally causing abscesses at the site of injection or bloodstream infections that could be fatal. Preservatives, originally added in the 1930s, solved this problem.

The most common preservative used was thimerosal, a mercury-containing compound. As more vaccines were given, children received greater quantities of thimerosal. By the late 1990s, the American Academy of Pediatrics and the Public Health Service requested that mercury be removed from vaccines to make "safe vaccines safer." No evidence existed to suggest that thimerosal was causing harm, but they wanted to be cautious. Unfortunately, their caution worried parents who wondered whether mercury in vaccines was causing subtle signs of mercury poisoning or autism. Addressing these concerns, scientists performed several studies, all of which showed that thimerosal at the level contained in vaccines hadn't caused harm. Today, the only routinely recommended childhood vaccine that contains thimerosal is some preparations of influenza vaccine.

Because mercury is a naturally occurring element found in the earth's crust, air, soil and water, we are all exposed to it regardless of whether it is contained in vaccines. In fact, infants who are exclusively breastfed consume more than twice the quantity of mercury than was previously contained in vaccines. Today, breastfed infants consume 15 times more mercury in breast milk than is contained in the influenza vaccine.

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Q&A VACCINE INGREDIENTS: WHAT YOU SHOULD KNOW

Q. What about the cumulative effect of vaccine ingredients when my child receives multiple vaccines in a single day?

A. Questions about the cumulative effect when multiple vaccines are given on the same day are reasonable. However, several sources of information provide reassurance:

- A study by Michael Smith and Charles Woods showed that 7- to 10-year-old children vaccinated according to the recommended schedule as infants did not have neuropsychological delays, such as speech and language delays, verbal memory, fine motor coordination, motor or phonic tics, and intellectual functioning.
- If a new vaccine is added to the schedule at a time when other vaccines are given, studies must be completed to show that neither vaccine interferes with the safety or ability of the other to work. Known as *concomitant use studies*, these studies are numerous and extensive, offering additional information regarding interference of vaccine ingredients or effects caused by too much of an ingredient.
- Studies of the immune system estimate that we can respond to about 10,000 different immunologic components at any one time. The number of immunologic components contained in all of the vaccines recommended for young children today is less than 200 immunologic components.
- Finally, vaccine additives, such as aluminum, have been studied regarding how they are processed in the body as well as what levels are toxic. For example, people who suffer toxic effects of aluminum must have had long-term exposure to aluminum (months or years) as well as non-functioning or improperly functioning kidneys.

With all of this information, we can conclude that multiple vaccines given in one day are not overwhelming an infant's immune system.

Q. Are some vaccines made using fetal cells?

A. Fetal cells are used to make these vaccines: rubella (the "R" in MMR), chickenpox, hepatitis A, (one version of) rabies, and the adenovirus-based COVID-19 (like J&J/Janssen). Fetal cells used to grow the vaccine viruses were isolated from three elective abortions. The cell line used for the COVID-19 adenovirus-based vaccines was isolated in 1985. Those used for the other vaccines listed were from two elective abortions performed in Sweden and England in the early 1960s. Because of cell culture technology, further abortions are not necessary as these three cell lines continue to be maintained in laboratory cultures.

Some people wonder why scientists would choose to use fetal cells at all. There are several reasons for this. First, viruses, unlike bacteria, require cells to grow, and human cells are often better than animal cells at supporting the growth of human viruses. Second, fetal cells are less likely to be contaminated with other viruses because the womb is a sterile environment. Finally, fetal cells can reproduce more times than older cells before dying, making it easier to maintain a supply to use over time.

Some questions have been raised regarding the use of vaccines grown in fetal cells by people whose religious beliefs are against abortions. In 2005, when Pope Benedict XVI was head of the Catholic Church's Congregation of the Doctrine of Faith, this question was addressed; it was determined that because of the life-saving nature of vaccines, Catholic parents could reasonably give these vaccines to their children. Similarly, the National Catholic Bioethics Center determined that use of vaccines grown in fetal cells isolated from historic abortions was morally acceptable. In 2017, the Pontifical Academy for Life also clarified their position in support of using vaccines grown in fetal cells.

Q. Do ingredients in vaccines cause allergic reactions?

A. In addition to gelatin, other ingredients in vaccines, such as egg proteins, antibiotics and yeast proteins, might cause an allergic reaction. Latex used in vaccine packaging is also a concern related to allergies.

Egg proteins
Because the influenza and yellow fever vaccines are grown in eggs, the final products may contain egg proteins. Advances in protein chemistry and alternative technologies have resulted in no or significantly lower quantities of egg proteins in the influenza vaccine; therefore, people with egg allergies can now get influenza vaccine. However, it is recommended that severely egg-allergic vaccine recipients remain in the office for 15 minutes after getting the influenza vaccine in case of any reaction. People with egg allergies who may need yellow fever vaccine should discuss their situation with a healthcare provider.

Antibiotics
Antibiotics are used to prevent bacterial contamination during production of some vaccines. However, the types of antibiotics used in vaccines, such as neomycin, streptomycin, polymyxin B, chlortetracycline and amphotericin B, are not those to which people are usually allergic.

Yeast proteins
A couple of viral vaccines are made in yeast cells; these include hepatitis B vaccine and the human papillomavirus vaccine. Although the vaccine is purified away from the yeast cells, about 1 to 5 millionths of a gram remain in the final product. The good news is that people who are allergic to bread or bread products are not allergic to yeast, so the risk of allergy from yeast is theoretical.

Latex packaging
A small number of vaccines are packaged with materials that include latex. While it is rare that patients have a reaction to latex in vaccine packaging, people with latex allergies should consult with their allergy doctor before getting any vaccines packaged in this way.

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Q&A DNA, FETAL CELLS & VACCINES: WHAT YOU SHOULD KNOW

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The idea of vaccines containing fetal cells or fetal DNA can be troublesome. For some, such as Catholics, concerns are often related to the use of fetal cells because the Catholic Church does not condone abortions. For others, the concerns are based on more general religious or personal beliefs. In the case of the Catholic Church, The Pontifical Academy for Life, the Vatican's major policymaking body, examined the issue of congregants accepting vaccines made using fetal cells. Their decision expressed a preference that vaccines be made without the use of fetal cells when possible, but they determined that Catholics who accept these vaccines are "morally justified" in doing so because of a lack of alternatives and the greater need to protect one's children and those who are in contact with the children. **Despite this decision, we understand that some individuals, regardless of which religion they practice, have concerns and questions relevant to this topic. This Q&A addresses some of the most common questions we receive.**

Q. Why are cells used to make vaccines?

A. Viruses are simple organisms. They usually only contain a few proteins and genes (DNA or RNA). As a result, they do not have the machinery needed to reproduce on their own. Therefore, viruses need to infect cells and use the cells' machinery to make more of themselves. This means that to study viruses — or make vaccines — scientists need cells in which the viruses reproduce. Different viruses cannot use any type of cell to reproduce, so an important part of viral research is figuring out which type of cell each virus favors.

Watch an animation that shows how viruses reproduce, *bit.ly/3wDqM7W*.

Q. Why were fetal cells used to make vaccines?

A. Scientists were originally studying fetal cells to understand the aging process. However, scientific collaboration and a challenge in vaccine development led to the use of fetal cells in vaccine development. Specifically, scientists had found a potentially cancer-causing virus, called simian virus 40 (SV40), in the polio vaccine, which was made by first growing polio virus in monkey kidney cells. It was called SV40 because it was the 40th monkey virus identified. Ultimately, SV40 was shown not to cause cancer in polio vaccine recipients, but that understanding took time to evolve. In the interim, vaccine scientists realized that because viruses need cells in which to grow, they had to be sure that SV40 or other harmful viruses would not be introduced in future vaccines. Serendipitously, one of the most prominent scientists studying aging, Leonard Hayflick, was working down the hall from two prominent vaccine scientists, Hilary Koprowski and Stanley Plotkin, at the Wistar Institute in Philadelphia. Together, the trio realized that because fetuses are not typically exposed to viruses in the womb, their cells offered a way to ensure that future viral vaccines did not inadvertently contain other viruses that might be harmful to people.

In addition to being free of potentially contaminating viruses, fetal cells offered another benefit for vaccine development. Because vaccines target viruses that infect people, the human viruses used to create vaccines grow best in human cells.

Q. Which vaccines use fetal cells?

A. Vaccines made using fetal cells include:

- Chickenpox (varicella)
- COVID-19 (viral vector versions, such as J&J/Janssen and AstraZeneca)
- Hepatitis A
- Rabies (one version, known as Imovax®)
- Rubella (the "R" in the MMR vaccine)

No other vaccines, including influenza and COVID-19 mRNA vaccines, are made using fetal cells.

Q. Do vaccines that use fetal cells require additional abortions?

A. No. Once cells are prepared from their original source, they can be maintained indefinitely in the laboratory. The process of maintaining these cells is commonly referred to as "cell culture" or "cell passage."

Cell culture involves growing cells in specialized containers in a sterile, temperature-controlled environment. Nutrients that encourage cell growth are added to the containers, and as the cells replicate and fill the surface of the container, scientists divide them into new sterile containers and add fresh ingredients. Periodically, they will also store some of the new cells in special freezers, called liquid nitrogen freezers. These freezers maintain temperatures of −190 degrees Celsius (−310 degrees Fahrenheit). Storage of the cells at this extreme temperature allows them to survive but remain biologically inactive. So, when scientists need a fresh supply of cells, they can thaw some and again start growing new cells. In this manner, the supply of cells is virtually limitless. As a consequence, additional abortions are not necessary. The fetal cells used to make vaccines today were first isolated in the 1960, 1970s, or 1980s depending on the vaccine.

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Q&A DNA, FETAL CELLS & VACCINES: WHAT YOU SHOULD KNOW

Q. Do fetal cells contain DNA? What is DNA?
A. All human cells, including fetal cells, contain DNA, which stands for deoxyribonucleic acid. DNA is a blueprint that provides instructions for our cells so they can function properly, meaning they can make proteins and enzymes, communicate with other cells, and more.

DNA is protected in a compartment in each cell, called the nucleus. The nucleus is like the air traffic control station, overseeing all activity in the cell from a protected place while ensuring that the cell accomplishes its work in an orderly manner.

Q. Is fetal cell DNA contained in vaccines?
A. Because vaccine viruses go through several steps of purification and because DNA does not withstand these processes very well, any components of DNA that remain are highly fragmented and minimal. When DNA from the production process has been measured in vaccines, it was only present in picogram quantities. A picogram is one-trillionth of a gram (0.000000000001). As such, this small amount of fragmented material is not able to cause damage or interact with our own DNA.

Q. Can fetal cell DNA alter our DNA?
A. No. Because the chickenpox, hepatitis A, rabies (one version), and rubella vaccines are grown in human fetal cell lines, some people wonder if the DNA from the fetal cells could change a person's own DNA. However, when viruses grow in cells, the cells are usually broken open to release the new virus particles. This is what happens in our bodies when we have a viral infection, and it happens in the laboratory, too. In the body, some immune system cells function as vacuum cleaners to remove debris, including cells destroyed by a viral infection. In the laboratory, scientists use purification methods to get rid of the cell debris. Because DNA is a relatively fragile molecule, any DNA that might have survived the viral infection is destroyed during the purification process. As such, even small fragments of DNA that might remain would not be recognizable or have any ability to cause issues when injected with a vaccine.

Additional resources

Stanley Plotkin: Pioneering the use of fetal cells to make rubella vaccine (video), *hillemanfilm.com/stanley-plotkin* (This webpage also contains greater detail about the cell passage process.)

A Look inside the Lab: Liquid Nitrogen Freezer (video), *bit.ly/3PA1ijb*

The Vaccine Race: Science, Politics, and the Human Costs of Defeating Disease (book) – Meredith Wadman, Penguin Random House, 2017 (This book is summarized on the Vaccine Update website at *bit.ly/3Gd7rxn*.)

Q. Do mRNA vaccines contain DNA?
A. No. The Pfizer and Moderna COVID-19 vaccines use messenger RNA, or mRNA. These vaccines do not contain DNA. RNA stands for ribonucleic acid. Messenger RNA instructs cells on how to make proteins.

Q. Even though mRNA vaccines don't contain DNA, can these vaccines alter our DNA? Why not?
A. Since mRNA is a nucleic acid, like DNA, some wonder if the mRNA can be converted into DNA and become part of a person's DNA. This cannot happen for several reasons. First, the mRNA is released into the cell's cytoplasm, and it is processed there. DNA, on the other hand, is protected in a cell's nucleus. For a nucleic acid to enter the nucleus, the proper enzymes must be available. These enzymes are not delivered with the vaccine and are not typically found in the cytoplasm because then the nucleus would be more easily breached by any nucleic acid. Second, even if the mRNA entered the nucleus, it would first need to be converted to DNA, which would require another enzyme that is not available in the vaccine. This enzyme is called reverse transcriptase. Third, even if the mRNA did get converted to DNA and enter the nucleus, a different enzyme, called integrase, would need to be available for the new DNA to become part of the individual's DNA. Integrase is not delivered with the vaccine nor is it readily available in a cell. As such, it is impossible for an mRNA vaccine to change a person's DNA.

Q. Do viral vector vaccines contain DNA?
A. Yes. Viral vector vaccines, like the J&J/Janssen and AstraZeneca COVID-19 vaccines, deliver DNA. The COVID-19 vaccines contain DNA that represents the spike protein of SARS-CoV-2, the virus that causes COVID-19.

The vaccine DNA enters the cell's nucleus where it is converted into mRNA. The mRNA is then sent to the cell's cytoplasm to be used as a blueprint for making the spike protein, which is then recognized as something the immune system needs to respond to by generating a coordinated immune response.

Q. Can viral vector vaccines alter our DNA? If not, why not?
A. Since DNA from the vaccine enters the nucleus, where our own DNA resides, one might wonder how we know that our DNA is not being altered. Because the viral vector that delivers the vaccine cannot replicate, it does not have necessary enzymes, such as integrase, that would be required for vaccine DNA to be incorporated into our own DNA. Interestingly, even if the DNA was able to incorporate itself, it is important to realize that the vaccine is not delivered to cells that are part of a germ line, meaning cells that would be involved in reproduction.

This information is provided by the Vaccine Education Center at Children's Hospital of Philadelphia. The Center is an educational resource for parents, the public and healthcare professionals and is composed of scientists, physicians, mothers and fathers devoted to the study and prevention of infectious diseases. The Vaccine Education Center is funded by endowed chairs from Children's Hospital of Philadelphia. The Center does not receive support from pharmaceutical companies.

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Q&A ALUMINUM IN VACCINES: WHAT YOU SHOULD KNOW

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Aluminum is present in several vaccines to improve the immune response. Some parents are concerned that aluminum in vaccines might be harmful to babies. However, healthy babies quickly eliminate aluminum from their bodies without harmful effects.

Q. What is aluminum?
A. Aluminum is the most common metal found in nature. It is present in the water we drink, the air we breathe, and the food we eat.

Q. Is aluminum in vaccines?
A. Yes. Aluminum is present in vaccines that prevent hepatitis A, hepatitis B (most versions), diphtheria-tetanus-pertussis (DTaP, Td, Tdap), *Haemophilus influenzae* type b (Hib; one version), human papillomavirus (HPV), Japanese encephalitis (JE), anthrax, meningococcal B, tick-borne encephalitis (TBE) and pneumococcus (conjugate versions). It is also present in combination vaccines that contain any of these individual vaccines.

Aluminum is not present in live, weakened viral vaccines, like those that prevent measles, mumps, rubella, chickenpox, mpox/smallpox, yellow fever and rotavirus, because the viral reproduction that occurs during processing generates strong immune responses. Aluminum is also not present in the following (non-live) vaccines: influenza, meningococcal ACWY, cholera, dengue, Ebola, rabies, pneumococcal (polysaccharide version), typhoid, shingles and polio vaccines.

Q. Why is aluminum in vaccines?
A. Aluminum is present in certain vaccines to improve the immune response. Substances used to improve immune responses are called *adjuvants*. Adjuvants often allow for lesser quantities of the vaccine and fewer doses. Aluminum salts, such as aluminum hydroxide, aluminum phosphate and aluminum potassium sulfate, have been used to improve the immune response to vaccines for more than 70 years.

Q. How much aluminum is in vaccines?
A. During the first six months of life, infants could receive about 4 milligrams of aluminum from vaccines. That's not very much: A milligram is one-thousandth of a gram, and a gram is the weight of one-fifth of a teaspoon of water. During the same period, babies will also receive about 10 milligrams of aluminum in breast milk, about 40 milligrams in infant formula, or about 120 milligrams in soy-based formula.

Q. What happens to aluminum after it enters the body?
A. Most of the aluminum that enters the body is eliminated quickly. Though all of the aluminum present in vaccines enters the bloodstream, less than 1% of aluminum present in food is absorbed through the intestines into the blood.

However, once aluminum is in the bloodstream, it is processed similarly regardless of the source. Approximately 90% is processed by binding to a protein called transferrin, and about 10% is bound by citrate. Once bound, the majority of aluminum will be eliminated through the kidneys, a small amount through bile, and a small amount will be retained in tissues of the body. About half of the aluminum in the bloodstream is eliminated in less than 24 hours, and more than three-quarters is eliminated within two weeks. The ability of the body to rapidly eliminate aluminum accounts for its excellent record of safety.

Q. What happens to the aluminum retained in the body?
A. The small quantity of aluminum retained in the body accumulates over time. Most of the aluminum that accumulates (50% to 60%) settles in the bones, some in the lungs (about 25%) and some in the brain (about 1%). The remaining quantities are distributed in serum, skin, lymph nodes, glands, and the gastrointestinal tract. In fact, low quantities of aluminum can be found in most organs.

By the time children become adults, they will have accumulated between 50 and 100 milligrams of aluminum. Almost all of that accumulated aluminum comes from food.

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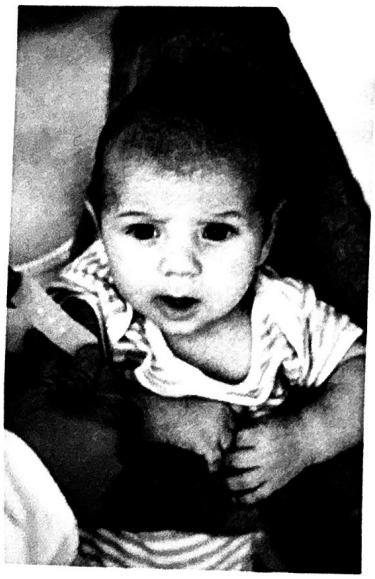
Q&A ALUMINUM IN VACCINES: WHAT YOU SHOULD KNOW

Q. Is the amount of aluminum in vaccines safe?
A. Yes. The best way to answer this question is to look at people who are harmed by aluminum. These people can be divided into two groups: severely premature infants who receive large quantities of aluminum in intravenous fluids and people with long-standing kidney failure who receive large quantities of aluminum, primarily in antacids. (The average recommended dose of antacids contains about 1,000 times more aluminum than is found in a vaccine.) Both of these groups of patients can suffer brain dysfunction, bone abnormalities or anemia because of the high quantities of aluminum that have accumulated in their bodies.

For aluminum to be harmful, two criteria must be met: People must have kidneys that don't work well or don't work at all, and they must receive large quantities of aluminum for months or years. In these situations, a lot of aluminum enters the body and not enough leaves the body.



Q. Isn't it possible that aluminum in vaccines could be harmful to some healthy babies?
A. No. The quantity of aluminum in vaccines is tiny compared with the quantity required to cause harm. Here's another way to think about this: All babies are either breastfed or bottle-fed. Because both breast milk and infant formula contain aluminum, all babies have small quantities of aluminum in their bloodstreams all the time. The amount is very small: about 5 nanograms (billionths of a gram) per milliliter of blood (about one-fifth of a teaspoon). Indeed, the quantity of aluminum in vaccines is so small that even after an injection of vaccines, the amount of aluminum in a baby's blood does not detectably change. In contrast, the amount of aluminum in the bloodstreams of people who suffer health problems from aluminum is at least 100 times greater than the amount found in the bloodstreams of healthy people.

Q. What is the harm in spacing out vaccines containing aluminum?
A. Delaying vaccines increases the time during which children are susceptible to catching vaccine-preventable diseases. Certain diseases, such as pertussis (whooping cough) and pneumococcus, still occur commonly in the United States. Given that aluminum is common in food and water, delaying vaccines will not significantly lessen a child's exposure to aluminum; it will only increase the child's chance of suffering a severe and potentially fatal infection.

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Q&A RECOMMENDED IMMUNIZATION SCHEDULE: WHAT YOU SHOULD KNOW

Q. Why are multiple doses of some vaccines necessary?
A. Most vaccines require more than one dose. This happens for a few reasons, including the type of vaccine, the level of disease in the community, and the nature of immunity:

- Vaccines that are given as live, weakened versions of the virus (e.g., MMR and chickenpox) usually require fewer doses because they reproduce at low levels in the body. The advantages are that the resulting immune response will be more robust in terms of quantity and diversity of antibodies. In contrast, when the vaccine is made from polysaccharides, individual proteins or toxoids (e.g., *Haemophilus influenzae* type B, hepatitis B, tetanus and pertussis), the immune response is limited to the specific antigens and the levels of antibody tend to be lower, so additional doses are needed to boost the immune response.
- When a vaccine is first made available, levels of disease in the community are typically high, so a child who was immunized will come in contact with the organism (i.e., virus or bacteria), but does not get sick. Even though as parents and healthcare providers, we often do not know about these encounters, they serve to boost the child's immunity to that organism. However, after the vaccine has been available for several years, the levels of disease in the community are often reduced making these anonymous encounters less frequent. As a result, immunity may wane making a second dose of vaccine necessary. This is what happened following introduction of the measles and chickenpox vaccines, so children are now recommended to get one dose around 12 to 15 months of age and a second dose before starting school around 4 to 6 years of age.
- As people get older, their immune systems may not be able to fend off bacterial and viral encounters as readily as they once did. For example, most of us have the virus that causes chickenpox living silently in cells of our nervous system. This virus can also cause shingles, but shingles only occurs if our immune system fails to keep the virus "in check," such as during times of high stress, compromised immunity or with increasing age. For this reason, people 50 years and older are recommended to get two doses of shingles vaccine.

Q. When is it OK to use a different vaccine schedule?
A. Children who have certain health conditions or acute illnesses may not be able to get vaccines according to the routine schedule. *Contraindications* are reasons not to get one or more vaccines; they include things like having an allergic reaction to a previous dose of vaccine or not getting a live virus vaccine, such as MMR or chickenpox, when receiving chemotherapy. *Precautions* are reasons to delay getting one or more vaccines either because of an increased chance of experiencing a severe side effect or a situation that may compromise the ability of the vaccine to work. Examples of precautions can include situations such as moderate or severe illness, recent blood transfusion, uncontrolled seizures or unstable neurological condition. If you are concerned about conditions that might delay or prevent getting vaccines, talk to your healthcare provider or contact your local health department.

Q. Why are so many vaccines necessary?
A. While it may seem like a lot of vaccines when you are watching your baby get multiple shots during the course of several office visits, the reality is that vaccines only protect babies from a small fraction of the potential disease-causing agents in the environment. The good news is that vaccines have been developed for the most deadly diseases, increasing life expectancy and decreasing infant mortality rates in the countries that use them.

Q. Wouldn't it be better for children to get some of these diseases naturally?
A. For each virus or bacteria, a specific level of immunity is needed to avoid getting sick. Once this protective level is reached, any additional protection doesn't make much difference. Vaccines are designed to introduce enough viral or bacterial antigens to induce protective immunity but not enough to cause symptoms of disease. So, while getting the disease usually creates better immune responses, not much is gained in terms of protection as compared with vaccination, and the price paid for natural infection can be great in terms of suffering and, sometimes, death.

Selected resources and references

Immunization schedules are available on the CDC website at cdc.gov/vaccines/schedules/index.html.

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Q&A RECOMMENDED IMMUNIZATION SCHEDULE: WHAT YOU SHOULD KNOW

Volume 2
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Although only one version of the immunization schedule is endorsed by the Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP), some parents prefer to be selective about which vaccines their children receive and when. Unfortunately, this approach can leave children susceptible to certain diseases at a time when they most need protection; worse, some children never catch up completely.

Q. Who determines when vaccines are added to the immunization schedule?
A. Before a vaccine can be added to the immunization schedule, it must be licensed by the Food and Drug Administration (FDA). Scientists at the FDA closely monitor and review vaccine trials; sometimes they request additional studies before making a decision. The FDA determines whether the vaccine is safe and whether it works (efficacy). Studies prior to licensure often last five to 10 years and are extensive. For example, if all of the paperwork from the pre-licensure studies of one of the rotavirus vaccines was piled up, the stack would be higher than the Empire State Building.

Once a vaccine is licensed, experts from the CDC, AAP and AAFP independently review data from scientific studies to determine whether or not a vaccine should be added to the immunization schedule. Not only will they look at the safety and efficacy of the vaccine, they will also look at disease rates and susceptible populations to determine if the vaccine is needed in the community and, if so, who should get it. Their recommendations are compiled to create the immunization schedule.

If a vaccine is recommended at an age when other vaccines are already given, *concomitant use studies* will be required to make sure the vaccine works and is safe when given as part of the existing schedule. If these studies reveal any negative consequences of giving certain vaccines together, restrictions will be placed on their use. For example, concomitant use studies have shown that if two live viral vaccines (for example, measles, mumps and rubella [MMR] and chickenpox vaccines) are given on the same day or separated by at least one month, no problems occur; however, if they are given between one and 28 days of each other, the immune response to the one administered later will be diminished. This is reflected on the schedule so that healthcare providers administer the vaccines correctly.

Q. How are the amounts of immunological components in a vaccine determined?
A. Vaccine doses are not chosen arbitrarily. During the four phases of vaccine development, different doses are tested to determine the lowest effective dose for the target group. For example, the rotavirus vaccine was tested at quantities as low as one-tenth the current dose and up to 10 times the current dose.

Vaccine developers must practice good medicine and good economics. Giving larger doses of active ingredients than required would increase the side effects and giving too little of the vaccine would lessen efficacy. It's a fine balance.

Q. How can the recommended schedule be appropriate for all children?
A. A common misconception is that the recommended immunization schedule is determined using a one-size-fits-all approach. These concerns are based on misconceptions about how vaccines work and misconceptions about the schedule itself:

- Vaccines and drugs aren't distributed in the body in the same manner. Medications must be distributed throughout the bloodstream to have the desired effect, so dosing is determined by body size. This is similar to the effects of a glass of alcohol on a large man compared with a small woman. In contrast, vaccines work by introducing cells of the immune system, known as B and T cells, to the parts of a virus or bacteria that cause disease. These cells are typically "educated" near the site the vaccine is given. Once they are equipped to recognize the agent that causes illness, they travel throughout the body. These educated patrol cells are known as memory cells; it typically takes about a week to 10 days after immunization for the memory response to develop completely. Memory cells allow for shorter infections and less severe symptoms if a person is exposed to the pathogen in the future.
- The immunization schedule is confusing. For this reason, it is often described more simply in terms of the age at which each vaccine is given. However, healthcare providers who administer vaccines know that many rules exist regarding when and if a vaccine can be given based on individual situations. Illnesses, allergies, age and health conditions all influence whether someone can get a vaccine. In fact, the published immunization schedule for children from birth through 18 years of age is eight pages long and is supported by a 195-page document on general recommendations as well as vaccine-specific recommendations. Documents describing specific vaccines are typically 25 to 40 pages long.

Q. How do we know who should get a vaccine?
A. A vaccine is added to the immunization schedule only after it has been studied in people who will receive it. Before a vaccine can be licensed, it must undergo rigorous scientific studies to make sure that it is safe and that it works in the age group for which it will be used.

One might reasonably ask then, how we know which age group might need to receive the vaccine. The answer is that scientists and public health officials perform "epidemiologic studies," which determine who gets a disease (susceptibility), when they get it (seasonality), how many people get it (morbidity), and how many people die from it (mortality). All of this information provides scientists and public health officials with a good understanding of how the disease is affecting communities and which individuals would benefit the most from a vaccine.

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PARENTS PACK

MONTHLY UPDATES ABOUT VACCINES ACROSS THE LIFESPAN

FEATURE ARTICLE: 9,000 REASONS FOR ROUTINE CHILDHOOD HEPATITIS B VACCINATION

July 2025

If hepatitis B virus was a superhero, its secret power would be its stealth. In fact, hepatitis B is so stealthy that many people don't even know they are infected until decades after their initial exposure when they are diagnosed with liver disease.

Hepatitis B is a virus that replicates in liver cells. While many people recover after their initial infection, some go on to develop chronic hepatitis B. Many never know they were infected — or that they are so-called "carriers" — until they are diagnosed with hepatitis (inflammation of the liver), cirrhosis (severe liver damage) or liver cancer.

Many people consider hepatitis B an infection of only high-risk individuals, such as sex workers and injection drug users, but that viewpoint discounts hepatitis B's superpower. Let's explore more about how this virus can hide in plain sight and why that has led to the current vaccine recommendations to protect against hepatitis B.

There's more to the spread of hepatitis B than meets the eye

Most people focus on the spread of hepatitis B through sex and injection drug use, but anyone can get hepatitis B, including children. Before hepatitis B vaccine was recommended for all children, each year about 18,000 infants and children were infected with the virus. About half of those children were infected during delivery or shortly thereafter because their mothers were infected. The other 9,000 often never knew when, where or how they were exposed to the virus. Three features contribute to hepatitis B's stealthiness:

1. Invisible blood — While hepatitis B replicates in the liver, the virus, as well as proteins from the virus, circulate in the blood of infected individuals. This is how it is spread from person to person. Some people infected with hepatitis B virus have about 10 million to 1 billion hepatitis B virus particles in *every milliliter* of blood (a milliliter is about one-fifth of a teaspoon). But even among those with lower quantities (e.g., 100 to 1,000 virus particles per milliliter of blood), hepatitis B can be transmitted in amounts of blood not visible to the naked eye. Some body fluids have also been demonstrated to spread the virus, likely because of undetectable quantities of blood, including saliva, semen and vaginal fluids.

The presence of the virus in small or invisible amounts of blood means transmission can occur in unexpected ways or at places that people might not think about. For example:

- Although hepatitis B virus DNA and hepatitis B virus surface protein can be found in breast milk from mothers who are hepatitis B positive, a baby won't be infected by the milk. However, if that mother has cracked or bleeding skin or nipples, the baby can be exposed to the virus while breastfeeding. In fact, the recommendation is that in this situation a hepatitis B-positive mother should not breastfeed until healed because of this likelihood.
- Hepatitis B can also be spread by other household contacts as well as people in day cares or schools and other non-household contacts. Examples include contact with blood from cuts in skin; pre-chewing of food; sharing gum or other foods; sharing toothbrushes, razors, utensils or other items that might contain undetectable amounts of blood, like washcloths or clothing; and contact with blood during sports or other physical activities.

2. Survival time — Hepatitis B virus is considered a hardy, or robust, virus, meaning it doesn't die quickly once outside of the body. In fact, it can live for up to seven days on surfaces or objects that have been touched by an infected person's blood or infected body fluids, including clothing, utensils, washcloths or bedding. People have also been infected in medical, dental, long-term care, and other facilities. These cases can occur from improperly sterilized medical equipment, needle sticks, or other exposures. For example, cases have resulted from acupuncture as well as tattooing and assisting with blood glucose monitoring.

3. Characteristics of infection — Two aspects of hepatitis B infections also contribute to the ease with which this virus can hide among us. First, only about 3 to 5 of every 10 older children and adults experience symptoms when they are initially exposed to the virus. In children less than 5 years of age, only 1 in 10 experience symptoms. As a result, it is easy for a person to be infected and not know. Second, the younger a person is when they are exposed, the more likely that they will become chronically infected. Fewer than 5 of every 100 healthy adults will become chronically infected, but about 3 of 10 children infected between 1 and 4 years of age and about 9 of 10 children infected during the first year of life will become chronically infected. Together these characteristics position the youngest children to unwittingly become chronically infected carriers. About 1 of every 4 people infected at birth or during early childhood will die earlier than others of the same age because of liver disease caused by hepatitis B.

The bottom line

In the U.S., about 4 in 5 people with chronic hepatitis B infections do not know they have this infection. They don't have symptoms, and if they were exposed as children, they may be carriers able to unwittingly spread the virus throughout life. Given that their blood is highly contagious and the virus can remain on surfaces or items for up to a week, chronically infected people provide a way for hepatitis B virus to hide in plain sight. Before routine vaccination, 9,000 children innocently got infected each year — that's 9,000 reasons why hepatitis B vaccine recommendations are designed to protect children as early in life as possible.

My baby isn't that baby: The argument against hepatitis B vaccine at birth

Historically, the main mode of transmission for hepatitis B in the U.S. was through sex; however, the opioid epidemic changed this. For example, a small study in 2019 found that about 60% of new cases resulted from injection drug use. Current estimates of cases due to sexual transmission are less than 4 in 10. But, because many people tend to focus on hepatitis B spread through sex and injection drug use, the birth dose recommendation for hepatitis B vaccine seems particularly unreasonable to some, so let's take a step back and retrace the history of hepatitis B vaccine recommendations because the end result doesn't tell the whole story.

The earliest recommendations — The hepatitis B vaccine was licensed in the U.S. in 1981, and the first vaccine recommendations were published in June 1982. Those recommendations targeted groups known to be at increased risk for hepatitis B, including healthcare providers, particularly those likely to be exposed to blood of infected patients; clients and staff at long-term care residencies for the developmentally disabled; patients getting hemodialysis and those with certain blood disorders; men who have sex with men; users of illegal injectable drugs; household and sexual contacts of those chronically infected with hepatitis B and those with acute cases of disease or recent needlestick injury exposures; classroom contacts of chronically infected individuals who may act aggressively or from whom exposure to their blood may be more likely; Alaskan natives, Pacific Islanders, and immigrants and refugees from areas with endemic disease; prison inmates; and infants born to hepatitis B-positive mothers.

Over time, a few other groups were added. In 1985, heterosexual people with multiple sexual partners and international travelers who were going to an area with endemic hepatitis B for more than six months were added to the recommended groups to be vaccinated. And in 1990, public safety workers likely to have contact with blood or blood-containing body fluids as family members of children adopted from countries with endemic hepatitis B were recommended to be vaccinated.

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Vaccinating all infants — By 1991, an assessment of the impact of the hepatitis B recommendations aimed at high-risk individuals had demonstrated the strengths and weaknesses of that approach:

1. The vaccine was preventing infections among people vaccinated before exposure, such as ethnic groups with high rates of childhood hepatitis B infections like Alaskan Natives where the rates had decreased 99% since introduction of the vaccine. Progress had also been made in decreasing infections among healthcare workers.
2. The vaccine was also preventing infections among babies born to hepatitis B-positive mothers but determining which mothers to test had proven difficult. It was estimated that 35 to 65 of 100 hepatitis B-positive mothers were not being identified. As such in 1988, the recommendations were changed to test all mothers during pregnancy.
3. Many high-risk teens and adults, however, remained unidentified or had already been infected, and conversely, many people diagnosed with a hepatitis B infection had no risk factors, so they never would have been identified even if the system was working well.

Cases were continuing to occur, and estimates at the time were that 1 million to 1.25 million people in the U.S. remained chronically infected and, therefore, could infect others. It was also clear that treatment would not eliminate the population of chronically infected individuals, which meant that prevention was even more important. First, vaccination would directly protect recipients, and second, fewer infections, especially during childhood, would translate to fewer chronically infected individuals and, therefore, less spread over time.

To decrease the likelihood of infection during childhood, all infants in the U.S. were recommended to be vaccinated against hepatitis B in 1991. Catch-up immunization campaigns followed in 1995 for all 11- to 12-year-olds not previously vaccinated against hepatitis B and in 1999 for all previously unvaccinated children up to 18 years of age.

Evolution of the birth dose — When a mother is determined to be hepatitis B positive, her baby is at much greater risk for hepatitis B infection. Often this occurs during birth when the baby is exposed to the mother's blood, but it can also happen in the weeks and months after birth. In these instances, the baby's chance of becoming infected can be significantly decreased if the baby receives a combination of vaccination and antibody at birth. As such, even the first set of hepatitis B vaccine recommendations in 1982 included these measures. However, because studies were ongoing related to the safety and effectiveness of the vaccine if given at birth, the 1982 recommendations indicated that the baby be vaccinated by 3 months of age. By 1991, when recommendations were changed to include hepatitis B vaccination of all infants, the studies looking at receipt of the vaccine within hours of birth had been completed without finding any concerns. As such, the updated recommendations indicated use of the birth dose for babies whose mothers were known to be hepatitis B positive and for those whose hepatitis B status was unknown. For babies whose mothers were known to be hepatitis B negative, the recommendation was to either get the dose before hospital discharge or at 1-2 months of age.

The success of targeting high-risk babies depends on both the mother's hepatitis B status and the effectiveness of the medical system. First, if the mother has a high quantity of viral DNA in her blood, the baby may still be infected even if they received vaccine and antibody treatment at birth. If these DNA levels are known early enough, the mother can be treated with an antiviral medication beginning at 28 weeks of gestation. However, the success of these measures depends on the second factor — the effectiveness of the medical system. Specifically:

- Testing needs to be completed during pregnancy.
- The results need to be accurate and reported in a timely manner.
- The pregnant woman must not be exposed to the virus in the period between testing and delivery.
- The antiviral medication must be prescribed and taken by the hepatitis B-positive patients before delivery.
- The baby needs to receive the appropriate vaccination and antibody treatments upon birth. This includes following home births or other births that do not occur in hospital settings.

While these efforts may seem straightforward, successful implementation 100% of the time is not a given. As such, by 2002, the schedule was altered to recommend that all babies receive the hepatitis B vaccine at birth. This change was made understanding that the vaccine was safe and knowing that it would save some babies the fate of chronic hepatitis B when any part of the system failed.

The bottom line

Some babies of hepatitis B-positive mothers will remain untreated due to undiagnosed hepatitis B in their mother or because of medical system failures. Others will be exposed by household contacts or others whose infected blood they unwittingly encounter. Those infected early in life often develop chronic, undiagnosed hepatitis B, positioning them to unwittingly continue the spread of this virus — in day cares, on elementary school playgrounds, at sleepovers, and in sports leagues. By giving a birth dose of hepatitis B vaccine, all babies can begin to develop protection before any potential exposure to hepatitis B.

The proven impact of hepatitis B vaccine

Some have suggested that the birth dose of hepatitis B vaccine should be delayed in the U.S. As described above, this virus hides in plain sight. People don't know they have it, so they don't always know to take precautions to prevent spreading it. As such, each moment a child is without protection is another moment they may unwittingly be exposed. The U.S. is not unique in its recommendation for hepatitis B vaccine at birth. The World Health Organization (WHO) recommends universal vaccination of infants within 24 hours of birth, and country after country has reduced the impact of this disease using a birth dose. For example: Qatar has had a hepatitis B vaccine birth dose since 1989. Saudi Arabia since 1995. The Dominican Republic since 1997. Albania since 1998. In fact, as shown in blue on the map, in 2024 most countries had adopted the universal birth dose of hepatitis B vaccine.

Hepatitis B vaccines are safe. They have been extensively studied, and no causal associations were found for multiple conditions, including Guillain-Barré syndrome (GBS), multiple sclerosis (MS) or other conditions that cause demyelination of nerves, chronic fatigue syndrome, arthritis, autoimmune disorders, asthma, sudden infant death syndrome (SIDS), alopecia or diabetes.

Hepatitis B vaccines work. Between 1990 and 2015, use of hepatitis B vaccine in children around the globe was estimated to prevent 310 million new chronic hepatitis B infections. Between 2000 and 2019, hepatitis B vaccination of newborns and infants was estimated to prevent 22 million deaths globally from hepatitis B — about one death for every 13 vaccinations administered. Further, because deaths tend to occur decades after infection, it is estimated that between 2020 and 2030, another 16 million deaths will have been prevented by use of hepatitis B vaccine.

If hepatitis B vaccine was not available, about 5 of every 10 deaths from hepatitis B in a birth cohort (all those born in the same year) would be the result of infections acquired during early childhood.

The bottom line

If the U.S. removes or delays its birth dose recommendation as some have suggested, the chronic illnesses being experienced by today's children would increase, not decrease, and the move would put the U.S. behind much of the rest of the world in terms of its approach to eliminating hepatitis B. Remember, before a hepatitis B vaccine was available in the U.S., about 9,000 children every year would be infected by an unknown source. If we begin sending our newborns home without their first dose of hepatitis B vaccine, those 9,000 annual cases will again begin accruing.

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