QEA 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 measlesmumps-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. 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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