Q A THE FACTS ABOUT CHILDHOOD VACCINES: WHAT YOU SHOULD KNOW

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Q. How can parents sort out conflicting information about vaccines?

A. Decisions about vaccine safety must be based on well-controlled scientific studies.

Parents are often confronted with "scientific" information found on television, on the internet, in magazines and in books that conflicts with information provided by healthcare professionals. But few parents have the background in microbiology, immunology, epidemiology and statistics to separate good scientific studies from poor studies. Parents and physicians benefit from the expert guidance of specialists with experience and training in these disciplines.

Committees of these experts are composed of scientists, clinicians and other caregivers who are as passionately devoted to our children's health as they are to their own children's health. They serve the Centers for Disease Control and Prevention (cdc.gov/vaccines), the American Academy of Pediatrics (aap.org), the American Academy of Family Physicians (aafp.org), the American College of Obstetricians and Gynecologists

(acog.org), and the National Foundation of Infectious Diseases (nfid.org), among other groups. These organizations provide excellent information to parents and healthcare professionals through their websites. Their task is to determine whether scientific studies are carefully performed, published in reputable journals and, most importantly, reproducible. Information that fails to meet these standards is viewed as unreliable.



When it comes to issues of vaccine safety, these groups have served us well. They were the first to figure out that intestinal blockage was a rare consequence of the first rotavirus vaccine, and the vaccine was quickly discontinued. And, they recommended a change from the oral polio vaccine, which was a rare cause of paralysis, to the polio shot when it was clear that the risks of the oral polio vaccine outweighed its benefits.

These groups have also investigated possible relationships between vaccines and asthma, diabetes, multiple sclerosis, SIDS and autism. No studies have reliably established a causal link between vaccines and these diseases — if they did, the questioned vaccines would be withdrawn from use.

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 re-emerge

Some diseases can easily re-emerge 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 children 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.

Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases*. 13th Edition. Hamborsky J, Kroger A, and Wolfe S. eds. Washington, DC: Public Health Foundation; 2015 and Supplement, 2017.

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.

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.

 $Offit\ PA,\ Jew\ RK.\ Addressing\ parents'\ concerns:\ Do\ vaccines\ contain\ harmful\ preservatives,\ adjuvants,\ additives,\ or\ residuals?\ Pediatrics.\ 2003;112:1394-1401.$

American Academy of Pediatrics. In Kimberlin DW, ed. Red Book: 2018 Report of the Committee on Infectious Diseases. 31st Edition. Elk Grove Village, IL.

Q. Are vaccines made using fetal cells?

A. Viruses require cells in which to reproduce. This means to make viral vaccines, the viruses 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 viruses because the womb is sterile.

The fetal cells used to grow vaccine viruses were isolated from two elective abortions that occurred in the early 1960s. The cells have been grown in the laboratory since then, and no additional abortions are needed to make the vaccines.

The vaccines made using these cell lines include the chickenpox, rubella (part of MMR), hepatitis A, and rabies (one version) vaccines.

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 to the child, 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. 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.

Plotkin S, et al. Vaccines. 7th Edition. Philadelphia, PA: W.B. Elsevier, 2017.

${\sf Q}.$ How can a "one-size-fits-all" approach to vaccines be ${\sf OK}$ for all children?

 $\boldsymbol{\mathsf{A}}.$ The recommended immunization schedule is not the same for all children.

In fact, recommendations for particular vaccines often vary based upon individual differences in current and long-term health status, allergies and age. Each vaccine recommendation, often characterized by a single line on the immunization schedule, is supported by about 25 to 40 additional pages of specific instructions for healthcare providers who administer vaccines. In addition, an approximately 190-page document titled "General Best Practice Guidelines for Immunization" serves as the basis for all vaccine administration. The recommendations are updated as needed by the CDC, and a comprehensive update is published every few years.

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Q. Is the amount of aluminum in vaccines safe?

A. Yes, 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 receive large quantities of aluminum in intravenous fluids and people who have long-term kidney failure and receive large quantities of aluminum, primarily in antacids. In both cases, the kidneys are not working properly or at all and the people are exposed 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 one-fifth of a teaspoon of water. 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.

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 as compared with the quantities already found in the blood.

Baylor NW, Egan W, Richman P. Aluminum salts in vaccines – U.S. perspective. *Vaccine*. 2002;20:S18-S23.

Bishop NJ, Morley R, Day JP, Lucas A. Aluminum neurotoxicity in preterm infants receiving intravenous-feeding solutions. New Engl J Med. 1997;336:1557-1561.

Committee on Nutrition: Aluminum toxicity in infants and children. *Pediatrics*.

 ${\it Ganrot\,PO.\,Metabolism\,and\,possible\,health\,effects\,of\,aluminum.} \textit{Env.\,Health\,Perspective.} \\ 1986; 65:363-441.$

Keith LS, Jones DE, Chou C. Aluminum toxicokinetics regarding infant diet and vaccinations. *Vaccine*. 2002;20:S13-S17.

Pennington JA. Aluminum content of food and diets. *Food Additives and Contam.* 1987;5:164-232.

 $Simmer\ K, Fudge\ A, Teubner\ J, James\ SL.\ Aluminum\ concentrations\ in\ infant\ formula. \ J\ Peds\ and\ Child\ Health.\ 1990; 26:9-11.$

Q. Do vaccines cause autism?

 $\mbox{\bf A}.$ 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 parents 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 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 see summaries of some of these studies and other studies related to vaccine safety concerns, visit vaccine.chop.edu/safety-references.

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

Q. Does my child still need to get vaccines if I am breastfeeding?

A. Yes. The types of immunity conferred by breastfeeding and immunization are different. Specifically, the antibodies that develop after immunization are made by the baby's own immune system and, therefore, will remain in the form of immunologic memory; this is known as active immunity. In contrast, antibodies in breast milk were made by the maternal immune system, so they will provide short-term protection, but will not last more than a few weeks. These antibodies are usually not as diverse either, so the baby may be protected against some infections but remain susceptible to others. Immunity generated from breast milk is called passive immunity. Passive immunity was practiced historically when patients exposed to diphtheria were given antitoxin produced in horses; antitoxins to snake venoms are also an example of passive immunity.

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 as many as 27 vaccine doses by the time they are 2 years old and as many as six shots in a single visit to the doctor, many parents wonder whether it is safe to give children so many vaccines.

Although the mother's 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 the 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.

Offit PA, et al. Addressing parents' concerns: Do vaccines weaken or overwhelm the infant's immune system? Pediatrics. 2002;109:124-129.

Q. What is the harm of separating, spacing out or withholding some vaccines?

A. Although the vaccine schedule can look intimidating, it is based upon the best scientific information available and is better tested for safety than any alternative schedules.

Experts review studies designed to determine whether the changes are safe in the context of the existing schedule. These are called concomitant use studies.

Separating, spacing out or withholding vaccines causes concern because infants will be susceptible to diseases for longer periods of time. When a child should receive a vaccine 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.

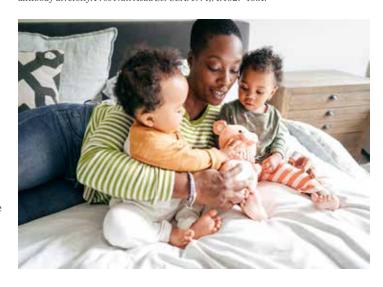
Finally, changing the vaccine schedule requires additional doctor's visits. Research measuring cortisol, a hormone associated with stress, has determined that children do not experience more stress when receiving two shots as compared with one shot. Therefore, an increased number of visits for individual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

Cohn M, Langman RE. The protection: the unit of humoral immunity selected by evolution. Immunol Rev. 1990;115:9-147.

Offit PA, Quarels J. Gerber MA, et al. Addressing parents' concerns: Do multiple vaccines overwhelm or weaken the infant's immune system? Pediatrics. 2002;109:124-129.

Ramsay DS, Lewis M. Developmental changes in infant cortisol and behavioral response to inoculation. *Child Dev.* 1994;65:1491-1502.

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 $This information is provided by the Vaccine \ Education \ Center\ at\ Children's\ Hospital\ of\ Philadelphia.\ The\ Center\ is\ an\ educational\ resource\ for\ parents\ and\ healthcare\ professional\ s\ and\ is\ composed\ of\ scientists,\ physicians,\ mothers\ and\ fathers\ who\ are\ devoted\ to\ the\ study\ and\ prevention\ of\ infectious\ diseases.\ The\ Vaccine\ Education\ Center\ is\ funded\ by\ endowed\ chairs\ from\ Children's\ Hospital\ of\ Philadelphia.\ The\ Center\ does\ not\ receive\ support\ from\ pharmaceutical\ companies.\ ©\ 2020\ Children's\ Hospital\ of\ Philadelphia.\ All\ Rights\ Reserved\ .\ 20121-07-20$

