

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. 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 ties, 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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