

Type of Vaccine Ingredients

Concern: There seem to be too many ingredients in vaccines that could harm my child.

General Responses on Ingredients:

- Vaccines are medications and like other medications, certain ingredients (components) are needed to make sure they work well.
- Millions of doses of vaccines are administered to children in this country each year. Ensuring that those vaccines are potent, sterile, and safe requires the addition of very small amounts of chemical additives.
- Chemicals are added to vaccines to inactivate a virus or bacteria and stabilize the vaccine, which helps to preserve the vaccine and prevent it from losing its potency over time.
- The amount of chemical additives found in vaccines is very small.
- 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 - a drop in the bucket of what your child can handle.

Risk of Disease:

- Some vaccine preventable diseases, like whooping cough (pertussis) and chickenpox remain common in the U.S. Without vaccines, your child is at risk for getting seriously ill and suffering pain, disability and even death from these diseases.
- Other diseases prevented by vaccine are no longer common in this country because of vaccines. However, if we stop vaccinating, even the few cases we have in the U.S. could very quickly become tens to hundreds of thousands of cases.

Benefit of Vaccination:

- Vaccines can prevent infectious disease that once killed or harmed many infants, children and adults.
- A child is far more likely to be seriously injured by a vaccine-preventable disease than by any vaccine.
 - In the U.S. in 1985-1992, complications from measles included:
 - Pneumonia in 6 out of 100 cases
 - Seizures in 6-7 out of 1,000 cases
 - Encephalitis in 1 out of 1,000 cases
 - Death in 2 out of 1,000 cases
 - MMR vaccine risk:
 - Fever in 5-15 out of 100 doses (most with fever are otherwise asymptomatic)
 - Rash in 5 out of 100 doses
 - Thrombocytopenia in less than 1 out of 30,000 doses (generally transient and benign; the risk for thrombocytopenia during rubella or measles infection is much greater than the risk after vaccination)
 - Encephalitis or severe allergic reaction: 1 in a 1,000,000
- The main risks associated with getting vaccines are side effects; most are mild and temporary (redness and swelling at the injection site or fever) and go away within a few days. Serious side effects following vaccination such as severe allergic reaction are very rare (about 1 occurrence in 1 million doses of vaccine administered) and doctors and clinic staff are trained to deal with them.

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Responses to Concerns about Aluminum (Adjuvant):

- 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.
- Aluminum salts (such as aluminum hydroxide, aluminum phosphate or aluminum potassium sulfate) are present in certain vaccines: hep A, hep B, Diphtheria-Tetanus-Pertussis (DTaP, DT, TD, Tdap), HIB, HPV and pneumococcal vaccines.
 - They are not present in flu, polio, or live viral vaccines such as measles, mumps, rubella, chickenpox, shingles or rotavirus
- Aluminum salts are used in vaccines to improve the immune response - how well the vaccine works. When used for this purpose, the substances are called “adjuvants”.
 - Adjuvants usually allow for the vaccine to need lesser quantities to work and fewer doses to be needed.
 - Aluminum salts have been used to improve vaccine immune responses for more than 70 years.
- During the first 6 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 1/5 of a teaspoon of water.)
- 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 breast-fed 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.
- During the first 6 months of life, babies will receive about:
 - 10 milligrams of aluminum in breast milk,
 - 40 milligrams of aluminum in infant formula, or
 - 120 milligrams of aluminum in soy-based formula

Responses to Concerns about Mercury (Thimerosal):

- **Since 2001, all routinely recommended pediatric vaccines manufactured for the U.S. market are available in formulations that contain no thimerosal or only trace amounts.** Now only multi-dose flu vials contain thimerosal.
- Mercury is a naturally occurring element found in the earth’s crust, air, soil and water and we are all exposed to it.
- There are 2 types of mercury—methylmercury and ethylmercury.
 - Methylmercury is the type that has raised health concerns. Methylmercury is formed in the environment when mercury metal is present. It makes its way through the food chain to fish, animals and humans. At high levels, this type can be very harmful (toxic) to people. For this reason, pregnant women are often advised to decrease or eliminate foods such as tuna or shellfish from their diets.
 - Tuna 5.6 oz can = .115 methylmercury
 - Breast milk, 1 liter = 0.015 methylmercury
 - Ethylmercury is formed when the body breaks down thimerosal. Ethylmercury is broken down and excreted from your body much more rapidly than methylmercury. Therefore, ethylmercury (type in the influenza vaccine) is much less likely than methylmercury (type in the environment) to accumulate in the body and cause harm.
 - Flu vaccine with thimerosal = 0.025 ethyl mercury
- Historically, thimerosal (mercury-containing compound) is a preservative that was used in multi-dose vaccine vials to make sure there was no bacterial growth (cause for infection) after the vial is opened.

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- However, by the late 1990s, due to the increased number of vaccines being given to infants, the American Academy of Pediatricians and the U.S. Public Health Service requested that mercury be removed from vaccines to make “safe vaccines safer”. **There was no evidence that suggested thimerosal caused any harm but they wanted to be cautious.**
- Even before this change, infants who were exclusively breastfed ingested more than twice the quantity of mercury than was found in all the vaccines.
- Today, breastfed infants ingest 15 times more mercury in breast milk than is contained in an influenza vaccine dose from a multi-dose vial.
- Reputable scientific studies have shown that mercury in vaccines given to young children is not a cause of autism. The studies used different methods:
 - Some examined rates of autism in a state or a country, comparing autism rates before and after thimerosal was removed as a preservative from vaccines.
 - In the United States and other countries, the number of children diagnosed with autism has not gone down since thimerosal was removed from vaccine.
- Many vaccines such as the combination measles, mumps and rubella never used thimerosal in the vaccine production process or as a preservative. **So, statements like “the mercury in the MMR vaccine” causes autism are false.**

Responses to Concerns about Formaldehyde:

- We often think about formaldehyde as something used to preserve dead bodies so hearing that it is an ingredient in vaccines seems concerning at first.
- However, formaldehyde is produced naturally in the human body to produce energy and build basic materials needed for important life processes (like making amino acids which are the building blocks of proteins that the body needs).
 - The quantity of formaldehyde found in the body is 10 times greater than that found in any vaccine.
- Formaldehyde is also found in the environment and is present in different ways. It is used in building materials, as a preservative in labs and to produce many household products.
- Formaldehyde has a long history of safe use in the manufacture of certain viral and bacterial vaccines. It is actually a by-product of vaccine production. It is used to inactivate viruses so they don't cause disease (such as with the polio virus used to produce polio vaccine) or to “detoxify” bacterial toxins (such as the toxin used to make diphtheria vaccine).
 - Most formaldehyde is purified away while only small quantities remain in the vaccine
- **The amount of formaldehyde present in some vaccines is so small compared to the concentration that occurs naturally in our bodies that it does not pose a safety concern.**

Responses to Concerns about Gelatin:

- Some vaccines contain gelatin as a “stabilizer”. Stabilizers are added to vaccine to protect the active ingredients from degrading during manufacture, transport and storage.
 - About 1 in every 2 million people might be allergic to gelatin
 - People with severe allergies to gelatin should avoid getting gelatin-containing vaccines (such as measles, mumps, rubella, varicella)
- For some, the use of gelatin may be a religious objection (Jews, Muslims, and Seventh Day Adventists).
 - Refer to “Religious Objections” handout for further information.

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Responses to Concerns about Antibiotics:

- Antibiotics, such as neomycin, are present in some vaccines to prevent bacterial contamination when the vaccine is made.
 - Trace amounts of antibiotics in vaccines rarely, if ever, cause allergic reactions.

Responses to Concerns about Egg Protein:

- Two vaccines are produced in eggs, so egg proteins are present in the final product of:
 - All flu vaccines recommended for children less than age 18 years
 - Yellow Fever vaccine
- An allergy to eggs is no longer considered a contraindication to receiving a flu shot.
- Advances in technology have allowed the quantities in current influenza vaccines given as shots to be so minimal that people with egg allergies may still be able to receive a flu vaccine without concern. For instance:
 - People who can eat lightly cooked eggs without reaction are unlikely to be allergic and can receive either the intranasal flu or flu shot.
 - People with a history of egg allergy who have only experienced hives after exposure to egg should receive a flu shot (not the intranasal flu).
 - The flu vaccine should be administered by a health care provider who is familiar with potential manifestations for egg allergy.
 - Vaccine recipients should be observed for at least 30 minutes for signs of a reaction after the administration of each dose.
 - For all other persons reporting an egg allergy, refer to:
 - “Influenza Vaccine Screening Algorithm for Persons who Report Egg Allergy”
http://www.michigan.gov/documents/mdch/Egg_allergy_algorithm_Final_08152014_465585_7.pdf

Responses to Concerns about Fetal Tissue:

- No fetal tissue is included in vaccines.
- Fetal cells are used to make 5 vaccines: varicella, rubella, hep A, zoster (shingles) and rabies.
- Two cell lines provide the cultures needed to produce vaccines.
- These lines were developed from two fetuses in the 1960s.
 - The fetuses were aborted for medical reasons, not for the purpose of producing vaccines.
- These cell lines have an indefinite life span, meaning that no new aborted fetuses are ever used.
- Why are fetal cells used for this purpose?
 - Viruses, unlike bacteria, require cells to grow and human cells are often better than animal cells at supporting the growth of human viruses.
 - Fetal cells are different from other types of cells; they are virtually immortal, meaning they can reproduce many, many times before dying.
 - Other cells only reproduce a limited number of times before dying.
- Some persons have religious objections to abortions and refuse live vaccines.
 - See “Religious Objections” handout for further information on the 2005 Catholic Church’s view on use of these vaccines

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Responses to Concerns about Antifreeze:

- Antifreeze is typically made of ethylene glycol, which is unsafe.
- Polyethylene glycol (a chemical used in personal care products like skin creams and toothpaste) is used in vaccines and is safe.
 - It is used to inactivate the influenza virus in some influenza vaccines
 - It is also used to purify other vaccines

Responses to Concerns about Latex:

- Latex is **not** a component of any vaccine.
- It may be in the vaccine packaging such as the vial or the syringe.
- There are two types of products used in making vaccine vials and syringes:
 - Synthetic rubber/latex **is not** a concern for persons reporting a latex allergy (sometimes labeled as “not made with natural rubber latex”)
 - Natural rubber/latex (often labeled as “dry natural rubber” or “natural rubber latex”) **is** a concern for persons who report a severe allergic reaction to latex
- If a person reports a severe (anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain natural rubber, or whose product information does not say “not made with natural rubber latex” should not be administered unless the benefit of vaccination outweighs the risk for a potential allergic reaction. In these cases, providers should be prepared to treat patients who are having an allergic reaction. For latex allergies other than anaphylactic allergies (e.g., a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain dry natural rubber or rubber latex may be administered. (ACIP *General Recommendations on Immunization*. 2011)

Resources: (*Available in Spanish)

Centers for Disease Control and Prevention (CDC)

Vaccine Excipients and Media Summary

<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf>

Latex in Vaccine Packaging

<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex-table.pdf>

Thimerosal Content in Some U.S. Licensed Vaccines

<http://www.vaccinesafety.edu/thi-table.htm>

Understanding Thimerosal, Mercury and Vaccine Safety <http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-thimerosal-bw-office.pdf>

Frequently Asked Questions about Ethylmercury

http://www.cdc.gov/vaccinesafety/Concerns/Thimerosal/thimerosal_faqs.html

Frequently Asked Questions about Adjuvants

<http://www.cdc.gov/vaccinesafety/Concerns/adjuvants.html#1>

Thimerosal

<http://www.cdc.gov/vaccinesafety/Concerns/thimerosal/index.html>

CDC study on “Prenatal and Infant Exposure to Thimerosal from Vaccines and Immunoglobulins and Risk of Autism” http://www.cdc.gov/vaccinesafety/Concerns/Thimerosal/QA_Pediatrics-thimerosal-autism.html

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Food and Drug Administration

<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm187810.htm>

Children's Hospital of Philadelphia

*Aluminum in Vaccines—what you should know

<http://vec.chop.edu/export/download/pdfs/articles/vaccine-education-center/aluminum.pdf>

*Vaccine Ingredients—what you should know

<http://vec.chop.edu/export/download/pdfs/articles/vaccine-education-center/vaccine-ingredients.pdf>

*Thimerosal in Vaccines—what you should know

<http://vec.chop.edu/export/download/pdfs/articles/vaccine-education-center/thimerosal.pdf>

*Vaccines and Autism—what you should know

<http://vec.chop.edu/export/download/pdfs/articles/vaccine-education-center/autism.pdf>

*Facts about Childhood Vaccines

<http://vec.chop.edu/export/download/pdfs/articles/vaccine-education-center/vaccines-fact.pdf>

Ari Brown, MD, FAAP

Clear Answers and Smart Advice about your Baby's Shots

<http://www.immunize.org/catg.d/p2068.pdf>

Immunization Action Coalition

MMR Does Not Cause Autism - Examine the Evidence! <http://www.immunize.org/catg.d/p4026.pdf>

American Academy of Pediatrics

(Link to further information regarding MMR Vaccine and Autism)

<http://www2.aap.org/immunization/families/mmr.html>

Questions and Answers about Vaccine Ingredients

<http://www2.aap.org/immunization/families/faq/Vaccineingredients.pdf>

Immunization Action Coalition (IAC)

Facts about Childhood Vaccine Ingredients

http://www.immunize.org/concerns/vaccine_components.pdf

Michigan Department of Community Health (MDCH)

Influenza Vaccine Screening Algorithm for Persons who Report Egg Allergy

http://www.michigan.gov/documents/mdch/Egg_allergy_algorithm_Final_08152014_465585_7.pdf