

## Coastal Children's Clinic Immunization Policy

At Coastal Children's Clinic, we are committed to providing the safest and best healthcare for our patients. Immunizations are one of the most important tools to protect children against serious illness, brain damage, and death. While we respect parents as the ultimate decision makers for their child's health, we require a minimum set of vaccines for continued care in our practice. The seven required vaccines include: DTaP/Tdap (Diphtheria, Tetanus, Pertussis), Hib (Haemophilus influenzae type B), MMR (Measles, Mumps, Rubella), Meningococcal Meningitis, IPV (Polio), Pneumococcal (Vaxneuvance) and Varicella (Chickenpox). These vaccines are designed to protect children from vaccine-preventable diseases and reduce transmission in our office and community.

Many of our physicians have seen the devastating effects of diseases like meningitis before these vaccines were available. Thanks to immunizations, such cases are now rare, and we are committed to keeping it that way.

Vaccines are safe, effective, and available through our office at modest cost. Please scan the QR codes below to be directed to reliable information from the Children's Hospital of Philadelphia Vaccine Education Center and the CDC.

If parents choose to decline any of these seven vaccines, it represents a fundamental difference in the goals of pediatric care. In such case, we will—with reluctance—discharge the patient from our practice. Care will be provided for 30 days to allow transition to another provider. Medical records can be transferred upon completion of a release form.

We encourage families to discuss any concerns with our providers. It is our hope that all families will choose vaccinating so your children can benefit from this lifesaving protection.



CHOP Vaccine Education Center



CDC Vaccine Sheets

# Q&A VACCINES AND AUTISM: WHAT YOU SHOULD KNOW

Volume 3  
Winter 2019

Some parents are concerned that vaccines can cause autism. Their concerns center on three areas: the combination measles-mumps-rubella (MMR) vaccine; thimerosal, a mercury-containing preservative previously contained in several vaccines; and the notion that babies receive too many vaccines too soon.

## Q. What are the symptoms of autism?

A. Symptoms of autism, which typically appear during the first few years of life, include difficulties with behavior, social skills and communication. Specifically, children with autism may have difficulty interacting socially with parents, siblings and other people; have difficulty with transitions and need routine; engage in repetitive behaviors such as hand flapping or rocking; display a preoccupation with activities or toys; and suffer a heightened sensitivity to noise and sounds. Autism spectrum disorders vary in the type and severity of the symptoms they cause, so two children with autism may not be affected in quite the same way.

## Q. What causes autism?

A. The specific cause or causes of autism in all children are not known. But one thing is clear: Autism spectrum disorders are highly genetic. Researchers figured this out by studying twins. They found that when one identical twin had autism, the chance that the second twin had autism was greater than 90 percent. But when one fraternal twin had autism, the chance that the second twin had autism was less than 10 percent. Because identical twins have identical genes and fraternal twins don't, these studies proved the genetic basis of autism. Researchers have successfully identified some of the specific genes that cause autism.

Some parents wonder whether environmental factors — defined as anything other than genetic factors — can cause autism. It's possible. For example, researchers found that thalidomide, a sedative, can cause autism if used during early pregnancy. Also, if pregnant women are infected with the rubella virus (German measles) during early pregnancy, their babies are more likely to have autism.

## Q. Does the MMR vaccine cause autism?

A. No. In 1998, a British researcher named Andrew Wakefield raised the notion that the MMR vaccine might cause autism. In the medical journal *The Lancet*, he reported the stories of eight children who developed autism and intestinal problems soon after receiving the MMR vaccine. To determine whether Wakefield's suspicion was correct, researchers performed a series of studies comparing hundreds of thousands of children who had received the MMR vaccine with hundreds of thousands who had never received the vaccine. They found that the risk of autism was the same in both groups. The MMR vaccine didn't cause autism.

Some parents wary of the safety of the MMR vaccine stopped getting their children immunized. As immunization rates dropped, particularly in the United Kingdom and, to some extent, the United States, outbreaks of measles and mumps led to hospitalizations and deaths that could have been prevented.

## Q. Does thimerosal cause autism?

A. No. Multiple studies have shown that thimerosal in vaccines does not cause autism. Thimerosal is a mercury-containing preservative that was used in vaccines to prevent contamination. In 1999, professional groups called for thimerosal to be removed from vaccines as a precaution. Unfortunately, the precipitous removal of thimerosal from all but some multi-dose preparations of influenza vaccine scared some parents. Clinicians were also confused by the recommendation.

Since the removal of thimerosal, several studies have been performed to determine whether thimerosal causes autism. Hundreds of thousands of children who received thimerosal-containing vaccines were compared to hundreds of thousands of children who received the same vaccines free of thimerosal. The results were clear: The risk of autism was the same in both groups; thimerosal in vaccines did not cause autism.

*continued >*

# Q&A VACCINES AND AUTISM: WHAT YOU SHOULD KNOW

**Q. Is autism caused by children receiving too many vaccines too soon?**

**A.** Several facts make it very unlikely that babies are overwhelmed by too many vaccines given too early in life.

First, before they are licensed, new vaccines are always tested alone and in combination with existing vaccines. These studies determine whether new vaccines alter the safety and efficacy of existing vaccines and, conversely, whether existing vaccines affect the new vaccine. These studies, called concomitant use studies, are performed every time a new vaccine is added to the existing vaccination schedule.

Second, although the number of vaccines has increased dramatically during the past century, the number of immunological components in vaccines has actually decreased. One hundred years ago, children received just one vaccine, for smallpox. The smallpox vaccine contained about 200 immunological components. Today, with advances in protein purification and recombinant DNA technology, the 14 vaccines given to young children contain only about 150 immunological components.

Third, the immunological challenge from vaccines is minuscule compared to what babies typically encounter every day. The womb is sterile, containing no bacteria, viruses, parasites or fungi. But when babies leave the womb and enter the world, they are immediately colonized by trillions of bacteria that live on the linings of their nose, throat, skin and intestines. Each bacterium contains between 2,000 and 6,000 immunological components. And babies often make an immune response to these bacteria to prevent them from entering the bloodstream and causing harm. The challenge that vaccines present is tiny in comparison to that from the environment.

Fourth, children have an enormous capacity to respond to immunological challenges. Susumu Tonegawa, a molecular biologist who won a Nobel Prize for his work, showed that people have the capacity to make between 1 billion and 100 billion different types of antibodies. Given the number of immunological components contained in modern vaccines, a conservative estimate would be that babies have the capacity to respond to about 10,000 different vaccines at once. Although this sounds like a huge number, when you consider the number of challenges that babies face from bacteria in their environment, it's not.

Here's another way to understand the difference in scale between immunological challenges from vaccines and natural challenges from the environment. The quantity of bacteria that live on body surfaces is measured in grams (a gram is the weight of about one-fifth of a teaspoon of water). The quantity of immunological components contained in vaccines is measured in micrograms or nanograms (millionths or billionths of a gram).

**Q. Are the studies showing that neither the MMR vaccine nor thimerosal causes autism sensitive enough to detect the problem in small numbers of children?**

**A.** The studies showing that neither the MMR vaccine nor thimerosal causes autism, called epidemiological studies, are very sensitive. For example, epidemiological studies have shown that a rotavirus vaccine used between 1998 and 1999 in the United States caused intestinal blockage in one out of every 10,000 vaccine recipients; that measles vaccine caused a reduction in the number of cells needed to stop bleeding (platelets) in one out of every 25,000 recipients; and that an influenza (swine flu) vaccine used in the United States in 1976 caused a type of paralysis called Guillain-Barré syndrome in one out of every 100,000 recipients.

About one out of every 59 children in the United States is diagnosed with an autism spectrum disorder. Even if vaccines caused autism in only 1 percent of autistic children, the problem would have easily been detected by epidemiological studies.

**Q. If I am concerned that vaccines cause autism, what is the harm in delaying or withholding vaccines for my baby?**

**A.** A study by Michael Smith and Charles Woods found that children who were fully vaccinated in the first year of life were not more likely to develop autism than those whose parents had chosen to delay vaccines. Further, all of the evidence shows that vaccines don't cause autism, so delaying or withholding vaccines will not lessen the risk of autism; it will only increase the period of time during which children are at risk for vaccine-preventable diseases. Several of these diseases, like chickenpox, pertussis (whooping cough) and pneumococcus (which causes bloodstream infections, pneumonia and meningitis) are still fairly common. Delaying or withholding vaccines only increases the time during which children are at unnecessary risk for severe and occasionally fatal infections.

# REFERENCES

## AUTISM REFERENCES

Because autism research is continually evolving, a great way to stay up-to-date is to visit the Autism Science Foundation's research pages at:

[www.autismsciencefoundation.org/research-year](http://www.autismsciencefoundation.org/research-year)

Alarcon M, Abrahams BS, Stone JL, et al. Linkage, association, and gene-expression analyses identify CNTNAP2 as an autism-susceptibility gene. *Am J Hum Genet.* 2008;82(1):150-159.

Arking DE, Cutler DJ, Brune CW, et al. A common genetic variant in the neurexin superfamily member CNTNAP2 increases familial risk of autism. *Am J Hum Genet.* 2008;82(1):160-164.

Bailey A, LeCouteur A, Gottesman I, et al. Autism as a strongly genetic disorder: evidence from a British twin study. *Psychol Med.* 1995;25:63-77.

Bauman M. Autism: clinical features and neurological observations. In: Tager-Flusberg H, ed. *Neurodevelopmental Disorders.* Cambridge, MA: The MIT Press;1999;383-399.

Chess S, Fernandez P, Korn S. Behavioral consequences of congenital rubella. *J Pediatr.* 1978;93:699-703.

Folstein S, Rutter M. Infantile autism: a genetic study of 21 twin pairs. *J Child Psychol Psychiatry.* 1977;18:297-321.

Gai X, Xie HM, Perin JC, et al. Rare structural variation of synapse and neurotransmission genes in autism. *Mol Psych.* 2011; 1-10.

Glessner JT, Wang K, Cai G, Korvatska O, et al. Autism genomewide copy number variation reveals ubiquitin and neuronal genes. *Nature.* 2009;459:569-573.

International Molecular Genetic Study of Autism Consortium (IMGSAC). A genomewide screen for autism: strong evidence for linkage to chromosomes 2q, 7q, and 16p. *Am J Hum Genet.* 2001;69:570-581.

Moessner R, Marshall CR, Sutcliffe JS, et al. Contribution of SHANK-3 mutations to autism spectrum disorder. *Am J Hum Genet.* 2007;81: 1289-1297.

Rodier PM. The early origins of autism. *Sci Am.* 2000;282:56-63.

Smith MJ and Woods CR. On-time vaccine receipt in the first year does not adversely affect neuropsychological outcomes. *Pediatrics.* 2010;125(6): 1134-1141.

Strömmland K, Nordin V, Miller M, Akerström B, Gillberg C. Autism in thalidomide embryopathy: a population study. *Dev Med and Child Neurol.* 1994;36:351-356.

Wang K, Zhang H, Ma D, Bucan M, et al. Common genetic variants on 5p14.1 associate with autism spectrum disorders. *Nature.* 2009;459: 528-533.

Wassink TH, Piven J, Vieland VJ, et al. Evidence supporting WNT2 as an autism susceptibility gene. *Am J Med Genet.* 2001;105:406-413.

## AUTISM AND VACCINES REFERENCES

Afzal MA, Ozoemena LC, O'Hare A, et al. Absence of detectable measles virus genome sequence in blood of autistic children who have had their MMR vaccination during the routine childhood immunization schedule of UK. *J Med Virol* 2006;78:623-630.

Dales L, Hammer SJ, Smith NJ. Time trends in autism and in MMR immunization coverage in California. *JAMA.* 2001;285:1183-1185.

Davis RL, Kramarz P, Bohlke K, et al. Measles-mumps-rubella and other measles-containing vaccines do not increase the risk for inflammatory bowel disease: a case control study from the Vaccine Safety Datalink project. *Arch Pediatr Adolesc Med.* 2001;155:354-359.

DeStefano F, Bhasin TK, Thompson WW, Yeargin-Allsopp M, Boyle C. Age at first measles-mumps-rubella vaccination in children with autism and school-matched control subjects: a population-based study in metropolitan Atlanta. *Pediatrics.* 2004;113:259-266.

DeStefano F, Chen RT. Negative association between MMR and autism. *Lancet.* 1999;353:1986-1987.

Farrington CP, Miller E, Taylor B. MMR and autism: further evidence against a causal association. *Vaccine.* 2001;19:3632-3635.

Fombonne E, Chakrabarti S. No evidence for a new variant of measles-mumps-rubella-induced autism. *Pediatrics.* 2001;108:E58.

Fombonne E, Cook EH Jr. MMR and autistic enterocolitis: consistent epidemiological failure to find an association. *Mol Psychiatry.* 2003;8: 133-134.

Honda H, Shimizu Y, Rutter M. No effect of MMR withdrawal on the incidence of autism: a total population study. *J Child Psychol Psychiatry.* 2005;46(6):572-579.

Hornig M, Briese T, Buie T, et al. Lack of association between measles virus vaccine and autism with enteropathy: a case-control study. *PLoS ONE* 2008;3(9):e3140.

Kaye JA, del Mar Melero-Montes M, Jick H. Mumps, measles, and rubella vaccine and the incidence of autism recorded by general practitioners: a time trend analysis. *BMJ.* 2001;322:460-463.

Madsen KM, Hviid A, Vestergaard M, et al. A population-based study of measles, mumps and rubella vaccination and autism. *N Engl J Med.* 2002;347:1477-1482.

Marshall JA, Buikema A, et al. Autism occurrence by MMR vaccine status among US children with older siblings with and without autism. *JAMA.* 2015;313(15):1534-1540.

Peltola H, Patja A, Leinikki P, Valle M, Davidkin I, Paunio M. No evidence for measles, mumps and rubella vaccine associated inflammatory bowel disease or autism in a 14-year prospective study. *Lancet.* 1998;351: 1327-1328.

Smeeth L, Cook C, Fombonne E, et al. MMR vaccination and pervasive developmental disorders: a case-control study. *Lancet* 2004;364:963-969.

Taylor B, Miller E, Farrington CP, et al. Autism and measles, mumps and rubella vaccine: no epidemiological evidence for a causal association. *Lancet.* 1999;353:2026-2029.

Taylor LE, Swerdfeger AL, Eslick GD. Vaccines are not associated with autism: an evidence-based meta-analysis of case-control and cohort studies. *Vaccine* 2014;32:3623-3629.

Uchiyama T, Kurosawa M, Inaba Y. MMR-vaccine and regression in autism spectrum disorders: negative results presented from Japan. *J Autism Dev Disord* 2007;37:210-217.

Wilson K, Mills E, Ross C, McGowan J, Jadad A. Association of autistic spectrum disorder and the measles, mumps and rubella vaccine: a systematic review of current epidemiological evidence. *Arch Pediatr Adolesc Med.* 2003;157:628-634.

## IMMUNOLOGICAL CAPACITY AND TOO MANY VACCINES REFERENCES

DeStefano F, Price CS, Weintraub ES. Increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines is not associated with risk of autism. *J Pediatr* 2013;163:561-567.

Glanz JM, Newcomer SR, Daley MF, DeStefano F, et al. Association between estimated cumulative vaccine antigen exposure through the first 23 months of life and non-vaccine-targeted infections from 24 to 47 months of age. *JAMA* 2018;319(9):906-913.

Hviid A, Wohlfahrt J, Stellfeld M, et al. Childhood vaccination and nontargeted infectious disease hospitalization. *JAMA* 2005;294(6):699-705.

Iqbal S, Barile JP, Thompson WW, and DeStefano F. Number of antigens in early childhood vaccines and neuropsychological outcomes at age 7-10 years. *Pharmacoepidemiol Drug Saf* 2013;22:1263-1270.

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

Sherrid AM, Ruck CE, Sutherland D, et al. Lack of broad functional differences in immunity in fully vaccinated vs. unvaccinated children. *Pediatr Res* 2017;81(4):601-608.

Smith MJ and Woods CR. On-time vaccine receipt in the first year does not adversely affect neuropsychological outcomes. *Pediatrics* 2010;125:1134-1141.

## THIMEROSAL REFERENCES

Andrews N, Miller E, Grant A, Stowe J, Osborne V, Taylor B. Thimerosal exposure in infants and developmental disorders: a retrospective cohort study in the United Kingdom does not support a causal association. *Pediatrics.* 2004;114:584-591.

Christensen DL, Baio J, Van Naarden Braun K, Charles J, Constantino JN, et al. Prevalence and characteristics of autism spectrum disorder among children age 8 years – Autism Developmental Disabilities Monitoring Network, 11 Sites, United States, 2012. *MMWR* 2016;65(3):1-23.

Fombonne E, Zakarian R, Bennett A, Meng L, McLean-Heywood D. Pervasive developmental disorders in Montreal, Quebec, Canada: prevalence and links with immunizations. *Pediatrics.* 2006;118:E139-150.

Heron J, Golding J. Thimerosal exposure in infants and developmental disorders: a prospective cohort study in the United Kingdom does not support a causal association. *Pediatrics.* 2004;114:577-583.

Hviid A, Stellfeld M, Wohlfahrt J, Melbye M. Association between thimerosal-containing vaccines and autism. *JAMA.* 2003;290:1763-1766.

Madsen KM, Lauritsen MB, Pedersen CB, et al. Thimerosal and the occurrence of autism: negative ecological evidence from Danish population-based data. *Pediatrics.* 2003;112:604-606.

Picciozzo IH, Green PG, Delwiche L, et al. Blood mercury concentrations in CHARGE study children with and without autism. *Environ Health Perspect.* 2010;118(1):161-166.

Price CS, Thompson WW, Goodson B, et al. Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism. *Pediatrics.* 2010;126:656-664.

Schechter R, Grether J. Continuing increases in autism reported to California's developmental services system: mercury in retrograde. *Arch Gen Psychiatry.* 2008;65:19-24.

Stehr-Green P, Tull P, Stellfeld M, Mortenson PB, Simpson D. Autism and thimerosal-containing vaccines: lack of consistent evidence for an association. *Am J Prev Med.* 2003;25:101-106.

Thompson WW, Price C, Goodson B, et al. Early thimerosal exposure and neuropsychological outcomes at 7 to 10 years. *N Engl J Med* 2007;357(13):1281-1292.

Tozzi AE, Bisiacchi P, Tarantino V, et al. Neuropsychological performance 10 years after immunization in infancy with thimerosal-containing vaccines. *Pediatrics.* 2009;123(2):475-482.

Verstraeten T, Davis RL, DeStefano F, et al. Study of thimerosal-containing vaccines: a two-phased study of computerized health maintenance organization databases. *Pediatrics.* 2003;112:1039-1048.

*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 professionals 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. ©2019 Children's Hospital of Philadelphia, All Rights Reserved. 18067-11-18.*



## RECOMMENDED IMMUNIZATION SCHEDULE: WHAT YOU SHOULD KNOW

Volume 2  
Fall 2021

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.

*continued >*



# 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](http://cdc.gov/vaccines/schedules/index.html).

Immunization recommendations are available on the CDC website at [cdc.gov/vaccines/hcp/acip-recs/index.html](http://cdc.gov/vaccines/hcp/acip-recs/index.html).

Cohn M, Langman RE. The protection: the unit of humoral immunity selected by evolution. *Immunol Rev*. 1990;115:11-147.

Offit PA, Moser CA. The Problem with Dr. Bob's Alternative Vaccine Schedule. *Pediatrics*. 2009;123(1):164-9.

Offit PA, Moser CA. *Vaccines and Your Child: Separating Fact from Fiction*. New York: Columbia University Press; 2011.

Offit PA, Quarles J, Gerber MA, Hackett CJ, Marcuse EK, Kollman TR, Gellin BG, Landry S. Addressing parents' concerns: Do multiple vaccines overwhelm or weaken the infant's immune system? *Pediatrics*. 2002;109(1):124-129.

Plotkin SA, Orenstein WA, Offit PA, Edwards KM. *Plotkin's Vaccines*, 7th Ed. Elsevier, 2017.

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

Tonegawa S, Steinberg C, Dube S, Bernardini A. Evidence for somatic generation of antibody diversity. *Proc Natl Acad Sci USA*. 1974;71:4027-4031.

*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. ©2021 Children's Hospital of Philadelphia. All Rights Reserved. 21157-09-21.*

# Q&A VACCINE INGREDIENTS: WHAT YOU SHOULD KNOW

Volume 6  
Summer 2023

*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.

*continued >*



# 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.

## Selected references

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

**Formaldehyde:** Epidemiology of chronic occupational exposure to formaldehyde: report of the ad hoc panel on health aspects of formaldehyde. *Toxicology and Industrial Health*. 1988;4:77-90.

**Gelatin:** Atkinson WL, Kroger AL, Pickering LK. Vaccine additives and manufacturing residuals in vaccines licensed in the United States. In: Orenstein WA, et al., eds, *Vaccines*, Eighth Edition. Saunders Elsevier, 2024.

**Cumulative effects:** Smith MJ, Woods CR. On-time vaccine receipt in the first year does not adversely affect neuropsychological outcomes. *Pediatrics*. 2010;125(6):1134-1141.

**Thimerosal:** Gerber JS, Offit PA. Vaccines and autism: A tale of shifting hypotheses. *Clinical Infectious Diseases*. 2009;48:456-461.

**Fetal cells:** Offit PA. *Vaccinated: One man's quest to defeat the world's deadliest diseases*. New York: Harper Perennial, 2007.

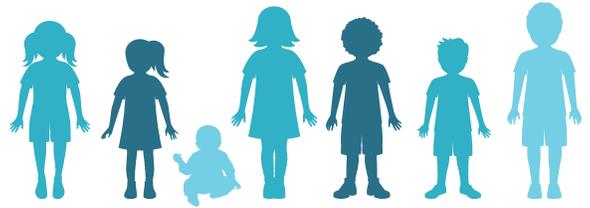
**Allergic reactions:** Offit PA, Jew RK. Addressing parents' concerns: do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics*. 2003;112:1394-1401.

**Multiple Vaccines:** Offit PA, Quarles J, Gerber MA, Hackett CJ, Marcuse EK, Kollman TR, Gellin BG, Landry S. Addressing parents' concerns: Do multiple vaccines overwhelm or weaken the infant's immune system? *Pediatrics*. 2002 Jan;109(1):124-129.

*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. ©2023 Children's Hospital of Philadelphia. All Rights Reserved. 23211-08-23.*

# THERE'S A CURRENT OUTBREAK OF MEASLES

Measles is a very contagious disease caused by a virus. It can be dangerous, especially for babies and young children. Protect your family and your community.



Measles spreads through the air when a sick person coughs or sneezes. The virus can stay in the air for 2 hours after a person with measles leaves the space. It is so contagious that about 9 out of 10 people who come near a person with measles and are not protected by vaccination will also become infected.

Measles symptoms appear 7 to 14 days after contact with the virus. Common measles symptoms include:



**High fever**  
(may spike to more than 104°F)



**Cough**



**Runny nose**



**Red and/or watery eyes**



**Rash**  
(breaks out 3-5 days after symptoms begin)

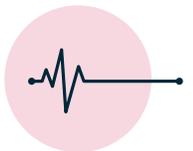
Measles can cause severe health problems, including:



**Pneumonia**



**Swelling of the brain**  
(encephalitis)



**Possibly even death**

## The best way to protect against measles ...

is with the measles, mumps, and rubella (MMR) vaccine. It's never too late to get vaccinated. Vaccination helps protect you, the people around you, and your community. If you are not vaccinated, consider staying at home or away from crowded areas until measles cases in the area decrease, especially to protect people in your family that could get very sick.

If you think that you or someone in your family have measles, stay away from others and call a healthcare provider, urgent care, or emergency room.



BE READY FOR MEASLES  
[cdc.gov/measles](https://cdc.gov/measles)





# COASTAL CHILDREN'S CLINIC

*Excellence in Pediatrics For Over 50 Years!*

## Vaccination Education Packet

### **NEW BERN**

703 Newman Road  
New Bern, NC 28562  
T (252) 633-2900  
F (252) 633-9609  
Mon-Fri 8am – 5pm  
Saturday 8am-12pm  
Sunday 8am-12pm

### **HAVELOCK**

218 Stonebridge Square  
Havelock, NC 28532  
T (252) 447-8100  
F (252) 447-1900  
Mon-Fri 8am-5pm

### **MAYSVILLE**

P.O. Box 160  
1004 Jenkins Avenue  
Maysville, NC 28555  
T (910) 743-2022  
F (910) 743-1283  
Mon-Fri 8:30am – 5pm

### MEDICAL STAFF

[doctor@coastalchildrens.com](mailto:doctor@coastalchildrens.com)  
Gregory G. Gunsten, MD FAAP  
Lee Ann Skladan, MD FAAP  
C. Marston Crawford, MD FAAP  
Lisa M. Kafer, MD, FAAP  
David Tayloe, III, MD, FAAP  
Kelly Grove, DO  
Justin Cimring, M.D. FAAP  
Mobby Chakanyuka, M.D.  
FAAP  
Melissa Hollifield, C-FP  
Stanton Ezzell, P-NP  
Kyla Beasley, CPNP  
Laura Landon, CPNP  
Sarah Nichols, FNP-BC

### Practice Administrator

Sami Bennett  
[Sami@coastalchildrens.com](mailto:Sami@coastalchildrens.com)  
(252) 633-2900

### Insurance

Alisha Rowe  
Leah Raines  
[insurance@coastalchildrens.com](mailto:insurance@coastalchildrens.com)  
(252) 633-2334

Enclosed are several documents including:

- 1) Coastal Children's Clinic Immunization Policy Statement
- 2) Vaccine Ingredient List
- 3) Measles Fact Sheet
- 4) Vaccines and Autism
- 5) Recommended Vaccine Schedule
- 6) Authorization to Transfer Medical Records

You have been given this Education Packet because of concerns you have over the safety of childhood vaccinations and /or because you have chosen to delay one or more very important vaccines - vaccines that we require of our patient(s) to remain our patient (s).

Please review the information presented. We feel this is the best available and should help you to realize that vaccinations are in the best interest of all children. There are no medical interventions; vaccines, medicines, surgeries, and procedures that are one hundred percent safe. Just by driving here you have put yourself at a small risk. We feel that there is no question but that any possible risk of vaccination is much less than the risk of catching a disease without the vaccination.

Please review this information and our immunization policy. We ask that you call our office in the next two weeks to either schedule a conference to answer additional questions you may have, or to schedule an immunization visit, or to arrange for transfer of your children's records to another physician's office.

July 2025

**NEW BERN**

*All Pediatrics, All The Time*

**HAVELOCK**

Office Hours 7 Days A Week in New Bern

**MAYSVILLE**

[www.COASTALCHILDRENS.com](http://www.COASTALCHILDRENS.com)