



POSITION STATEMENT

VACCINE SAFETY: A POSITION STATEMENT OF THE PHYSICIANS RESOURCE COUNCIL

Vaccines have been at the center of a storm of controversy for well over a decade, and much of the debate involves issues of safety. Parents are looking for advice on how best to protect their children from unnecessary health risks, but when one considers the huge volume of vaccine information available (much of that on the Internet), that task suddenly becomes much more daunting and confusing. Some people claim that vaccines do more harm than good; others say vaccines are ineffective. Still others say vaccines are both safe and effective. How can you make the right choice for your child?

Parents ought to raise their concerns and ask questions when it comes to their children's well-being. In fact, the members of the Physicians Resource Council (PRC) of Focus on the Family have heard many of these concerns and questions about immunizations. While the PRC recognizes that vaccine research and monitoring must continue in order to produce the safest vaccines possible, it also recognizes that the vaccines currently available are not only beneficial but essential to the health of children and society in general.

To provide the most pertinent information possible regarding vaccines, here are some of the most common vaccine-related questions asked by parents, along with research-based answers.

Are vaccines safe?

Yes. While every medication, including vaccines, pose some level of risk, vaccines today are safer and more effective than ever. Before any vaccine reaches your doctor's office, it has undergone several rounds of rigorous clinical testing. The government, through monitoring programs at the Food and Drug Administration and the Centers for Disease Control and Prevention, continues to critically evaluate all vaccines after their release to ensure that they are as safe as possible.

While most children receiving vaccinations suffer no side effects, some children experience mild reactions that may include irritability, tenderness in the area of injection, and low-grade fever. The likelihood of a severe reaction to the vaccine is extremely small, and is *much* lower than the likelihood of complications due to the disease. For instance, according to the CDC, the chance of having a severe allergic reaction in response to the combined measles-mumps-rubella vaccine (MMR-II) is less than 1 in 1,000,000; other serious reactions (deafness, long-term seizures, coma, brain damage), have been

reported, but they occur so infrequently that it's difficult to know for sure whether they are actually even caused by the vaccine¹. In contrast, the chance of developing pneumonia (the most common cause of childhood death from measles) after infection with measles virus is approximately 1 in 20, while the risk of encephalitis is about 1 in 1,000. Roughly one or two children in 1,000 with measles disease will die². The risk of encephalitis from mumps is about 1 in 50,000, while the disease causes permanent hearing loss in 1 out of 20,000 cases³. Clearly, the risks associated with the MMR-II vaccine are lower than those posed by the diseases it prevents.

It is worth noting, however, that there may be instances in which your family doctor or pediatrician might postpone immunization. If your child is given a vaccine while ill, for example, it might be difficult to determine whether subsequent symptoms, especially fever, are due to the vaccine or to the illness. Likewise, a severe illness might prevent your child from developing a sufficient immune response to a vaccine, rendering the immunization less effective than if your child were healthy. Also, some vaccines contain live (but weakened) viruses, and these should not be administered to children with suppressed immune systems (for example, children who have HIV or are undergoing certain cancer chemotherapies). Talk with your doctor if you have any questions or concerns.

I've heard that the MMR-II vaccine causes autism. Is this true?

The alarm over the MMR-II vaccine can be traced back to 1998, when Dr. Andrew Wakefield and twelve coauthors published a preliminary report in the British medical journal *The Lancet* based on their examinations of twelve children, all of whom were reported to have symptoms of both inflammatory bowel disorder and developmental regression⁴. Nine of these children were reportedly diagnosed with autism. The parents of these children concluded that there must have been a connection between the onset of the regression and immunization with the MMR-II vaccine. Their assumption was based on the age of the children in whom autism was identified: most cases of autism are diagnosed before age three, which is also when the initial MMR-II vaccine is usually administered.

Although the authors of this study did not make the direct claim that the MMR-II vaccine caused autism, their report received wide media attention. As a result, the notion of a causal connection has persisted.

Since that time, ten authors of the Wakefield study have retracted the interpretation of their work which hinted at an association between the vaccine and autism⁵. Between 2007 and 2010, the U.K. General Medical Council held hearings to investigate the conduct of Dr. Wakefield and two coauthors in the study. The GMC found clear evidence of professional misconduct in regard to the study and the treatment of the children enrolled in the research. Their investigations revealed that data in the study had been manipulated and that Wakefield had gross conflicts of interest tied to the study's outcome⁶. The council revoked the ability of Dr. Wakefield and another of the study's coauthors to

practice medicine in the U.K. (the ruling against Wakefield's coauthor was later overturned upon appeal). *The Lancet* subsequently retracted the study completely⁷.

Since the Wakefield study was originally published, numerous studies have been published investigating a possible link between autism and the MMR-II vaccine, and so far no association has been discerned. Studies in Great Britain looked at trends in autism incidence after introduction of MMR vaccination^{8,9}. No support for a link between the MMR vaccine and autism was noted. Other studies in the U.K.¹⁰ and the U.S.¹¹ found that increases in the number of newly diagnosed autism cases had occurred in places where MMR vaccine coverage had remained relatively consistent over time, indicating that the vaccine was not a factor.

Reputable and respected organizations operating independently of one another (e.g., the American Academy of Pediatrics and the Institute of Medicine) have extensively reviewed the studies mentioned above (and other research) and have reached the same conclusion: the available evidence does not indicate a causal relationship between the MMR-II vaccine and autism^{12,13}.

We understand that it can be devastating to have a child diagnosed with autism, and our hearts go out to families who experience this. It's only natural for parents to try to identify the cause for their child's condition. However, the evidence points away from MMR-II as a potential cause of autism, and we believe children across the nation would suffer enormous health risks if parents withhold the vaccine based on unfounded fears.

What about vaccines containing mercury? Aren't these a health hazard?

A mercury-containing preservative called thimerosal has been added to some vaccines since the 1930s. A number of parents of children with neurological and developmental problems have raised the question of whether vaccines with thimerosal were responsible for their children's conditions.

In 1997, the Food and Drug Administration performed a comprehensive review of vaccines containing thimerosal and found that the amount of mercury a child might receive under existing recommended vaccine schedules was within acceptable FDA limits¹⁴. However, depending on the vaccine formulation administered and the weight of the infant, it was determined that a child could possibly be exposed during the first six months of life to a level of mercury higher than that recommended by the Environmental Protection Agency. As a precautionary measure, the U.S. Public Health Service and the American Academy of Pediatrics issued a joint statement (later affirmed by the American Academy of Family Physicians) calling upon vaccine manufacturers to eliminate or greatly reduce the amount of thimerosal used in vaccines¹⁵. Although several reports indicated that toxicity from thimerosal did not occur until the level of exposure reached 100 or 1000 times that found in vaccines¹⁶, it was nonetheless considered prudent to urge the reduction of mercury content to as low a level as possible.

Today, all vaccines on the recommended childhood immunization schedule appear in either thimerosal-free or thimerosal-reduced forms (with a greater than 95% reduction in thimerosal)¹⁷. And while some flu vaccines still contain thimerosal, many formulations do not.

I'm concerned about the number of immunizations my child is scheduled to get. Is it safe for her to get so many at once, especially while she is so young?

Some parents have expressed concerns that their infant's immune system might be weakened as a result of getting too many vaccines at one time. Currently, some vaccines are administered in combination (such as the measles-mumps-rubella and the diphtheria-tetanus-pertussis triple vaccines), and infants often receive several vaccines during a single office visit. This means fewer office visits, which not only saves time and money for the parents but is also less traumatic for the child. Research indicates that this multiple vaccination strategy offers no increased risk of adverse reactions compared to the administration of single vaccinations over a course of many office visits.

Part of the concern over multiple immunizations is that it "overloads" a child's immune system. However, a child's immune system is capable of responding to many antigens (large molecules that can provoke an immune response) even before the child is born. And because an infant's immune system has never encountered some of the viruses or bacteria that cause specific diseases (and therefore is not primed to defend against them), it is vital that immunization occur at this time when children are most vulnerable to infectious diseases.

The total number of immune challenges given during vaccinations is negligible. Over the *entire* recommended immunization schedule, a young child's immune system is exposed to roughly 150 antigens¹⁸. That is tiny compared to the number of immune challenges a child experiences on a regular basis. Kids are exposed to thousands of antigens from bacteria found on the skin and in the intestinal tract, mouth, and nasal passages. Considering illnesses that children face, a single viral respiratory infection introduces between four and 10 antigens, while a case of "strep throat" can introduce between 25 and 50¹⁹.

While some parents suggest that, just to be safe, children receive only one vaccine per visit and that multiple vaccines be given in their individual components, many medical professionals and child-health advocates disagree. Spreading immunizations over a longer period of time decreases the likelihood of children being up-to-date on all their vaccinations and may leave them vulnerable to disease during the intervals between vaccinations.

If most of these childhood diseases have been eradicated, why vaccinate?

With the help of immunization, it is possible to eradicate diseases from the global population. Once this is done, routine vaccinations for the disease are no longer necessary. Smallpox, the last naturally

occurring case of which was reported in 1977, is the prime example. Because of aggressive vaccination programs worldwide, smallpox has been eradicated and immunization against the disease is no longer performed as part of recommended childhood vaccinations.

However, those diseases for which vaccines are currently recommended have *not* been eradicated; we simply see these diseases less frequently because children continue to be immunized against them. In regions where vaccination coverage has lapsed, the incidence of disease as well as accompanying complications have risen.

Even for diseases that have not occurred in North America for years, vaccination is still essential. For instance, “wild” polio has not occurred in the Western hemisphere since 1991²⁰, yet the accessibility of international travel means that someone elsewhere in the world who is infected with polio could carry that disease to parts of the world that have not seen it for years.

I can understand vaccinating against crippling diseases like polio, but why do we vaccinate against diseases that are not dangerous?

It is widely believed that many of the diseases against which children are immunized are benign childhood ailments, but consider the following:

- Rubella (German measles) can result in infant death or serious birth defects (including deafness, blindness, and mental impairment) if a pregnant woman becomes infected. In 1964 and 1965, before immunization against rubella was widespread, approximately 20,000 children were born with birth defects caused by the disease, while an additional 2,100 neonatal deaths and over 11,000 miscarriages resulted from rubella infections²¹.
- Prior to immunization against pertussis (whooping cough), the disease typically struck between 150,000 and 260,000 individuals annually²² and caused as many as 9,000 deaths per year²³.
- Measles — which can cause ear infections, diarrhea, pneumonia, and, in more severe cases, inflammation of the brain called encephalitis — infected nearly everyone in the United States prior to immunization. In the decade before 1963, when a vaccine was made available, between 400 and 500 deaths occurred yearly in the U.S. due to measles, with an additional toll of 48,000 hospitalizations and 4,000 cases of encephalitis annually²⁴.
- Even chickenpox, commonly considered a harmless infection, has been responsible for roughly 11,000 hospitalizations and 100-150 deaths annually in recent decades.²⁵

I've been told that physicians and others in the healthcare field are inclined to deny vaccine safety problems because they are conditioned by their training or because they have financial interests in promoting vaccination. Is this true?

This is not true. First, physicians are conditioned by their training to seek the best interests of their patients, not those of pharmaceutical companies. Second, considering the matter from a purely economic perspective, it is hard to imagine that anyone would make himself legally and financially liable for keeping an unsafe product on the market. The idea that physicians are involved in a global conspiracy to promote immunization at the expense of children's health simply because they are blindly adhering to their training or because they seek to make money is ludicrous at best — life-threatening at worst. In fact, the case of RotaShield shows that vaccines posing unacceptable risks are not tolerated.

In August 1998, a vaccine called RotaShield was approved for use against rotavirus, a virus that can cause fever, nausea, severe diarrhea, and dehydration, and accounts for more than 500,000 physician visits and 50,000 hospitalizations each year among children under the age of 5. Between September 1998 and July 1999, 15 cases of a rare bowel blockage had been associated with the administration of the vaccine. That July, the CDC recommended the suspension of RotaShield, and in October 1999 the group that develops recommendations for routine vaccinations in the U.S., the Advisory Committee on Immunization Practices, withdrew its recommendation of the vaccine. Safer formulations of the rotavirus vaccine were later introduced to the market.

Discovery of problems with the early rotavirus vaccine and its subsequent withdrawal from the market demonstrate that the procedures in place to monitor vaccines are working, and that unsafe vaccines will not be tolerated.

I know people who have never been immunized and yet have never contracted these diseases. Doesn't this support the idea that children don't need to be vaccinated?

It's true that people who are not immunized may never become infected with diseases such as mumps or measles. These people are most likely the beneficiaries of *herd immunity*, a phenomenon that relies on a buffer of immunized individuals between infected persons and unvaccinated ones.

For example, someone with a disease that is spread from person to person may encounter many individuals during the course of his or her infection. If few people in the community are immunized against the disease, the chance of it being spread throughout the community is higher than it would be if many people are immunized. As more people are immunized, the chance of an unvaccinated individual coming in contact with the infected person (and thereby possibly contracting and spreading the disease) becomes smaller.

Herd immunity requires that a large number of people in the community be immunized. In regions where vaccination rates drop, herd immunity decreases and the incidence of disease rises. Thus, refusing vaccination not only puts individuals at risk but also increases the risk of disease for others in the community.

Are immunizations required by law?

Immunization requirements vary by state. Talk with your family doctor or pediatrician, or contact your state or local public health department for further information.

Where else can I get reliable information about immunizations?

Your family doctor or pediatrician can provide more information about vaccines. Also, the American Academy of Pediatrics' website [www.aap.org] and the CDC's vaccine and immunization website [<http://www.cdc.gov/vaccines/>] give answers to many questions you might have about immunization.

¹ Centers for Disease Control and Prevention, see <http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.html>

² Centers for Disease Control and Prevention, see <http://www.cdc.gov/measles/about/complications.html>

³ Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 12th Edition. 2012, p. 206

⁴ Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet*. 1998;351:637-641

⁵ Murch SH, Anthony A, Casson DH, et al. Retraction of an interpretation. *Lancet*. 2004;363:750

⁶ Wakefield's article linking MMR vaccine and autism was fraudulent. *BMJ*. 2011;342:c7452

⁷ Retraction — Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet*. 2010;375:445

⁸ Taylor B, Miller E, Farrington CP, et al. Autism and measles, mumps, and rubella vaccine: no epidemiological evidence for a causal connection. *Lancet*. 1999;353:2026-2029

⁹ Taylor B, Miller E, Lingam R, et al. Measles, mumps, and rubella vaccination and bowel problems or developmental regression in children with autism: population study. *Brit. Med. J*. 2002;324:393-396

¹⁰ Kaye JA, Melero-Montes M, Jick H. Mumps, measles, and rubella vaccine and the incidence of autism recorded by general practitioners: a time trend analysis. *Brit. Med. J*. 2001;322:460-463

¹¹ Dales L, Hammer SJ, Smith NJ. Time trends in autism and in MMR immunization coverage in California. *J. Amer. Med. Assoc*. 2001;285:1183-1185

¹² American Academy of Pediatrics. Vaccine studies: examine the evidence. See <http://www.aap.org/en-us/advocacy-and-policy/Documents/vaccinestudies.pdf>

¹³ Institute of Medicine. *Adverse Effects of Vaccines: Evidence and Causality*. 2012:145-153

¹⁴ U.S. Food and Drug Administration, see <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/UCM070430>

¹⁵ American Academy of Pediatrics, United States Public Health Service. Joint statement of the American Academy of Pediatrics (AAP) and the United States Public Health Service (USPHS). *Pediatrics*. 1999;104:568-569

¹⁶ U.S. Food and Drug Administration, see

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/UCM070430>

¹⁷ Institute for Vaccine Safety, see <http://www.vaccinesafety.edu/thi-table.htm>

¹⁸ American Academy of Pediatrics. Immunization. See <http://www2.aap.org/immunization/families/safety.html>

¹⁹ Centers for Disease Control and Prevention, see <http://www.cdc.gov/vaccinesafety/vaccines/multiplevaccines.html>

²⁰ Centers for Disease Control and Prevention, see <http://www.cdc.gov/mmwr/preview/mmwrhtml/00032760.htm>

²¹ Centers for Disease Control and Prevention, see <http://www.cdc.gov/vaccines/vac-gen/whatifstop.htm>;
<http://www.cdc.gov/features/rubella>

²² Centers for Disease Control and Prevention, see <http://www.cdc.gov/pertussis/surv-reporting/cases-by-year.html>

²³ Centers for Disease Control and Prevention, see <http://www.cdc.gov/pertussis/about/faqs.html>

²⁴ Centers for Disease Control and Prevention, see <http://www.cdc.gov/measles/about/history.html>

²⁵ Centers for Disease Control and Prevention, see <http://www.cdc.gov/chickenpox/vaccination.html>