



## VACCINE SAFETY

### A POSITION STATEMENT OF THE PHYSICIANS RESOURCE COUNCIL

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Vaccines have been at the center of a storm of controversy in the past few years, 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 amounts 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?

It's only right for parents 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 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.

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

#### **Are vaccines safe?**

Yes. 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 continues to monitor 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 may 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 Centers for Disease Control and Prevention (CDC), the chance of having a severe allergic reaction or developing encephalitis (inflammation of the brain) in response to the combined measles-mumps-rubella vaccine (MMR-II) is about 1 in 1,000,000<sup>1</sup>. In contrast, the chance of developing pneumonia after infection with measles virus is approximately 1 in 20, while the risk of measles encephalitis is about 1 in 1,000. Roughly one or two children in 1,000 with measles disease will die<sup>2</sup>. 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 cases<sup>3</sup>. Clearly, the risks posed by the MMR-II vaccine are lower than those posed by the diseases they prevent, and the benefits offered by the vaccine far outweigh the risks posed by the disease.

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 are part of the natural history of 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.

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<sup>1</sup> Centers for Disease Control and Prevention, see <http://www.cdc.gov/nip/publications/6mishome.htm>

<sup>2</sup> Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 7<sup>th</sup> Edition. 2002, p. 97

<sup>3</sup> Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 7<sup>th</sup> Edition. 2002, p. 116

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**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 his colleagues published a preliminary report based on their examinations of twelve children, all of whom showed symptoms of both inflammatory bowel disorder and developmental regression<sup>4</sup>. Nine of these children were 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 vaccination is usually administered.

Although the authors of this study set forth no assertion regarding a definitive link between autism and the MMR-II vaccine, their report received wide media attention. As a result, the notion of a causal connection has persisted.

Since that time, several 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<sup>5,6</sup>. No support for a link between MMR vaccine and autism was noted. Other studies in the U.K.<sup>7</sup> and the U.S.<sup>8</sup> found that increases in the number of newly diagnosed autism cases in recent years had occurred in places where MMR coverage had remained relatively consistent over the time course of increasing autism incidence, indicating that the MMR 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 indicates that autism has no relationship to the MMR-II vaccine<sup>9,10</sup>.

We recognize that having a child diagnosed with autism can be devastating, and our hearts go out to those parents. It is entirely appropriate for parents to try to find some 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 child'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 limits<sup>11</sup>. 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 Public Health Service and the American Academy of Pediatrics issued a joint statement (later agreed to by the American Academy of Family Physicians) calling upon vaccine manufacturers to eliminate or greatly reduce the amount of thimerosal used in vaccines<sup>12</sup>. Although data from several studies indicated that toxicity from thimerosal did not occur until the level of exposure reached 100 or 1000 times that found in vaccines<sup>13</sup>, 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)<sup>14</sup>.

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<sup>4</sup> 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

<sup>5</sup> 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

<sup>6</sup> 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

<sup>7</sup> 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

<sup>8</sup> 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

<sup>9</sup> Halsey NA, Hyman SL, Conference Writing Panel of the American Academy of Pediatrics. Measles-mumps-rubella vaccine and autistic spectrum disorder: report from the New Challenges in Childhood Immunization conference convened in Oak Brook, Illinois, June 12-13, 2000. *Pediatrics*. 2001;107:1-23

<sup>10</sup> Institute of Medicine. *Immunization Safety Review: Measles-Mumps-Rubella Vaccine and Autism*. 2001.

<sup>11</sup> See <http://www.fda.gov/cber/vaccine/thimfaq.htm>

<sup>12</sup> 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

<sup>13</sup> Food and Drug Administration, see <http://www.fda.gov/cber/vaccine/thimfaq.htm>

<sup>14</sup> See <http://www.vaccinesafety.edu/thi-table.htm>

**I'm concerned about the many vaccines my child is scheduled to get. Is it safe for her to get so many shots 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 antigens (large molecules that can provoke an immune response) even before the child is born. Since an infant's immune system has never encountered some of the viruses or bacteria that cause specific diseases (and therefore cannot defend against them), it is important that immunization occur at this time when children are most vulnerable.

The total number of immune challenges given during vaccinations is negligible. Over the entire recommended immunization schedule, a child's immune system is exposed to 126 or fewer antigens<sup>15</sup>. That is tiny compared to the number of immune challenges a child experiences every day. A viral respiratory infection introduces between four and 10 antigens, while a case of "strep throat" can introduce between 25 and 50<sup>16</sup>. Furthermore, thousands of bacteria can be found on a baby's skin and in a baby's intestinal tract, mouth, and nasal passages.

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 will decrease 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?**

There are diseases that have been eradicated and for which vaccinations are no longer given. Smallpox, the last naturally occurring case of which was reported in 1977, is a prime example. Because of aggressive vaccination programs worldwide, smallpox has been eradicated and immunization against the disease is no longer performed as part of routine 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 1994<sup>17</sup>, 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 infections<sup>18</sup>.
- Prior to immunization against pertussis (whooping cough), the disease struck between 150,000 and 260,000 individuals annually and caused as many as 9,000 deaths per year<sup>19</sup>.
- 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. On average, 450 deaths occurred yearly due to measles<sup>20</sup>.
- Even chickenpox, commonly considered a harmless infection, has been responsible for 11,000 hospitalizations and about 100 deaths annually in recent years<sup>21</sup>. Additionally, 300,000 people each year develop shingles, a painful inflammation of the

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<sup>15</sup> Offit, PA, Quarles, J, Gerber, MA, et al. Addressing parent's concerns: Do multiple vaccines overwhelm or weaken the infant's immune system? *Pediatrics*. 2002;109:124-129

<sup>16</sup> <http://www.cdc.gov/nip/vacsafe/concerns/gen/multiplevac.htm>

<sup>17</sup> World Health Organization, see <http://www.polioeradication.org/all/global/challenge.asp>

<sup>18</sup> Centers for Disease Control and Prevention, see <http://www.cdc.gov/nip/publications/fs/gen/WhatIfStop.htm>

<sup>19</sup> Centers for Disease Control and Prevention, see <http://www.cdc.gov/nip/publications/fs/gen/WhatIfStop.htm>

<sup>20</sup> Centers for Disease Control and Prevention, see <http://www.cdc.gov/nip/publications/fs/gen/WhatIfStop.htm>

<sup>21</sup> Centers for Disease Control and Prevention, see <http://www.cdc.gov/nip/publications/fs/gen/WhatIfStop.htm>

nerves that strikes individuals who have been exposed to the chickenpox virus earlier in life. (While shingles can occur in people who have received the chicken pox vaccine as well as those who contracted chicken pox naturally, preliminary data suggest that the rate of shingles is many times higher in naturally infected individuals than in vaccinated individuals<sup>22</sup>.)

**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?**

Absolutely not. If physicians are indeed conditioned by their training it is to seek the interests of their patients. Even 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—slanderous and dangerous at worst. In fact, a recent case shows that vaccines posing unacceptable risks are not tolerated and are removed from the market immediately.

In August 1998, a vaccine 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 rotavirus vaccine. That July, the CDC recommended the suspension of the vaccine, 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 rotavirus vaccine.

Discovery of the problems with the 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 continue to be recommended.

**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 provides 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 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 may also increase 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' web site ([www.aap.org](http://www.aap.org)) and the CDC's National Immunization Program's web site ([www.cdc.gov/nip](http://www.cdc.gov/nip)) give answers to many questions you might have about immunization.

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<sup>22</sup> Centers for Disease Control and Prevention. Prevention of varicella: updated recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 1999;48(RR06):1-5