



Parental concerns about vaccine safety have risen, posing significant challenges for today's pediatricians. Anti-vaccine Web sites, media attention to false claims about vaccine safety, and a decrease in once-common vaccine-preventable diseases has contributed to the number of parents who question vaccines. Pediatricians are faced with a new challenge of educating parents about the importance of vaccination, benefits and risks of vaccination, and vaccine safety. This resource will assist pediatricians in understanding why parents are hesitant to vaccinate, explain common concerns, and provide resources for addressing parental concerns. A complementary piece to address common concerns is available at:

http://www2.aap.org/immunization/families/faq/FAQ_Safety.pdf

Characteristics of Vaccine-Hesitant Parents

Concerns about vaccine safety are more common among parents of under-immunized children, but many parents of fully immunized children have also expressed concerns.¹ Vaccine-hesitant parents tend to believe they can control their child's susceptibility to disease, have doubts about the reliability of vaccine information, prefer negative outcomes due to inaction (not vaccinating) versus negative outcomes due to action (vaccinating), or rely on herd immunity to protect their child.² Studies show that some parents and physicians follow invalid contraindications, such as not vaccinating a child with a mild illness (e.g., low grade fever), leading to undervaccination. Other characteristics include parents with alternative medical beliefs, those with direct experience with adverse events to vaccines, college graduates, females, and whites.³

Why Some Parents Hesitate to Vaccinate

Vaccine hesitation is associated with perceived risk. Since vaccine-preventable diseases are rare, an adverse event from a vaccine is perceived by the parent to be of greater risk. Risk perception is critical. To illustrate, it is unlikely that anyone in the United States (US) will die of smallpox, but approximately 36,000 people will die of influenza. Yet, parents who question the influenza vaccine express interest in the smallpox vaccine because of risk perception.⁴

Additional characteristics that have been associated with parental hesitance include false beliefs about contraindications, not wanting to deliberately expose healthy children to diseases,⁵ exposure to negative media messages, beliefs that the disease is not harmful, and philosophical and religious beliefs.⁶



¹ Gust DA, Strine TW, Maurice E, et al. Underimmunization among children: effects of vaccine safety concerns on immunization status. *Pediatrics*. 2004; 114:e16-e22

² Meszaros JR, Asch DA, Baron J, Hershey JC, Kunreuther H, Schwartz-Buzaglo J. Cognitive processes and the decisions of some parents to forego pertussis vaccination for their children. *J Clin Epidemiol*. 1996; 49:697-703

³ Gellin BG, Maibach EW, Marcuse EK. Do parents understand immunizations? A national telephone survey. *Pediatrics* 2000; 106(5):1097-1102.

⁴ CDC. Key Facts About Influenza (Flu) & Flu Vaccine. Last updated 2010. <http://www.cdc.gov/flu/keyfacts.htm>.

⁵ Bedford H, Elliman D. Concerns about immunization. *BMJ*. 2000; 320:240-243

⁶ Fredrickson DD, Davis TC, Arnold CL, Kennen EM, Humiston SG, Cross JT, Bocchini JA. Childhood immunization refusal: provider and parent perceptions. *Clinical Research and Methods*. 2004; 36:431-439



Specific Concerns of Parents and Responses

Too Many Shots Too Soon

The CDC and the American Academy of Pediatrics (AAP) recommend vaccination against 16 diseases (including influenza). To be most effective some of these vaccines need to be given more than once. As a result, children may receive up to 29 vaccinations by the time they are 2 years old. A child may receive up to 6 shots during one visit to the doctor. Combination vaccines are a way to protect children from disease, but require fewer needle sticks.

Studies and years of experience show that vaccines used for routine childhood immunizations can be safely given together, at one visit. The vaccines work just as well, and this does not increase the risk of side effects. In addition, the scientific data show that receiving multiple vaccines has no harmful effect on a healthy child's immune system. In a study published in the June 2010 issue of *Pediatrics*, M.J. Smith, et al., conducted a retrospective cohort study of 1,047 children. The children were studied for neurological outcomes, when they were between 7-10 years of age. Researchers found no evidence that receipt of all vaccines on time, during infancy is associated with any undesirable neuropsychological outcomes compared to children who received vaccines on a delayed schedule. They recommend that communicating the information in this study may be helpful to vaccine-hesitant parents.

Resources

Smith, MJ, Woods, CR. On-time Vaccine Receipt in the First Year Does Not Adversely Affect Neuropsychological Outcomes. *Pediatrics*. 2010; 125, 4; 1134-1141-711. Available at: <http://pediatrics.aappublications.org/cgi/content/full/125/6/1134>.

Offitt, PA, et al. Addressing Parents' Concerns: Do Multiple Vaccines Overwhelm or Weaken the Infant's Immune System? *Pediatrics*. 2002; 109, 1: 124-129. Available at: <http://www.pediatrics.org/cgi/content/full/109/1/124>.

AAP. The Childhood Immunization Schedule: Why Is It Like That? Available at: <http://www2.aap.org/immunization/families/faq/Vaccineschedule.pdf>.

Use of Thimerosal as an Additive in Vaccines

Some parents have expressed concerns about a potential link between health problems, particularly autism, and vaccines containing thimerosal. Thimerosal is a preservative that contains a form of mercury (organomercurial). Beginning in the 1930s, thimerosal was used in very small amounts as a preservative in vaccines. Thimerosal is effective in preventing bacterial and fungal contamination, particularly in opened multi-dose vaccine containers. In 1999, the Public Health Service agencies and the AAP recommended that thimerosal be taken out of vaccines as a precautionary measure. By the end of 2001, all routine pediatric vaccines contained no thimerosal or only trace amounts, except for some influenza and Td vaccines. Rates of autism have not fallen since the removal of thimerosal in vaccines. There is no convincing evidence of harm caused by the small amounts of thimerosal in vaccines, except for minor effects like swelling and redness at the injection site due to sensitivity to thimerosal.



Prior to the recent initiative to reduce or eliminate thimerosal from childhood vaccines, the maximum cumulative exposure to mercury via routine childhood vaccinations during the first six months of life was 187.5 micrograms. With the newly formulated vaccines, the maximum cumulative exposure during the first six months of life is less than 3 micrograms of mercury; this represents a greater than 98 percent reduction in the amount of mercury a child would receive from vaccines in the first six months of life. [Influenza (flu) vaccine is not given until six months or older.]

Resources

Ofit PA, Jew RK. Addressing parents' concerns: do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics*. 2003; 112: 1394 – 1397. Available at: <http://pediatrics.aappublications.org/cgi/content/full/112/6/1394>.

AAP. What Parents Should Know About Thimerosal. Available at: <http://www2.aap.org/immunization/families/ingredients.html>.

CDC. Thimerosal. Available at: <http://www.cdc.gov/vaccinesafety/Concerns/thimerosal/>.

CDC. Infant and Environmental Exposures to Thimerosal and Neuropsychological Outcomes at Ages 7 to 10 years. Available at: http://www.cdc.gov/vaccinesafety/vsd/thimerosal_outcomes.

MMR Vaccine and Autism

Autism is a common developmental disability, affecting an estimated 1 in 150 children. Because the MMR vaccine is first given at age 12-15 months, and the first signs of autism (eg, poor social interaction and speech, repetitive behaviors) often appear at 15-18 months of age, concerns have been raised about a possible link between the vaccine and the development of autism.

Studies conducted in the US and Europe have found no association between the MMR vaccine and autism. Over the years, the Institute of Medicine and the AAP have organized several panels of independent scientists to study MMR and autism –all concluded no association between MMR and autism. Research on this topic continues in an effort to assure the safety of vaccines and based in part on this research. Recently the *Lancet*, a prominent British medical journal, retracted a 1998 article linking the MMR vaccines to autism.

Although the cause of autism is unknown in most instances, the theory favored by many experts is that it is a genetically based disorder that occurs before birth. Evidence that genetics is an important, but not exclusive, cause of autism includes a 3-8% risk of recurrence in families with one affected child. Research on the cause of autism is ongoing.



Resources

Halsey NA, Hyman SL, and the Conference Writing Panel. Measles-Mumps-Rubella Vaccine and Autism Spectrum Disorder: A Report from the New Challenges in Childhood Immunizations. Pediatrics. 2001; 107:84. Available at:

<http://pediatrics.aappublications.org/cgi/content/full/107/5/e84>.

Institute of Medicine. Immunization Safety Review. Available at:

<http://www.immunize.org/catg.d/p4026.pdf>.

AAP. MMR Vaccine and Autism: What Parents Need to Know. Available at:

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

Immunization Action Coalition (IAC). Does MMR Cause Autism? Examine the Evidence.

Available at: <http://www.immunize.org/catg.d/p4026.pdf>.

CDC. Vaccines and Autism Theory. Available at:

<http://www.cdc.gov/vaccinesafety>.

Importance of Hepatitis B Vaccine in Infancy

Some parents believe that the hepatitis B vaccine should not be given to infants and children since it is associated with high-risk behavior including intravenous drug use and sexual activity.

The hepatitis B vaccine is the best protection a child can have against a dangerous and lifelong disease. Before the vaccine was introduced, 20,000 children under the age of 10 became infected each year in the US. Vaccinating early against hepatitis B assures children's immunity when they are the most vulnerable to the worst complications of the disease and before they enter the high-risk adolescent years. Because of common scrapes, falls, and lack of personal hygiene, children (particularly in child care settings) are more exposed to bodily fluids than some adults. Infants who catch hepatitis B from their mothers at birth are at a greater risk of suffering a premature death from liver cancer or liver failure later in life. Even if the mother and the baby are both negative for hepatitis B at birth, it is important to get the vaccine. Since individuals that are infected with hepatitis B often do not feel sick or show symptoms of the disease, they can pass the virus on unknowingly. In two-thirds of the cases of childhood transmission of the virus, the mother was HBsAg (hepatitis B surface antigen) negative but the unvaccinated infant was exposed from a family member or caregiver.

Resources

AAP. Summary - AAP Preference for Birth Dose of Hepatitis B. Available at:

<http://www2.aap.org/immunization/illnesses/hepb/hepb.html>

IAC. Give the Birth Dose: Hepatitis B Vaccine at Birth Saves Lives. Available at:

<http://www.immunize.org/catg.d/p2125.pdf>.

CDC. Hepatitis B. Available at:

<http://www.cdc.gov/vaccines/vpd-vac/hepb/default.htm>.



Relative Danger of Influenza (need for yearly vaccination)

Some parents question the need for a yearly dose of the flu vaccine. They believe that influenza is a relatively mild disease (one that they have had and have survived) and that the risk of vaccination outweighs the risk of the disease. Parents also may have concerns about thimerosal in the flu vaccine (see above).

Influenza is a serious disease, and people of any age can get it. In an average year, the flu causes 36,000 deaths and 200,000 hospitalizations in the US. The “flu season” is usually from November-April each year. An annual flu vaccine (either the flu shot or the nasal-spray flu vaccine [in recommended age groups]) is the best way to reduce circulation of the flu. Annual shots are necessary because flu viruses change from year to year. This means that a person can get the flu more than once during their lifetime. The immunity that is built up from having the flu caused by one virus strain doesn’t always provide protection when a new strain is circulating. In other words, a vaccine made against flu viruses circulating last year may not protect against the newer viruses. Further, immunity to the disease declines over time and may be too low to provide protection after one year.

Resources

CDC. Questions & Answers: Thimerosal-Containing Influenza Vaccine. Available at:
<http://www.cdc.gov/flu/about/qa/thimerosal.htm>.

CDC. Influenza Web site. Available at:
<http://www.cdc.gov/flu>.

AAP Childhood Immunization Support Program. Influenza Guidance Web site. Available at:
<http://www2.aap.org/immunization/pediatricians/influenzguidance.html>

Relative Danger of Varicella Vaccine

Some parents question the need for the varicella vaccine. Like influenza, they believe that chickenpox is a harmless illness and that the risk of vaccination outweighs the risk of the disease.

In 1999, an average of 1 child per week died in the US from complications of chickenpox. These complications include encephalitis, a brain infection; severe staph and strep secondary infections (flesh-eating strep and toxic shock syndrome); hepatitis; and pneumonia.

Before the vaccine, there were 4 million cases of chickenpox, 11,000 hospitalizations, and 100 deaths per year in the US. The varicella vaccine prevents chickenpox in about 70-90% of people who get the shot and prevents severe chickenpox in over 95%.



Resources

CDC. Varicella Vaccine Web site. Available at:
<http://www.cdc.gov/vaccines/vpd-vac/varicella/default.htm>.

AAP Committee on Infectious Diseases. Prevention of Varicella: Recommendations for Use of Varicella Vaccines in Children, Including a Recommendation for a Routine 2-Dose Varicella Immunization Schedule. *Pediatrics*. 2007; 120: 221-231. Available at:
<http://pediatrics.aappublications.org/cgi/content/full/120/1/221>.

Strategies for Communicating with Vaccine-Hesitant Parents

As the occurrence of vaccine-preventable diseases declines, the challenge of communicating the risk of not being immunized increases.⁷ Every situation is unique; parents have diverse concerns for various reasons. Including:

- To determine parental concerns, ask the following questions:⁸
 - Do you have any cultural, religious, or personal belief regarding immunization?
 - Has your child or any child you know has a serious adverse event after an immunization?
 - Do you have any vaccine safety concerns?
 - What vaccine safety information can I provide?
- Be sure to listen to parents' concerns and acknowledge them in a nonconfrontational manner. Allowing parents to express their concerns will increase their willingness to listen to the pediatrician's views.⁹
- Promote partnerships with parents in decision-making and personalize these relationships. Provide the important information first. Make sure the parent understands the information. Clarify and reaffirm parents' correct beliefs about immunization and modify misconceptions.
- Discuss the benefits of vaccines and the possibility of adverse events. Be open about what is known about immunizations and what is not known. Provide parents with Vaccine Information Statements, educational resources, and reliable Web sites. Personalize the information provided to parents based on cultural beliefs, vaccine concerns, and literacy level.
- Stress the number of lives saved by immunization, as a positive approach, rather than focusing on the number of deaths from not immunizing.
- Discuss state laws for school entry and the rationale for them. Some parents disagree with mandatory immunization and resist immunization because they believe their rights as parents are being taken away. Explain that vaccines benefit individual children and communities through herd immunity.
- Provider attitudes and beliefs about vaccine safety have been linked to vaccination coverage in preschool children.¹⁰ The majority of parents believe immunization is important and trust pediatricians as the most important source of immunization information.

If, after discussion about the benefits of vaccination and the risks of not vaccinating, the parent refuses, you should document the discussion and have the parent sign a waiver affirming the decision not to vaccinate. If the situation becomes such that you are no longer comfortable treating the parent/patient, the AAP manual, "Medical Liability for Pediatricians," offers resources for termination of the physician-patient relationship.

⁷ Bostrom A. Vaccine risk communication: lessons from risk perception, decision making and environmental risk communication research. *Risk: Health Safety Environ*. 1997; spring: 173-200

⁸ Red Book 2003: Report of the Committee on Infectious Diseases. American Academy of Pediatrics, 6-7

⁹ Kimmel SR, Wolfe RM. Communicating the benefits and risks of vaccines. *The Journal of Family Practice*. 2005; 54:S51-S57

¹⁰ Zhang J, Yu KF. What's the relative risk? A method of correcting the odds ratio in cohort studies of common outcomes. *JAMA*. 1998; 280:1690-1691



Additional Resources

AAP Refusal to Vaccinate Form. Available at:

<http://www2.aap.org/immunization/pediatricians/pdf/RefusaltoVaccinate.pdf>

AAP Policy Statement: *Responding to Parental Refusals of Immunization of Children* Available at: <http://pediatrics.aappublications.org/content/115/5/1428.abstract?sid=9024f777-2348-4779-8b64-66666d57ba1a>.

CDC. Provider Resources for Vaccine Conversations with Parents. Available at:

<http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/index.html>

Immunization Action Coalition. Responding to Concerns About Vaccines. Available at:

<http://www.immunize.org/concerns>.

CDC. Six Common Misconceptions About Vaccinations and How to Respond to Them.

Available at: <http://www.cdc.gov/vaccines/vac-gen/6mishome.htm>.

IAC. Reliable Sources of Immunization Information. Available at:

www.immunize.org/catg.d/p4012.pdf.

National Network for Immunization Information. Evaluating Information on the Web. Available at: www.immunizationinfo.org/parents/evaluatingWeb.cfm.