

Refusal to Vaccinate

Child's Name _____ Child's ID# _____

Parent's/Guardian's Name _____

My child's doctor/nurse, _____, has advised me that my child (named above) should receive the following vaccines:

Recommended	Declined
<input type="checkbox"/> Hepatitis B vaccine	<input type="checkbox"/>
<input type="checkbox"/> Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Diphtheria tetanus (DT or Td) vaccine	<input type="checkbox"/>
<input type="checkbox"/> <i>Haemophilus influenzae</i> type b (Hib) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Pneumococcal conjugate or polysaccharide vaccine	<input type="checkbox"/>
<input type="checkbox"/> Inactivated poliovirus (IPV) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Measles-mumps-rubella (MMR) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Varicella (chickenpox) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Influenza (flu) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Meningococcal conjugate or polysaccharide vaccine	<input type="checkbox"/>
<input type="checkbox"/> Hepatitis A vaccine	<input type="checkbox"/>
<input type="checkbox"/> Rotavirus vaccine	<input type="checkbox"/>
<input type="checkbox"/> Human papillomavirus vaccine	<input type="checkbox"/>
<input type="checkbox"/> Other _____	<input type="checkbox"/>

I have been provided with and given the opportunity to read each Vaccine Information Statement from the Centers for Disease Control and Prevention explaining the vaccine(s) and the disease(s) it prevents for each of the vaccine(s) checked as recommended and which I have declined, as indicated above. I have had the opportunity to discuss the recommendation and my refusal with my child's doctor or nurse, who has answered all of my questions about the recommended vaccine(s). A list of reasons for vaccinating, possible health consequences of non-vaccination, and possible side effects of each vaccine is available at www.cdc.gov/vaccines/pubs/vis/default.htm. I understand the following:

- The purpose of and the need for the recommended vaccine(s).
- The risks and benefits of the recommended vaccine(s).

- That some vaccine-preventable diseases are common in other countries and that my unvaccinated child could easily get one of these diseases while traveling or from a traveler.
- If my child does not receive the vaccine(s) according to the medically accepted schedule, the consequences may include
 - Contracting the illness the vaccine is designed to prevent (the outcomes of these illnesses may include one or more of the following: certain types of cancer, pneumonia, illness requiring hospitalization, death, brain damage, paralysis, meningitis, seizures, and deafness; other severe and permanent effects from these vaccine-preventable diseases are possible as well).
 - Transmitting the disease to others (including those too young to be vaccinated or those with immune problems), possibly requiring my child to stay out of child care or school and requiring someone to miss work to stay home with my child during disease outbreaks.
- My child's doctor and the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers for Disease Control and Prevention all strongly recommend that the vaccine(s) be given according to recommendations.

Nevertheless, I have decided at this time to decline or defer the vaccine(s) recommended for my child, as indicated above, by checking the appropriate box under the column titled "Declined." I know that failure to follow the recommendations about vaccination may endanger the health or life of my child **and others with whom my child might come into contact. I therefore agree to tell all health care professionals in all settings what vaccines my child has not received because he or she may need to be isolated or may require immediate medical evaluation and tests that might not be necessary if my child had been vaccinated.**

I know that I may readdress this issue with my child's doctor or nurse at any time and that I may change my mind and accept vaccination for my child any time in the future.

I acknowledge that I have read this document in its entirety and fully understand it.

Parent/Guardian Signature: _____ Date: _____

Witness: _____ Date: _____

I have had the opportunity to rediscuss my decision not to vaccinate my child and still decline the recommended immunizations.

Parent's Initials: _____ Date: _____ Parent's Initials: _____ Date: _____



Parental Refusal to Accept Vaccination: Resources for Pediatricians

The following are some of the resources available to help pediatricians develop a productive dialogue with vaccine-hesitant parents and answer questions about vaccine risks and benefits:

Web Sites

1. AAP Childhood Immunization Support Program (CISP)

Information for providers and parents.

www.aap.org/immunization and

www2.aap.org/immunization/pediatricians/refusaltovaccinate.html

2. Immunization Action Coalition (IAC)

The IAC works to increase immunization rates by creating and distributing educational materials for health professionals and the public that enhance the delivery of safe and effective immunization services. The IAC “Unprotected People Reports” are case reports, personal testimonies, and newspaper and journal articles about people who have suffered or died from vaccine-preventable diseases.

www.immunize.org/reports

3. Centers for Disease Control and Prevention (CDC) National Immunization Program

Information about vaccine safety.

www.cdc.gov/vaccines/hcp.htm

4. National Network for Immunization Information (NNii)

Includes information to help answer patients’ questions and provide the facts about immunizations.

<http://www.immunizationinfo.org/professionals>

5. Vaccine Education Center at Children’s Hospital of Philadelphia

Information for parents includes “Vaccine Safety FAQs” and “A Look at Each Vaccine.”

www.vaccine.chop.edu

6. Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health

Provides an independent assessment of vaccines and vaccine safety to help guide decision-makers and educate physicians, the public, and the media about key issues surrounding the safety of vaccines.

www.vaccinesafety.edu

7. Immunize Canada

Immunize Canada aims to meet the goal of eliminating vaccine-preventable disease through education, promotion, advocacy, and media relations. It includes resources for parents and providers.

www.immunize.cpha.ca/en/default.aspx

8. Sample office policy/letter to parents about refusal to vaccinate

Journal Articles

1. Offit PA, Jew RK. Addressing parents’ concerns: do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics*. 2003;112(6 Pt 1):1394–1397

2. 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(1):124–129

3. Diekema DS, American Academy of Pediatrics Committee on Bioethics. Responding to parental refusals of immunization of children. *Pediatrics*. 2005;115(5):1428–1431

Books

1. American Academy of Pediatrics. *Red Book: 2012 Report of the Committee on Infectious Diseases*. Pickering LK, Baker CJ, Long SS, Kimberlin DW, eds. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2012

2. Marshall GS. *The Vaccine Handbook: A Practical Guide for Clinicians*. 4th ed. West Islip, NY: Professional Communications, Inc; 2012

Handout

1. Immunization Action Coalition. Reliable sources of immunization information: where to go to find answers! <http://www.immunize.org/catg.d/p4012.pdf>. Accessed October 17, 2012

Reliable Immunization Resources for Parents

Web Sites

1. Centers for Disease Control and Prevention (CDC) Vaccine

Information Statements

Provide possible health consequences of non-vaccination and possible side effects of each vaccine.

www.cdc.gov/vaccines/pubs/vis/default.htm

2. AAP Childhood Immunization Support Program (CISP)

Information for providers and parents.

www.aap.org/immunization

3. Why Immunize?

A description of the individual diseases and the benefits expected from vaccination.

www2.aap.org/immunization/families/faq/whyimmunize.pdf

4. Pennsylvania Immunization Education Program of Pennsylvania Chapter, AAP

Includes answers to common vaccine questions and topics, such as addressing vaccine safety concerns; evaluating anti-vaccine claims; sources of accurate immunization information on the Web; and talking with parents about vaccine safety.

www.paiep.org

5. CDC For Parents: Vaccines for Your Children

Information about vaccine safety.

www.cdc.gov/vaccines/parents/index.html

6. National Network for Immunization Information (NNii)

Includes information to help answer patients’ questions and provide the facts about immunizations.

www.immunizationinfo.org/parents

7. Vaccine Education Center at Children’s Hospital of Philadelphia

Information for parents includes “Vaccine Safety FAQs” and “A Look at Each Vaccine.”

www.vaccine.chop.edu

8. Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health

Provides an independent assessment of vaccines and vaccine safety to help guide decision-makers and educate physicians, the public, and the media about key issues surrounding the safety of vaccines.

www.vaccinesafety.edu

9. Immunize Canada

Immunize Canada aims to meet the goal of eliminating vaccine-preventable disease through education, promotion, advocacy, and media relations. It includes resources for parents and providers.

<http://immunize.cpha.ca/en/default.aspx>

10. Vaccinate Your Baby

This Every Child By Two site serves as a central resource of vaccine information for parents. The site links to the latest research and studies about vaccines, an interactive timeline on the benefits of vaccines, information about vaccine safety and ingredients, and the importance of adhering to the recommended schedule.

www.vaccinateyourbaby.org

Books

1. American Academy of Pediatrics. *Immunizations and Infectious Diseases: An Informed Parent’s Guide*. Fisher MC, ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006

2. Myers MG, Pineda D. *Do Vaccines Cause That?! A Guide for Evaluating Vaccine Safety Concerns*. Galveston, TX: Immunizations for Public Health; 2008

3. Offit PA. *Autism’s False Prophets: Bad Science, Risky Medicine, and the Search for a Cure*. New York, NY: Columbia University Press; 2008

4. Offit PA. *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All*. New York, NY: Basic Books; 2011

5. Mnookin S. *The Panic Virus: A True Story of Medicine, Science, and Fear*. New York, NY: Simon and Schuster; 2011

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

Alternative Vaccine Schedules:

Helping Parents Separate Fact From Fear



A Guide for Physicians

Parents want to keep their children safe and healthy. Help empower parents to make an informed decision about vaccinating their kids. Questions about the recommended immunization schedule create an opportunity for you to listen and respond to requests for “alternative schedules,” including the Dr. Bob Sears’ schedule. We offer these tips to assist practitioners to respond effectively and compassionately and to build trusting relationships with patients and parents.

► **CONCERN: CDC schedules seem generic; alternative schedules cater to individual needs**

The immunization schedule exists to protect children at the age they are most vulnerable to each disease. Children are vaccinated as soon as they are developmentally able to create an effective immune response.

Explain: Alternative schedules are not custom-made. That’s actually what doctors do. Doctors consider a patient’s medical history and give the best advice for each child. Shots are especially important to many medically-vulnerable kids (whose parents may be concerned about vaccines).

Ask: *Do you have specific concerns about your child’s health? Let’s talk about it.*

► **CONCERN: “Too many” vaccines, “too soon” could be harmful**

Are there more vaccines now than 20 years ago? Yes—and that’s a good thing. Newer vaccines save children from terrible diseases like Meningococcal disease. This devastating infection can cause organ failure, limb amputations, and brain damage. Postponing shots increases the time a child is defenseless. Recent outbreaks of measles and Hib tell us that postponing shots puts healthy kids at risk for diseases none of us thought would come back.

Explain: A baby’s immune system can handle multiple shots with weakened or killed virus much better than it can fight off a serious disease. Postponing shots means your child could get sick and risk serious complications. It’s obvious you want to protect your child, but alternative schedules take advantage of parents’ worries; they’re not based on science.

Ask: *Which vaccines are causing you worry?*

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► **CONCERN: Doctors give more shots than needed because they make a profit or are influenced by drug companies**

Most doctors do *not* profit from administering vaccines, and drug companies do not set the recommended schedule. CDC's and AAP's recommendations come from medical and science experts in an open, transparent public process.

Explain: We believe in vaccines because we consider it a tragedy when any child gets sick from a preventable disease. We vaccinate our own kids.

Ask: *Can you tell me more about your concerns? Does it help to know that we do not get any money from drug companies to give vaccines?*

► **CONCERN: Alternative schedules reduce exposure to vaccine ingredients.**

Groups that raise fears about vaccine ingredients do not have scientific evidence to support their claims. Spreading out shots means more trips to the doctor without any real benefit to the child.

Explain: While some vaccine ingredients sound scary, safety studies show that vaccine ingredients are safe. In fact, every vaccine ingredient is used for a reason—often to make sure the vaccine is free of contamination and creates the immune response it's supposed to create.

Aluminum gets attention now as a vaccine ingredient some groups say could be harmful. The truth is, aluminum is a naturally occurring element

found in many foods including fruits and vegetables. It helps trigger the body's immune response, and some vaccines need it to work. The tiny amounts used in vaccines are very safe.

Ask: *Did you know aluminum is found at higher levels in breast milk and infant formula than in vaccines?*

Thimerosal was removed as a preservative from all children's vaccines by 2002 (except multi-dose vials of influenza vaccine). California law also now does not permit children under 3 to get thimerosal-containing vaccines. Even so, autism rates have remained the same. Scientific research continues to show no link between thimerosal and autism.

Ask: *Did you know autism experts support vaccines? Over 20 scientific studies have failed to show a connection between thimerosal in vaccines and autism. Can you tell me about your concerns?*

► **CONCERN: Waiting on some vaccines is fine since the diseases are so rare in the U.S.**

U.S. Disease rates are low because immunization rates are high overall. But there are California schools where 30% or more of kids are missing recommended shots. This means your children may be surrounded by others who are susceptible to diseases and could get them sick. A 2009 study showed that a child without DTaP shots is 23 times more likely to get whooping cough.

Explain: Measles reached epidemic levels in England, Switzerland, and Japan because fewer children have received MMR shots. Children have even died. Today, diseases are just a plane ride away from any California city. Recently, we had outbreaks of measles in San Diego and whooping cough in Contra Costa. These caused children to get sick, schools to close, and parents to take weeks off work to keep quarantined children at home.

Ask: *Does your family ever travel abroad? Have you thought about how many foreign tourists visit California?*



Alternative Vaccine Schedules:

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► **CONCERN: Waiting on some vaccines is fine because the diseases aren't a big deal.**

Infectious diseases are a big deal. Hib and meningococcal disease can kill. Even chickenpox lands some children in the hospital. Whooping cough and measles can be fatal to babies. Even if a child's illness is not severe, it still means extra doctor visits and days off work or school. Any child exposed to a contagious person may need to stay at home for weeks if not immunized.

Ask: *If skipping recommended shots, do you have a plan for how to keep your child at home for several weeks? Could you afford to take the time off work?*

► **CONCERN: It's nobody else's business if you skip some vaccines for your child**

It's true that this is a choice a parent must make. But that choice carries a responsibility. If your child gets sick, others in your family or household are also likely to get sick. If someone who's at high risk—like a pregnant woman or a relative with asthma—catches the disease from your child, s/he could get gravely ill.

Explain: We have learned to be careful about the dangers of second-hand smoke. Contagious diseases are similar. Without vaccinations, we're exposing others to dangerous diseases.

Ask: *What would you think if someone smoked right next to your child? Do you think there might be high-risk people who live near you who need to be protected from preventable diseases?*

► **CONCERN: Parents who read about alternative schedules on the Internet and books know as much as any doctor.**

Groups or individuals with websites can misinterpret data or make claims based on flawed studies. Respected medical associations continuously educate providers with peer-reviewed, science-based vaccine information allowing the provider to make the best medical decisions for individual patients.

Ask: *How do you ensure the information you read is reliable? What makes you trust one point of view over another?*



Alternative Vaccine Schedules:

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Make your research work for you

Be choosy about what you read and the information you rely on.

We recommend these trusted sites:

American Academy of Pediatrics

www.aap.org/immunization

National Network for Immunization

www.immunizationinfo.org

Thimerosal FAQs

www.fda.gov/CBER/vaccine/thimerosal.htm

Do Vaccines Cause That? (Book)

www.i4ph.org

Evaluating Health Information on the Web

www.immunizationinfo.org/parents/evaluatingWeb.cfm

Parents of Kids with Infectious Diseases

www.pkids.org

Every Child By Two

www.ecbt.org

Vaccine Education Center

(Children's Hospital of Philadelphia)

www.chop.edu/service/vaccine-education-center/home.html

Johns Hopkins Institute for Vaccine Safety

www.vaccinesafety.edu

Centers for Disease Control

www.cdc.gov/vaccinesafety/concerns

I Choose campaign

www.whyichoose.org

The California Immunization Coalition (CIC) is a non-profit, public-private partnership dedicated to achieving and maintaining full immunization protection to promote health and prevent serious illness across the life span.

California Immunization Coalition

909 12th Street, Suite 200

Sacramento, CA 95814

(916) 447-7063 ext. 333

www.immunizeCA.org

Need Help Responding to Vaccine-Hesitant Parents?

Science-based materials are available from these respected organizations

American Academy of Pediatrics (AAP)

Healthcare providers can find numerous resources on the AAP's website to help with parents and caregivers who have questions about vaccinating their child at www.healthychildren.org/english/safety-prevention/immunizations/pages/default.aspx. When parents cannot be convinced, consider using AAP's Refusal to Vaccinate form at www.aap.org/en-us/documents/immunization_refusaltovaccinate.pdf.

California Department of Public Health

The Immunization Branch of the California Department of Public Health has developed several excellent provider pieces that discuss common questions parents may have regarding vaccines for their children. These include

- "Vaccine Safety: Answers to Parents' Top Questions" – www.eziz.org/assets/docs/IMM-916.pdf
- "Community Immunity" – www.eziz.org/assets/docs/IMM-1056.pdf

Centers for Disease Control and Prevention (CDC)

Among CDC's many online immunization resources is the "Parent's Guide to Childhood Immunization," a 64-page booklet that can be ordered or printed at www.cdc.gov/vaccines/pubs/parents-guide. In addition, visit CDC's "Talking to Parents about Vaccines" web section at www.cdc.gov/vaccines/hcp/conversations/conv-materials.html.

Other CDC materials, designed to help healthcare providers work with hesitant parents, include the following:

- "If You Choose Not to Vaccinate Your Child, Understand the Risks and Responsibilities" – www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/not-vacc-risks-color-office.pdf
- "Infant Immunizations FAQs" – www.cdc.gov/vaccines/parents/parent-questions.html

Immunization Action Coalition (IAC)

IAC's Talking about Vaccines web section provides healthcare professionals with top vaccination resources from trusted sources such as CDC, AAP, IAC, VEC, and many more. Visit www.immunize.org/talking-about-vaccines. Refer parents to IAC's website for the public at www.vaccineinformation.org.

IAC has developed several patient handouts for vaccine-hesitant parents. These include:

- "Clear Answers and Smart Advice About Your Baby's Shots," an excerpt from the popular book "Baby 411" by Dr. Ari Brown – www.immunize.org/catg.d/p2068.pdf
- "Decision to Not Vaccinate My Child" – www.immunize.org/catg.d/p4059.pdf
- "Reliable Sources of Immunization Information: Where Parents Can Go to Find Answers!" – www.immunize.org/catg.d/p4012.pdf
- "Vaccines Work!" – www.immunize.org/catg.d/p4037.pdf

Institute for Vaccine Safety, Johns Hopkins University

The Institute for Vaccine Safety collects vaccine-specific safety information. Of particular interest is its "Components of Vaccines" section, which contains tables specifying the contents of various vaccines: www.vaccinesafety.edu/components.htm.

Vaccinate Your Family (formerly Every Child By Two)

Created by Vaccine Your Family, www.vaccinateyourfamily.org/questions-about-vaccines focuses on answering parents' commonly asked questions about vaccines. It features video clips and links to current vaccine news stories.

Vaccine Education Center (VEC) Children's Hospital of Philadelphia

VEC offers handouts in English and Spanish as well as four colorful booklets covering immunization of infants, teens, and adults, as well as one about vaccine safety. These educational materials can be downloaded at www.chop.edu/centers-programs/vaccine-education-center/resources. VEC has developed a number of patient handouts covering vaccine topics of interest. These include the following:

- "Vaccine Safety: Are Vaccines Safe?" – www.chop.edu/centers-programs/vaccine-education-center/vaccine-safety/are-vaccines-safe
- "Vaccine Safety: Dosing Safety" – www.chop.edu/centers-programs/vaccine-education-center/vaccine-safety/dosing-safety
- "Vaccine Safety: Immune System and Health" – www.chop.edu/centers-programs/vaccine-education-center/vaccine-safety/immune-system-and-health
- "Vaccine Ingredients" – www.chop.edu/centers-programs/vaccine-education-center/vaccine-ingredients

For parents with concerns about vaccines and autism

AAP has issued a statement that can be printed at www.healthychildren.org/English/health-issues/conditions/Autism/Pages/Where-We-Stand-Autism.aspx. Parents may wish to investigate further at www.healthychildren.org/English/health-issues/conditions/Autism/Pages/default.aspx. IAC also recommends these books:

- *Autism's False Prophets: Bad Science, Risky Medicine, and the Search for a Cure*, by Paul A. Offit, MD
- *Unstrange Minds: Remapping the World of Autism*, by Roy Richard Grinker, PhD

And, here are two more well-researched handouts for parents, one from IAC and another from VEC:

- "MMR Vaccine Does Not Cause Autism: Examine the Evidence!" – www.immunize.org/catg.d/p4026.pdf
- "Vaccines and Autism: What you should know" – <https://media.chop.edu/data/files/pdfs/vaccine-education-center-autism.pdf>

Frequently Asked Questions: Evaluating Internet Information

With so many internet sites on childhood immunization or vaccines, how do I know which one is reliable?

The Internet has made vast amounts of immunization resources available to the parents. Unfortunately, it is sometimes difficult to determine whether the information being presented is credible or not. In order to make an informed decision on the accuracy of immunization information obtained from the Internet, ask yourself the following questions:

Who is providing this information?

The source of the information (i.e., organization or individual) should be made clear, and more information about the source should be available. Be cautious of information attributed to unnamed sources.

Is the information based on sound medical research?

Scientific studies published in medical journals are reviewed by qualified professionals and are therefore credible sources. Information should contain references from and to peer-reviewed publications.

Is the information up to date?

Reliable sites show when they were last updated. Make sure the pages have been updated recently, and that the research cited is new.

Does the information make sense?

If you find information that is too good (or bad) to be true, it probably is.

A lot of people get the flu each season, it's not that serious, right?

You should be able to follow up on the information through posted contact information. Additional reading lists should contain information from sources not directly linked to the site's owner.

Don't assume that flawed information will be easy to detect. Always evaluate the credibility of material taken from the Internet. Remember, your child's pediatrician is your best resource for immunization information – ask him/her to answer any questions you might have about information gathered from the Internet.

Where can I find reliable web sites and books on this topic?

[Immunizations and Infectious Diseases: An Informed Parent's Guide](#) by Margaret Fisher, MD. This evidence-based guide for parents explains what infections are, how they progress, and how to prevent them.

[Vaccinating Your Child: Questions and Answers for the Concerned Parent](#) by S.G. Humiston, MD, MPH, and Cynthia Good. This book addresses the medical, ethical, and legal issues related to immunization to help parents make informed decisions about individual vaccines.

[Vaccines and Your Child](#). Paul Offit, MD, and Charlotte Moser (2011). A book for parents who want to know detailed information about the science and safety of modern vaccines.

[Do Vaccines Cause That?](#) By M. Myers, MD, and Diego Pineda. This guide will help you sort through all the misinformation that makes it hard to decide what's best for your child's health.

[Parents Guide to Childhood Immunization](#). A 94-page booklet from the Centers for Disease Control and Prevention that introduces parents to 12 childhood diseases and the vaccines that can protect children from them.

[Vaccinations: What Parents Need to Know](#) by the American Council of Science and Health (ACSH). This report summarizes the evidence on both the benefits and the potential risks of vaccines, with an emphasis on the vaccines used in routine childhood immunization.

Health Professional Associations

Academic Pediatric Association

www.ambpeds.org

American Academy of Family Physicians

www.familydoctor.org

American Academy of Pediatrics

<http://www.aap.org/immunization/>

American College Health Association

www.acha.org

American Medical Association

www.ama-assn.org

American Nurses Association

www.nursingworld.org

Association of Teachers of Preventive Medicine

www.atpm.org

Infectious Diseases Society of America

www.idsociety.org

National Association of School Nurses

www.nasn.org

National Medical Association

www.nmanet.org

Non-Profit Groups and Universities

Albert B. Sabin Vaccine Institute

www.sabin.org

All Kids Count

www.allkidscount.org

Allied Vaccine Group

www.vaccine.org

Program for Appropriate Technology (PATH) Children's Vaccine Program

<http://www.path.org/vaccineresources/>

Every Child By Two

www.vaccinateyourbaby.org

Global Alliance for Vaccines and Immunization

www.vaccinealliance.org

Immunization Action Coalition

www.immunize.org

Institute for Vaccine Safety Johns Hopkins University

www.vaccinesafety.edu

Institute of Medicine

www.iom.edu

National Alliance for Hispanic Health

www.hispanichealth.org

National Foundation for Infectious Diseases

www.nfid.org

National Network for Immunization Information

www.immunizationinfo.org

Vaccine Education Center at CHOP

www.vaccine.chop.edu

Government Organizations

Association of State and Territorial Health Officials

www.astho.org

Centers for Disease Control and Prevention (CDC)

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

Food and Drug Administration

www.fda.gov

National Association of City and County Health Officials

www.naccho.org

National Institute of Allergy and Infectious Diseases

www.niaid.nih.gov

National Vaccine Injury Compensation Program

<http://www.hrsa.gov/vaccinecompensation/>

National Vaccine Program Office

www.hhs.gov/nvpo/

Pan American Health Organization

www.paho.org

Vaccine Adverse Event Reporting System

<http://vaers.hhs.gov/index>

World Health Organization

www.who.int



If You Choose Not to Vaccinate Your Child, Understand the Risks and Responsibilities.

Last updated October 2009

If you choose to delay some vaccines or reject some vaccines entirely, there can be risks. Please follow these steps to protect your child, your family, and others.

With the decision to delay or reject vaccines comes an important responsibility that could save your child's life, or the life of someone else.

Any time that your child is ill and you:

- call 911;
- ride in an ambulance;
- visit a hospital emergency room; or
- visit your child's doctor or any clinic

you must tell the medical staff that your child has not received all the vaccines recommended for his or her age.

Keep a vaccination record easily accessible so that you can report exactly which vaccines your child has received, even when you are under stress.

Telling healthcare professionals your child's vaccination status is essential for two reasons:

- When your child is being evaluated, the doctor will need to consider the possibility that your child has a vaccine-preventable disease. Many of these diseases are now uncommon, but they still occur, and the doctor will need to consider that your child may have a vaccine-preventable disease.
- The people who help your child can take precautions, such as isolating your child, so that the disease does not spread to others. One group at high risk for contracting disease is infants who are too young to be fully vaccinated. For example, the measles vaccine is not usually recommended for babies younger than 12 months. Very young babies who get measles are likely to be seriously ill, often requiring hospitalization. Other people at high risk for contracting disease are those with weaker immune systems, such as some people with cancer and transplant recipients.

Before an outbreak of a vaccine-preventable disease occurs in your community:

- Talk to your child's doctor or nurse to be sure your child's medical record is up to date regarding vaccination status. Ask for a copy of the updated record.
- Inform your child's school, childcare facility, and other caregivers about your child's vaccination status.
- Be aware that your child can catch diseases from people who don't have any symptoms. For example, Hib meningitis can be spread from people who have the bacteria in their body but are not ill. You can't tell who is contagious.



When there is vaccine-preventable disease in your community:

- It may not be too late to get protection by getting vaccinated. Ask your child's doctor.
- If there are cases (or, in some circumstances, a single case) of a vaccine-preventable disease in your community, you may be asked to take your child out of school, childcare, or organized activities (for example, playgroups or sports).
- Your school, childcare facility, or other institution will tell you when it is safe for an unvaccinated child to return. Be prepared to keep your child home for several days up to several weeks.
- Learn about the disease and how it is spread. It may not be possible to avoid exposure. For example, measles is so contagious that hours after an infected person has left the room, an unvaccinated person can get measles just by entering that room.
- Each disease is different, and the time between when your child might have been exposed to a disease and when he or she may get sick will vary. Talk with your child's doctor or the health department to get their guidelines for determining when your child is no longer at risk of coming down with the disease.

Be aware.

- 🔊 Any vaccine-preventable disease can strike at any time in the U.S. because all of these diseases still circulate either in the U.S. or elsewhere in the world.
- 🔊 Sometimes vaccine-preventable diseases cause outbreaks, that is, clusters of cases in a given area.
- 🔊 Some of the vaccine-preventable diseases that still circulate in the U.S. include whooping cough, chickenpox, Hib (a cause of meningitis), and influenza. These diseases, as well as the other vaccine-preventable diseases, can range from mild to severe and life-threatening. In most cases, there is no way to know beforehand if a child will get a mild or serious case.
- 🔊 For some diseases, one case is enough to cause concern in a community. An example is measles, which is one of the most contagious diseases known. This disease spreads quickly among people who are not immune.

If you know your child is exposed to a vaccine-preventable disease for which he or she has not been vaccinated:

- Learn the early signs and symptoms of the disease.
- Seek immediate medical help if your child or any family members develop early signs or symptoms of the disease.

IMPORTANT: Notify the doctor's office, urgent care facility, ambulance personnel, or emergency room staff that your child has not been fully vaccinated before medical staff have contact with your child or your family members. They need to know that your child may have a vaccine-preventable disease so that they can treat your child correctly as quickly as possible. Medical staff also can take simple precautions to prevent diseases from spreading to others if they know ahead of time that their patient may have a contagious disease.

- Follow recommendations to isolate your child from others, including family members, and especially infants and people with weakened immune systems. Most vaccine-preventable diseases can be very dangerous to infants who are too young to be fully vaccinated, or children who are not vaccinated due to certain medical conditions.
- Be aware that for some vaccine-preventable diseases, there are medicines to treat infected people and medicines to keep people they come in contact with from getting the disease.
- Ask your healthcare provider about other ways to protect your family members and anyone else who may come into contact with your child.
- Your family may be contacted by the state or local health department who track infectious disease outbreaks in the community.

If you travel with your child:

- Review the CDC travelers' information website (www.cdc.gov/travel) before traveling to learn about possible disease risks and vaccines that will protect your family. Diseases that vaccines prevent remain common throughout the world, including Europe.
- Don't spread disease to others. If an unimmunized person develops a vaccine-preventable disease while traveling, to prevent transmission to others, he or she should not travel by a plane, train, or bus until a doctor determines the person is no longer contagious.

Talking with Parents about Vaccines for Infants

Strategies for Health Care Professionals

Immunization professionals and parents agree: times have changed.

Because of questions or concerns about vaccines, well-child visits can be stressful for parents. As their infant's health care provider, you remain parents' most trusted source of information about vaccines. This is true even for parents with the most questions and concerns. Your personal relationship uniquely qualifies you to help support parents in understanding and choosing vaccinations.

However, time for infant health evaluation at each well visit is at a premium, as you check physical, cognitive, and other milestones and advise parents on what to expect in the coming months. Therefore, making time to talk about vaccines may be stressful for *you*. But when an infant is due to receive vaccines, nothing is more important than making the time to assess the parents' information needs as well as the role they desire to play in making decisions for their child's health, and then following up with communication that meets their needs.

When it comes to communication, you may find that similar information—be it science or anecdote or some mix of the two—works for most parents you see. But keep a watchful eye to be sure that you are connecting with each parent to maintain trust and keep lines of communication open.

We hope that these brief reminders—and the materials that you, your staff, and parents can find on our website— will help ensure your continued success in immunizing infants and children. Success may mean that all vaccines are accepted when you recommend them, or that some vaccines are scheduled for another day. If a parent refuses to vaccinate, success may simply mean keeping the door open for future discussions about choosing vaccination.



THIS RESOURCE COVERS:

- What you may hear from parents about their vaccine safety questions and how to effectively address them
- Proven communication strategies and tips for having a successful vaccine conversation with parents
- This brochure is part of a comprehensive set of educational materials for health care professionals and parents available at <http://www.cdc.gov/vaccines/conversations>

Nurses, physician assistants, and other office staff play a key role in establishing and maintaining a practice-wide commitment to communicating effectively about vaccines and maintaining high vaccination rates: from providing parents with educational materials, to being available to answer their questions, to making sure that families who may opt for extra visits for vaccines make and keep vaccine appointments.



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What You May Hear From Parents

As you plan for responding to parents' concerns, it may be useful to think of parental questions in the following categories.

Questions about whether vaccines cause autism

Parents may encounter poorly designed and conducted studies, misleading summaries of well-conducted studies, or anecdotes made to look like science—claiming that vaccines cause autism. Many rigorous studies show that there is no link between MMR vaccine or thimerosal and autism. Visit <http://www.cdc.gov/vaccines/conversations> for more information to help you answer parents' questions on these two issues. If parents raise other possible hypotheses linking vaccines to autism, four items are key: (1) patient and empathetic reassurance that you understand that their infant's health is their top priority, and it also is your top priority, so putting children at risk of vaccine-preventable diseases without scientific evidence of a link between vaccines and autism is a risk you are not willing to take; (2) your knowledge that the onset of regressive autism symptoms often coincides with the timing of vaccines but is not caused by vaccines; (3) your personal and professional opinion that vaccines are very safe; and (4) your reminder that vaccine-preventable diseases, which may cause serious complications and even death, remain a threat.

"All those people who say that the MMR vaccine causes autism must be on to something."

"Autism is a burden for many families and people want answers—including me. But well designed and conducted studies that I can share with you show that MMR vaccine is not a cause of autism."

Questions about whether vaccines are more dangerous for infants than the diseases they prevent

Today, parents may not have seen a case of a vaccine-preventable disease firsthand. Therefore, they may wonder if vaccines are really necessary, and they may believe that the risks of vaccinating infants outweigh the benefits of protecting them from infection with vaccine-preventable diseases. Visit <http://www.cdc.gov/vaccines/conversations> for up-to-date information on diseases and the vaccines that prevent them that you can share with parents. You may be able to provide information from your own experience about the seriousness of the diseases, the fact that cases and outbreaks of vaccine-preventable diseases are occurring now in the U.S., and that even when diseases are eliminated in the U.S., they can make a rapid return in children and adults who are not immunized if travelers bring the diseases into the U.S. You also can remind parents about ongoing efforts to ensure the safety of vaccines, including the large-scale reporting system, Vaccine Adverse Event Reporting System (<http://www.vaers.hhs.gov>), used

to alert FDA and CDC to any possible problems with a vaccine so that they can be studied in more detail.

*"What are all these vaccines for?
Are they really necessary?"*

"I know you didn't get all these vaccines when you were a baby. Neither did I. But we were both at risk of serious diseases like Hib and pneumococcal meningitis. Today, we're lucky to be able to protect our babies from 14 serious diseases with vaccines."

Questions about the number of vaccines and vaccine ingredients

Some parents may have a general concern that there are too many vaccines. With respect to timing and spacing of vaccines, the childhood vaccine schedule is designed to provide protection at the earliest possible time against serious diseases that may affect infants early in life. *The Childhood Immunization Schedule* fact sheet (<http://www.cdc.gov/vaccines/conversations>) may be useful for those parents, as well as for parents who have specific questions. Some parents may be able to specify their concerns: whether each vaccine is needed, whether giving several vaccines at one time can cause harm, whether vaccine ingredients are harmful, or how well each vaccine works. For these parents, you can specifically reinforce the seriousness of the diseases prevented by vaccines, and share your knowledge that no evidence suggests that a healthy child's immune system will be damaged or overwhelmed by receiving several vaccines at one time. *Understanding Vaccine Ingredients* (<http://www.cdc.gov/vaccines/conversations>) can help you counter myths that have circulated about vaccine ingredients. You may need to share with some parents that not only should each vaccine series be started on time to protect infants and children as soon as possible, but each multi-dose series must be completed to provide the best protection.

"I'm really not comfortable with my 2-month-old getting so many vaccines at once."

"There's no proven danger in getting all the recommended 2-month vaccines today. Any time you delay a vaccine you leave your baby vulnerable to disease. It's really best to stay on schedule. But if you're very uncomfortable, we can give some vaccines today and schedule you to come back in two weeks for the rest, but this is not recommended."

Questions about known side effects

It is reasonable for parents to be concerned about the possible reactions or side effects listed on the Vaccine Information Statements, especially fever, redness where a shot was given, or fussiness that their child may experience following vaccination. Remind parents to watch for the possible side effects and provide information on how they should treat them and how they can contact you if they observe something they are concerned about. To reinforce how rare serious side effects really are, share your own experience, if any, with seeing a serious side effect from a vaccine.

"I'm worried about the side effects of vaccines. I don't want my child to get any vaccines today."

"I'll worry if your child *doesn't* get vaccines today, because the diseases can be very dangerous—most, including Hib, pertussis, and measles, are still infecting children in the U.S. We can look at the Vaccine Information Statements together and talk about how rare serious vaccine side effects are."

Questions about unknown serious adverse events

Parents who look for information about vaccine safety will likely encounter suggestions about as-yet-unknown serious adverse events from vaccines. It is not unreasonable that parents find this alarming. You can share what the world was like for children before there were vaccines. And you can share that increases in health problems such as autism, asthma, or diabetes don't have a biologic connection to vaccination. We have no evidence to suggest that vaccines threaten a long, healthy life. We know lack of vaccination threatens a long and healthy life.

"You really don't know if vaccines cause any long-term effects."

"We have years of experience with vaccines and no reason to believe that vaccines cause long-term harm. I understand your concern, but I truly believe that the risk of diseases is greater than any risks posed by vaccines. Vaccines will get your baby off to a great start for a long, healthy life."

Communication Strategies—How to Have a Successful Dialogue

A successful discussion about vaccines involves a two-way conversation, with both parties sharing information and asking questions. These communication principles can help you connect with parents by encouraging open, honest, and productive dialogue.

Take advantage of early opportunities such as the prenatal, newborn, 1-week, and 1-month visits to initiate a dialogue about vaccines. These also are good opportunities to provide take-home materials or direct parents to immunization websites that you trust. This gives parents time to read and digest reputable vaccine information before the first and all future immunizations. And when parents have questions, you can build on the reputable information that they already have reviewed. With parents who have many questions, consider an extended visit to discuss vaccinating their child.

Take time to listen.

If parents need to talk about vaccines, give them your full attention. Despite a full schedule, resist the urge to multi-task while a parent talks. Maintain eye contact with parents, restate their concerns to be sure you understand their viewpoint, and pause to thoughtfully prepare your reply. Your willingness to listen will likely play a major role in helping parents with their decisions to choose vaccination.

Solicit and welcome questions.

If parents seem concerned about vaccines but are reluctant to talk, ask them open-ended questions and let them know that you want to hear their questions and concerns.

Put yourself in parents' shoes and acknowledge parents' feelings and emotions, including their fear and desire to protect their children. Remind parents that you know why they are concerned—their infant's health is their top priority. Remind them that it is yours, too.

Keep the conversation going.

If parents come to you with a long list of questions or information from the Web or other sources, don't interpret this as a lack of respect for you. Instead, acknowledge that spending time to research vaccines means that this is an important topic for the parents. If you appear offended by questions, or if you imply that a parent's questions are uncalled for, dialogue may shut down and trust may be eroded.



Science versus anecdote?

Too much science will frustrate some parents. Too little science will frustrate others. For some parents, too much anecdotal information won't hit the mark. For others, a story from your experience about an unprotected child who became ill, or knowing that children in your family have received all of their vaccines, will be exactly on target. Which approach to use will depend on your knowledge of the family. Watch and listen. Be prepared to use the mix of science and personal stories that will be most effective in addressing parents' questions.

Acknowledge benefits and risks.

Always discuss honestly the known side effects caused by vaccines. But don't forget to remind parents of the overwhelming benefit of preventing potentially serious diseases with vaccines. It's honest to say that not vaccinating is a risk that will worry you.

Respect parents' authority.

Many parents today want to work in partnership with their child's physician. Of course, you work in partnership with parents every day, for example, by eliciting reports from them about how their infants are progressing. By talking respectfully with parents about their immunization concerns, you can build on this partnership, build trust, and support parents in the decision to choose vaccination.

Reduce the stress of shots.

Show parents ways they can make the vaccination visit less stressful for the child. It can begin by reinforcing that crying is a normal response for the child and suggesting that they stay calm so that the child does not become aware of their stress. For infants, you can suggest that parents use a favorite blanket or toy to distract the baby from the pain of the shots, and that they touch and soothe the baby, talk softly, and smile and make eye contact during the shots. After shots for infants, mothers may wish to cuddle or breastfeed. For toddlers, there are many more

options to distract from the pain of the shot, including telling a favorite story, singing, or taking deep breaths and blowing out the pain. After the shots, toddlers can be praised for getting through the shots and reassured that everything is OK.

After the Office Visit

Document parents' questions and concerns.

A thorough record of your discussion will be an invaluable reference during the child's future visits.

Follow up.

If parents express extreme worry or doubt, contact them a few days after the visit. A caring call or e-mail will provide comfort and reinforce trust.

What If Parents Refuse to Vaccinate?

Excluding children from your practice when their parents decline immunizations is not recommended. It can put the child at risk of many different health problems—not just vaccine-preventable diseases. Remember, unvaccinated infants did not decide for themselves to remain unvaccinated. They need your care. Make sure that parents are fully informed about clinical presentations of vaccine-preventable diseases, including early symptoms. Diseases like pertussis and measles are highly contagious and may present early as a non-specific respiratory illness. Parents who refuse vaccines should be reminded at every visit to call before bringing the child into the office, clinic, or emergency department when the child is ill so appropriate measures can be taken to protect others. When scheduling an office visit for an ill child who has not received vaccines, take all possible precautions to prevent contact with other patients, especially those too young to be fully vaccinated and those who have weakened immune systems.

If a parent refuses to vaccinate, you can share the fact sheet *If You Choose Not to Vaccinate Your Child, Understand the Risks and Responsibilities* (<http://www.cdc.gov/vaccines/conversations>), which explains the risks involved with this decision including risks to other members of their community, and the additional responsibilities for parents, including the fact that, when their child is ill, they should always alert health care personnel to their child's vaccination status to prevent the possible spread of vaccine-preventable diseases. You also can tell the parent that you would like to continue the dialogue about vaccines during the next visit, and then make sure to do so. You may wish to have them sign AAP's *Refusal to Vaccinate* form (<http://www.aap.org/immunization/pediatricians/pdf/refusaltovaccinate.pdf>) each time a vaccine is refused so that you have a record of their refusal in their child's medical file.

Remember, not all parents want the same level of medical or scientific information about vaccines. By assessing the level of information that a particular parent wants, you can communicate more effectively and build trust.

For the information resources mentioned in this sheet, and others, look for *Provider Resources for Vaccine Conversations with Parents* at <http://www.cdc.gov/vaccines/conversations> or call **800-CDC-INFO** (800-232-4636). These resources are free to download and ready for color or black and white printing and reproduction.



VOLUME 2 Spring 2016

Vaccines and Autism: What you should know

 The Children's Hospital
of Philadelphia®



VACCINE EDUCATION CENTER

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. More recently, 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 multidose 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.

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 or 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 100,000 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 100 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 recent 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.

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.

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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.

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This information is provided by the Vaccine Education Center at The 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 The Children's Hospital of Philadelphia. The Vaccine Education Center does not receive support from pharmaceutical companies.

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Today, young children receive vaccines to protect them against 14 different diseases. Because some vaccines require more than one dose, children can receive as many as 27 inoculations by 2 years of age and up to five shots at one time. For this reason, some parents now ask their doctors to space out, separate or withhold vaccines. The concern that too many vaccines might overwhelm a baby's immune system is understandable, but the evidence that they don't is reassuring.

Q. What are the active components in vaccines?

A. Vaccines contain parts of viruses or bacteria that induce protective immune responses. These active ingredients are called immunological components.

Vaccines that protect against bacterial diseases are made from either inactivated bacterial proteins (e.g., diphtheria, tetanus and whooping cough [pertussis]) or bacterial sugars called polysaccharides (e.g., *Haemophilus influenzae* type b [Hib] and pneumococcus). Each of these bacterial proteins or polysaccharides is considered an immunological component, meaning that each evokes a distinct immune response.

Vaccines that protect against viral diseases (e.g., measles, mumps, rubella, polio, rotavirus, hepatitis A, hepatitis B, chickenpox and influenza) are made of viral proteins. Just like bacterial proteins, viral proteins induce an immune response.

Q. Do children encounter more immunological components from vaccines today than they did 30 years ago?

A. No. Although children receive more vaccines now than ever before, most people would probably be surprised to learn that the number of immunological components in vaccines has dramatically decreased.

Thirty years ago, children received vaccines that protected against eight diseases: measles, mumps, rubella, diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b and polio. The total number of bacterial and viral proteins contained in these vaccines was a little more than 3,000.

Today, children receive vaccines that protect against 14 diseases, but the total number of immunological components in these vaccines is only about 150. This dramatic reduction is the result of scientific advances that have allowed for purer, safer vaccines.

Q. Can too many vaccines overwhelm an infant's immune system?



A. No. Compared to the immunological challenges that infants handle every day, the challenge from the immunological components in vaccines is minuscule. Babies begin dealing with immunological challenges at birth. The mother's womb is a sterile environment, free from viruses, bacteria, parasites and fungi. But after babies pass through the birth canal and enter the world, they are immediately

colonized with trillions of bacteria, which means that they carry the bacteria on their bodies but aren't infected by them. These bacteria live on the skin, nose, throat and intestines. To make sure that colonizing bacteria don't invade the bloodstream and cause harm, babies constantly make antibodies against them.

Colonizing bacteria aren't the only issue. Because the food that we eat and the dust that we breathe contain bacteria, immunological challenges from the environment are unending. Viruses are also a problem. In the first few years of life, children are constantly exposed to a variety of different viruses that cause runny noses, cough, congestion, fever or diarrhea.

Given that infants are colonized with trillions of bacteria, that each bacterium contains between 2,000 and 6,000 immunological components, and that infants are infected with numerous viruses, the challenge from the 150 immunological components in vaccines is minuscule compared to what infants manage every day.

Too Many Vaccines? What you should know

Q. How many vaccines can children effectively handle at one time?

A. A lot more than they're getting now. The purpose of vaccines is to prompt a child's body to make antibodies, which work by preventing bacteria and viruses from reproducing themselves and causing disease. So, how many different antibodies can babies make? The best answer to this question came from a Nobel Prize-winning immunologist at the Massachusetts Institute of Technology named Susumu Tonegawa, who first figured out how people make antibodies.

Tonegawa discovered that antibodies are made by rearranging and recombining many different genes, and found that people can make about 10 billion different antibodies. Given the number of antibody-producing cells in a child's bloodstream, and the number of immunological components contained in vaccines, it is reasonable to conclude that babies could effectively make antibodies to about 100,000 vaccines at one time. Although this number sounds overwhelming, remember that every day children are defending themselves against a far greater number of immunological challenges in their environment.

Q. How do we know that multiple vaccines can be given safely?

A. The Food and Drug Administration (FDA) requires extensive safety testing before vaccines are licensed. Before a new vaccine can be licensed by the FDA, it must first be tested by something called "concomitant use studies." Concomitant use studies require new vaccines to be tested with existing vaccines.

These studies are performed to make sure the new vaccine doesn't affect the safety or effectiveness of existing vaccines given at the same time, and vice versa. Because concomitant use studies have been required for decades, many studies have been performed showing that children can be inoculated with multiple vaccines safely.

Q. What is the harm of separating, spacing out or withholding vaccines?

A. Delaying vaccines can be risky. The desire by some parents to separate, space out or withhold vaccines is understandable. This choice, however, is not necessarily without consequence.

First, delaying vaccines only increases the time during which children are susceptible to certain diseases, some of which are still fairly common. Chickenpox, whooping cough (pertussis), *Haemophilus influenzae* type b, influenza and pneumococcus still cause hospitalizations and deaths in previously healthy children every year. And, for example, before the chickenpox vaccine, every year about 70 children died from the disease.

Second, spacing out or separating vaccines will require children to visit the doctor more often for shots. Researchers have found that children experience similar amounts of stress, as measured by secretion of a hormone called cortisol, whether they are getting one or two shots at the same visit. This study suggests that although children are clearly stressed by receiving a shot, two shots aren't more stressful than one. For this reason, more visits to the doctor created by separating or spacing out vaccines will actually increase the trauma of getting shots.

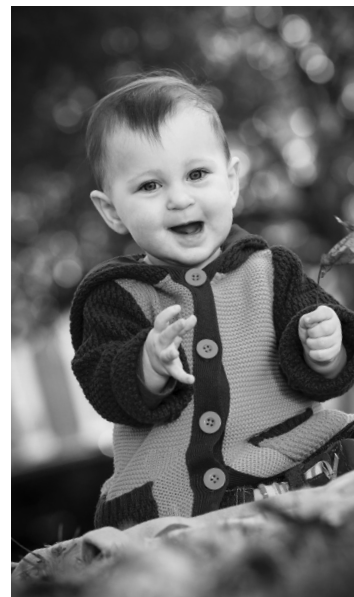
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This information is provided by the Vaccine Education Center at The Children's Hospital of Philadelphia. The Center is an educational resource for parents and healthcare professionals and is composed of scientists, physicians, mothers and fathers who are devoted to the study and prevention of infectious diseases. The Vaccine Education Center is funded by endowed chairs from The Children's Hospital of Philadelphia. The Center does not receive support from pharmaceutical companies.

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VOLUME 3, SUMMER 2016

Vaccine Ingredients: What you should know

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VACCINE EDUCATION CENTER

Some parents are concerned about ingredients in vaccines, specifically aluminum, mercury, gelatin and antibiotics. However, parents can be reassured that ingredients in vaccines are minuscule and 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. In 2009, a second adjuvant, known as monophosphoryl lipid A, was also 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, aluminum is present in our environment; the air we breathe, the water we drink and the food we eat all contain aluminum.

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 ingest 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.

Some people wonder about the difference between aluminum injected in vaccines versus aluminum ingested 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 about half of the aluminum from vaccines 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.

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.

*A milligram is one-thousandth of a gram, and a gram is the weight of one-fifth of a teaspoon of water.

Q. Why is formaldehyde in vaccines?

A. Formaldehyde is a by-product 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 by-product 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 ingested (except the rotavirus vaccine, which does not contain gelatin). Second, gelatin in vaccines has been highly purified and hydrolyzed (broken down by water), so that 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. 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 who had received vaccines 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, additives in vaccines, 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.

Vaccine Ingredients: What you should know

Q. Why is mercury in vaccines?

A. Mercury is contained in some multidose 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 vaccine back in the refrigerator. Unfortunately, sometimes bacteria would inadvertently enter the vial and cause abscesses at the site of injection or bloodstream infections that were occasionally 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.

Further, because mercury is a naturally occurring element found in the earth's crust, air, soil and water, we are all exposed to it. In fact, infants who are exclusively breastfed ingest more than twice the quantity of mercury than was contained in vaccines. Today, breastfed infants ingest 15 times more mercury in breast milk than is contained in the influenza vaccine.



Q. Are some vaccines made using fetal cells?

A. Fetal cells are used to make five vaccines: rubella, chickenpox, hepatitis A, shingles and rabies. Fetal cells used to grow the vaccine viruses were isolated from two elective abortions performed in Sweden and England in the early 1960s. Further abortions are not necessary as the cells isolated in the 1960s continue to be maintained in laboratory cultures.

Some parents 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 different from other types of cells in that they are virtually immortal, meaning they can reproduce many, many times before dying. Other cells reproduce only a limited number of times before they die.

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.

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 have resulted in 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.

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.

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THE FACTS ABOUT CHILDHOOD VACCINES: WHAT YOU SHOULD KNOW

Volume 9
Spring 2019

Q. How can parents sort out conflicting information about vaccines?

A. Decisions about vaccine safety must be based on well-controlled scientific studies.

Parents are often confronted with “scientific” information found on television, on the internet, in magazines and in books that conflicts with information provided by healthcare professionals. But few parents have the background in microbiology, immunology, epidemiology and statistics to separate good scientific studies from poor studies. Parents and physicians benefit from the expert guidance of specialists with experience and training in these disciplines.

Committees of these experts are composed of scientists, clinicians and other caregivers who are as passionately devoted to our children’s health as they are to their own children’s health. They serve the Centers for Disease Control and Prevention (cdc.gov/vaccines), the American Academy of Pediatrics (aap.org), the American Academy of Family Physicians (aafp.org), the American College of Obstetricians and Gynecologists (acog.org), and the National Foundation of Infectious Diseases (nfid.org), among other groups. These organizations provide excellent information to parents and healthcare professionals through their websites. Their task is to determine whether scientific studies are carefully performed, published in reputable journals and, most importantly, reproducible. Information that fails to meet these standards is viewed as unreliable.



When it comes to issues of vaccine safety, these groups have served us well. They were the first to figure out that intestinal blockage was a rare consequence of the first rotavirus vaccine, and the vaccine was quickly discontinued. And, they recommended a change from the oral polio vaccine, which was a rare cause of paralysis, to the polio shot when it was clear that the risks of the oral polio vaccine outweighed its benefits.

These groups have also investigated possible relationships between vaccines and asthma, diabetes, multiple sclerosis, SIDS and autism. No studies have reliably established a causal link between vaccines and these diseases — if they did, the questioned vaccines would be withdrawn from use.

Q. Are vaccines still necessary?

A. Although several of the diseases that vaccines prevent have been dramatically reduced or eliminated, vaccines are still necessary:

- *to prevent common infections*

Some diseases are so common in this country that a choice not to get a vaccine is a choice to get infected. For example, choosing not to get the pertussis (whooping cough) vaccine is a choice to risk a serious and occasionally fatal infection.

- *to prevent infections that could easily re-emerge*

Some diseases in this country can easily re-emerge with relatively small decreases in immunization rates (for example, measles, mumps and *Haemophilus influenzae* type b, or Hib). We are seeing this now with measles and mumps. Unvaccinated children are more likely to be infected.

- *to prevent infections that are common in other parts of the world*

Although some diseases have been completely eliminated (polio) or virtually eliminated (diphtheria) from this country, they still occur commonly in other parts of the world. Children are still paralyzed by polio and sickened by diphtheria in other areas of the world. Because there is a high rate of international travel, outbreaks of these diseases are only a plane ride away.

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Q. Do vaccines contain additives?

A. Many vaccines contain trace quantities of antibiotics or stabilizers.

Antibiotics are used during the manufacture of vaccines to prevent inadvertent contamination with bacteria or fungi. Trace quantities of antibiotics are present in some vaccines. However, the antibiotics contained in vaccines (neomycin, streptomycin or polymyxin B) are not those commonly given to children. Therefore, children with allergies to antibiotics such as penicillin, amoxicillin, sulfa or cephalosporins can still get vaccines.

Gelatin is used to stabilize live, “weakened” viral vaccines and is also contained in many food products. People with known allergies to gelatin contained in foods may have severe allergic reactions to the gelatin contained in vaccines. However, this reaction is extremely rare.

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Q. Are vaccines made using fetal cells?

A. Viruses require cells in which to reproduce. This means to make viral vaccines, the viruses must be grown in cells in the laboratory. In a few cases, the types of cells chosen were from pregnancies that were terminated electively. The scientists made this decision for two reasons. First, viruses that infect people reproduce best in cells from people. Second, cells isolated from a fetus are not likely to contain viruses because the womb is sterile.

The fetal cells used to grow vaccine viruses were isolated from two elective abortions that occurred in the early 1960’s. The cells have been grown in the laboratory since then, and no additional abortions are needed to make the vaccines.

The vaccines made using these cell lines include the chickenpox, rubella (part of MMR), hepatitis A, shingles, and rabies (one version) vaccines.

Q. Are vaccines safe?

A. Because vaccines are given to people who are not sick, they are held to the highest standards of safety. As a result, they are among the safest things we put into our bodies.

How does one define the word safe? If safe is defined as “free from any negative effects,” then vaccines aren’t 100 percent safe. All vaccines have possible side effects. Most side effects are mild, such as fever, or tenderness and swelling where the shot is given. But some side effects from vaccines can be severe. For example, the pertussis vaccine is a very rare cause of persistent, inconsolable crying, high fever or seizures with fever. Although these reactions do not cause permanent harm to the child, they can be quite frightening.

If vaccines cause side effects, wouldn’t it be “safer” to just avoid them?

Unfortunately, choosing to avoid vaccines is not a risk-free choice — it is a choice to take a different and much more serious risk. Discontinuing the pertussis vaccine in countries like Japan and England led to a tenfold increase in hospitalizations and deaths from pertussis. And declines in the number of children receiving measles vaccine in the United Kingdom and the United States have led to increases in cases of measles.

When you consider the risk of vaccines and the risk of diseases, vaccines are the safer choice.

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Q. Do children get too many shots?

A. Newborns commonly manage many challenges to their immune systems at the same time.

Because some children could receive as many as 27 shots by the time they are 2 years old and as many as five shots in a single visit to the doctor, many parents wonder whether it is safe to give children so many vaccines.

Although the mother’s womb is free from bacteria and viruses, newborns immediately face a host of different challenges to their immune systems. From the moment of birth, thousands of different bacteria start to live on the surface of the skin and intestines. By quickly making immune responses to these bacteria, babies keep them from invading the bloodstream and causing serious diseases.

In fact, babies are capable of responding to millions of different viruses and bacteria because they have billions of immunologic cells circulating in the bodies. Therefore, vaccines given in the first two years of life are a raindrop in the ocean of what an infant’s immune system successfully encounters and manages every day.

Offit PA, et al. Addressing parents’ concerns: Do vaccines weaken or overwhelm the infant’s immune system? *Pediatrics*. 2002;109:124-129.

continued >



THE FACTS ABOUT CHILDHOOD VACCINES: WHAT YOU SHOULD KNOW

Q. Is the amount of aluminum in vaccines safe?

A. Yes. All of us have aluminum in our bodies and most of us are able to process it effectively. The two main groups of people who cannot process aluminum effectively are severely premature infants who receive large quantities of aluminum in intravenous fluids and people who have long-term kidney failure and receive large quantities of aluminum, primarily in antacids. In both cases, the kidneys are not working properly or at all and the people are exposed to large quantities of aluminum over a long period of time.

The amount of aluminum in vaccines given during the first six months of life is about 4 milligrams, or four-thousandths of a gram. A gram is about one-fifth of a teaspoon of water. In comparison, breast milk ingested during this period will contain about 10 milligrams of aluminum, and infant formulas will contain about 40 milligrams. Soy-based formulas contain about 120 milligrams of aluminum.

When studies were performed to look at the amount of aluminum injected in vaccines, the levels of aluminum in blood did not detectably change. This indicates that the quantity of aluminum in vaccines is minimal as compared with the quantities already found in the blood.

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Q. Do vaccines cause autism?

A. Carefully performed studies clearly disprove the notion that vaccines cause autism.

Because the signs of autism may appear in the second year of life, at around the same time children receive certain vaccines, and because all causes of autism are unknown, some parents wondered whether vaccines might be at fault. These concerns focused on three hypotheses — autism is caused by the measles-mumps-rubella (MMR) vaccine; thimerosal, an ethylmercury-containing preservative used in vaccines; or receipt of too many vaccines too soon.

A large body of medical and scientific evidence strongly refutes these notions. Multiple studies have found that vaccines do not cause autism. These studies included hundreds of thousands of children, occurred in multiple countries, were conducted by multiple investigators and were well controlled.

To see summaries of some of these studies and other studies related to vaccine safety concerns, visit vaccine.chop.edu/safety-references.

To find the most up-to-date information about the causes of autism, visit the Autism Science Foundation website, autismsciencefoundation.org.

Q. Does my child still need to get vaccines if I am breastfeeding?

A. Yes. The types of immunity conferred by breastfeeding and immunization are different. Specifically, the antibodies that develop after immunization are made by the baby’s own immune system and, therefore, will remain in the form of immunologic memory; this is known as active immunity. In contrast, antibodies in breast milk were made by the maternal immune system, so they will provide short-term protection, but will not last more than a few weeks. These antibodies are usually not as diverse either, so the baby may be protected against some infections but remain susceptible to others. Immunity generated from breast milk is called passive immunity. Passive immunity was practiced historically when patients exposed to diphtheria were given antitoxin produced in horses; antitoxins to snake venoms are also an example of passive immunity.

Q. How can a “one-size-fits-all” approach to vaccines be OK for all children?

A. The recommended immunization schedule is not the same for all children.

In fact, recommendations for particular vaccines often vary based upon individual differences in current and long-term health status, allergies and age. Each vaccine recommendation, often characterized by a single line on the immunization schedule, is supported by about 25 to 40 additional pages of specific instructions for healthcare providers who administer vaccines. In addition, an approximately 190-page document titled “General Best Practice Guidelines for Immunization” serves as the basis for all vaccine administration. The recommendations are updated as needed by the CDC, and a comprehensive update is published every few years.

Q. What is the harm of separating, spacing out or withholding some vaccines?

A. Although the vaccine schedule can look intimidating, it is based upon the best scientific information available and is better tested for safety than any alternative schedules.

Experts review studies designed to determine whether the changes are safe in the context of the existing schedule. These are called concomitant use studies.

Separating, spacing out or withholding vaccines causes concern because infants will be susceptible to diseases for longer periods of time. When a child should receive a vaccine is determined by balancing when the recipient is at highest risk of contracting the disease and when the vaccine will generate the best immune response.

Finally, changing the vaccine schedule requires additional doctor’s visits. Research measuring cortisol, a hormone associated with stress, has determined that children do not experience more stress when receiving two shots as compared with one shot. Therefore, an increased number of visits for individual shots will mean an increase in the number of stressful situations for the child without benefit. In addition, there is an increased potential for administration errors, more time and travel needed for appointments, potentially increased costs and the possibility that the child will never get some vaccines.

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Navigating Parental Vaccine Hesitancy

CME EDUCATIONAL OBJECTIVES

1. Explain the processes to ensure vaccine safety in the United States.
2. List strategies to allay concerns regarding the purported connection between vaccines and autism in vaccine-hesitant parents.
3. Identify parents' understanding of the risks of alternative vaccine schedules.

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doi: 10.3928/00904481-20100726-05



Pediatricians routinely encounter families who question the safety and necessity of childhood immunizations. Responding effectively to this begins with understanding the basis for concern and addressing each issue in a straightforward,

comprehensive manner. This article reviews some of the common themes underlying vaccine hesitancy, delineates the processes that are in place to ensure vaccine safety, and explains the science behind the most common vaccine safety concerns.

Michael J. Smith, MD, MSCE and Gary S. Marshall, MD

TABLE 1.

Fear of Vaccines Can Lead to Public Harm

Vaccine ^a	Event or Finding	Evidence that Event Resulted From Willful Refusal to Vaccinate
DTwP	Outbreaks of pertussis in the U.K., late 1970s	Intense media coverage of anecdotal reports of neurologic reactions resulted in a decrease in vaccination rates from 81% to 31%. Outbreaks were not seen in countries without anti-vaccine movements.
DTaP	Higher risk of pertussis in certain states	Risk correlates with availability of personal belief exemptions and the ease with which such exemptions are granted.
DTaP	Pertussis cases and controls in Colorado, 1996-2007	Odds of vaccine refusal 23 times higher among cases. Virtually all cases among refusers, and 11% of cases in the whole population were caused by refusal itself.
MMR	Measles eliminated from the U.K. in 1994 but endemic again in 2008	Immunization rates fell dramatically after Wakefield's 1998 article suggesting a causal link with autism.
MMR	33 cases of measles among members of a church in Indiana, 2005	31 cases occurred among members who refused vaccination because they feared adverse reactions.
MMR	Measles outbreaks in the U.S., 2008	The vast majority of cases were unvaccinated or vaccination status unknown. Of eligible persons, 66% not vaccinated because of religious or personal beliefs.
MMR	Measles outbreaks in Japan, mid 1990s	Measles vaccine made optional in Japan, resulting in more than 100,000 cases and 50 to 100 deaths per year.
Hib	<i>H influenzae</i> disease in Minnesota in 2008—highest number of cases since 1992	Three of the five cases were intentionally not immunized, including one who died.
Varicella	Varicella cases and controls in Colorado, 1998-2008	Odds of vaccine refusal 9 times higher among cases. Five percent of cases in the whole population were caused by refusal itself.

^a In some cases, the concern may have been about all vaccines, or multiple vaccines, rather than the one cited.

Adapted from Marshall GS. The Vaccine Handbook: A Practical Guide for Clinicians. 3rd ed. Professional Communications, Inc., West Islip, NY: 2010.²⁰

VACCINE CONCERNS

It is difficult to measure exactly how many parents have serious concerns about vaccine safety. As recently as 2008, National Immunization Survey (NIS) data show coverage rates well above 90%, implying that most parents have their children vaccinated.¹ However, this is a national estimate that may not account for clustering of unvaccinated children; 90% coverage may mean that nine in every 10 children across the county are vaccinated, or that all children are vaccinated in nine communities and none in another. The recent measles outbreaks in the United States, which were for the most part limited to communities with low MMR uptake, suggest the latter.²

The best way to understand vaccine hesitancy may be to ask parents about it directly. Here's the good news: In a nationally representative survey of 1,552 parents, 90% of respondents stated that vaccines were a good way to protect their children.³ But 54% also reported that they had concerns about serious ad-

verse effects of vaccines; 25% believed that vaccines cause autism; and 11.5% had refused at least one vaccine.

Vaccines have been one of the most effective public health interventions of all time. Because vaccines have done their job, and vaccine-preventable diseases are no longer as prevalent as they once were, many parents do not see these diseases as a threat. However, the threat is real. The United States recently experienced the largest measles outbreak in more than a decade — with more than 90% of cases occurring in unvaccinated patients, mostly because of a specific choice made by parents.² Although there were no deaths during this outbreak, children actually do die of vaccine-preventable diseases in the United States.

In 2008, for example, an unvaccinated child died of *Haemophilus influenzae* type b (Hib) meningitis, which had been virtually eliminated by the introduction of Hib conjugate vaccines in the late 1980s.⁴ Table 1 offers other examples

of the public health consequences attributed to the fear of vaccines.

Will scattered disease outbreaks and occasional deaths be enough to restore public faith in our immunization program? At a minimum, they should serve as powerful reminders that not vaccinating is risky business. The question is, why has it come to this — a public that needs to witness disease and death before accepting a safe and effective preventive measure?

**VACCINE SAFETY:
FROM SCIENCE TO LAW**

It is clear that vaccine-preventable diseases still exist, and explaining this to parents is the cornerstone of effective vaccine risk-benefit communication. Although vaccines are among one of the most thoroughly tested substances that are put into people's bodies for medical purposes, physicians must also be prepared to discuss the fact that vaccines are not 100% safe. Similar to any other pharmaceutical products, they have potential side effects.

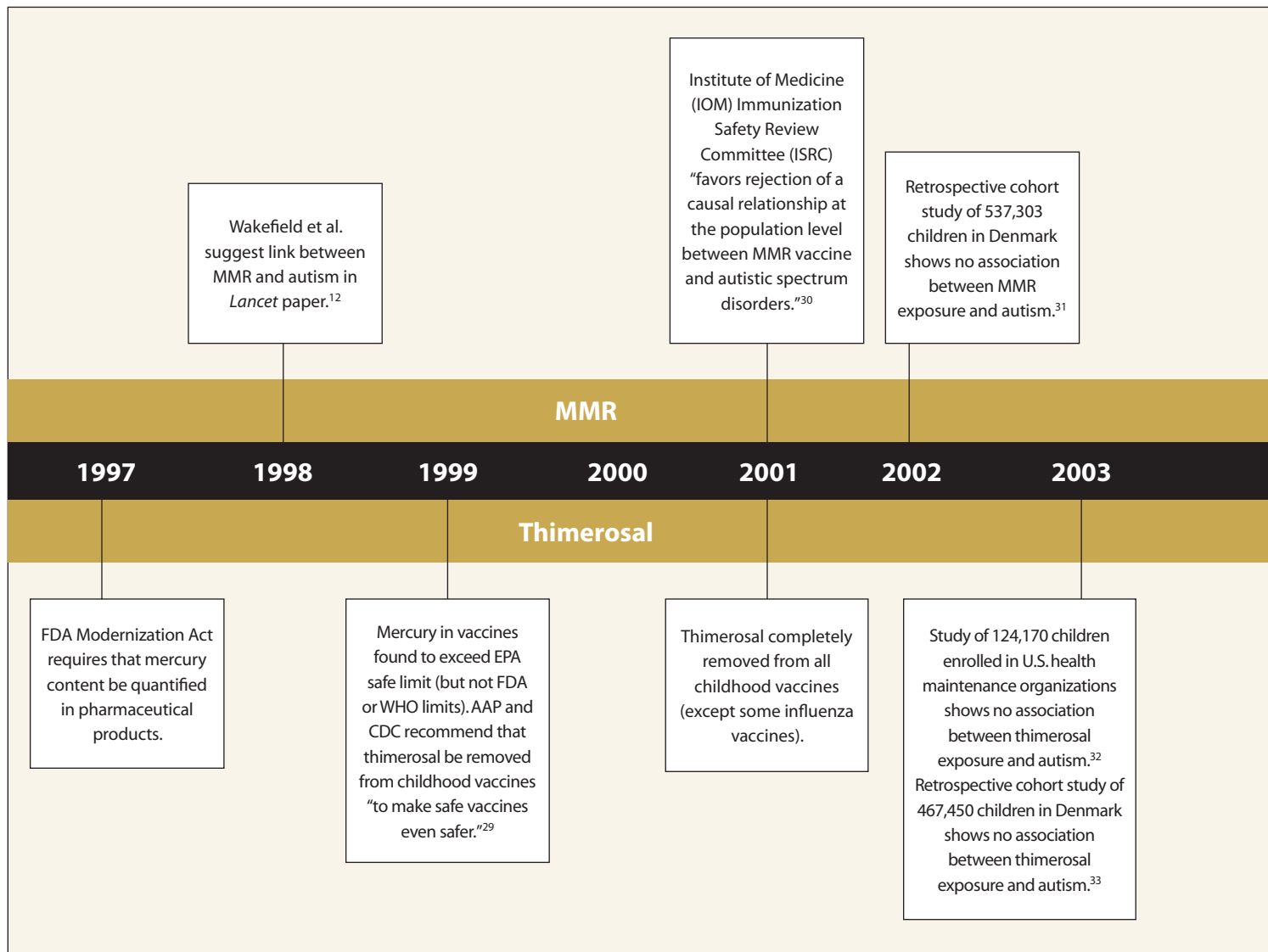


Figure. Vaccines and autism timeline.

Fortunately, most of these are minor, such as fever and pain, erythema, or swelling at the injection site.

However, unlike medicines, which treat diseases and are given to sick people, vaccines are given to healthy people to prevent disease, so the threshold for establishing safety must be very high. The proof required by the Food and Drug Administration (FDA) before licensure is granted is daunting, involving thousands of people enrolled in rigorous clinical trials. The most reliable data come from large, randomized, controlled, phase 3 clinical trials that compare efficacy and safety of a new vaccine

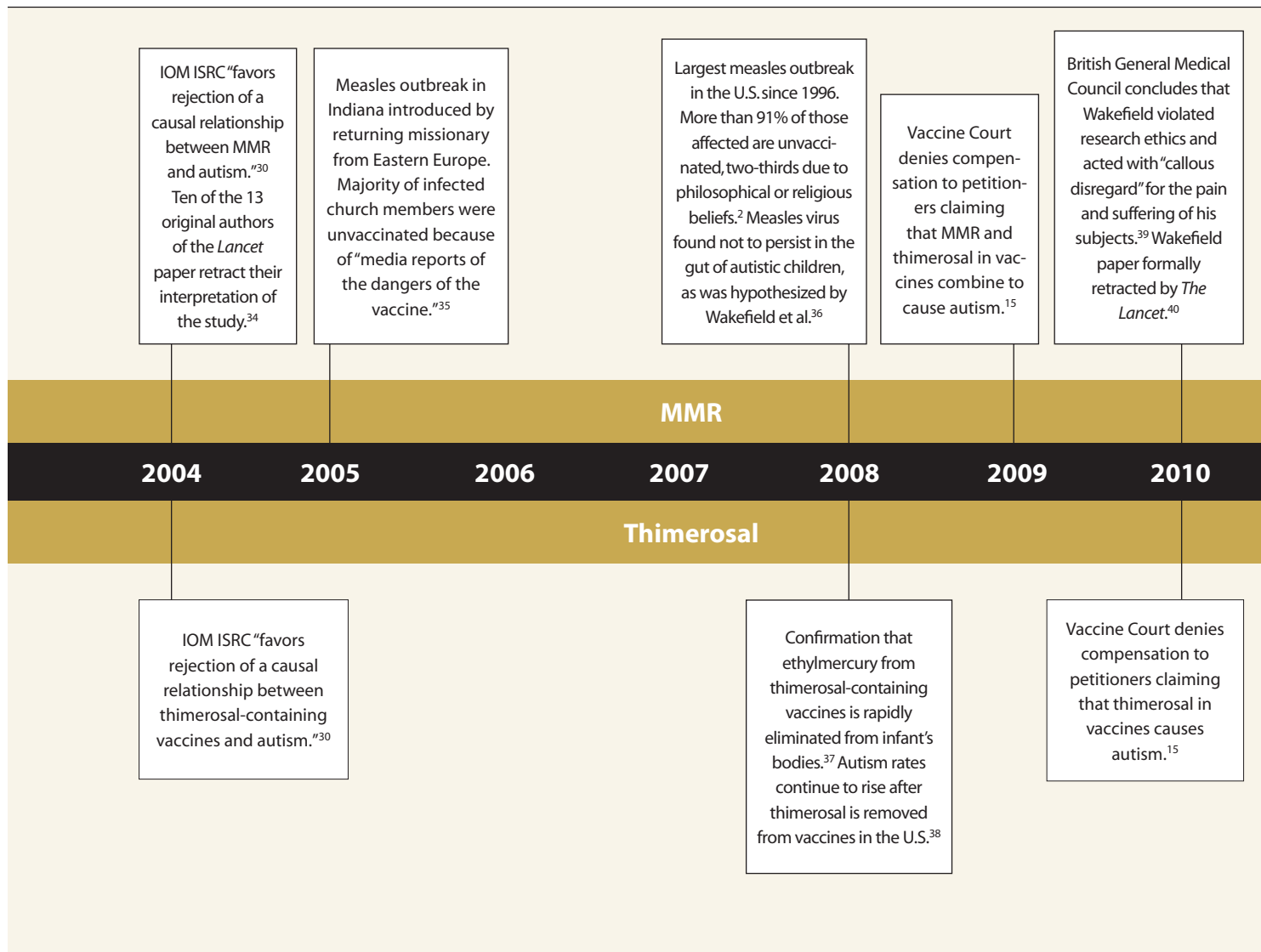
to a placebo (if there isn't already a vaccine for the disease) or to a currently licensed vaccine (if one exists). Occasionally, these studies are not large enough to detect rare vaccine adverse events.

For instance, a four-valent rhesus rotavirus vaccine (RotaShield, Wyeth) was approved for use in the United States in 1998 but was withdrawn within a year because of an association with intussusception, which occurred in approximately one of every 10,000 vaccine recipients.⁵ This association was not detected in the prelicensure trials because, even though more than 10,000 children had

been studied, those trials were not powered to detect such a small risk.

Because of the RotaShield experience, each of the current rotavirus vaccines (RotaTeq, Merck and Rotarix, GlaxoSmithKline) was studied in about 70,000 children before licensure. How do we know how many people to include in a clinical trial to detect a rare side effect? Parents (and providers) need to appreciate the mathematics behind the answer to this question.

Let's say, for example, that a given event occurs at a background rate of one in 100,000 people. To detect a twofold in-



crease in the rate of that event in a vaccinated population, 1,238,000 people would have to be enrolled in a randomized, controlled clinical trial.⁶ The cost and logistics of conducting such a trial would be prohibitive. Researchers are therefore compelled to establish a reasonable balance between risk tolerance and feasibility to bring vaccines to the public in a timely manner.

Our obligation to ensure safety begins with prelicensure trials but continues after a vaccine is released, when the number of people vaccinated increases exponentially.

This is where postmarketing surveillance systems come in. The Vaccine Ad-

verse Event Reporting System (VAERS), a passive surveillance system jointly maintained by the FDA and Centers for Disease Control and Prevention (CDC), serves as an early warning system, encouraging reports to be filed by anyone about anyone who might have suffered an adverse event after vaccination. In fact, such systems picked up the intussusception problem with RotaShield. This all-inclusive approach maximizes sensitivity and generalizability. However — and this is key — it does nothing to establish causation.

VAERS cannot distinguish temporal associations from true cause-and-effect

relationships because it only includes data about people who received the vaccine and had the adverse event of interest. It does not include reports of vaccinated individuals who have no adverse events, or unvaccinated people who experience the same adverse events (eg, autism in children who never received the MMR vaccination). Demonstration of causation requires population-based study designs that compare risk among vaccine-exposed and unexposed individuals.

The Vaccine Safety Datalink (VSD), which incorporates data from eight large managed-care organizations, is a good

TABLE 2.

Organizations Offering Credible Information About Vaccines and Vaccine Safety

Professional Organizations	
American Academy of Family Physicians (AAFP)	www.aafp.org
American Academy of Pediatrics (AAP)	www.cispimmunize.org
Association for Prevention Teaching and Research (APTR) (formerly the Association of Teachers of Preventive Medicine)	www.atpm.org
Centers for Disease Control and Prevention (CDC)	www.cdc.gov/vaccines
Infectious Diseases Society of America (IDSA)	www.idsociety.org
Pediatric Infectious Diseases Society (PIDS)	www.pids.org
Advocacy and Safety Assessment	
All Kids Count	www.allkidscount.org
Allied Vaccine Group	www.vaccine.org
Every Child by Two (ECBT)	www.ecbt.org
Global Alliance for Vaccines and Immunization (GAVI)	www.gavialliance.org
Immunization Action Coalition (IAC)	www.immunize.org
Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health	www.vaccinesafety.edu
National Foundation for Infectious Diseases (NFID)	www.nfid.org
Sabin Vaccine Institute (SVI)	www.sabin.org
For Parents	
Children's Hospital of Philadelphia Vaccine Education Center	www.vaccine.chop.edu
National Network for Immunization Information (NNii)	www.immunizationinfo.org
Parents of Kids with Infectious Diseases (PKID)	www.pkids.org
Vaccinate Your Baby	www.vaccinateyourbaby.com
Voices for Vaccines	http://www.voicesforvaccines.org

example of this. Because it includes data on those who did/did not receive specific vaccines and did/did not experience given events, the VSD allows calculation of true incidence rates and relative risks. Approximately 9 million people are included in the VSD, so even very rare events can be captured.⁷

Ultimately, the benefits of routine childhood immunization far outweigh the risks of serious adverse events, which, fortunately, are extremely rare. However, from time to time, children may be injured by a vaccine. In these cases, families may file a claim for compensation from the federal government through the National Vaccine Injury Compensation Program (VICP); in fact, they are required by law to pur-

sue remedy through the VICP first, rather than through the tort system. If the injury is included on a list of scientifically validated vaccine injuries (listed in the Vaccine Injury Table),⁸ the family is awarded compensation from a trust fund created from an excise tax on all vaccines. If the injury is not listed in the Vaccine Injury Table, the petitioner may be compensated by demonstrating that an injury was caused by the vaccine, or that the vaccine aggravated a pre-existing condition. Unlike the scientific rigor of epidemiologic studies, causation in the "vaccine court" relies on a "preponderance of the evidence," or proof of "more likely than not."⁹ As a result, neither biological plausibility nor epidemiologic data are needed for favorable adjudication.

Since its inception, the VICP has awarded 2,400 petitioners more than \$1.8 billion.¹⁰

VACCINES AND AUTISM

As highlighted by recent studies of parents³ and pediatricians,¹¹ the putative association between vaccines and autism has been the most prominent vaccine safety concern over the last decade. Most prominent has been the now disproven association between MMR and autism claimed by Andrew Wakefield and colleagues in a 1998 article in *The Lancet*.¹² The mercury-containing preservative thimerosal also has been subject to claims implicating it as a cause of autism, although thimerosal has not been added to routine childhood vaccines as a preservative for nearly a decade. Key moments in the parallel evolution of the hypothetical association between autism and MMR or thimerosal are outlined in the Figure (see page 478-479).

Many rigorous epidemiologic studies involving hundreds of thousands of person-years of exposure (and non-exposure) have failed to detect an association between vaccines and autism.¹³ Providers and parents alike would be well-served to read Dr. Paul Offit's book on this topic.¹⁴ Unfortunately, and in a sad commentary on the state of scientific thinking in modern America, the science supporting this simply hasn't gotten much traction, especially when it has been juxtaposed against the personal beliefs of celebrities who are given much television airtime.

What may grab the public's attention, however, are the two recent landmark decisions made by the vaccine court. In what has been called the Omnibus Autism Proceedings, designed to expedite the 5,200 autism cases filed with the VICP, countless hours of testimony and thousands of pages of scientific articles pertaining to several "test cases" were reviewed by Special Master Judges.¹⁵ On Feb. 12, 2009, the Vaccine Court formally rejected claims that thimerosal and MMR combine to cause autism. On March 12, 2010, the court like-

wise rejected claims that thimerosal alone causes autism. The judges did not mince words: Special Master Vowell, in *Dwyer v. Secretary of Health and Human Services* (No. 03-1202V), wrote, “The witnesses setting forth this improbable sequence of cause and effect were outclassed in every respect by the impressive assembly of true experts in their respective fields who testified on behalf of respondent.” Hopefully, these findings will serve to solidify in the court of public opinion what was decided in the court of science long ago — namely, that vaccines do not cause autism.

TOO MANY, TOO SOON?

A decade ago, nearly a quarter of parents reported the concern that children receive too many vaccines.¹⁶ Since then, the number of vaccines routinely given to children has increased, which is a good thing, or so it would seem, as a wider spectrum of infections are prevented. Unfortunately, the increased shot burden has fueled a concern that infants’ immune systems are being overwhelmed and that this may lead to a host of conditions, from autism (yes, the hypothesis has shifted yet again) to diabetes, allergies, and autoimmune diseases. In fact, “alternative schedules” that “space out” routine childhood immunizations have been offered.¹⁷

Although this may seem like a reasonable compromise to maintain adequate immunization coverage, there are many reasons it is a bad idea.

First, the notion of “immune overload” is not valid scientifically. An infant can (and does, in the course of everyday life) respond to thousands of antigenic challenges at the same time.¹⁸ The 14 vaccines included in the official 2010 vaccination schedule¹⁹ prevent 16 diseases but represent only 177 separate antigens spread out over 18 years.²⁰ In contrast, the three vaccines included in the 1980 vaccination schedule prevented eight diseases but represented about 3,041 separate antigens.

Second, delaying vaccines not only increases the risk of contracting infectious

diseases but forces prioritization. Which shots should be delayed? It is not a good idea to delay the diphtheria/tetanus/acellular pertussis vaccine (DTaP), given the prevalence, morbidity, and mortality of pertussis among young infants.²¹ But, then, do we delay the pneumococcal conjugate vaccine in deference to DTaP? What if the child develops pneumococcal meningitis in the interim — without question a terrible, utterly preventable event? For that matter, should we defer measles vaccination until 3 years, as has been suggested?¹⁷ That is not a good idea when measles is just a plane flight away.

Third, delaying vaccination makes it more likely that a given series will not be completed.²²

Finally, “spreading out” immunizations increases the number of visits needed to protect children. Who is going to pay for those extra visits, and how much extra work will it be to track down the children who don’t show up for each of those visits?

There are many reasons delaying vaccines has negative consequences, but no evidence that it has any benefits.²³ In fact, a recent study demonstrated that children who received all vaccines on time during the first year of life performed the same or better on neuropsychologic testing at 7 to 10 years than children with delayed receipt of vaccines.²⁴

MOVING FORWARD

Some parents will find these scientific arguments reassuring. However, science alone will not convince others. According to Michael Specter, author of *Denialism: How Irrational Thinking Hinders Scientific Progress, Harms the Planet, and Threatens Our Lives*, distrust of vaccines is part of a broader cultural trend that favors “science by consensus” — if many people make the same claim, it must be true.²⁵ Unfortunately, modern technology has made it difficult to determine exactly how many people are in the crowd.

Near universal access to the Internet and other social media make it surprisingly

easy to find stories of children who were completely normal until they were vaccinated. Given that most children in the United States are completely vaccinated, any adverse event that occurs in the first year of life is likely to occur within weeks of a vaccination. Now that all adults are recommended to receive a flu vaccine every year, the perception that vaccination is temporally associated with adverse events is also likely to increase.

Let’s put this into perspective. For instance, if 10 million women are given a vaccine, 86 will develop optic neuritis in the next 6 weeks.²⁶ If all 10 million are pregnant, 16,684 will have a spontaneous abortion. All of this is true — even if the shot is a placebo. This illustrates two things. First, as epidemiologists know but the public may not, sequence does not mean consequence. More importantly, as human beings, we have trouble grasping the big numerical picture — it is more natural to assume a relationship with the shot than to contemplate thousands of lost pregnancies (or cases of autism or SIDS) caused by chance alone (or to something other than the shot).

Yet, anti-vaccine websites are replete with personal stories of alleged vaccine injury, exploiting this human tendency to believe anecdote.^{27,28} Unfortunately, Internet users may reach such sites accidentally using standard search engines. In a sense, we need to psychologically “immunize” parents against anecdotal thinking, giving them a firm foundation in probabilistic reasoning and scientific evidence. We can also direct them to reliable websites with science-based information about vaccines, vaccine safety, and vaccine-preventable diseases (see Table 2, page 480).

Don’t be surprised, however — some of these websites tell their own anecdotal stories about children with bad outcomes from vaccine-preventable diseases. This is, in essence, fighting fire with fire. For those parents who distrust the pharmaceutical industry and the government agencies that study and approve vaccines,

stories from other parents may be seen as more trustworthy.

In the final analysis, the most important factor in effective vaccine risk-benefit communication is a trusting relationship with you, the primary care pediatrician. And one way to help parents understand that the risk-benefit equation comes out strongly in favor of vaccination is your own personal advocacy. Pediatricians recommend vaccines because they care about children. Even their own children and grandchildren are vaccinated. The approach begins with listening to parents and respecting their concerns, but it ends with a strong, evidence-based recommendation to strap the children into their “vaccine car seat” before they head out onto the highway of life.

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Quick Answers to Tough Questions

Vaccine Talking Points for Healthcare Professionals

October 2018 • Item #S8030



Are you spending more and more time with vaccine-hesitant parents?

Parents Wonder: Is it Safe to **Vaccinate**?

Many families of autistic kids blame the MMR shot for the disorder. Experts say they shouldn't.

2



Talking about vaccines

- **Effective, empathetic communication** is critical in responding to parents who are considering not vaccinating
 - **Parents** should be helped to feel comfortable voicing any concerns or questions they have about vaccination.
 - **Providers** should be prepared to listen and respond effectively.

"Parents consider their child's healthcare professionals to be their most trusted source of information when it comes to vaccines. This is true even for parents who are vaccine-hesitant or who have considered delaying one or more vaccines."

Talking with Parents about Vaccines for Infants (CDC)
www.cdc.gov/vaccines/hcp/conversations/talking-with-parents.html



3



Talking about vaccines

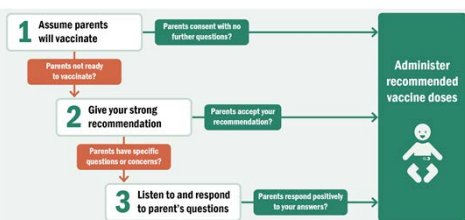
Although research shows most parents in the U.S. support vaccines, you will encounter parents with questions. If a parent has concerns, resists following the recommended vaccine schedule, or questions your strong recommendation, this doesn't necessarily mean they won't accept vaccines. Sometimes parents simply want your answers to their questions. Your willingness to listen to their concerns will play a major role in building trust in you and your recommendation.

When listening, seek to understand the concerns behind parents' questions before responding with information the parent may not be asking about. If you encounter questions you do not know the answer to, or information from sources you are unfamiliar with, it is best to acknowledge the parent's concerns and share what you do know. Offer to review the information they have found and, if necessary, schedule another appointment to discuss it further."

Talking with Parents about Vaccines for Infants (CDC)
www.cdc.gov/vaccines/hcp/conversations/talking-with-parents.html



4



Talking with Parents about Vaccines for Infants (CDC)
www.cdc.gov/vaccines/hcp/conversations/talking-with-parents.html



5



Dialogue

- If parents have safety concerns or misconceptions about vaccination, ask them to identify the source(s) of those concerns or beliefs.
- Listen carefully, paraphrase to the parent what they have told you, and ask them if you have correctly interpreted what they have said.
- Provide factual information in understandable language that addresses the specific concerns or misconceptions the parent has about vaccination.



6



Be prepared with quick answers to tough questions

- The following is an outline of answers to questions about vaccine effectiveness and safety
- It includes:
 - suggestions for further provider reading
 - helpful handouts for patients



7

Common Questions Asked by Vaccine-Hesitant Parents and Patients



Won't giving my baby so many vaccines overwhelm his/her immune system?

- Babies begin being exposed to immunological challenges immediately at the time of birth:
 - As babies pass through the birth canal and breathe, they are immediately colonized with trillions of bacteria, which means that they carry the bacteria in their bodies but aren't infected by them.
 - Healthy babies constantly make antibodies against those bacteria and viruses.
- Vaccines use only a tiny proportion of a baby's immune system's ability to respond
 - Though children receive more vaccines than in the past, today's vaccines contain fewer antigens (e.g., sugars and proteins) than previous vaccines.
 - Smallpox vaccine alone contained 200 proteins; the 14 currently recommended routine vaccines contain fewer than 150 immunologic components.



9

Why don't you recommend spacing out vaccines using an alternative schedule?

- Delaying vaccines increases the time children will be susceptible to serious diseases
 - Measles: There were 667 cases of measles in the U.S in 2014. The majority of people who got measles were unvaccinated. Measles is still common in many parts of the world including some countries in Europe, Asia, the Pacific, and Africa, and can easily be imported.
 - Pertussis: This disease is especially dangerous in infants before they're fully vaccinated. In 2014, 32,971 pertussis cases were reported in the U.S., and many more cases were undiagnosed.
- Requiring many extra appointments for vaccinations increases the stress for the child and may lead to a fear of medical procedures.
- There is no evidence that spreading out the schedule decreases the risk of adverse reactions.



10

References

- *Too Many Vaccines? What you should know* (Vaccine Education Center, Children's Hospital of Philadelphia-VEC)
www.chop.edu/export/download/pdfs/articles/vaccine-education-center/too-many-vaccines.pdf
- *Multiple Vaccines and the Immune System* (CDC)
www.cdc.gov/vaccinesafety/Vaccines/multiplevaccines.html
- *The Problem With Dr. Bob's Alternative Vaccine Schedule* by Paul Offit, MD and Charlotte Moser
<http://pediatrics.aappublications.org/content/pediatrics/123/1/e164.full.pdf>
- *Vaccines and Autism: A Tale of Shifting Hypotheses* by Paul Offit, MD and Jeffery Gerber, MD
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2908388/>



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References

- *Multiple Immunizations and Immune Dysfunction* (Institute of Medicine Report)
www.nap.edu/read/10306/chapter/1
- *The Childhood Immunization Schedule: Why Is It Like That?*
www.aap.org/en-us/advocacy-and-policy/Documents/Vaccineschedule.pdf
- *Parental Refusal of Pertussis Vaccination is Associated with an Increased Risk of Pertussis Infection in Children* (Glanz et al, *Pediatrics*, June 2009)
<http://pediatrics.aappublications.org/content/pediatrics/123/6/1446>



12

Hasn't the mercury in vaccines been shown to cause autism?

- The form of mercury found in thimerosal is *ethylmercury* (not methylmercury, which is the form that has been shown to damage the nervous system).
- Although no evidence of harm has been proven, thimerosal was taken out of vaccines in the U.S. as a precaution and "because it can be" (due to single dose vials, other preservative options).
- Since 2001, with the exception of some influenza vaccines, thimerosal has not been used as a preservative in routinely recommended childhood vaccines in the U.S.



13

Hasn't the mercury in vaccines been shown to cause autism? (cont.)

- Multiple studies comparing vaccinated and unvaccinated children have shown that thimerosal in vaccines does not cause autism.
- Studies of three countries compared the incidence of autism before and after thimerosal was removed from vaccines (in 1992 in Europe and 2001 in the U.S.) and found no decrease in autism with the use of thimerosal-free vaccines.



14

References

- Common Vaccine Safety Concerns web page (CDC)
www.cdc.gov/vaccinesafety/concerns
- Thimerosal (IAC)
www.immunize.org/thimerosal
- Reports on thimerosal (Institute of Medicine)
www.nap.edu/books/030909237X/html and
www.nap.edu/read/10208/chapter/1
- *Understanding Thimerosal, Mercury, and Vaccine Safety* (CDC)
www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-thimerosal-color-office.pdf



15

References (cont.)

- *Thimerosal: What you should know* (CHOP)
www.chop.edu/export/download/pdfs/articles/vaccine-education-center/thimerosal.pdf
- *Vaccines & Autism: What you should know* (CHOP)
www.chop.edu/export/download/pdfs/articles/vaccine-education-center/autism.pdf
- *Studies on Thimerosal in Vaccines* (CDC)
www.cdc.gov/vaccinesafety/pdf/cdcstudiesonvaccinesandautism.pdf
- *Vaccines and Autism: A Tale of Shifting Hypotheses* by Paul Offit, MD and Jeffery Gerber, MD
<http://cid.oxfordjournals.org/content/48/4/456.full>



16

Don't the ingredients found in vaccines hurt children?

Aluminum

- Aluminum is used in some vaccines as an adjuvant—an ingredient that improves the immune response.
 - Adjuvants can allow for use of less antigen.
 - They have been used for this purpose for more than 70 years.
- Aluminum is the most common metal found in nature. It is in the air and in food and drink. Infants get more aluminum through breast milk or formula than vaccines.
- Most of the aluminum in the body is quickly eliminated.



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Don't the ingredients found in vaccines hurt children? (cont.)

Formaldehyde

- Formaldehyde is used to detoxify diphtheria and tetanus toxins or to inactivate a virus.
- The *tiny* amount which may be left in these vaccines is safe.
- Formaldehyde is also in products like paper towels, mascara, and carpeting.
- Humans normally have formaldehyde in the blood stream at levels higher than in vaccines.



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Don't the ingredients found in vaccines hurt children? (cont.)

Miscellaneous

- **Antibiotics** are present in some vaccines to prevent bacterial contamination when the vaccine is made.
- **Additives** such as gelatin, albumin, sucrose, lactose, MSG, and glycine help the vaccine stay effective while being stored.
- Trying to make vaccines without adjuvants, additives, and preservatives is difficult—these ingredients keep vaccines safe and effective.



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References

- *Vaccine Ingredients: Frequently Asked Questions* (AAP) www.healthychildren.org/English/safety-prevention/immunizations/Pages/Vaccine-Ingredients-Frequently-Asked-Questions.aspx
- *Ingredients of Vaccines* web page (CDC) www.cdc.gov/vaccines/vac-gen/additives.htm
- *Package Inserts* web section (IAC) www.immunize.org/fda
- *Adjuvants and Ingredients* web section (IAC) www.immunize.org/talking-about-vaccines/adjuvants.asp



20

References (cont.)

- *Vaccine Safety and Your Child* (VEC) <http://media.chop.edu/data/files/pdfs/vaccine-education-center-vaccine-safety-eng.pdf>
- *Aluminum in Vaccines: What you should know* (VEC) www.chop.edu/export/download/pdfs/articles/vaccine-education-center/aluminum.pdf



21

Wasn't there a study that proved MMR vaccine causes autism?

- Many large, well-designed studies have found no link between MMR and autism.
- Autism usually becomes apparent around the same age MMR is given—no causality proven.
- Autism probably has multiple components, including genetics (twin studies).



22

Wasn't there a study that proved MMR vaccine causes autism? (cont.)

- 1998 study by Andrew Wakefield that started this concern was based on 12 children who were preselected for study.
- In 2004, 10 of the 13 authors retracted the study's interpretation.
- On 2/2/10, the editors of *The Lancet* retracted the paper following the ruling of the U.K.'s General Medical Council that stated the primary author's conduct regarding his research was "dishonest" and "irresponsible" and that he had shown a "callous disregard" for the suffering of children involved in his studies.
- In January 2011, the *BMJ* published a series of articles showing Wakefield's work was not just bad science, but deliberate fraud.



23

References

- *MMR Vaccine Does Not Cause Autism. Examine the evidence!* (IAC) www.immunize.org/catg.d/p4026.pdf
- *Clear Answers & Smart Advice about Your Baby's Shots* by Ari Brown, MD, FAAP www.immunize.org/catg.d/p2068.pdf
- *Measles, Mumps, and Rubella (MMR) Vaccine Safety* (CDC) www.cdc.gov/vaccinesafety/Vaccines/MMR/index.html
- *The Fraud Behind the MMR Scare* (web section) www.immunize.org/bmj-deer-mmr-wakefield



24

References (cont.)

- *Vaccine Safety and Your Child (VEC)*
<http://media.chop.edu/data/files/pdfs/vaccine-education-center-vaccine-safety-eng.pdf>
- *MMR Vaccine and Autism (IOM)*
www.nap.edu/catalog.php?record_id=10101
- *Vaccines and Autism: What you should know (VEC)*
www.chop.edu/export/download/pdfs/articles/vaccine-education-center/autism.pdf
- "Vaccines and Autism: A Tale of Shifting Hypotheses" by Paul Offit, MD and Jeffery Gerber, MD
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2908388/>



25

References (cont.)

- *Fitness to Practice Panel Hearing* (report from the U.K.'s General Medical Council regarding Dr. Andrew Wakefield)
www.neurodiversity.com/wakefield_gmc_ruling.pdf
- *The Lancet* retraction
[www.thelancet.com/journals/lancet/article/PIIS0140-6736\(97\)11096-0/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(97)11096-0/abstract)



26

Wouldn't it be safer to receive MMR as three separate shots?

- There is no evidence that MMR vaccine causes autism.
- There is no evidence that dividing the vaccine into three antigens would provide any benefit.
- Requiring more doses would leave the child potentially susceptible to serious diseases while waiting to receive the additional doses.
- Separate doses would increase the number of doctor visits, costs, and discomfort to child.
- Moot point now: the manufacturer has stopped producing single antigen measles, mumps, and rubella vaccines.



27

Reference

- Q&As about Monovalent M-M-R Vaccines
www.cdc.gov/vaccines/hcp/clinical-resources/mmr-faq-12-17-08.html

See also the references in the previous section.



28

Isn't it true that most people who get a disease have been vaccinated against it?

- This occurs because:
 - almost everyone is vaccinated, *but*
 - no vaccine is 100% effective.
- In an outbreak:
 - The **NUMBER** of vaccinated people who get a disease will be greater than the number of unvaccinated people simply because the number of unvaccinated people is so small.
 - However, the **PERCENTAGE** of vaccinated people getting the disease will be tiny, whereas the **percentage of unvaccinated people getting the disease will be close to 100%**.
- Most childhood vaccines are very effective (~80–100%, depending on the vaccine) when properly administered and all doses are received according to the recommended schedule.



29

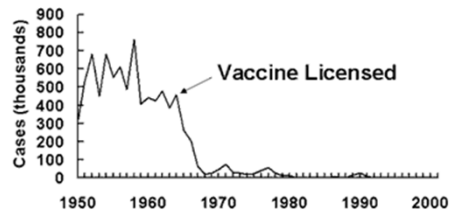
Isn't better sanitation really the reason disease rates have dropped?

- It's true that better living conditions (less crowded housing, better nutrition, etc.) have had an impact on disease rates. BUT, the **only real decrease in a vaccine-preventable disease (VPD) has occurred after the introduction of a vaccine to prevent it.**
- This also is true for newer vaccines like Hib (1987) and varicella (1995), which were introduced during times of modern hygiene.
- When developed countries (U.K., Sweden, Japan) stopped using DTP vaccine, their pertussis rates jumped dramatically.
- Several recent outbreaks of measles, pertussis, and varicella in the U.S. have been traced to pockets of unvaccinated children in states that allow personal belief exemptions. When vaccination rates go down, disease rates go up.



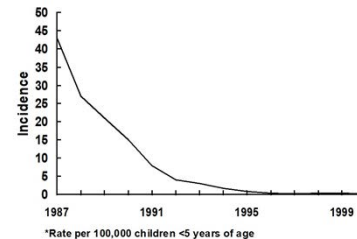
30

Measles – United States, 1950–2001



31

Estimated Incidence* of Invasive Hib Disease, 1987–2000



*Rate per 100,000 children <5 years of age

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References

- What Would Happen If We Stopped Vaccinations? (CDC)
www.cdc.gov/vaccines/vac-gen/whatifstop.htm
- *Personal belief exemptions for vaccination put people at risk. Examine the evidence for yourself.* (IAC) www.immunize.org/catg.d/p2069.pdf
- *Top 20 Questions about Vaccination* (History of Vaccines) www.historyofvaccines.org/content/articles/top-20-questions-about-vaccination
- Vaccines Work (HHS)
www.vaccines.gov/basics/work/index.html

33

Doesn't VAERS data prove that vaccines are dangerous?

VAERS data cannot "prove" anything:

- Anyone can report anything...no proof of causality is required.
- Only reports of special interest (e.g., hospitalizations) are verified. When checked, many reports are not accurate.
- Reports include many non-serious reactions.
- The number of reported adverse events is influenced by publicity.
- VAERS is properly used to detect early warning signals and generate hypotheses.

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References

- Vaccine Safety Monitoring web page (CDC)
www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/index.html
- Ensuring Vaccine Safety (CDC)
www.cdc.gov/vaccinesafety/ensuringsafety/index.html
- Causality assessment of adverse events following immunization (WHO)
www.who.int/vaccine_safety/causality/en
- Understanding the Vaccine Adverse Event Reporting System (VAERS) (CDC)
www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-vaers-color-office.pdf
- Vaccine Adverse Events Reporting System
<https://vaers.hhs.gov>

35

Hasn't it been proven that there are dangerous "hot lots" of vaccines?

- The Food and Drug Administration regulates the production of vaccines carefully.
- The concept of "hot lots" is based on the presumption that more reports to VAERS mean that a vaccine lot is more dangerous.
 - Reports to VAERS prove nothing about causality.
 - Because the size of vaccine lots varies widely (a lot may vary from several hundred thousand to several million doses), it's not unexpected that some lots would generate more reports (i.e., the larger lots).

36

Isn't natural infection better than immunization?

- Infection usually *does* cause better immunity than vaccination.
- *However*, the price paid for natural disease can include:
 - paralysis
 - permanent brain damage
 - liver cirrhosis/cancer
 - deafness
 - blindness
 - pneumonia
 - death



37

References

- *Natural Infection vs. Immunization* by Paul Offit, MD
www.chop.edu/centers-programs/vaccine-education-center/vaccine-safety/immune-system-and-health
- Photos of people with vaccine-preventable diseases
www.immunize.org/photos
- *Unprotected People Stories*: Real-life accounts of people who have suffered or died from vaccine-preventable diseases
www.immunize.org/reports
- *How Do Vaccines Fit into a Natural Lifestyle?* (Boost Oregon)
www.boostoregon.org/how-do-vaccines-fit-into-a-natural-lifestyle



38

Didn't the courts decide that vaccines cause autism?

- The Vaccine Injury Compensation Program awarded *ONE* family a monetary settlement for a very specific situation.
- The child, Hannah Poling, was born with a rare genetic disorder (mitochondrial disorder). The health of individuals with mitochondrial disorder can deteriorate after many types of stresses, including contracting a vaccine-preventable disease.
- In this case, the government concluded that vaccines aggravated a rare underlying metabolic condition in one child, *not* that vaccines cause autism in general, or even that vaccines are contraindicated for all children with mitochondrial disorder.



39

References

- *Clear Answers & Smart Advice About Your Baby's Shots* by Ari Brown, MD, FAAP
www.immunize.org/catg.d/p2068.pdf
- *Mitochondrial Disease: Frequently Asked Questions* (CDC)
www.cdc.gov/ncbddd/autism/mitochondrial-faq.html



40

Don't drug companies make big profits from pushing vaccines?

- Vaccines are not high-profit products. Vaccine sales are dwarfed by prescription sales.
- Costs for research, development, and compliance with standards are high, with no guarantee that a vaccine will be licensed.
- If vaccines were highly profitable, why would only a few companies produce almost all of the U.S. childhood vaccines today, when there used to be 25 companies producing vaccines?
- Vaccine manufacturing is a public service.



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References

- *The Vaccine Enterprise* (Health Affairs, May 2005, Supplement)
www.healthaffairs.org/doi/10.1377/hlthaff.24.3.596
- *The myth of Big Pharma Vaccine Profits— it's not what they say it is* (The Skeptical Raptor's Blog)
<https://www.skepticalraptor.com/skepticalraptorblog.php/the-myth-of-big-pharma-vaccine-profits-updated/>
- *Drug versus vaccine investment: a modelled comparison of economic incentives*
www.ncbi.nlm.nih.gov/pmc/articles/PMC3846654
- *Aren't Vaccines Just Money-makers for Pharmaceutical Companies?* (Boost Oregon)
www.boostoregon.org/arent-vaccines-just-money-makers-for-pharmaceutical-companies



42

Aren't abortions required to make vaccines?

- It's true that production of varicella, rubella, rabies, and hepatitis A vaccines involves growing the viruses in human cell culture.
- Two human cell lines provide these cultures; they were developed from two legally aborted fetuses in the 1960s.
- The donor fetuses were not aborted for the purpose of obtaining these cells.
- The same cell lines have been used for 40 years—no new fetal tissue is required.



43

References

- Web page about religious concerns (IAC)
www.immunize.org/talking-about-vaccines/religious-concerns.asp
- *Why Were Fetal Cells Used to Make Certain Vaccines?*
www.chop.edu/news/news-views-why-were-fetal-cells-used-make-certain-vaccines?utm_term=new+views&utm_content=vaccine+hesitancy&utm_campaign=vecupdatesApr2017



44

Isn't it my right not to vaccinate my child?

- Vaccination laws have been found to be constitutional in U.S. courts. Seminal case was *Jacobson v. Massachusetts* in 1905.
- All states offer medical exemptions.
- Parents need to be aware that if they don't vaccinate their children, they are putting them, and their contacts, at risk of serious disease.
- Unvaccinated children often have to stay home from school or daycare during outbreaks.



45

References

- *What If You Don't Vaccinate Your Child?* (IAC)
www.immunize.org/catg.d/p4017.pdf
- *Decision to Not Vaccinate My Child* (declination form) (IAC)
www.immunize.org/catg.d/p4059.pdf
- *Personal belief exemptions for vaccination put people at risk. Examine the evidence for yourself.* (IAC)
www.immunize.org/catg.d/p2069.pdf
- Sample Vaccine Policy Statement (IAC)
www.immunize.org/catg.d/p2067.pdf
- Mandates and Exemptions web page (IAC)
www.immunize.org/laws



46

Good Resources for *Providers*

- Vaccine web section for health professionals (CDC)
www.cdc.gov/vaccines/hcp
- *Provider Resources for Vaccine Conversations with Parents* (CDC) www.cdc.gov/vaccines/conversations
- *Talking about Vaccines* web section (IAC)
www.immunize.org/talking-about-vaccines
- *Responding to Parents* web section (IAC)
www.immunize.org/talking-about-vaccines/responding-to-parents.asp
- Vaccine Education Center website
www.chop.edu/centers-programs/vaccine-education-center




47

Good Resources for *Providers*

- *Talking with Parents about Vaccines for Infants* (CDC)
www.cdc.gov/vaccines/hcp/conversations/downloads/talk-infants-508.pdf
- *Preparing for Vaccine Questions Parents May Ask* (CDC)
www.cdc.gov/vaccines/hcp/conversations/downloads/prepare-infants-508.pdf
- AAP's immunization website www.aap.org/immunization
- *Making the CASE for Vaccines: A new model for talking to parents about vaccines*
www.albany.edu/sph/cphce/phihandouts/12_9_10.pdf
- Addressing Vaccine Hesitant Parents: Role-playing Videos for Healthcare Providers
<http://whyimmunizekids.org/role-playing-video-clips>




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Good Resources for *Parents*

- Parent immunization education handouts (IAC)
www.immunize.org/handouts/discussing-vaccines-parents.asp
- Vaccine- and Vaccine Safety-Related Q&A Sheets (VEC) www.chop.edu/centers-programs/vaccine-education-center/resources/vaccine-and-vaccine-safety-related-qa-sheets#.V5kYd63Xkqp
- IAC's website for the public www.vaccineinformation.org
- Parents Guide to Childhood Immunization (CDC)
www.cdc.gov/vaccines/pubs/parents-guide
- Provider Resources for Vaccine Conversations with Parents (CDC)
www.cdc.gov/vaccines/conversations




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Good Resources for *Parents*

- Immunization website for parents (CDC)
www.cdc.gov/vaccines/parents/index.html
- Infant Immunizations FAQs (CDC)
www.cdc.gov/vaccines/parents/parent-questions.html
- Vaccinate Your Family's website:
www.vaccinateyourfamily.org
- *Parents' Guide to Children's Vaccines* (Boost Oregon)
www.boostoregon.org/parents-guide-to-childrens-vaccines
- Website for parents (AAP)
www.healthychildren.org
- Videos for parents
www.vaccineinformation.org/videos/index.asp




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Finally...

Don't worry about every possible question

- Be able to recommend good websites and handouts for patients/parents.
- Be aware of major vaccine-critical groups and individuals and become familiar with their websites.
- Be ready to answer the most common questions—many concerns haven't changed in over 200 years!
- Remember, it's acceptable to say you'll look into a particular question and get back with more information.
- It's worth your time—studies show that people respect the opinion of their healthcare providers.



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