American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

California Chapter 3 - San Diego and Imperial Counties

Parent Handouts for Physicians to distribute

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.aap.org/immunization/families/deciding.html, including:

- "Why immunize?" www.aap.org/immunization/families/whyimmunize.html
- "Are Vaccines Safe?" www.aap.org/immunization/families/safety.html
- "Evaluating Web Information" www.aap.org/immunization/families/evaluatingwebinfo.html
- "Misconceptions and Frequently Asked Questions" www.aap.org/immunization/families/faq.html
- When parents cannot be convinced, consider using AAP's Refusal to Vaccinate form at www.aap.org/immunization/pediatricians/pdf/RefusaltoVaccinate.pdf.

California Immunization Coalition

The California Immunization Coalition (CIC) has developed several excellent provider pieces that discuss common questions many parents may have regarding vaccines for their children. These include

- "Responding to Parents' Top 10 Concerns" http://immunizeca.org/documents/IMM-917_web.pdf
- "Talking with Parents About Vaccine Safety" http://immunizeca.org/documents/IMM-915_web.pdf
- "Alternate Vaccine Schedules: Helping Parents Separate Fact From Fear" http://immunizeca.org/documents/IMM-988.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.

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/spec-grps/hcp/conv-materials.htm#understand
- "Parents who question vaccines" www.cdc.gov/vaccines/spec-grps/parents.htm#question
- "Common questions parents ask about infant immunizations" www.cdc.gov/vaccines/spec-grps/infants/parent-questions.htm
- "Talking with parents about vaccines for infants" www.cdc.gov/vaccines/spec-grps/hcp/conv-materials.htm#talkpvi

Every Child by Two (ECBT)

Created by Every Child by Two, www.vaccinateyourbaby.org focuses on answering parents' commonly asked questions about vaccines. It features video clips and links to current vaccine news stories.

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

- "Clear Answers & 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
- "Reliable Sources of Immunization Information: Where to 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.

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

- Tear sheets—offered in tear-off pads of 50, intended for physicians to hand out to patients. Useful titles for hesitant parents include "Aluminum in Vaccines," "The Facts About Childhood Vaccines," "Thimerosal," "Too Many Vaccines?," "Vaccine Ingredients," and "Vaccines and Autism."
- Videos—"Vaccines: Separating Fact from Fear" and "Vaccines and Your Baby" come in DVD format.

Materials can be viewed or printed at http://vaccine.chop.edu/resources. Tear-off pads and DVDs, as well as other VEC materials, can be ordered at nominal cost.

For parents with concerns about vaccines and autism

AAP has issued a statement that can be printed at www.aap.org/advocacy/releases/autismparentfacts.htm. Parents may wish to investigate further at www.aap.org/healthtopics/Autism.cfm. 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 well-researched handouts from IAC:

- "MMR Vaccine Does Not Cause Autism: Examine the Evidence!" www.immunize.org/catg.d/p4026.pdf
- "Evidence shows vaccines unrelated to autism" www.immunize.org/catg.d/p4028.pdf

Technical content reviewed by the Centers for Disease Control and Prevention, May 2011.

www.immunize.org/catg.d/p2070.pdf • Item #P2070 (5/11)

Clear Answers & Smart Advice About Your Baby's Shots

By Ari Brown, MD, FAAP

Dr. Brown received her medical degree from Baylor College of Medicine in Houston, Texas; she did her pediatric residency at Harvard Medical School/Boston Children's Hospital. In private practice since 1995, Dr. Brown is perhaps best known as the coauthor of the 411 parenting book series — ***Expecting 411: Clear Answers and Smart Advice for Your Pregnancy, Baby 411,*** **and** ***Toddler 411*** (Windsor Peak Press).

In response to the recent media attention given to vaccines, autism, and other controversies concerning vaccines, the Immunization Action Coalition (IAC) has reprinted a special excerpt from *Baby 411* that answers these questions and more. IAC thanks Dr. Brown for this clearly written information, but mostly, we are grateful for her continued advocacy for safe and effective vaccines.

Vaccines. Autism. Controversy. As a new parent (or parent-to-be), it's hard not to hear the great debate in parenting circles these days—do vaccines cause autism? If not, what causes autism and why is it on the rise?

Let's start at the beginning—just what is autism?

Q: What is autism?

Autism Spectrum Disorder (ASD) is really a collection of several disorders that have three abnormal areas in common: social skills, communication skills, and repetitive or obsessive traits. Specialists use the terms ASD and Pervasive Developmental Disorders (PDD) interchangeably. To add even more confusion, Pervasive Developmental Disorder, not otherwise specified (PDD-NOS), and Asperger's Syndrome also are other categories that fall under the ASD umbrella.

There is a very broad range of severity within ASD. A child may have normal intelligence and language, but be socially awkward and have panic attacks if his sandwich is cut in triangles instead of squares. Or a child may appear out of touch with reality and spend his entire day rocking and flapping his hands. Both children have ASD. As you might suspect, children with severe problems as in classic autism are diagnosed much earlier than kids who can communicate but have trouble with social skills, as in Asperger's Syndrome.

Children are usually diagnosed by 18-24 months of age when language delays are obvious. Many children with Asperger's Syndrome may not be diagnosed until preschool (or sometimes even later).

However, clues to the diagnosis appear long before that time. Some early clues include: not smiling back at people, poor eye contact, not imitating, not gesturing (waving bye-bye), not responding to being called by name, and not trying to communicate/connect/engage with other people by 1 year of age.

There also are some unusual behaviors. Cuddling may not be soothing. In fact, an autistic child may get very upset by being touched. Bright lights and noises often bother them. Because they are bugged by the outside world, they may turn inward and find comfort in repetitive behaviors (rocking, head banging, spinning). Autistic children may have little interest in playing with toys. Or they may play in an odd way— such as using a phone as a comfort object.

Bottom line: Children with autism have autism long before their first birthdays, even though their "official" diagnosis usually occurs in their second year of life.

Q: I have a friend whose child has autism. She said he was "perfectly normal" until he was about 18 months old. Does this happen?

A small minority of ASD children have completely normal milestones and then regress, which is known as "late onset autism." These children most likely have a distinct genetic abnormality that turns on or off without any trigger.

However, for most kids with ASD, parents and doctors just miss (or dismiss) the early signs in the first year of life and the child's atypical development only becomes apparent at 18 months.

Doctors rely heavily on parents to point out concerns. And parents (especially first-timers) don't know what is normal and what isn't.

The mother of one of my ASD patients told me that she only realized how unusual her son's development was after she watched her second child, without ASD, breeze through her milestones. Even the most vocal ASD mom of all, Jenny McCarthy, agrees. Her son was 5 months old when he first smiled at her (that's abnormal), when all of her friends' babies smiled at 2 months of age (that's normal).

Some parents report that their ASD child spoke a few words and then "lost" the ability to say them. If you delve a bit deeper, the child may have randomly said a few things, but was not consistently using words like "juice" or "no" to communicate his needs.

There is growing research in language development that looks at brain anatomy. Primitive brain parts control early language development from birth to 18 months. At 18 to 24 months, the mature brain parts turn on and language takes off. With autistic children, mature language does not take off. But from a parent's perspective, it may look like a loss of skills.

And again, children with subtle atypical behaviors may be harder to diagnose early on. Reviewing home movies of a child once the diagnosis is made often shows that early signs are overlooked.[1]

Q: OK, so what causes autism?

The million-dollar question.

In the 1980s, one in 10,000 kids was diagnosed with autism. Today, one in 150 American 8-year-olds has some form of autism. Boys outnumber girls four to one. The United States is not the only country seeing this trend. It is increasingly diagnosed worldwide.

For starters, is it really an epidemic? Or, are more people being diagnosed? Many children who were diagnosed with mental retardation 30 years ago are children who are diagnosed with classic autism today. And mildly disabled ASD kids today are children who *never* would have had a diagnosis 30 years ago. Those verbal, but socially awkward, children account for the majority of new ASD cases.

Here are the hottest areas of autism research today:

- **Genetics:** There is no question genetics plays a role. Autism runs in families. I have a family in my practice and all four children have a diagnosis on the autism spectrum.

  Studying twins is an obvious way to detect genetic disorders. If one identical twin has autism, up to 90 percent of the time, so will the other twin. To date, studies suggest there is more than just one "autism gene"; there appear to be several.

  ASD children have several different abnormalities with their DNA. However the X chromosome is one of interest because of the high prevalence of boys with ASDs.[2]

  Fragile X Syndrome, which is a known genetic cause of autism, also points to a defective X chromosome in ASD.

  And Rett Syndrome, which is a disorder causing developmental regression and autistic behaviors in girls, is caused by a defective MECP2 gene located on the X chromosome.[3]

  We also know that kids with autism and defects on Chromosome 11 have dysfunctional "neurexin 1 protein." Researchers are looking into how this defective protein affects fetal and infant brain growth.

  Finding these specific genetic defects may help in genetic counseling, as well as therapies, in the future. Animal studies already are underway for targeted genetic therapy in both Fragile X and Rett Syndrome.

- **Abnormal brain growth:** ASD children have problems with brain growth. Babies are born with immature brains that grow rapidly and make nerve connections called synapses ... like an information superhighway. In the normally growing brain, some branches of this superhighway get "pruned." In the autistic brain, this pruning process seems to be defective. This may explain why babies who are autistic have abnormally rapid head growth under 1 year of age. No one has yet figured out what causes that defective nerve growth. Of note, boys with ASD have higher levels of hormones (insulin-like growth factor) that may contribute to their larger head size, weight, and body mass index.[4]

- **Environmental triggers:** Is there some environmental exposure that sets off abnormal brain development in a genetically predisposed baby? Maybe. And that exposure may happen at or shortly after conception, before a mother even knows she is pregnant. The embryo has a critical period of brain development at 20–24 days after conception. That is when the developing brain is most sensitive to injury. Studies done by the Environmental Working Group have detected over 280 environmental toxins in umbilical cord blood, so clearly pregnant moms are exposed to a variety of toxins. Could one of these be the autism trigger? We don't know.

  Viral infections during pregnancy also may be a key environmental trigger that causes abnormal genes in the fetus. Those infections include rubella, CMV (cytomegalovirus), and influenza (yes, "the flu").[5]

  What about vaccines as an environmental trigger? Researchers and scientists have taken a long, hard look at vaccines—and there is conclusive evidence that vaccine exposure is NOT the turn-on switch for autism.[6]

  Bottom line: There's evidence that newborns who are later diagnosed with ASD already have abnormal levels of certain proteins in their brains. So, whatever the trigger is (if there is one), it has been fired before the baby even enters the world.

- **Prematurity:** A developing brain is quite vulnerable. Premature, very low birth-weight babies (under three pounds) have a 25 percent chance of developing an autism spectrum disorder.[7]

- **Older parents:** Another possible reason for the increase of autism: the trend of parents having babies at a later age. Moms who conceive after the age of 40 have a 30 percent increased risk of having a child with autism. Dads who conceive after the age of 40 have a 50 percent increased risk of having an autistic child.[8] Scientists speculate that an older dad's sperm may have defective genetic material, possibly altered by environmental toxins.

- **Closely spaced pregnancies:** A 2011 study compared children who were conceived at least three years after their sibling was born to closer-spaced pregnancies and found that babies conceived less than 12 months after the birth of the first-born child were THREE times more likely to be diagnosed with autism spectrum disorder. Babies conceived from 12 to 23 months after the birth of the first-born child had almost two times the risk of ASD. And, even babies conceived 23 to 35 months after the first-born child had a slightly greater risk of ASD.

  Unfortunately, the researchers have no idea why the odds are greater when the spacing between pregnancies is shorter. Perhaps it's because a woman's nutritional stores have not had enough time to be replenished. Or maybe women who have put off parenthood until later in life have more closely spaced babies—and parental age itself is a risk factor for having a child with an ASD.

  This study alone should not necessarily influence your decision on how long to wait between pregnancies. However, the current recommendation from the Centers for Disease Control and Prevention is to wait at least 18 to 23 months between pregnancies for a mother's and baby's optimal health.[9]

Bottom line: Researchers don't know what causes autism, although the above factors provide clues. The goal is to find a way to prevent autism … but we aren't there yet.

Vaccines

Q: Why do you care whether I vaccinate my child or not?

For starters, we want your baby to be protected.

But we also want you to realize that the decision to vaccinate your child impacts the health of other children in the community. Choosing NOT to vaccinate your child is choosing to put your child AND your community's children at risk. As a parent, you want to make the right choices to protect your child. I want you to ask questions. I want you to be informed. And I want you to get your child vaccinated. YOUR decision impacts ALL children. Why?

There are two critical points for vaccination to work:

1. You need to be vaccinated.
2. Your neighbor needs to be vaccinated.

This concept is called herd immunity. And yes, you are a member of a herd. When 90 to 95 percent of "the herd" is protected, it is nearly impossible for a germ to cause an epidemic. Think of germs as rain. Vaccination is a raincoat. Even with a raincoat on, you can still get wet. You need an umbrella, too. The umbrella is "herd immunity." Those who don't vaccinate expect someone to share their umbrella when it rains. But society can only buy umbrellas TOGETHER. And raincoats aren't made for newborns—they need umbrellas!

Some parenting decisions have little or no impact on the community at large. Deciding whether or not your child eats organic baby food, goes to preschool, or sleeps in a family bed is entirely up to you—your decision only affects your child.

However, your decision whether or not to vaccinate your child affects all our kids. If you are a parent who is considering delaying or skipping vaccinations altogether, please realize the impact of your decision.

If more than 10 percent of American parents choose to "opt out" of vaccines, there's no question that our entire country will see these horrible diseases of bygone days return. Fortunately, very few parents decide to do this. What is most concerning today is that there are pockets of under-vaccinated children. Birds of a feather flock together. Like-minded parents who don't vaccinate their kids tend to live in the same community and send their kids to the same schools. With lower immunization rates, there is no herd immunity. We have these "Ground Zero" areas to thank for recent measles and whooping cough outbreaks of 2008 and 2011.[10]

Q: I've heard that the MMR vaccine might cause autism. Is this true?

No. Parents also hear that vaccinations cause multiple sclerosis, diabetes, asthma, and Sudden Infant Death Syndrome (SIDS). None of these are caused by vaccination. The government operates a safety monitoring system (Vaccine Adverse Event Reporting System, Food and Drug Administration, CDC) watching for any possible adverse effects from vaccines. No one wants to increase autism rates.

One small case report of only eight patients in 1998 led a research group to feel that the combination measles, mumps, and rubella (MMR) vaccine might cause autism.[11] But, don't try to find the article online because the journal that published it later retracted it when a former member of the research lab revealed that the data reported in the study was fabricated![12] Twelve years later, the lead author lost his license to practice medicine in England and was accused of fraud. The whole thing was a hoax.

Before this came to light, several reputable scientists tried to duplicate the findings of this now discredited researcher. No one ever could—and now we know why!

Unfortunately, frightened parents chose to skip the MMR vaccine and measles epidemics occurred in the United Kingdom and the United States as a result of these unfounded claims.

Bottom line: Don't base health decisions for your child on one research study or what the media says! Talk to your child's doctor about any vaccine safety concerns.

Q: If the MMR vaccine doesn't cause autism, why is the diagnosis made around the same time as the vaccination?

One of the criteria used to make a diagnosis of autism is a language delay. Because children do not have significant expressive language under a year of age, doctors have to wait until 15 to 18 months to confirm a language delay and make the diagnosis. That's about the same time as the MMR vaccination, which leads some parents to wonder about autism and vaccination.

Q: I've heard mercury preservative is in vaccines. Is this true?

Only a few remain. Preservatives and stabilizers are used in vaccines so the vaccinations remain potent and uncontaminated. A popular preservative used to be a chemical called thimerosal, which contained trace amounts of ethylmercury. Thimerosal use began in the 1940s.

Thimerosal was removed from all vaccines given to infants younger than age 6 months by 2001. This deserves repeating: YOUR young baby will not be getting vaccines that contain mercury (thimerosal) as a preservative. The one exception is the influenza vaccine that is found in multi-dose vials that need a preservative to prevent contamination. Influenza vaccine that is packaged in single dose vials does not need a preservative and many clinics choose to use these individual vials with the youngest patients. Remember, it's very important that children get vaccinated against influenza each fall or winter beginning when they are 6 months old.

Despite the fact that most vaccines are mercury preservative-free now, speculation persists about vaccines previously containing mercury and links to autism. This speculation continues even after the Institute of Medicine (IOM) published a conclusive report in 2004 negating any association between vaccines and autism. (The IOM spent four years studying both the mercury question and the MMR combo vaccine question and published a series of eight reports on the subject.)

A quick chemistry lesson: Certain compounds have completely

different properties even though they may be related. For instance, take the alcohol family. Methanol is anti-freeze; ethanol is a Bud Light. Keep this in mind when we discuss mercury. We are all exposed to small amounts of mercury. The type of mercury that has raised health concerns is called methylmercury. High concentrations of methylmercury can be found in tuna, swordfish and shark from contaminated waters. The information known about mercury poisoning comes from unfortunate communities that have experienced it. Example: There is a large amount of data from the Faroe Islands, near Iceland. The people there would eat whale blubber contaminated with toxic levels of methylmercury and polychlorinated biphenyls (PCBs). Children, especially those exposed as fetuses during their mother's pregnancy, seemed to have lower scores on memory, attention, and language tests than their unexposed peers. (They were not diagnosed with autism or Attention Deficit Disorder, however.)[13]

Chronic exposure to liquid methylmercury causes Mad Hatter's Disease, named for hat makers who used liquid mercury in the hat-making process. The disease consists of psychiatric problems, insomnia, poor memory, sweating, tremors, and red palms. Chronic mercury poisoning also impairs kidney function.

Methylmercury is a small molecule that can get into the brain—it takes almost two months to break down in the body. Ethylmercury (the type of mercury that was previously used as a vaccine preservative) is a large molecule that cannot enter the brain and is rapidly eliminated from the body within a week.

Because of the increased number of vaccinations that children get, the potential cumulative exposure to mercury became a concern in 1999.

There are three federal groups that set standards for acceptable daily mercury exposure (the Environmental Protection Agency [EPA], the Food and Drug Administration [FDA], and the Agency for Toxic Substances and Disease Registry). When the exposure was calculated, the cumulative dose was higher than acceptable levels set by the EPA only (the other groups' standards were higher). As a result of these findings, the Public Health Service (which includes the FDA) and the American Academy of Pediatrics issued a joint statement as a precautionary measure, urging vaccine manufacturers to reduce or eliminate thimerosal in vaccines as soon as possible.[14] This was issued in 1999 before scientists had an opportunity to study the potential health effects of thimerosal-containing vaccines. Numerous studies have since shown that there is no relationship between vaccines, either with or without thimerosal, and the development of autism or other neurologic problems in children.

Q: I heard that I should still ask my doctor if the vaccines for my baby are thimerosal-free. What do you suggest?

We think you should ask as many questions as you need to feel comfortable. Remember that since 2001, most childhood vaccines given to infants and children went thimerosal (mercury) preservative-free. If your doctor has a 2001 vintage vaccine vial sitting on the shelf (which would be expired by now), he needs to re-stock. To give you some perspective, my practice buys its vaccine supply on a monthly basis.

Why does flu vaccine need thimerosal or any other preservative?

First, understand the flu vaccine is reformulated every year to reflect the anticipated flu strains. Since millions of doses of flu vaccine are needed every year, the most efficient way to produce the shot is in multi-dose vials, which require a preservative.

Hence, some flu shots (not the flu nasal spray) contain the preservative thimerosal. However, there are single-dose preparations of flu vaccine that are mercury preservative-free. These can be given to young children and pregnant women. Ask your doctor for a thimerosal-free flu vaccine if you are concerned.

Even though thimerosal is safe, it would be ideal for all flu vaccines to be thimerosal preservative-free—this would put any concerns to rest. However, the technology just isn't there yet.

The Institute for Vaccine Safety at Johns Hopkins University has a chart online that tracks any thimerosal content in vaccines: www.vaccinesafety.edu/thi-table.htm.

FYI: Many vaccines such as the combination measles, mumps, and rubella vaccine never used thimerosal in the production process or as a preservative.

Reality Check: Worried about the mercury preservative (thimerosal) in your child's flu vaccine? Consider this: A tuna fish sandwich has five times more mercury than a thimerosal-preserved flu vaccine.[15] And the type of mercury (methylmercury) found in tuna is the one that has health concerns. Also, a baby who is exclusively breastfed for six months of life consumes about 0.36 mg of methylmercury from breast milk. That's 15 times the quantity of ethylmercury in one flu vaccine!

Bottom line: As a doc, I am much more concerned about your baby's mercury exposure from the environment than what's in a flu shot. Here's a look at the numbers:

Product	Amount of Mercury	Type of Mercury
Tuna, 5.6 oz can	0.115 mg	Methyl
Breast milk, 1 liter	0.015 mg	Methyl
Flu vaccine with thimerosal	0.025 mg	Ethyl

Q: Does thimerosal cause autism?

No. The Institute of Medicine reached this conclusion in 2004. What proof do we have?

Thimerosal has been removed from most vaccines since 2001, but the rates of autism are still skyrocketing. A 2008 survey of autism rates in California confirms that mercury is essentially out and autism rates are still going up. If thimerosal was the cause and it was removed from vaccines seven years ago, autism rates would be going down by now. Why? Because autism spectrum disorders are usually diagnosed by 3 years of age. By now, any reduction in autism should have been obvious if thimerosal caused the disorder.[16]

- Mercury preservatives were removed from vaccines in Denmark in 1992. Canada and the European Union followed suit shortly thereafter. However, their autism rates are going up too.
- Mad Hatter's Disease (mercury poisoning) and autism are very different disorders (see chart in next column).
- A study of 100,000 kids in England compared those receiving thimerosal-containing vaccines to those who did not. The ones

who had the t-free shots had HIGHER rates of autism.[17]

- A 2007 study showed that children between 7 and 10 years of age who got those mercury-containing vaccines (before 2001) have no significant differences in tests of attention and processing information. Although the study did not look specifically at autism, it showed that mercury preservatives did not make much of an impact on brain functions in general. A follow-up study that specifically addresses autism is underway.[18]

Did thimerosal cause autism? Notice the differences between autism and mercury poisoning:

	Autism	**Mercury Poisoning**[19]
Motor	Repetitive movements	Wobbly, shaky gait
Vision	Normal	Impaired
Speech	Delay, repetitive sounds	Articulation problem
Sensory	Hyper-responsive	Loss of sensation
Psychiatric	Aloof, likes sameness	Psychosis, depression
Head size	Large	Small

Q: Are there other additives in the vaccines?

Yes. And you should know about them.

Vaccines contain the active ingredients that provide immunity. But there are inactive ingredients that improve potency and prevent contamination. Below is a list of additives and why they are there. These products are present in trace amounts and none have been proven harmful in animals or humans.[20]

- **Preservatives:** Prevent vaccine contamination with germs (bacteria, fungus). Examples: 2-phenoxyethanol, phenol, and thimerosal (prior to 2001).
- **Adjuvants**: Improve potency/immune response. Example: aluminum salts.
- **Additives:** Prevent vaccine deterioration and sticking to the side of the vial. Examples: gelatin, albumin, sucrose, lactose, MSG, glycine.
- **Residuals:** Remains of vaccine production process. Examples: formaldehyde, antibiotics (Neomycin), egg protein, yeast protein.

See our website (www.Baby411.com, click on "Bonus Material") for a list of ingredients for the routine childhood vaccination series.

Q: Why is aluminum in vaccines?

Now that the mercury (thimerosal) saga is coming to an end, anti-vaccine crusaders have come up with a new bad guy: aluminum. Yes, trace amounts of aluminum salts are used in some childhood vaccines. Here's all you need to know (and more) about aluminum.

Bottom line: We are not worried about it.

Aluminum is everywhere. It's the most common metal in our earth's crust. So it is naturally present in our water, soil, and even in the air. Fruits, vegetables, nuts, flour, cereal, dairy products, and yes, even baby formula and breast milk … all contain some aluminum. Do you wear antiperspirant? It's in there, too. To avoid aluminum exposure, you'd have to quit wearing antiperspirant … and basically leave the planet.

Why is aluminum used in vaccines? Aluminum enhances the immune system's response to the vaccine. It's been used safely for several decades. By using aluminum salts, some inactivated vaccines require fewer booster shots for the body to mount an adequate immune response.

Are there any health concerns with aluminum in vaccines? No. There is significantly less aluminum in vaccines than what babies are exposed to in the environment. Both the National Vaccine Program Office and the World Health Organization have determined that the aluminum content in the childhood vaccination series is safe.

Does aluminum poisoning cause autism? No. People with aluminum poisoning have bone problems (osteomalacia) and anemia, as well as neurologic issues. These include memory loss, fatigue, depression, behavioral changes, and learning impairment. Aluminum also has been proposed as the cause of Alzheimer's Disease. To date, however, there is little evidence that aluminum causes that disorder.[21]

How much aluminum is in vaccines? Very little. If your baby follows the standard immunization schedule, he is exposed to about four to six milligrams (mg) of aluminum at six months of life. By comparison, he's also exposed to 10 mg of aluminum if he is breastfed, 40 mg if he is fed cow's milk-based formula, or 120 mg if he is fed soy formula. None of these are very large amounts, by the way. To put things in perspective, there are about 200 mg of aluminum in a standard antacid tablet. In fact, the average adult ingests seven to nine milligrams of aluminum every day. Here's a look at how much aluminum is in breast milk/formula, compared with vaccines:

Amount of aluminum exposure (milligrams per liter)[22]

Product	**Amount of aluminum**
Breast milk	0.01–0.05 mg/L
Cow's milk-based infant formula	0.06–0.15 mg/L
Soy-based infant formula	0.46–0.93 mg/L
Prevnar vaccine	0.125 mg/dose
DTaP vaccine	0.17–0.625 mg/dose
HIB vaccine	0.225 mg/dose
Hep A vaccine	0.225–0.25 mg/dose
Hep B vaccine	0.25–0.5 mg/dose
DTaP/IPV/HIB vaccine	1.5 mg/dose

Is it a good idea to space out vaccinations that contain aluminum salts? No. Since aluminum-containing vaccines do not cause any health risk, separating or spacing out these vaccines has no benefit. In fact, there is a risk to spacing out the vaccines—your baby will go

Reality Check: If vaccines contain ingredients like aluminum or formaldehyde, wouldn't it be better if vaccine makers got rid of these additives? Shouldn't vaccines be "greener"?
This is a red herring argument against vaccines—current vaccines are safe, even with tiny/trace amounts of preservatives or additives like aluminum. And your baby is exposed to many of these ingredients every day … simply by eating or breathing.

unprotected against real vaccine-preventable disease.

Q: Why is formaldehyde in vaccines?

Small amounts of formaldehyde are used to sterilize the vaccine fluid so your child doesn't get something like flesh-eating Strep bacteria when he gets his shots. We know when you think of formaldehyde, you think of that ever-present smell wafting from the anatomy lab in high school. But what you probably don't know is that formaldehyde is also a naturally occurring substance in your body. And if you use baby shampoo, paper towels or mascara, or have carpeting in your home, you've been exposed to formaldehyde. The small amount used in vaccines is not a health concern.[23]

Q: Is it true that anti-freeze is used in vaccines?

No. There is a chemical used in some vaccines (called polyethylene glycol) that is also found in antifreeze, as well as toothpaste, lubricant eye drops, and various skin care creams. Polyethylene glycol is used in the production process to purify vaccines (it is used in one flu vaccine, among others).

Q: Is it safer to delay vaccines or use an alternative vaccination schedule?

Easy answer: No. The CDC publishes a recommended vaccine schedule for American children. Many, many doctors, scientists, and researchers work together with the CDC to decide what is the best timing to give shots. The goal: Protect babies as soon as it is safe and effective to do so. This schedule was not created out of thin air.

Between anti-vaccine activists shouting "too many shots, too soon" and Dr. Bob Sears hawking his book, new parents wonder if it would somehow be safer to wait on shots altogether or stagger them out on "Dr. Bob's schedule."

Here's a nasty little truth about alternative vaccination schedules: They are all fantasy. There is absolutely no research that says delaying certain shots is safer. Dr. Bob is making up "Dr. Bob's Schedule" all by himself. He even admits that. In an interview with iVillage, he commented, "My schedule doesn't have any research behind it. No one has ever studied a big group of kids using my schedule to determine if it's safe or if it has any benefits."

A 2010 study actually did evaluate children whose vaccinations were delayed and found absolutely no difference in their development compared with children who had received their shots on time. I'd much rather follow a schedule that has been extensively researched for both safety and effectiveness by experts in the field of infectious diseases.

What we do know about alternative vaccination schedules is that delaying shots is playing Russian roulette with your child. The simple truth is that you are leaving your child unprotected, at a time when she is the most vulnerable.

We realize that parents who choose to delay or opt out on vaccines are not bad parents. They are scared parents. What we are trying to help you realize is that the fear you should have is for the diseases that vaccines prevent. If you are on the fence about vaccinations, please take the time to research the disease—and talk to your child's doctor.

Q: If I want to do a staggered vaccination schedule, how should I do it?

I suggest setting up a consultation with your own pediatrician to discuss what both of you feel comfortable with doing. Remember, the ultimate goal is to have your child vaccinated in a timely manner.

Q: Didn't the government concede that vaccines caused a child's autism?

During the equivalent of a class action lawsuit against the government (called the "Omnibus Autism Proceedings"), one child, Hannah Poling, received a monetary settlement. The court did not hear her case. Hannah's case was being reviewed to serve as one of the test cases for a suit to represent 5,000 families who believe vaccines caused their child's autism.

During the review process, it was determined that Poling did not represent a test case because she had a rare, underlying genetic mitochondrial disorder that caused her deterioration and autism. For rare kids like her, any stress could have caused her to deteriorate. This is the equivalent of being born with an aneurysm, a ticking time bomb that could go off at any moment. Although she was not diagnosed prior to being vaccinated, experts recommend that even children with known mitochondrial disorders still be vaccinated.

Bottom line: The government did NOT concede that vaccines cause autism in the Poling case.

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Evidence Shows Vaccines Unrelated to Autism

Many parents have heard claims that vaccines cause autism. The most common and specific claims are that autism stems from the measles-mumps-rubella (MMR) vaccine or from vaccines that contain the preservative thimerosal. Many large studies have been conducted to investigate these specific concerns, but no link has ever been found between vaccines and autism. Still, these unproven claims persist, and they have led some parents to refuse vaccination for their children. The causes of autism are not fully understood, but overwhelmingly, scientific evidence does not point toward vaccines as a possible cause. The information that follows lays out scientific evidence that (1) refutes claims that any relationship exists between vaccines and autism and (2) presents some of the current thinking on the causes of autism.

Medical and legal authorities agree that no evidence exists that vaccines cause autism.

In 2004, the Institute of Medicine—a prestigious group of impartial experts who advise Congress on science issues—stated strongly that the evidence from five large epidemiological studies, three of which involved more than 100,000 children each, did not support a connection between autism and thimerosal-containing vaccines. Similarly, evidence from 14 large epidemiological studies showed no association between measles-mumps-rubella (MMR) vaccine and autism. Since that time, even more studies have reinforced the conclusion that there is no evidence for a connection between vaccines and autism. In 2009, after extensive proceedings that generated 5,000 pages of transcript and included 939 medical articles, the federal court that administers the National Vaccine Injury Compensation Program found the scientific evidence is "overwhelmingly contrary" to the theory that autism is linked to MMR vaccine, thimerosal, or a combination of the two. The World Health Organization, the European Medicines Agency, Health Canada, and other national and international health groups have all dismissed the possibility of a link between vaccines and autism.

The causes of autism are not fully understood, but the evidence does not point toward vaccines.

The influence of vaccines on a child cannot explain the measurable differences in brain structure and brain function that exist between autistic and non-autistic children. Starting in the first six months of life, many autistic children experience unusually rapid growth in areas of the brain that are responsible for the skills typically impaired in autism. Researchers have used "functional" MRI scans to study the connections of nerve cells within the brains of autistic individuals. These scans show—in very young autistic infants and toddlers—abnormal connections in areas of the brain that control language, social, and emotion processes, suggesting that these abnormalities contribute to the development of autism. The results of these and other studies provide promising clues for future research on the causes of autism and emphasize that finding its causes will not be as simple as pointing to vaccines as the cause.

What is known with great certainty is that genetics play a major role in determining whether a child will be autistic. The study of twins bears this out. Identical twins have 100% of their genes in common; fraternal twins have 50% in common (like any other pair of siblings). In more than three out of four cases, when one identical twin has a form of autism, the other one does too. Among fraternal twins, though, this is true for one out of about seven pairs, at most. A child who has one or more older siblings with autism is between 20 and 50 times more likely to be diagnosed with a form of autism, compared with a child who has no autistic older siblings. In addition, in families affected by autism, many parents and non-autistic siblings display mild autistic-like traits. The inherited or spontaneous mutations that seem to be associated with autism are in genes that control the development of the brain—including how brain cells develop and make circuits that operate correctly. This finding agrees with the discovery of abnormalities in the way the brain operates even in very young infants and toddlers with autism.

Autism is present before it becomes apparent to a child's family.

Parents often first notice the behaviors of autism when their child is 18–24 months old—the age by which most childhood vaccines have been given. Because of this, many parents incorrectly associate vaccination with the onset of autism. Developmental specialists, however, can identify early signs of autism in children when they are much younger, before their parents have noticed anything unusual. This research supports the scientific consensus that, in most cases, the precursors of autism are present before a child is born.

A baby's immune system can easily handle the vaccines recommended for infants and toddlers.

Some people worry that receiving too many vaccines early in life can overwhelm a baby's immune system and that this might somehow lead to autism. This doesn't fit with what we know about the remarkable capacity of the immune system. From the moment of a baby's birth, the immune system begins coping with microorganisms in the form or bacteria, viruses, and fungi. Like vaccines, these microorganisms contain foreign antigens—proteins that stimulate the immune system. When you realize that a single bacterium contains a larger variety and number of antigens than are found in all the recommended early childhood vaccines combined, you can see that a baby's immune system, which copes with exposure to countless bacteria each day, can easily withstand exposure to the antigens in vaccines.

Vaccines contain only the components necessary to make them work safely.

Vaccines contain a few components, such as formaldehyde and aluminum, that may sound dangerous until you understand that everything in a vaccine is there either because it helps the vaccine do its job or because it is part of making the vaccine. For instance, some vaccines contain a very small quantity of formaldehyde, which is used in vaccine

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manufacturing to deactivate viruses so they can provide immunity without causing disease. Though formaldehyde may sound dangerous, it is actually a natural byproduct of the normal functioning of human cells. The amount of formaldehyde found in vaccines is much less than the amount found in a healthy human body at any given time. Aluminum is an important component of some vaccines. It is an adjuvant, an ingredient that makes it possible for the vaccine to contain a smaller dose of its core substance (called an antigen) and still protect against disease. Aluminum is the most plentiful substance in the Earth's crust. One dose of vaccine contains about as much aluminum as a quart of baby formula does. People have heard rumors that vaccines contain antifreeze. They do not.

Many studies have looked for a link between thimerosal-containing vaccines and autism, but none has been found.

A mercury-containing compound, thimerosal has been used since the 1930s as a vaccine preservative in vials that contain several doses of vaccine (called multi-dose vials). Before giving a vaccine, a healthcare professional inserts the needle of the syringe that will be used to administer the vaccine into the stopper of the multi-dose vial and draws out a single dose of vaccine. When the needle pierces the stopper, it is possible that contaminants from outside the vial might be introduced, even when sterile technique is used. Thimerosal keeps bacteria or other microorganisms that might have entered the vaccine vial from multiplying.

Studies to determine if a relationship exists between thimerosal-containing vaccines and autism have taken two different approaches: (1) some examined groups of children who had received childhood vaccines that contained varying amounts of thimerosal. Autism occurred at essentially the same rate no matter how much or little thimerosal the children had received. (2) Other studies took the opposite approach, comparing autistic and non-autistic children to see if the autistic children had received more thimerosal-containing vaccines. No significant differences were found in the number of thimerosal-containing vaccines the two groups had received.

Different forms of mercury exist.

The mercury compound in thimerosal—ethylmercury—is chemically different from methylmercury, which is widely recognized as an environmental pollutant. Two key differences are that, unlike methylmercury, ethylmercury is (1) excreted from the body quickly, and (2) not easily transported across the blood-brain barrier (a structure of tightly packed cells that keeps potentially harmful substances in the bloodstream from entering the brain). The amount of ethylmercury in a thimerosal-preserved vaccine is minuscule compared with the amount of mercury that is required to cause symptoms of mercury poisoning. Also, the signs and symptoms of mercury poisoning are very different from the characteristics of autism. The chemical difference between ethylmercury and methylmercury is similar to the difference between ethyl alcohol, found in wine and beer, and methyl alcohol (wood alcohol), a poison found in antifreeze.

As a precaution, by 2001, all routinely recommended childhood vaccines were changed to single-dose packaging so they wouldn't require thimerosal. At the time, this was thought prudent, but all the evidence that has emerged since then shows that there was never a danger of children being harmed by thimerosal in vaccines. In 2004, the CDC began recommending influenza vaccine for all children 6 to 23 months old; some influenza vaccine formulations come in multi-dose vials that are preserved with thimerosal. Today, influenza vaccine is the only childhood vaccine licensed for use in the U.S. that contains more than a trace of thimerosal, and we know that it is safe for children.

Studies have found no link between autism and MMR vaccine.

Some studies of MMR vaccine compared groups of children who had received MMR vaccine against those who had not. These studies found that neither group was more likely to develop autism. Other studies looked at comparable groups of autistic and non-autistic children. These studies found that autistic children were no more likely to have received MMR vaccine.

Rumors about the safety of MMR vaccine first arose about a decade ago after a British physician (a gastroenterologist, not a person trained in either vaccinology or in neurological disorders) announced he had found virus from measles vaccines lingering in the intestines of 12 autistic children. He believed this accounted for their autism. Other researchers, however, were never able to replicate these results, which implied the gastroenterologist's conclusions were erroneous. Later, a press investigation revealed that the doctor had falsified patient data and relied on laboratory reports that he had been warned were incorrect. The journal that originally published his study took the unusual step of retracting it from the scientific literature on the grounds that it was the product of dishonest and irresponsible research, and British authorities revoked the doctor's license to practice medicine.

The fear that vaccines might cause autism is a dangerous myth. Much scientific research has been devoted to this topic. The result has been an ever-increasing and uniformly reassuring body of evidence that childhood vaccination is, in fact, entirely unrelated to the development of autism. The readings below may be of interest to parents who wish to learn more.

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MMR vaccine does not cause autism

Examine the evidence!

In February 1998, *The Lancet* published an article titled "Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children," which suggested that MMR vaccine could contribute to the development of autism. Intense media coverage of the article followed its publication, and many parents, particularly in the UK, refused MMR vaccination of their children.

In 2004, *The Lancet* published a retraction submitted by 10 of the 13 original authors. The authors stated that there was no connection between the MMR vaccine and the bowel disease/autism syndrome.

In 2008, the number of articles published in peer-reviewed medical journals that refute a connection between MMR vaccine and autism totals more than 20; whereas the number of articles that suggest a connection between the vaccine and autism stands at 3.

The following list of studies published in peer-reviewed journals is provided so that parents and practitioners can themselves compare the balance of evidence about MMR and autism.

25 studies that refute a connection between MMR vaccine and the development of autism

25. *Lack of Association between Measles Virus Vaccine and Autism with Enteropathy: A Case-Control Study.* Hornig M et al. PLoS ONE 2008; 3(9): e3140 doi:10.1371/journal.pone.0003140 *Subjects: 25 children with autism and GI disturbances and 13 children with GI disturbances alone (controls)

24. *Measles Vaccination and Antibody Response in Autism Spectrum Disorders.* Baird G et al. Arch Dis Child 2008; 93(10):832-7. Subjects: 98 vaccinated children aged 10-12 years in the UK with autism spectrum disorder (ASD); two control groups of similar age: 52 children with special educational needs but no ASD and 90 children in the typically developing group

23. *MMR-Vaccine and Regression in Autism Spectrum Disorders: Negative Results Presented from Japan.* Uchiyama T et al. J Autism Dev Disord 2007; 37(2):210-7 *Subjects: 904 children with autism spectrum disorder (Note: MMR was used in Japan only between 1989 and 1993.)

22. *No Evidence of Persisting Measles Virus in Peripheral Blood Mononuclear Cells from Children with Autism Spectrum Disorder.* D'Souza Y et al. Pediatrics 2006; 118(4):1664-75 *Subjects: 54 children with autism spectrum disorder and 34 developmentally normal children

21. *Immunizations and Autism: A Review of the Literature.* Doja A, Roberts W. Can J Neurol Sci. 2006; 33(4):341-6 *Literature review

20. *Pervasive Developmental Disorders in Montreal, Quebec, Canada: Prevalence and Links with Immunizations.* Fombonne E et al. Pediatrics. 2006;118(1):e139-50 *Subjects: 27,749 children born from 1987 to 1998 attending 55 schools

19. *Relationship between MMR Vaccine and Autism.* Klein KC, Diehl EB. Ann Pharmacother. 2004; 38(7-8):1297-300 *Literature review of 10 studies

18. *Immunization Safety Review: Vaccines and Autism.* Institute of Medicine. The National Academies Press: 2004 (www.nap.edu/books/030909237X/html) *Literature review

17. *MMR Vaccination and Pervasive Developmental Disorders: A Case-Control Study.* Smeeth L et al. Lancet 2004; 364(9438):963-9 *Subjects:1294 cases and 4469 controls

(continued on next page)

3 studies that suggested a connection between MMR vaccine and the development of autism

3. *Potential Viral Pathogenic Mechanism for a New Variant Inflammatory Bowel Disease.* Uhlmann V et al. Mol Pathol 2002; 55(2):84-90 *Subjects: 91 patients with a confirmed diagnosis of ileal lymphonodular hyperplasia and enterocolitis and 70 controls

★ Read about limitations of this study: www.cdc.gov/vaccinesafety/concerns/mmr_autism_factsheet.htm

2. *Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children.* Wakefield AJ et al. Lancet 1998; 351(9103):637-41 *Subjects: 12 children with chronic enterocolitis and regressive developmental disorder

★ Read about limitations of this study: www.immunize.org/catg.d/p2065.pdf

★ "A Statement by the Editors of the Lancet," Lancet 2004; 363(9411):820-1, regarding this paper and an undisclosed potential conflict of interest: www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)15699-7/fulltext

★ "Retraction of an Interpretation," Lancet 2004; 363(9411):750 Go to www.thelancet.com and register (no charge) to access this article.

1. *Evidence of Persistent Measles Virus Infection in Crohn's Disease.* Wakefield AJ et al. J Med Virol 1993; 39(4):345-53 *Subjects: Electron microscopy specimens from Crohn's disease and control patients

★ The validity of this finding has been called into question when it could not be reproduced by other researchers (Nielsen et al., Jones et al., Feeney et al., Hermon-Taylor, Liu et al., Haga, Iizuka, Afzal).

Technical content reviewed by the Centers for Disease Control and Prevention, November 2008.

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7. ***Measles outbreak associated with a church congregation: a study of immunization attitudes of congregation members.*** Kennedy AM, Gust DA. *Public Health Reports* 2008; 123(2):126–34.

   Summary: Researchers conducted a focus group and interviews with church leaders and families following a measles outbreak among church members in Indiana.

   Key findings: Vaccine refusal was attributed to a combination of personal religious beliefs and safety concerns among a subgroup of church members. Among interviewees from outbreak households, none had received MMR vaccine prior to the outbreak. Four of the six outbreak households reported that they would consider some or all recommended vaccines in the future.

   Link: www.ncbi.nlm.nih.gov/pubmed/18457065

8. ***Update: Measles—United States, January–July 2008.*** CDC. *Morbidity and Mortality Weekly Report (MMWR)* 2008; 57(33):893–6.

   Summary: A descriptive analysis of reported cases of measles occurring in the U.S. from January through July 2008.

   Key findings: A total of 131 measles cases were reported to CDC during the first 7 months of 2008, the highest number of year-to-date reports since 1996. Fifteen patients, including 4 children younger than age 15 months, were hospitalized. One hundred twelve of the reported cases were unvaccinated or had unknown vaccination status; of these, 95 were eligible for vaccination. The majority of these 95 cases (66%) were children who were unvaccinated because of philosophical or religious beliefs.

   Link: www.cdc.gov/mmwr/preview/mmwrhtml/mm5733a1.htm

9. ***Impact of addition of philosophical exemptions on childhood immunization rates.*** Thompson JW, Tyson S, Card-Higginson P, et al. *American Journal of Preventive Medicine;* 2007;32(3):194–201.

   Summary: In fall 2003, Arkansas implemented a nonmedical (i.e., religious or philosophical) exemption process (Act 999). Investigators evaluated and compared the number and geographic clustering of exempted students 2 years before (year 1, year 2) and 2 years after (year 3, year 4) philosophical exemptions were made available in Arkansas.

   Key findings: The addition of a philosophical or religious exemption from school mandates resulted in a significant increase in the total number of exemptions granted in Arkansas. In year 4, nonmedical exemptions were 2.58-fold higher than in year 1, whereas the absolute number of medical exemptions dropped by more than half compared with year 1. In the 10 districts with the highest exemption rates (range, 7.85–22.97 per 1,000 students), all exemptions granted were categorized as religious or philosophical.

   Link: www.ncbi.nlm.nih.gov/pubmed/17296471

10. ***Nonmedical exemptions to school immunization requirements: secular trends and association of state policies with pertussis incidence.*** Omer SB, Pan WK, Halsey NA, et al. *JAMA* 2006; 296(14):1757–63.

    Summary: Analysis of children claiming nonmedical exemptions at school entry, 1991–2004, and incidence of pertussis in children ages 18 years and younger, 1986–2004.

    Key findings: Exemption rates for states that allowed only religious exemptions remained at about 1% between 1991 and 2004; however, in states that allowed exemptions for personal beliefs, the mean exemption rate increased from 0.99% to 2.54%. The study found associations between increased pertussis incidence and state policies that allowed personal belief exemptions or easily-obtained exemptions in general.

    Link: www.ncbi.nlm.nih.gov/pubmed/17032989

11. ***Implications of a 2005 measles outbreak in Indiana for sustained elimination of measles in the United States.*** Parker AA, Staggs W, Dayan GH, et al. *N Engl J Med* 2006;355:447–55.

    Summary: A case-series investigation of the largest documented U.S.-based measles outbreak since 1996; included molecular typing of viral isolates, surveys of vaccination rates, interviews about vaccination attitudes, and cost surveys.

    Key findings: This U.S. measles outbreak was caused when an unvaccinated teenager returned from Romania and introduced measles into a group of children whose parents objected to vaccination. Among people exposed at a church gathering, 50 lacked immunity to measles, 16 (32%) of whom acquired measles. During the 6 weeks after the gathering, a total of 34 cases of measles were confirmed. Of the people with confirmed measles, 97% were members of the church, 94% were unvaccinated, and 82% were children ages 5 to 19 years. In this outbreak, 68% of the containment cost was incurred by a single hospital, where an undervaccinated employee potentially exposed children, immunocompromised patients, and employees to measles.

    Link: www.ncbi.nlm.nih.gov/pubmed/16885548

12. ***The cost of containing one case of measles: the economic impact on the public health infrastructure—Iowa, 2004.*** Dayan GH, Ortega-Sanchez IR, LeBaron CW, Quinlisk MP, Iowa Measles Response Team. *Pediatrics* 2005;116:e1–e4.

    Summary: Measurement of activities performed, personnel time and materials allocated, and direct costs incurred in 2004 U.S. dollars by the Iowa public health infrastructure during the study period of March 5 (date of first contact about possible case) through May 12, 2004 (date of final meeting).

    Key findings: Total estimated cost of one case of measles: $142,452, of which 75% was attributable to personnel costs and overhead.

    Link: www.ncbi.nlm.nih.gov/pubmed/15995008

13. ***Individual and community risk of measles and pertussis associated with personal exemptions to immunizations.*** Feikin DR, Lezotte DC, Hamman RF, Salmon DA, Chen RT, Hoffman RE. *JAMA.* 2000; 284(24):3145–50.

    Summary: A population-based, retrospective cohort study of all reported measles and pertussis cases among children ages 3–18 years in Colorado during 1987–1998.

    Key findings: Exemptors were 22.2 times more likely to acquire measles and 5.9 times more likely to acquire pertussis than were vaccinated children. At least 11% of vaccinated children in measles outbreaks acquired infection through contact with exemptors.

    Link: www.ncbi.nlm.nih.gov/pubmed/11135778

14. ***Health consequences of religious and philosophical exemptions from immunization laws: individual and societal risk of measles.*** Salmon DA, Haber M, Gangarosa EJ, Phillips L, Smith NJ, Chen RT. *JAMA* 1999; 281(2):47–53.

    Summary: A population-based, retrospective cohort study of measles surveillance data collected by the CDC from 1985 through 1992 and a review of annual state immunization program reports on prevalence of exemptors and vaccination coverage. The study group was restricted to school-aged children (5–19 years old).

    Key findings: On average, exemptors were 35 times more likely to contract measles than were vaccinated persons.

    Link: www.ncbi.nlm.nih.gov/pubmed/10404911

Personal belief exemptions for vaccination put people at risk. Examine the evidence for yourself.

Enforcement of mandatory immunization requirements for children entering childcare facilities and schools has resulted in high immunization coverage levels. While all states and the District of Columbia allow exemptions from the requirements for medical reasons, and all but two offer exemptions to accommodate religious beliefs, 20 states allow exemptions based on parents' personal beliefs. Several recent outbreaks of measles, pertussis, and varicella (chickenpox) have been traced to pockets of unvaccinated children in states that allow personal belief exemptions. To understand the impact of vaccine refusal, examine the evidence for yourself.

1. ***Measles in the United States during the postelimination era.*** Parker Fiebelkorn A, Redd SB, Gallagher K, et al. *J Infect Dis* 2010; 202(10):1520–28.

   Summary: A descriptive analysis of all cases of measles reported in the United States during 2001–2008.

   Key findings: A total of 557 confirmed cases of measles and 38 outbreaks were reported during 2001–2008. Of these outbreaks, the 3 largest occurred primarily among personal belief exemptors (defined as persons who were vaccine eligible, according to recommendations of the Advisory Committee on Immunization Practices or the World Health Organization, but remained unvaccinated because of personal or parental beliefs). During 2004–2008, a total of 68% of reported measles cases were among unvaccinated U.S. residents, who were age-eligible for vaccination but who claimed a personal belief exemption to state immunization requirements.

   Link: www.ncbi.nlm.nih.gov/pubmed/20929352

2. ***Measles outbreak in a highly vaccinated population, San Diego, 2008: role of the intentionally undervaccinated.*** Sugerman DE, Barskey AE, Delea MG, et al. *Pediatrics* 2010;125(4):747–55.

   Summary: Researchers mapped vaccination-refusal rates by school and school district, analyzed measles-transmission patterns, and conducted discussions and surveys to examine beliefs of parents who decline vaccination for their children.

   Key findings: An intentionally unvaccinated 7-year-old child who was unknowingly infected with measles returned from Switzerland, resulting in 11 additional measles cases and in known measles exposure of more than 800 people. In San Diego, high personal belief exemption (PBE) rates were found in 10 schools (range, 42%–100%); schools and districts with high refusal rates were clustered geographically. Across all surveyed kindergartens, higher PBE rates correlated strongly with lower measles vaccination rates.

   Link: www.ncbi.nlm.nih.gov/pubmed/20308208

3. ***Parental refusal of varicella vaccination and the associated risk of varicella infection in children.*** Glanz JM, McClure DL, Magid DJ, Daley MF, France EK, Hambidge SJ. *Archives of Pediatrics & Adolescent Medicine* 2010; 164(1):66–70.

   Summary: A case-control study of 133 physician-diagnosed cases of varicella among Kaiser Permanente Colorado members between 1998 and 2008; each case was matched with 4 randomly selected controls (i.e., people who did not have varicella disease).

   Key findings: Compared with children of vaccine-accepting parents, children of vaccine-refusing parents had a 9-fold higher risk of varicella illness. Overall, 5% of varicella cases in the study population were attributed to vaccine refusal.

   Link: www.ncbi.nlm.nih.gov/pubmed/20048244

4. ***Parental refusal of pertussis vaccination is associated with an increased risk of pertussis infection in children.*** Glanz JM, McClure DL, Magid DJ, et al. *Pediatrics* 2009;123(6):1446–51.

   Summary: A case-control study of 156 physician-diagnosed cases of pertussis among Kaiser Permanente Colorado members between 1996 and 2007; each case was matched with 4 randomly selected controls (n=595).

   Key findings: Vaccine refusers had a 23-fold higher risk for pertussis when compared with vaccine acceptors, and 11% of pertussis cases in the entire study population were attributed to vaccine refusal.

   Link: www.ncbi.nlm.nih.gov/pubmed/19482753

5. ***Invasive* Haemophilus influenzae *type b disease in five young children — Minnesota, 2008.*** CDC. *Morbidity and Mortality Weekly Report (MMWR)* 2009;58(03):58–60.

   Summary: In 2008, during routine surveillance conducted by public health workers in Minnesota for invasive *H. influenzae* type b (Hib) disease, five children ages 5 months to 3 years were reported with invasive Hib disease; one child died.

   Key findings: Three of the five children with invasive Hib disease had not been vaccinated. One of the children was too young to complete the primary series of Hib vaccine, and another child, who had completed the primary series, was found to have an immune disorder that impairs response to vaccination.

   Link: www.cdc.gov/mmwr/preview/mmwrhtml/mm5803a4.htm

6. ***Geographic clustering of nonmedical exemptions to school immunization requirements and associations with geographic clustering of pertussis.*** Omer SB, Enger KS, Moulton LH, Halsey NA, Stokley S, Salmon DA. *Am J Epidemiol* 2008;168:1389–96.

   Summary: Researchers evaluated the geographic clustering of personal belief exemptions in Michigan (1991–2004: N=4,495 schools) and measured the geographic overlap between exemption clusters and clusters of reported pertussis cases (1993–2004: N=1,109 cases among people18 years and younger).

   Key findings: Researchers reported significant overlap between clusters of exemptions and clusters of pertussis cases. In addition, exemption rates appear to be increasing in Michigan, and nonmedical exemptions tend to be geographically clustered.

   Link: www.ncbi.nlm.nih.gov/pubmed/18922998

(Page 1 of 2)

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25 studies that refute a connection between MMR vaccine and the development of autism

16. *Age at First Measles-Mumps-Rubella Vaccination in Children with Autism and School-Matched Control Subjects:* A Population-Based Study in Metropolitan Atlanta. DeStefano F et al. Pediatrics 2004; 113(2): 259-66 *Subjects: 624 children with autism and 1,824 controls
15. *Prevalence of Autism and Parentally Reported Triggers in a North East London Population.* Lingam R et al. Arch Dis Child 2003; 88(8):666-70 *Subjects: 567 children with autistic spectrum disorder
14. *Neurologic Disorders after Measles-Mumps-Rubella Vaccination.* Makela A et al. Pediatrics 2002; 110:957-63 *Subjects: 535,544 children vaccinated between November 1982 and June 1986 in Finland
13. *A Population-Based Study of Measles, Mumps, and Rubella Vaccination and Autism.* Madsen KM et al. N Engl J Med 2002; 347(19):1477-82 *Subjects: All 537,303 children born 1/91–12/98 in Denmark
12. *Relation of Childhood Gastrointestinal Disorders to Autism: Nested Case Control Study Using Data from the UK General Practice Research Database.* Black C et al. BMJ 2002; 325:419-21 *Subjects: 96 children diagnosed with autism and 449 controls
11. *Measles, Mumps, and Rubella Vaccination and Bowel Problems or Developmental Regression in Children with Autism: Population Study.* Taylor B et al. BMJ 2002; 324(7334):393-6 *Subjects: 278 children with core autism and 195 with atypical autism
10. *No Evidence for a New Variant of Measles-Mumps-Rubella-Induced Autism.* Fombonne E et al. Pediatrics 2001;108(4):E58 *Subjects: 262 autistic children (pre- and post-MMR samples)
9. *Measles-Mumps-Rubella and Other Measles-Containing Vaccines Do Not Increase the Risk for Inflammatory Bowel Disease: A Case-Control Study from the Vaccine Safety Datalink Project.* Davis RL et al. Arch Pediatr Adolesc Med 2001;155(3):354-9 *Subjects: 155 persons with IBD with up to 5 controls each
8. *Time Trends in Autism and in MMR Immunization Coverage in California.* Dales L et al. JAMA 2001; 285(9):1183-5 *Subjects: Children born in 1980-94 who were enrolled in California kindergartens (survey samples of 600–1,900 children each year)
7. *Mumps, Measles, and Rubella Vaccine and the Incidence of Autism Recorded by General Practitioners: A Time Trend Analysis.* Kaye JA et al. BMJ 2001; 322:460-63 *Subjects: 305 children with autism
6. *Further Evidence of the Absence of Measles Virus Genome Sequence in Full Thickness Intestinal Specimens from Patients with Crohn's Disease.* Afzal MA, et al. J Med Virol 2000; 62(3):377-82 *Subjects: Specimens from patients with Crohn's disease
5. *Autism and Measles, Mumps, and Rubella Vaccine: No Epidemiological Evidence for a Causal Association.* Taylor B et al. Lancet 1999;353 (9169):2026-9 *Subjects: 498 children with autism
4. *Absence of Detectable Measles Virus Genome Sequence in Inflammatory Bowel Disease Tissues and Peripheral Blood Lymphocytes.* Afzal MA et al. J Med Virol 1998; 55(3):243-9 *Subjects: 93 colonoscopic biopsies and 31 peripheral blood lymphocyte preparations
3. *No Evidence for Measles, Mumps, and Rubella Vaccine-Associated Inflammatory Bowel Disease or Autism in a 14-year Prospective Study.* Peltola H et al. Lancet 1998; 351:1327-8 *Subjects: 3,000,000 doses of MMR vaccine
2. *Exposure to Measles in Utero and Crohn's Disease: Danish Register Study.* Nielsen LL et al. BMJ 1998; 316(7126):196-7 *Subjects: 472 women with measles
1. *Immunocytochemical Evidence of Listeria, Escherichia coli, and Streptococcus Antigens in Crohn's Disease.* Liu Y et al. Gastroenterology 1995; 108(5):1396-1404 *Subjects: Intestines and mesenteric lymph node specimens from 21 persons from families with a high frequency of Crohn's disease

Immunization Issues

Concerns About Vaccine Safety

Updated: February 12, 2009

Decades ago, when thousands of children and adults in the United States contracted smallpox, diphtheria, poliomyelitis or measles each year,[1] vaccine safety concerns were not very common. People were more afraid of the diseases themselves than of possible side effects of the vaccines. Because of the success of vaccines, the situation is very different today: the diseases aren't feared and concerns about vaccine safety are common.

Fortunately, the majority of parents understand the benefits of immunizations. But it is hard for some to appreciate risks that they don't see. For example, most parents today have never seen a child paralyzed by polio, or choking to death from diphtheria, or brain damaged by measles. As a consequence, fear of these diseases does not—but should—haunt parents as it did historically.

It is also difficult to understand the importance of new vaccines that target illnesses that many know little about, like a vaccine to prevent infection by the sexually-transmitted **human papillomaviruses** (HPV). Looking at an innocent 10 year old, it is hard to imagine her being sexually active, much less her being at risk of cervical cancer decades later because she wasn't **vaccinated against HPV**, a common infection that causes no symptoms.

While no vaccine is 100% safe, serious side effects are rare. However, because many vaccines are given to children at the ages when developmental and other problems are first being recognized, some parents may think that vaccines are to blame—it is difficult to grasp that the coincidence of **timing does not mean that the vaccine caused the problem.**

To compound the problem, the media carries stories about children whose parents believe that their child has been harmed by a vaccine, naturally causing concerns among other parents. And then, when parents try to get more information on the Internet, their concerns can be further heightened because the information they find may seem reasonable—but may be very wrong.

The vaccine-preventable diseases are not gone

Although we personally don't see them very often,[2] these illnesses are very much waiting for an opportunity to return. Except for smallpox (for which we no longer give vaccine), the vaccine-preventable diseases are still here. For example, tetanus—which does not spread from person-to-person—is still in the soil; cases of mumps and rubella (and congenital rubella) continue to occur; and measles—the most contagious disease—is active many places in the world, often arriving in our midst by airplane.

When an unimmunized child develops a vaccine-preventable disease, the child gets all the risks of that disease: 1-4 per thousand will die from measles, half will die from tetanus, 1-2 per hundred will develop paralytic polio, and so on.

Much of the protection against vaccine-preventable diseases that we have in our country is because so many children are immunized. Having many immunized children **indirectly protects** those who cannot get vaccine and protects those children for whom the vaccine didn't work—because no vaccine protects 100% of those who get it. Indirect protection occurs because susceptible children are not exposed to the disease-causing agents.

For example, in 2008 **three unimmunized children in Minnesota** developed invasive disease do to Haemophilus influenzae, type B (Hib) infection. One of the children died. Two other children who also developed invasive Hib disease should have been protected by community immunity, but were not—one was too young to be immune from vaccine and the other had a congenital immune deficiency.[3]

That is why we need to continue giving vaccines, even if we don't see the diseases they prevent. To not immunize a child can have tragic consequences for the child, the child's family, and for the child's classmates and friends.

Vaccine safety concerns and risk perception

No vaccine is 100% effective; no vaccine is 100% safe. As with any drug, there are risks and side effects with vaccines, although serious side effects are rare. However, there is a much higher standard of safety expected of preventive vaccines than for drugs because vaccines are given to many people most of whom are healthy.

For example, people tolerate far less risk from the vaccine used to prevent infection with Haemophilus influenzae type b than they do the antibiotics that are used to treat the infections it causes.

Research shows that people respond better to some types of risks than others. Natural risks (such as infections for which there are no vaccines) are better tolerated than manmade risks (such as vaccine side effects). Also, risks that affect adults are better tolerated than risks affecting our children. Risks that are perceived to have unclear benefits may be less tolerated than risks where the benefits are understood.

TOPICS

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General (14)
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ARTICLES

Asthma and Vaccines
BSE Transmission and Vaccines
Causa o Coincidencia
Cause or Coincidence
Concerns About Vaccine Safety
El asma y las vacunas
Hepatitis B Vaccine and Multiple Sclerosis
Intussusception and Rotavirus Vaccine
Mitochondrial Disorders and Vaccines
Post-Polio Syndrome, Vaccine-Associated Paralytic Polio and Poliomyelitis Elimination
Should My Child Receive the Measles, Mumps, and Rubella Vaccines Individually Rather Than as a Combination?
Vaccine Adverse Event Reporting System
Vaccine Safety Datalink

For example, because measles, mumps and rubella (MMR) are no longer epidemic in the United States, some parents incorrectly assume that the risks of contracting the diseases are lower than the risk of their child experiencing an adverse reaction to MMR vaccine. They conclude that there may be little benefit from immunizing their child, hence there may seem to be no reason to take the risk of an adverse event. However, serious side effects from the MMR vaccine are rare—but there have been introductions of measles from other countries, cases of rubella and a large outbreak of mumps in 2006.[2] These infections remain a risk to children and communities; many are "just a plane ride away".

Perception of risk depends on people's experiences and knowledge. A person who experienced an adverse event after vaccination—or thinks that they know someone who did—will perceive vaccines as riskier than a person who has not. Conversely, one who has survived a vaccine-preventable disease—or a physician who has had to treat that disease—will likely be an advocate for vaccines.

Many vaccines are given to children at the ages when developmental and other problems are being recognized for the first time. Because something happened at about the same time that a vaccine was given, does not mean that one caused the other.

Missing information

Information may be available but that information may be unknown. Families need to be aware of the risks of exposure to infection, the importance of the proportion of children who are immune, and what the actual risks of complications from the different infections are. Without this information, families are uninformed and may develop a false sense of security and regard immunizations as unimportant.

For example, many are unaware that their community is at risk for exposure to the vaccine-preventable diseases. Others may not realize that their child could become ill if exposed to a vaccine-preventable disease—even if their child has received the vaccine.

In contrast to the uninformed, needed information may just not exist. For example, when a vaccine safety concern is first suggested, the necessary data to support or reject the hypothesis may not yet have been collected—in fact sometimes this may take several years of research.

The experience concerning the concern that thimerosal in vaccines might cause autism—first suggested in 1999—is illustrative of this. In 2001, when the Institute of Medicine's Immunization Safety Review Committee first examined the issue, there was little data available about exposure to thimerosal in vaccines among children who subsequently were recognized as being autistic. Thus the Committee was unable to say that there was no such association. By 2004, however, much more scientific data was available and the **IOM Committee concluded that there was no association between vaccines and autism.**[4]

Misinformation (false or misleading information)

The uninformed person can unwittingly spread misinformation. However, there are also intentional misinformers, who actively seek to mislead others.

Unfortunately, the timing and widespread use of vaccines make them easy scapegoats to be blamed for all sorts of serious illnesses, particularly those diseases that are poorly understood. Of course not all vaccine safety concerns are misinformation—only those that persist despite the evidence against them.

Misinformation tends to rely on emotion-filled stories about bad things that happened to children or were first recognized—coincidental in time with vaccine administration. Misinformation is often presented with distorted or misquoted scientific studies.[5]

Many media stories use faulty reports and parental concerns to depict a "controversy" about vaccines, failing to mention that the scientific community does not feel that a controversy exists. For example, in spite of the substantial evidence now available that allows rejection of the hypotheses that vaccines cause autism, there are some who continue to state that they do. These claims now fall into the category of misinformation but may continue to be portrayed in media stories as 'controversies'.

Does it matter if other children are not vaccinated?

The unimmunized child is at risk from vaccine preventable diseases. For example, a couple in Tennessee, confused about vaccine safety because of what they had read on the Internet, decided to delay their daughter's vaccinations. Some time later, the baby girl was stricken with a form of meningitis that could have been prevented by a vaccine.[6]

In addition to a child's personal risk, the unimmunized child puts all children at risk because unimmunized children are more likely to acquire—and they are more likely to spread—vaccine preventable diseases within the community.[7][8][9]

This is the reason why all parents should be concerned when other parents do not have their children fully immunized.

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Parents PACK

Influenza-Related Resources

- Q&A: "Influenza: What You Should Know" - English (PDF) and Spanish (PDF)
- Additional Information: A Look at Each Vaccine - Influenza Vaccine
- Videos:
  Influenza FAQs - Answers From CHOP Doctors
  Influenza Vaccine and Egg Allergy - Jonathan M. Spergel, MD

Welcome to Parents PACK

Parents PACK — Possessing, Accessing and Communicating Knowledge about vaccines — was established by the Vaccine Education Center at The Children's Hospital of Philadelphia to:

- Develop a dialogue with you about vaccines
- Provide you with vaccine information more regularly than your family's doctor visits
- Establish a place where you can easily get up-to-date information and answers to your vaccine questions

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Immunization Issues

Chickenpox Parties

Updated: April 26, 2007

Before vaccine became available, "chickenpox parties" were considered a way to get a child protected from serious chickenpox at an age when the infection is ordinarily less severe. Since varicella disease (a.k.a. chickenpox) is generally thought to provide lifelong immunity, prior to an available vaccine, 'chickenpox parties' were a strategy to reduce the risk of acquiring chickenpox as an adolescent or adult when the disease is much more severe.

However, after the varicella vaccine was licensed in 1995, children could obtain immunity against varicella without the risks of natural infection and its potential complications. While chickenpox is generally milder in children, severe disease with serious complications does occur. Indeed, most serious disease occurs in previously well children.

Although it is possible for vaccinated children to develop chickenpox after exposure to chickenpox (or to shingles), the illness is much milder (fewer pox, shorter illness) in those who have been vaccinated than in those who haven't been vaccinated[1,2].

The typical case of chickenpox begins 10 to 14 days after exposure and is often associated with fever. The rash is very itchy: there may be 10 to 1500 blisters but the usual child will have about 300 lesions.

One of the most common complications of chickenpox is that the blister can become infected with bacteria; this happens to about one in 20 children. One of the most dreaded complications of chickenpox is invasive Group A streptococcal infection which may be fatal. Since the vaccine was licensed this type of infection has decreased as a complication of chickenpox[3].

Children with chickenpox who are treated with aspirin are at risk of a serious complication called Reye's Syndrome with brain swelling and liver failure; this complication decreased before vaccine was introduced when aspirin was no longer recommended for treating fever in children. Another complication of chickenpox is encephalitis (brain inflammation with abnormal gait and clumsiness that may last for a number of days (this occurs in about 1 in every four thousand cases of chickenpox).

Children with immune problems, such as those being treated for leukemia, may develop a very severe form of chickenpox. They are best protected by not being exposed to chickenpox; that is, by their brothers, sisters and classmates being immune.

Chickenpox vaccine's effectiveness to protect against **all** chickenpox symptoms decreases after the first year but it is still protective against 'full blown' chickenpox after 8 years (it was licensed in the US in 1995). Thus, children who have been immunized who later develop chickenpox after exposure tend to have mild episodes (usually without fever and the lesions are often just bumps, although sometimes a few blisters form) because the vaccine is still protective against full blown chickenpox.

Because mild chickenpox does occur in some vaccinated children that are exposed to chickenpox, researchers have asked what the ideal immunization strategy for chickenpox is; whether there should be a second dose of varicella vaccine for all children; whether varicella vaccination should be given after 15 months of age instead of after 12 months.[4,5]

Children who develop chickenpox despite having received the vaccine are less contagious than unvaccinated children who develop chickenpox, largely as a consequence of having fewer lesions. A recent study found that even under the circumstances of intense exposure in a household, chickenpox vaccine was about 80% effective in preventing all disease and reduced the number of persons with large numbers of lesions.[6]

Varicella vaccine recommendations are regularly updated as new information becomes available to assure optimal safety and protection.

Risks of Chickenpox vs. Risks of the Chickenpox Vaccine

Risks of Chickenpox Parties

- Varicella (chickenpox) is an infection caused by the varicella-zoster virus (VZV).
- Varicella is generally a mild disease which causes several days of fever and very itchy rash.
- Varicella is highly contagious.
- A child will often get 300 to 500 blisters during the infection, but can

Risks of the Vaccine

- Varicella vaccine is a live, attenuated virus vaccine.
- Most people who get the vaccine have no side effects.
- A very mild rash or several small bumps (between 2 and 6) can result in about 1% to 4% of vaccine recipients.
- In children, the vaccine does not cause fever.

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ARTICLES

Chickenpox Parties
Fiestas de Varicela
Measles Parties
Rubella Parties

have up to 1500; these crust over and fall off in one to two weeks.

- Varicella can be severe and even fatal in otherwise healthy children (but less than 1 out of every 10,000 cases).
- Chickenpox can cause pneumonia (23 out of every 10,000 cases)
- Bacterial infections of the blisters (usually impetigo) occur commonly (up to 5% of cases).
- Chickenpox is an important risk factor for severe invasive group A streptococcal disease, which can be fatal.
- Other complications of varicella include decreased platelets, arthritis, hepatitis, and brain inflammation.
- Complications are more common among adolescents and adults.
- In immunocompromised persons of all ages, varicella may be fatal.
- The virus which causes chickenpox remains in the body for life and may reappear as shingles, particularly in the elderly.
- A woman who contracts chickenpox in early pregnancy can pass the virus to her fetus, causing abnormalities in 2% of cases.
- In adults, the vaccine may cause a mild fever 2 weeks after vaccination.
- A seizure (jerking and staring spell) usually caused by fever may occur in less than 1 in 1000 vaccine recipients. This may not be related to the vaccine.
- The vaccine virus, like the wild-type virus, remains in the body and can return to cause shingles. Current evidence suggests that this occurs less commonly with vaccine virus then after natural infection.
- Immunocompromised children should not receive the vaccine, such as children with leukemia.

Additional Sources

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Diseases Prevented by Vaccines

Vaccine Safety:

Responding to Parents' **Top 10** Concerns

California Immunization Coalition



1. Are Vaccines safe?

Yes. Millions of children and adults have been vaccinated safely. While any medication, even foods, can cause reactions, a child takes a much greater risk of getting a disease if he or she is not vaccinated. The most common vaccine side effects are mild and include swelling, tenderness, and fever. Set realistic expectations by acknowledging that vaccines cause mild, self-limited reactions, like injection site swelling and pain, in many children. A pain reliever may help, but parents should call the office if concerned. Serious reactions are very rare and can occur in about 1 or 2 people per million shots given.

Scientists and doctors are very careful about the way we test and use vaccines. We also vaccinate our own kids. That's because we know that thousands of people participate in clinical trials to test vaccines before they can be approved by the Food and Drug Administration (FDA). Even after licensing, the Vaccine Adverse Events Reporting System (VAERS) tracks any adverse reaction that could be associated with a vaccine. Newer vaccines like HPV (Gardasil®) are tracked closely. Continued monitoring helps ensure that vaccines have a safe track record over time.

2. Why do children today need so many immunizations?

To save lives. Advances in medical science have developed vaccines to protect us against more than 15 dangerous diseases. Only a few years ago vaccines prevented just a small handful of diseases. Babies are especially vulnerable. Children under age one (still too young to get some shots like varicella) are at high risk of hospitalization or serious complications from vaccine-preventable diseases. These include seizures, brain damage, blindness, and even death. That's why we have continued to develop new vaccines. And, that's the reason children get more immunizations today than in the past.

3. Are diseases of the "old days" really still something to worry about?

Vaccine-preventable diseases still occur—though many young parents haven't seen them. This is due to the success of our country's immunization program. But unvaccinated children (and adults) are still at-risk for common illnesses like influenza, whooping cough, and chicken pox. Some parents may be surprised to learn that before the chicken pox vaccine, almost 11,000 Americans had to be hospitalized, and over 100 died, each year from

chicken pox. Pertussis has been on the rise in California in recent years. Children can stay sick for a week or more, may need to be hospitalized, and could even die if complications develop. Less common diseases like Hib, measles, and mumps happen unexpectedly and can spread quickly. Meningococcal disease can cause blindness, limb amputations, brain damage, and death.

Many diseases no longer common in the US are only a plane ride away. Measles and mumps are common in Europe. Rubella still occurs worldwide. Diphtheria is a problem in Russia and former Soviet countries. Hepatitis is in Africa, much of Asia, the Philippines, and certain parts of the Caribbean. Polio is still seen in South Asia, Africa, and the Middle East.

Recent outbreaks:

- In 2008, San Diego had a measles outbreak when one unvaccinated child became infected in Switzerland and then spread it to siblings, classmates, and even children at the doctor's office. Only unvaccinated kids got ill. Dozens of exposed children also had to miss school and be quarantined at home for weeks.
- In 2008, a pertussis outbreak affected a school in Contra Costa County. About 20 kids got sick. Others had to be quarantined at home for 3 weeks. Pertussis outbreaks continue in many California communities.
- In a 2006 outbreak in the Midwest, over 5,000 people, mainly teens and young adults, developed mumps. Many people were exposed in school settings or came in contact with the disease during air travel.

4. What about holistic medicine or "natural immunity"?

Many holistic medicines have beneficial effects but they do not provide immunity to diseases prevented by vaccines. Before vaccines were widely available, millions of children became ill with pertussis, measles, mumps, and other diseases every year. Most vaccines are over 99% effective in preventing illness.

Some people believe that having the disease is the "natural" way to trigger the body's immune response. Vaccines work the same way—they trigger an immune response—but do not cause disease. Vaccine immunity **is** natural immunity. According to Dr. Andrew Weill, a supporter of holistic medicine, "*...Immunization facilitates a natural process by stimulating encounters between the body's immune system and killed or weakened viruses and bacteria (or pieces and products of them).*" Building immunity from the real disease can be dangerous because it means getting sick, which can have serious complications, even permanent disability or death.

5. Is it safe for a child's immune system to have multiple shots?

Yes. The human immune system deals with hundreds of viruses and bacteria during everyday activities like eating and playing. Therefore, vaccines are only a small drop in the bucket compared to what an infant's immune system faces every day. If vaccines overwhelmed or weakened the immune system, one would expect lesser immune responses when vaccines are given at the same time as compared with when they are given at different times. In contrast, many studies have demonstrated similar immune responses whether multiple vaccines are given together or separately.

Today's vaccines are more refined than in the past. Even though kids get more shots than in the past, they contain far fewer antigens than in the past.

For example, the old whole-cell pertussis vaccine had over 3,000 antigens, while today's acellular formulation has only up to five.

6. What about getting shots later or more spread out?

There is no proof that delaying vaccines or stretching out the recommended schedule is any safer. Young children and babies are the most likely to get very sick or die if they get certain diseases. That's why many shots are given so young and why most pediatricians support the regular childhood immunization schedule.

Understand that it's a parent's role to worry about their children. If they want to delay shots, you may choose to have them sign a declination form to document that they understand the increased risks of their choice to wait. Some parents (and physicians) prefer to limit the number of shots in one visit. If shots are deferred, you should plan how to "catch up" with additional shots later. Reminder systems are a good strategy to help ensure that the child comes back later to finish the series.

7. Do vaccines cause autism?

No. Autism has been increasing around the world for many years. In fact, autism rates are the same in vaccinated and unvaccinated children. No one knows yet what causes autism. Researchers are looking at genetic and environmental factors. Doctors are very concerned and want to find the cause and the cure. What we do know at this point is that children tend to start autistic symptoms at about the same age that they get their immunizations. This can make them seem related, but vaccines have not been shown to be the underlying cause. Reputable information for parents can be found at Autism Speaks and the Organization for Autism Research.

Twenty-three studies have tested hundreds of thousands of children and found no link between autism and the MMR vaccine. The study that first suggested a connection back in 1998 was retracted by ten of its authors in 2004 and has been discredited. The American Medical Association, American Academy of Pediatrics, Institute on Medicine, and the World Health Organization have all issued statements saying that there is no connection between vaccines and autism.

8. What about kids with rare disorders like mitochondrial disease?

Mitochondrial disease, a rare disorder, has been in the news recently. A federal claims court has been examining whether symptoms of brain injury and autism in a girl with mitochondrial disease may have been related to her vaccinations. The child's family has discussed her case with the press, but as of September 2008, the court has not yet issued its rulings or documents on her case.

The important question is: Should a child with mitochondrial disease be vaccinated? According to mitochondrial disease specialists, the answer is **yes**. Illnesses prevented by vaccines, such as measles, mumps, or chicken pox, are especially dangerous to children with mitochondrial disease.

9. What about thimerosal (or mercury) in vaccines?

Thimerosal was removed from all routine child vaccines in 2001 (except some types of influenza vaccine) as a way to reduce mercury exposure to children from all sources. Thimerosal is a preservative containing ethylmercury that prevents vaccine vial contamination. Some people worry that mercury exposure from vaccines could be

Vaccine Safety:

Responding to Parents' Top 10 Concerns

California Immunization Coalition

dangerous. However, no reliable study has found any link between thimerosal in vaccines and autism or other developmental diseases. A recent study of children with autism in California indicates that the prevalence of autism in children 3 years and older has increased despite the fact that levels of thimerosal in vaccines have *decreased* markedly.

By California law, vaccines with more than "trace" thimerosal cannot be given to any child under age three or pregnant women. "Trace" means that the thimerosal used in manufacturing is removed at the end, leaving a tiny residual amount (1 microgram, compared to 25 or 50). Only some flu vaccines for adults and older children still use thimerosal. Patients may ask for a thimerosal-free flu vaccine.

10. What about other vaccine ingredients?

There is no evidence that vaccine ingredients are harmful. They are used in tiny amounts for very specific purposes. See below for more information.

- **Aluminum:** Aluminum in vaccines is used as an adjuvant to trigger the body's immune response to a disease. There is no information to support that aluminum is dangerous in vaccines. Aluminum is common in food and drinks including fruit and vegetables—even breast milk and infant formula. It's also in antacids, antiperspirants, cooking pots, and soda cans. According to the Children's Hospital of Philadelphia, by age six months, an on-schedule infant would have 4.4 milligrams of aluminum from vaccines, compared to 7 milligrams from breast milk. Formula-fed babies ingest 38 milligrams and the those drinking soy-based formulas get the most —nearly 117 milligrams of aluminum.
- **Formaldehyde** is used in tiny amounts in some vaccines to prevent microbial contamination. Formaldehyde is in the environment and is also a naturally occurring byproduct of the body's metabolism.
- **False claims:** Vaccines **do not** contain anti-freeze, chick embryos, or monkey kidneys; this is false information.

Connect parents with credible immunization resources.

Our companion fact sheet for parents can be offered as a handout during an office visit. Find it at www.immunizeCA.org. On the parent handout, we list these trusted websites for parents who are looking for additional information.

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

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.

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SPECIAL ARTICLE

The Problem With Dr Bob's Alternative Vaccine Schedule

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Financial Disclosure: Dr Offit is the coinventor of and co-patent holder for RotaTeq.

What's Known on this Subject

Many books misrepresenting the science of vaccines or vaccine safety have been published. None has been as influential as that published by Dr Robert Sears, *The Vaccine Book: Making the Right Decision for Your Child.*

What This Study Adds

This article reviews the flaws in Dr Sears' logic, as well as misinformation contained in his book that likely will lead parents to make the wrong decisions for their children.

ABSTRACT

In October 2007, Dr Robert Sears, in response to growing parental concerns about the safety of vaccines, published *The Vaccine Book: Making the Right Decision for Your Child*. Sears' book is enormously popular, having sold >40 000 copies. At the back of the book, Sears includes "Dr Bob's Alternative Vaccine Schedule," a formula by which parents can delay, withhold, separate, or space out vaccines. Pediatricians now confront many parents who insist that their children receive vaccines according to Sears' schedule, rather than that recommended by the American Academy of Pediatrics, the Centers for Disease Control and Prevention, and the American Academy of Family Physicians. This article examines the reasons for the popularity of Sears' book, deconstructs the logic and rationale behind its recommendations, and describes how Sears' misrepresentation of vaccine science misinforms parents trying to make the right decisions for their children. *Pediatrics* 2009;123:e164–e169

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Key Words
vaccines, schedule, adverse reactions

Abbreviations
CDC—Centers for Disease Control and Prevention
VAERS—Vaccine Adverse Event Reporting System
MMR—measles-mumps-rubella

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MANY PARENTS ARE hesitant about vaccinating their children. Vaccine hesitancy can be explained in part by a lack of trust in those who make vaccine recommendations; a suspicion of profit motive driven by pharmaceutical companies; misinformation on the Internet; failure to appreciate the seriousness of vaccine-preventable diseases, given their low rates; and constant stories in the media claiming that vaccines cause a variety of illnesses, ranging from allergies to autism. Most recently, with the addition of several new vaccines to the infant schedule, some parents have become concerned that children receive too many vaccines too early. Given that young infants currently receive 14 different vaccines, requiring as many as 5 shots at a single visit and 26 inoculations by 2 years of age, the concern that children might be overwhelmed by too many vaccines is understandable.

To address parents' concerns about vaccines, Dr Robert Sears, son of noted pediatrician and author Dr William Sears, wrote *The Vaccine Book: Making the Right Decision for Your Child.*[1] Sears' book, published in October 2007 as part of the Sears Parenting Library, has already sold >40 000 copies and has moved into the top 100 on the Amazon.com bestseller list. The popularity of Sears' book centers in part on 2 schedules, called alternative and selective, that offer parents a way to avoid giving their children several vaccines at one time.

Sears' book is unique. Unlike typical antivaccine books, he offers a middle ground, allowing parents to act on their fears without completely abandoning vaccines. Unfortunately, Sears sounds many antivaccine messages.

THE MESSAGE

Doctors Do Not Understand Vaccines

In his preface, Sears writes, "Doctors, myself included, learn a lot about diseases in medical school, but we learn very little about vaccines. . . . We don't review the research ourselves. We never learn what goes into making vaccines or how their safety is studied. . . . So, when patients want a little more information about shots, all we can really say as doctors is that the diseases are bad and the shots are good." Implicit in Sears' premise is the idea that doctors do not know much about vaccines and that if parents educate themselves they will know more than their doctors. For some parents, this admission can be quite reassuring, allowing them to negate their doctor's advice and take control of a worrisome situation.

Although Sears is correct that doctors do not often review all of the studies on vaccine science, safety, and efficacy, he ignores the expert committees that do, specifically the Advisory Committee on Immunization Practices, which advises the Centers for Disease Control and Prevention (CDC), and the Committee on Infectious Diseases, which advises the American Academy of Pediatrics. Collectively, these advisory committees and their parent agencies have the expertise in virology, microbiology, statistics, epidemiology, and pathogenesis necessary to review the studies that inform their recommendations. Their advice to doctors has served us well; during the past century, vaccines have helped to increase the lifespan of individuals in the United States by ~30 years, with an excellent record of safety.

Public Health Agencies and Pharmaceutical Companies Are Not Trustworthy

Sears casts doubt on the reliability and motives of the CDC and pharmaceutical companies. For example, he writes, "Twenty years ago a group of doctors from the CDC, several US medical centers, and two pharmaceutical companies (GlaxoSmithKline and Merck) undertook the task of determining just how common the hep B [hepatitis B] infection was in infants and children. If they found that hep B was very common in kids, it would make sense to begin vaccination of all newborns. . . . The consensus of the researchers was that approximately 30 000 infants and children were being infected with this virus each year." After taking a closer look at the data, Sears thought that only "about 360 cases [were] reported in kids from birth through age nine each year." Sears' implication is clear, that is, to provide a rationale for newborn hepatitis B vaccine, the CDC, in league with pharmaceutical companies, misrepresented the data.

It is not difficult in today's society to appeal to the notion of corporate or government malfeasance. But Sears' estimate of the impact of hepatitis B infections is not supported by the facts. Before the hepatitis B vaccine became part of the routine schedule for children, every year ~16 000 children <10 years of age were infected with hepatitis B virus after nonsexual, person-to-person contact.[2] Given that reported cases might not include subclinical infections, this estimate is probably low.

Vaccine Mandates Should Be Eliminated

Sears thinks that vaccines should be optional. "Only twenty states allow parents to decline some or all vaccines at public school registration on the basis of personal beliefs," writes Sears. "Parents who decline vaccination in [some] states can have their children taken away from them." Sears fails to mention that enforcement of vaccine mandates, which were initiated because of measles outbreaks that swept across the United States in the middle 1970s, has dramatically reduced hospitalizations and deaths resulting from vaccine-preventable diseases[3,4] or that states with philosophical exemptions have higher rates of vaccine-preventable diseases (such as pertussis), compared with states without such exemptions.[5] His claim that unvaccinated children have been removed from the home is alarming and false, only inflaming an already frightened public.

Vaccine-Preventable Diseases Are Not That Bad

In his chapter on pneumococcal infection, Sears tells the following story. "A six-month-old unvaccinated infant had a pneumococcal ear infection that spread to the skull bones behind the ear. She required surgery and IV [intravenous] antibiotics. Afterward, I asked the parents if they regretted their decision not to vaccinate. They said no. They were both well-educated professionals, had done a lot of reading on this issue, and still felt comfortable with their decision." Sears implies that vaccine-preventable diseases, although occasionally serious, are not really that bad. Before the conjugate pneumococcal vaccine became part of the routine schedule in 2000, however, pneumococci caused ~17 000 cases of invasive disease every year in children <5 years of age, resulting in 700 cases of meningitis and 200 deaths.[6] The parents in Sears' story were fortunate that their child did not suffer sepsis, severe pneumonia, or fatal or debilitating meningitis.

Hide in the Herd

Perhaps the most disingenuous comment in the book is directed at parents who are afraid of the measles-mumps-rubella (MMR) vaccine. "I also warn [parents] not to share their fears with their neighbors," writes Sears, "because if too many people avoid the MMR, we'll likely see the diseases increase significantly." In other words, hide in the herd, but do not tell the herd you're hiding; otherwise, outbreaks will ensue. Sears' advice was prescient. Recent outbreaks of measles in 15 states, caused by an erosion of herd immunity in communities where parents had chosen not to vaccinate their children, were the largest in the United States since 1996.[7]

Natural Infection Is Better Than Vaccination

Sears describes the value of chickenpox parties. "Some parents . . . may purposely get their child exposed to get the disease over with," he writes. "If you've ever been invited to a 'chickenpox party,' you'll know what I'm referring to. Having the disease in most cases provides lifelong immunity (better immunity than the shot provides), so there is practically no worry about catching the disease as an adult." Sears' concern that immunity to chickenpox will fade, only shifting the burden of disease from children to adults, fails to take into account decades of experience with other live viral vaccines. Although measles, mumps, and rubella infections are often more serious in adults, widespread immunization of children has not shifted the burden of disease; rather, it has reduced dramatically or eliminated these infections. Furthermore, although Sears is correct in stating that natural immunity is generally better than vaccine-induced immunity, the high price of natural immunity, that is, occasionally severe and fatal disease, is a risk not worth taking.

Vaccination Has Eliminated Infectious Diseases at the Price of Causing Chronic Diseases

Sears writes, "When I reviewed numerous studies, I did find some that show a possible link between a vaccine and a chronic disease. Examples include the Hib [*Haemophilus influenzae* type b] vaccine and diabetes, the hep B vaccine and multiple sclerosis and rheumatoid arthritis, and the MMR vaccine and eczema." Sears fails to point his readers to the clear body of evidence that has exonerated vaccines as a cause of these disorders (reviewed in ref 8).

Vaccine Safety Testing Is Insufficient

Sears writes, "A new medication goes through many years of trials in a select group of people to make sure it is safe. . . . Vaccines, on the other hand, don't receive the same type of in-depth short-term testing or long-term safety research." On the contrary, vaccines are tested in larger numbers of children for longer periods of time than drugs. For example, the human papillomavirus vaccine was tested in 30 000 women,[9] the conjugate pneumococcal vaccine in 40 000 children,[10] and each of the current rotavirus vaccines in ~70 000 children before licensure.[11,12] No medication receives this level of scrutiny. Furthermore, safety mechanisms such as the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink Project are model systems for detecting rare adverse events after licensure. Drug surveillance would benefit from mimicking these vaccine catchment systems.

Public Health Officials Make Recommendations for the Public and Not for Individuals

Sears writes, "Obviously, the more kids who are vaccinated, the better our country is protected and the less likely it is that any child will die from a disease. Some parents, however, aren't willing to risk the very rare side effects of vaccines, so they choose to skip the shots. Their children benefit from herd immunity . . . without risking the vaccines themselves. Is this selfish? Perhaps. But as parents you have to decide. . . . Can we fault parents for putting their own child's health ahead of the other kids' around him?" Sears' argument represents a fundamental flaw in logic. For example, Sears states that the polio vaccine, which prevents a disease that has not occurred in the United States since 1979, is given to protect the population and not the individual. "[Polio] doesn't occur in our country," he writes, "so the risk is zero for all age groups." Although it is true that polio has been eliminated from the United States, it has not been eliminated from the world. The disease is still prevalent in India, Africa, Southeast Asia, and the Middle East. Because international travel is common and because only 1 of every 200 people infected with poliovirus exhibits symptoms, it is likely that people who are unknowingly shedding poliovirus come into the United States every year. An unimmunized child would be particularly susceptible if an outbreak occurred. Furthermore, the unimmunized child might later travel to a country where polio is endemic. Therefore, every individual benefits from receiving polio vaccine.

THE PROBLEM

Decision-Making

Sears wants parents to use the information he has provided to make their own decisions about whether to vaccinate their children. "I have offered you all the information you need to make this decision," he writes, "but I have held back from actually telling you what to do. I want you to formulate your own decision without letting my opinion sway you one way or the other." Unfortunately, Sears, who wants parents to make informed decisions, has written a book that will largely misinform them.

Distinguishing Good Science From Bad Science

At the end of every chapter describing individual vaccines, Sears includes sections titled "Reasons to get the vaccine" and "Reasons some people choose not to get the vaccine." In the latter sections, Sears often takes the position that, if parents think that a vaccine is problematic, then the vaccine is problematic. He believes that parents' fears should be indulged by offering alternative schedules, not countered by scientific studies, and he fails to explain that good science is the only way to determine whether a vaccine causes a particular adverse event. Instead, Sears alludes to evidence on both sides of any issue, failing to distinguish studies on the basis of their quality, internal consistency, or reproducibility and failing to distinguish those that are accepted by the scientific community from those that are not.

Risks From Vaccines

In chapters describing individual vaccines, Sears lists side effects found in product inserts and VAERS reports. Weighing the risks and benefits of the conjugate pneumococcal vaccine, he writes, "In the first two years of Prevnar's use in the United States, about 32 million doses were given, and about 4100 adverse reactions were reported to VAERS. Most reactions were fairly mild, but about 15 percent (around 600) were considered serious. This means that for every 53 000 doses, one serious reaction occurred." Like many parents who are concerned about vaccines, Sears thinks that reports to VAERS represent an accurate profile of a vaccine's side effects. However, VAERS is a passive surveillance system and cannot be used to determine the true incidence of adverse events, which can be determined only by using control groups (not provided by VAERS). For this reason, VAERS reports often represent coincidental and not causal associations. Furthermore, the source of VAERS reports can be misleading. For example, many of the recent VAERS reports of autism after receipt of vaccines came not from parents, doctors, nurses, or nurse practitioners but from personal-injury lawyers.[13] Finally, pharmaceutical company lawyers often list in product inserts all adverse events that occurred after receipt of vaccines even if those events occurred at rates similar to those found among placebo recipients.

Risks From Vaccine-Preventable Diseases

Sears often counters data on the national incidence of specific infectious diseases with personal experience. For

example, in the section on pneumococcal disease, he writes, "I've seen only one serious case of [pneumococcal] infection in my office in my ten years of practice." Regarding meningococcal disease, he writes, "I saw one case during my medical training, and I haven't seen it since." Because Sears works in a private practice and not a hospital, he is unlikely to see serious infectious diseases commonly. His individual experience should be enriched by his knowledge of published studies, however, and not used to negate them. This see-no-evil approach only misinforms his readers.

Animal Products

Sears explains that some vaccines are made by using fetal bovine serum, raising the specter of mad cow disease. "All animal and human tissues are carefully screened for all known infectious diseases," he writes. "Some vaccine critics are still worried, however, that there may be other viruses or infectious agents (called 'prions') . . . that are much smaller than viruses and that we don't yet know how to screen for." Sears fails to mention that prions propagate in the nervous system and not the bloodstream, that they do not grow in the mammalian cells used to produce attenuated viral vaccines, that they have never been found to contaminate fetal bovine serum, that mad cow disease is not a human health problem in the United States, and that studies found no increased risk of mad cow disease in children who did or did not receive vaccines in the United Kingdom, where mad cow disease was a problem (reviewed in ref 14). Rather, in keeping with his theme that parental fears trump scientific studies, he concludes, "If exposure to animal tissues worries you, you may want to choose the brand that doesn't use cow extract."

Thimerosal

Sears does not take a clear stand on this issue, writing, "Do I think mercury is harmful? Yes. Do I think the amount in the old vaccines caused harm? I'm not 100% convinced one way or the other." It is hard to imagine a better conceived, better designed study on the subtle effects of mercury poisoning than that performed by Bill Thompson and colleagues at the CDC and published in 2007.[15] The study carefully identified the quantity of mercury exposure from thimerosal before birth (from RhoGam; Ortho Diagnostics, Raritan, NJ) and after birth (from vaccines) for >1000 children. Researchers then subjected the children to >40 neurologic, psychological, and developmental tests and found no significant differences for those who received greater or lesser quantities of mercury. By choosing not to evaluate the quality of the scientific findings on this issue, Sears again fails to educate his readers.

Aluminum

Sears' main argument for spacing out vaccines is to avoid giving infants too much aluminum at one time, writing, "When a baby gets the first big round of shots at two months, the total dose of aluminum can vary from 295 micrograms . . . to a whopping 1225 micrograms if the highest aluminum brands are used and a hep B vaccine is also given. . . . These doses are repeated at four and six months." Extrapolating studies of patients undergoing hemodialysis and severely premature infants to healthy newborns, Sears claims that these quantities might be unsafe. However, Sears fails to put aluminum exposure in context. By 6 months of age, infants typically ingest ~6700 μg of aluminum in breast milk, 37 800 μg in infant formula, or 116 600 μg in soy-based formula.[16] Furthermore, Sears fails to describe scientific studies that led the National Vaccine Program Office to conclude that the amount of aluminum contained in vaccines did not warrant changing the vaccine schedule.[17]

Other Vaccine Ingredients

Sears claims that the MMR vaccine contains human albumin purified from human blood. "The human and cow blood products used in manufacturing may also concern some parents," he writes. However, the MMR vaccine contains genetically engineered human serum albumin, a product that is not derived from human blood, as a stabilizer.

MMR Vaccine and Autism

Sears writes, "Some doctors and researchers who suspect the MMR vaccine may play a role in autism also feel it is safer to give the three injections separately, spaced out one year apart. I can't find enough research to determine if this precaution is justified, but in theory it does make sense." For this reason, Sears recommends that the measles, mumps, and rubella components of MMR be administered separately. Sears fails to mention the many epidemiological studies that showed that the MMR vaccine did not increase the risk for autism[18–24] or to note that the theory that measles-containing vaccine causes intestinal inflammation has been thoroughly debunked.[25–27] Worse, Sears takes the discredited notion that measles vaccine causes intestinal disease one step further, recommending that "the MMR vaccine not be given when a child is suffering from diarrhea or has taken antibiotics in the past few weeks. This vaccine may cause more reactions when the intestines aren't at peak health."

THE LOGIC

Coincidence Versus Causality

Sears' general theories of science and medicine are often poorly reasoned or illogical. Sears writes, "Sometimes infants and children develop medical problems . . . within days or weeks of a vaccination. Although it can be highly suspected that the vaccine was the cause, it can't be proven. I'm sure the truth of the matter is somewhere in between causality and coincidence." Epidemiological studies, which are the single best way to determine whether a vaccine is associated with an adverse event, have shown consistently that vaccines cause certain problems, such as measles-containing vaccine causing thrombocytopenia[28] and diphtheria-tetanus toxoids-pertussis vaccine causing seizures.[29] Some studies have failed consistently to find an association, such as

thimerosal in vaccines causing autism.[30,31] In all of these cases, it can be said that a truth has emerged. There is no middle ground between coincidence and causality; a vaccine either causes a problem or it does not.

Scientific Proofs

Sears has a poor grasp of the scientific method. "Some studies have been published in recent years that have failed to show statistical proof of a relationship between vaccines and autism," he writes. "However, by the same token, it is also difficult to prove that there is not a connection." Using the scientific method, investigators form the null hypothesis. Good epidemiological studies are powered to reject or not to reject the null hypothesis. However, the scientific method does not allow investigators to accept the null hypothesis. Said another way, scientists can never prove never. The most that scientists can show is that 2 events are not associated statistically; scientists cannot prove that the events can never be associated statistically. In stating that it is "difficult to prove that there is not a connection," Sears is suggesting the impossible.

Context

Sears argues that elements such as mercury are neurotoxins and the presence of mercury in thimerosal makes some vaccines (such as multidose preparations of inactivated influenza vaccines) dangerous. However, Sears never discusses the fact that mercury is present on the earth's surface and that, like aluminum, children ingest mercury in breast milk and infant formula at levels that often exceed those contained in vaccines.[32] Sears also fails to explain that small quantities of heavy metals such as cadmium, beryllium, lead, and thallium, which can be toxic in large quantities, are present in everyone who lives on our planet. By creating the notion of zero tolerance, Sears fails to educate his readers that the dose makes the poison, that it is the amount of a potential toxin and not its mere presence that counts.

Understanding Risk

Sears does not recommend the meningococcal vaccine for teenagers because of the possible risk of Guillain-Barré syndrome. Indeed, the most recent estimates are that the conjugate meningococcal vaccine might cause Guillain-Barré syndrome for ~1 per 1 million recipients.[33] However, the risk of meningococcal disease for a child who is not vaccinated is ~10-fold greater than the possible risk of Guillain-Barré syndrome for a child who is vaccinated. Furthermore, the high rates of death and permanent sequelae caused by meningococci make the choice not to be vaccinated an illogical one. By failing to weigh the relative risks of the disease and vaccine side effects accurately, Sears again misinforms his readers.

THE HARM

For parents who are worried about vaccines, Sears offers 2 alternative schedules. One, titled "Dr Bob's Selective Vaccine Schedule," is for parents who want to decline or to delay vaccines. Children whose parents choose this schedule might not be receiving the measles, mumps, rubella, varicella, and hepatitis A vaccines and will not be receiving the polio and influenza vaccines or a booster dose of pertussis vaccine.

The other schedule, titled "Dr Bob's Alternative Vaccine Schedule," is written for parents who worry that children are receiving too many vaccines too early. Children whose parents choose this schedule will not be receiving the influenza vaccine until 5 years of age (which is unfortunate, given that tens of thousands of children <4 years of age are hospitalized with complications resulting from influenza every year),[34] will not be receiving the hepatitis B vaccine until 2.5 years of age, will not be receiving measles vaccine until 3 years of age, and, to space out vaccines so that children do not receive >2 shots at 1 visit, will be visiting the doctor for vaccines at 2, 3, 4, 5, 6, 7, 9, 12, 15, 18, 21, and 24 months and 2, 2.5, 3, 3.5, 4, 5, and 6 years of age. Increasing the number of vaccines, the number of office visits, and the ages at which vaccines are administered will likely decrease immunization rates. In addition to the logistic problem of requiring so many office visits, Sears' recommendation might have another negative consequence; recent outbreaks of measles showed that several children acquired the disease while waiting in their pediatricians' offices.[7]

At the heart of the problem with Sears' schedules is the fact that, at the very least, they will increase the time during which children are susceptible to vaccine-preventable diseases. If more parents insist on Sears' vaccine schedules, then fewer children will be protected, with the inevitable consequence of continued or worsening outbreaks of vaccine-preventable diseases. In an effort to protect children from harm, Sears' book will likely put more in harm's way.

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The Problem With Dr Bob's Alternative Vaccine Schedule

Paul A. Offit and Charlotte A. Moser

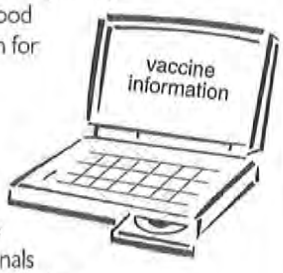
Pediatrics 2009;123;e164
DOI: 10.1542/peds.2008-2189

Reliable Sources of Immunization Information: Where to go to find answers!

Websites

American Academy of Pediatrics (AAP)

www.aap.org/immunization AAP's childhood immunization website contains information for both parents and clinicians.



Centers for Disease Control and Prevention (CDC)

www.cdc.gov/vaccines The information on this website ranges from official vaccine recommendations for healthcare professionals to information for the general public about vaccines.

Every Child by Two (ECBT) www.ecbt.org and www.vaccinateyourbaby.org ECBT, founded by Rosalynn Carter and Betty Bumpers, has created these two websites. Each contains a broad array of educational materials and information about vaccines, their safety, vaccine research and science, vaccine misperceptions, and many other topics to help clinicians and parents.

Immunization Action Coalition (IAC)

www.immunize.org and www.vaccineinformation.org IAC is a nonprofit organization that promotes immunization for all people against vaccine-preventable diseases. These websites offer educational materials, photos, and video clips for parents, healthcare professionals, the media, and the general public.

National Network for Immunization Information (NNii)

www.immunizationinfo.org NNii provides current, science-based, extensively reviewed information to healthcare professionals, the media, policy makers, and the public.

U.S. Dept of Health and Human Services (HHS)

www.vaccines.gov Vaccines.gov is the federal gateway to information on vaccines and immunizations for infants, children, teenagers, adults, and seniors.

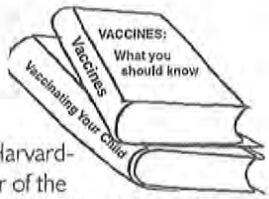
Vaccine Education Center (VEC) www.vaccine.chop.edu The goal of the VEC at Children's Hospital of Philadelphia is to accurately communicate the facts about each childhood vaccine. VEC publishes a monthly vaccine e-newsletter for parents titled "Parents PACK." For more information or to subscribe, visit www.vaccine.chop.edu/parents

Phone Numbers

CDC-INFO Contact Center

A toll-free number for consumers and healthcare professionals who have questions about immunization and vaccine-preventable diseases. Call (800) CDC-INFO or (800) 232-4636. The Center operates 24/7 in English & Spanish. TTY: (888) 232-6348.

Books for Parents



Baby 411, 4th edition

By Denise Fields and Ari Brown, MD, Windsor Peak Press, 2009. Written by a Harvard-trained pediatrician (Brown) and the author of the best-selling *Baby Bargains* (Fields), this book is the ultimate compilation of frequently asked questions for baby's first year. It includes a special section on vaccines. To purchase, visit your local bookstore or www.windsorpeak.com/baby411

Do Vaccines Cause That?! A Guide for Evaluating Vaccine Safety, 1st edition

By Martin Myers, MD, and Diego Pineda, MS. Published by Immunizations for Public Health, 2008. Get straight, science-based answers to parents' questions about the safety of vaccines. To purchase, visit your local bookstore or www.dovaccinescausethat.com

Parents Guide to Childhood Immunization, 2010

This 68-page booklet from CDC introduces parents to 14 childhood diseases and the 10 vaccines that can protect children from them. Parents can order a free booklet or print their own copy by visiting www.cdc.gov/vaccines/pubs/parents-guide

Plain Talk About Childhood Immunization, 6th edition

Washington State Department of Health, et al., 2008. This 54-page booklet provides parents with accurate information about immunizations and the diseases they prevent, vaccine safety, and other topics of interest to the public. The publication, available in English and Spanish, can be downloaded at http://here.doh.wa.gov/materials/plain-talk-about-childhood-immunizations in either low resolution (for printing on office copiers) or high resolution (for professional printing).

Vaccines and Your Child, Separating Fact from Fiction, 2011 By Paul Offit, MD, and Charlotte Moser, Columbia University Press, 2011. This book answers questions about the science and safety of modern vaccines. In straightforward prose, Offit and Moser explain how vaccines work, how they are made, and how they are tested. Most important, they separate the real risks of vaccines from feared but unfounded risks. To purchase, visit your local bookstore or www.cup.columbia.edu

Videos

"Vaccines and Your Baby" and "Vaccines: Separating Fact from Fear" Available for a nominal charge in English and Spanish in DVD format, these videos answer many questions that new parents have. Ordering information is available at www.chop.edu/service/vaccine-education-center/familyOrder.cfm or parents can watch the videos online at www.chop.edu/service/vaccine-education-center/related-information/multimedia.html.

Technical content reviewed by the Centers for Disease Control and Prevention, May 2011.

www.immunize.org/catg.d/p4012.pdf • Item #P4012 (5/11)