

# Clear Answers and Smart Advice About Your Baby's Shots

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In response to the recent media attention given to vaccines, autism, and other controversies concerning vaccines, the Immunization Action Coalition (IAC) offers this **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.

It's time to jump right into a hot topic you'll find in parent circles – vaccines. Nothing seems to stir the blood these days more than a good ol' fashion debate on vaccinating your child. And after the 2015 measles outbreak at Disneyland, the silent majority of parents who believe in vaccinations are far from silent.

A head's up: since there is so much misinformation out there on vaccines, you need to be armed with detailed, accurate information. And like the rest of this book, that is what you will get in this chapter. The information we provide is based on scientific evidence and solid peer-reviewed research. Remember our mantra: show us the science! Your child is too precious to make such important decisions on anything less. This chapter is not based on personal anecdotes, conspiracy theories, "research" done in people's basements (we are not kidding), or the crusades of B-list celebrities.

However, before we get to our take on this debate, let's go back in time a bit. Well, more than a bit. How did the human race survive when other early humans didn't? Yes, making tools and finding food most efficiently played a big role. But here's another key element: we built civilizations. And we developed a sense of responsibility – to ourselves and to our society. Every time we respond to a tragedy in our nation – whether it be 9/11, Hurricane Sandy, or the Boston Marathon bombing – we are reminded of how we are not just individuals living in our own little worlds. It's part of our civic duty to lend a hand and take care of our neighbors.

So, what's this pontificating have to do with vaccines? Again, it is our responsibility to work together as a community... this time, the subject isn't terrorism or storms, but something that can be just as terrifying: infectious diseases. Consider a bit of history: in the 1890s, people would have seven or eight children in their families and only half of them would survive childhood. Just go to an old graveyard sometime and look at the ages listed on the headstones. Many of the diseases that killed those children are now prevented by vaccination. It's a fact: vaccinations have increased the life expectancy of our nation's children. That's why our grandparents and parents embraced vaccines.

Here's a crucial point: the key to a vaccine's success is that everyone in the community gets vaccinated. Vaccines won't work if a large number of folks just choose to opt out of the system and their responsibility. Please keep this in mind as you read about vaccinations. Your

decision (and every other parent's decision) affects your child. And society as a whole. Germs are rather simple creatures... they just look for a new person to infect. They don't play politics.

## ■ REALITY CHECK

The concept of "public health" has been around since antiquity. Obviously, rulers had a vested interest in keeping their subjects healthy so they had a society to rule. Through the years, governments have been responsible for managing numerous programs. The most important advances in public health have been vaccination programs, water purification, and waste disposal/sanitation systems. The only way for public health to work, though, is for all members of the community to follow the same rules.

## Who came up with the idea of vaccinations in the first place?

It took centuries of observation as well as trial and error. (And sometimes, error meant death.) The first real step was describing the disease, in this case, smallpox. Smallpox was a deadly disease that, historically, wiped out entire civilizations. The earliest descriptions can be found as far back as the ninth and tenth centuries among Turks. In fact, "inoculation," or the infecting of a person with the disease in hopes of introducing a mild form and then creating immunity, was practiced first in Asia. In the 1700s an English aristocrat, Lady Mary Wortly Montagu, was living in Constantinople and learned of the practice of inoculation (known then as variolation). She had her son inoculated and subsequently, brought the practice back to England.

At about the same time, an English country doctor, Edward Jenner, made an interesting connection: milkmaids who had been exposed to cowpox (a common disease in cattle at the time) never seemed to get smallpox infections during epidemics. He began to study the idea that vaccinating humans with cowpox virus would make them immune to smallpox. In 1798 he published a paper on his idea and called it "Vaccination." Not to say, by the way, that Dr. Jenner's idea was accepted with completely open arms. In the nineteenth century there did emerge a group opposed to vaccination led by Mary C. Hume. See, even the anti-vaccination lobby has been around a long time! Of course, in those days, you could be prosecuted for refusing to vaccinate.<sup>1</sup>

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People were inoculated with a small amount of cowpox virus on their arm. It caused a localized infection at that site (hence, the scar that we forty-somethings and above bear). And true to Dr. Jenner's hypothesis, it provided protection against smallpox disease. In 1972, the United States stopped vaccinating against smallpox because it was no longer a threat to the population. In 1977, the last case of smallpox occurred in Somalia. In 1980, the World Health Organization declared the world free of smallpox, thanks to a global effort to immunize all children.

The success of the smallpox vaccine and other scientific discoveries led to the evolution of many vaccines. These new, safer vaccines are extremely effective in preventing diseases and epidemics that our grandparents and parents can still remember.

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

For starters, I want your baby to be protected. But I 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 for your child to protect them. 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 90–95% 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!

As comedian Jon Stewart once put it, herd immunity is like a zombie movie. You are in an isolated farmhouse and the occupants rely on each other to board up their windows to keep the zombies (germs) out. The zombies get in when some lady from Marin County decides not to board up her windows because she read an article on a wellness blog about the potential health risks of boarding up windows. You can guess what happens!

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% 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.<sup>2</sup>

### REALITY CHECK

**The Good News** – While parents are asking more questions, they are still choosing to vaccinate their kids. The most recent Centers for Disease Control and Prevention (CDC) survey (2013) showed 99.3% of U.S. children aged 19 to 35 months are being vaccinated. Yes, 99.3%. Despite all the media stories on vaccine “controversy,” only a tiny fraction of parents – less than 1% – are choosing to forgo vaccinations.

## Some Common Vaccine Questions

### What are vaccines?

Vaccines are materials that are given to a person to protect them from disease (that is, provide immunity). The word vaccine is derived from “vaccinia” (cowpox virus), which was used to create the first vaccine in history (smallpox). Modern medicine has created many vaccines. Vaccines PREVENT viral and bacteria infections that used to cause serious illness and death.

### How do vaccines work?

Here is your microbiology lesson for today. Your immune system is your body's defense against foreign invaders (viruses, bacteria, parasites). Vaccines prepare your body to recognize foreigners without getting infected. A vaccine revs up your immune system to make antibodies (smart bombs with memory) for the signature of a particular germ. So, if your body sees the real germ, voila! You already know how to fight it off. There are three types of vaccinations: inactivated, live attenuated, and inactivated bacterial toxins.

- Inactivated vaccines do not contain any living germs. An immune response forms against either a dead germ, part of the germ (recombinant DNA), or a protein or sugar marker that sits on the outer layer of the germ (its signature). Very cool. These vaccines are safe to give to immune-compromised people. The only down side is that several doses of the vaccine are needed to provide full, life-long protection against disease. Some of these types of vaccines include: influenza, hepatitis A & B, *Haemophilus influenzae* type B (Hib), pertussis (whooping cough), inactivated polio, pneumococcal.
- Live attenuated vaccines are weak forms of the germs that cause infection. An immune response occurs just as if your body had the infection. So one or two doses of vaccine gives you lifelong protection. These vaccines are not given to immune-compromised people because they can make them sick. Examples include: measles, mumps, and rubella, oral polio, smallpox, tuberculosis, varicella (chickenpox), rotavirus.
- Toxoids (inactivated bacterial toxins) are vaccines that create a defense against the toxin (poison) that a bacteria germ makes. Examples of toxoid vaccines include: diphtheria, tetanus.

### What are the diseases we are protected against with vaccination?

Good question. You are probably unfamiliar with most of these diseases since we don't see them much anymore in the U.S. After you hear about the many successes we've had in eradicating disease with vaccination, thank your parents for immunizing you. As you read

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through the vaccination schedule, note that some diseases are viruses. Antibiotics kill bacteria only. Doctors have no medications to cure the viral infections. Doubt the effectiveness of vaccines? Just take a look at the sharp decline of illness and death rates from these diseases since 1950. Here is the link if you want to check it out: [www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/E/reported-cases.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/E/reported-cases.pdf). Rather amazing, no? Diseases that used to kill thousands (if not hundreds of thousands) now only harm a handful of people – thanks to vaccines.

### How are vaccines tested to make sure they're safe?

Vaccines are researched extensively for an average of 15 years before being approved for use. A pharmaceutical company conducts medical research trials in a series of stages. Once safety is proven, the vaccine is tested in several thousand volunteers to make sure the vaccine actually works. These volunteers are followed for at least one year to be sure that no serious side effects occur.

Nothing in this world is 100% foolproof, including vaccine science. But the research trials that occur before licensing are very rigid. If you think there are a lot of vaccines on the market, imagine how many didn't make it through the research phase of development.

The Food and Drug Administration (FDA) governs this whole process. The FDA is the watchdog for any medication that is sold over-the-counter or by prescription. There are extremely high standards that must be met before any product is allowed for human use.

After a vaccine is approved for use, long-term follow-up studies are done to assess for side effects, adverse reactions, and potency over a lifetime.

#### ■ REALITY CHECK

Given the FDA's mixed track record, you may be skeptical about trusting the government when it comes to vaccine safety. But in truth, the system is in place to protect consumers. Although conspiracy theorists might disagree, the FDA really is on our side.

To improve drug and vaccine safety, the Institute of Medicine has called for an overhaul of how the FDA works – in the future, the FDA will do more ongoing safety reviews of medicines and make all clinical study results public. This should help boost public confidence in the FDA and vaccine safety.

### Why is my child getting more shots than I did?

Simple answer: we've been successful inventing vaccines to fight more diseases. It's one of the important advances in modern medicine – vaccines prevent disease, injury, and death. More vaccines are a good thing!

An important point: many of the vaccine-preventable diseases are viruses. These viral infections cannot be treated with medicine once an infection occurs (for example, Hepatitis B).

Vaccines that protect against bacterial diseases are often serious ones, and resistant to many antibiotics (for example, Prevnar).

And even though the number of shots has gone up, the total load on the immune system has gone down. Today's vaccines are smarter and better engineered than the shots from a few decades ago. In fact, the total number of immunologic agents in the entire childhood vaccination series today is less than what was in just two vaccines in 1980!

Our children are getting smarter, safer vaccines today and better protection than we ever got as kids.

### Are we giving too many shots, too soon?

This is a false mantra of the anti-vaccine crowd: they say babies are receiving too many shots (compared to say, 1980) and too soon (infants can't handle all these shots, they say).

So, let's look at this scientifically. On any given day, your baby is exposed to literally thousands of germs (it doesn't matter how spotless your house is). Exposing your child to five to eight different germs in the form of vaccines is a spit in the bucket.

Young children have better immune responses to vaccines than adults and older children. So they will form adequate immune responses to various vaccines simultaneously. (This is studied extensively before a vaccine is licensed.) Even if your baby got 11 shots at the same time, he would only need to use about 0.1% of his immune system to respond to them.<sup>3</sup>

Giving several vaccines at once does not damage, weaken, or overload the immune system. Vaccines boost the immune system. Also, the diseases that the vaccines protect against are the most severe in infants and young children. Your doctor wants to get those vaccinations in as safely and effectively as possible. That's why the timing is so important (and why a staggered or delayed vaccination schedule is a bad idea – more on that in the controversies section of this handout).

### Can't you just give one big shot that has all the vaccines in it?

Medical science is working on it!

There have been a few combination vaccines licensed for use. The largest combination vaccines are Pediarix (DTaP, IPV, Hepatitis B) and Pentacel (DTaP, IPV, Hib). The reason there isn't just one big shot is that some vaccines are ineffective when they are sitting together in a solution. Your baby may still need more than one shot, but if your doctor uses a combo vaccine, at least it will be fewer shots than if they are all administered separately.

More combination vaccines are on the horizon.

### What groups make decisions about vaccinations for children?

There are four governing panels of experts in infectious diseases that make recommendations for vaccinations. These smart folks include: American Academy of Pediatrics (AAP), American Academy of Family Physicians (AAFP), Advisory Committee on Immunization Practices (ACIP), and the Centers for Disease Control and Prevention (CDC). Because there are several groups involved in this effort, there is some variability in vaccination schedule recommendations.

### My baby has a cold. Should I hold off on vaccinations?

No! This is a common misconception of parents. Even if your baby has a minor illness, he can still get his shots. We cannot stress how important it is to get your child vaccinated in a timely manner. So don't let a sniffle or two make you reschedule an office visit for shots. Your child can also get his shots even if he is on antibiotics.

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## Can I choose not to vaccinate my child?

Yes, but we wouldn't advise it. Choosing not to vaccinate is not a risk-free choice. It's choosing to expose your child to potentially serious infection. It's also choosing to expose other children in your community to serious, preventable diseases. And if you think your child will be safe because everyone else vaccinates his or her kids, you'd be wrong (and very selfish, we might add). You can also choose not to stop at a stop sign, but we wouldn't advise it!

### ■ REALITY CHECK

Vaccine requirements for school entry vary by state. There is no one consistent policy. All 50 states allow vaccine exemptions for medical reasons, 47 states allow exemptions for religious reasons, and about 21 states allow exemptions for philosophical reasons.<sup>4</sup> After the 2015 measles outbreak, several state legislatures are reconsidering their existing laws for vaccine exemptions. Limiting the exemptions improves vaccination rates and thus protects more children.

## I've heard that getting a disease provides immunity forever and vaccinations might not provide lifelong protection. Wouldn't it be better to get the disease? Isn't that a more "natural" way of creating immunity?

No. The diseases we prevent by vaccination are not minor illnesses (this includes chickenpox). For instance, would you rather have your child get meningitis and die or get the vaccine? Getting chickenpox or any other disease the "natural way" is a much greater health risk without any significant benefit. And just think of the discomfort, pain and perhaps serious injury that come with getting any of these diseases.

It is true that some vaccinations require a booster dose to keep antibody levels high. That is why we need a tetanus booster every ten years.

## What would happen if we stopped using vaccinations?

That's an easy one. The diseases would come back.

Vaccinations keep us from getting sick from these infections. But all of the infections we protect against are alive and well in our world. As of today, the only disease we have completely eliminated is smallpox. And when it was eliminated, we stopped vaccinating for it.

Anyway, it's a simple fact: when immunization rates drop, epidemics occur. Just look at states with lower immunization rates – their rates of pertussis (whooping cough) are twice the number seen in states with higher percentages of immunization rates. Children whose parents opt out of vaccines face a 23x greater risk of getting whooping cough.<sup>5</sup> In the 2015 measles outbreak, most cases occurred in communities with measles immunization rates below 80%.

### ■ REALITY CHECK

In 1990, low immunization rates led to a measles epidemic of 55,000 cases and over 100 preventable deaths in the U.S. The U.S. saw a measles epidemic again in 2008 – over 90% of these cases were unvaccinated children, two-thirds of which were by parental choice. But a few of the cases were infants who were too young to be vaccinated (and exposed to an infected child in the doctor's waiting room). You would think we would have learned our lesson, but 2015 was another banner year for measles. This serves as a reminder that vaccine-preventable diseases have not disappeared.

## What are the typical side effects of vaccination?

Fever, fussiness, redness, or lump at the site of the injection.

Inactivated vaccines cause an immediate immune response. The body mounts a response to the foreign invader as if it were being infected. The result, typically, is a fever within 24 hours of vaccination. Babies sometimes feel like they are coming down with a cold or flu (body aches, pains). Some babies prefer to sleep through the experience; some choose to tell you how they feel (fussiness, crying). All of these symptoms resolve within 24 to 48 hours of vaccination.

Live attenuated vaccines (MMR, Varicella) cause a delayed immune response. This occurs one to four weeks after the vaccination is given. Long after the doctor's visit, your child may wake up one morning and have a fever.

This may be accompanied by a rash that looks like measles (pimples) or chickenpox (clear, fluid-filled pimples). The rash can sometimes be dramatic. Both the fever and the rash tell you that your baby is forming an immune response to the vaccination. Babies are not contagious and aren't too bothered by the rash. You don't need to call your doctor. This reaction is expected.

Redness at the injection site is common. In particular, the fifth booster dose of the DTaP (at age five years) can cause a pretty dramatic area of redness. No worries. We do get quite a few phone calls about it, though!

A firm lump may develop at the injection site if some of the fat in the arm/leg gets nicked as the needle goes into the muscle. This is called fat necrosis. It usually goes away within six to eight weeks. It doesn't hurt.

**Red flag!** If your baby has a fever more than 72 hours after being vaccinated, it's not from the vaccination. You need to call your doctor. The only exceptions are the MMR and chickenpox vaccines, which typically cause a fever one to four weeks afterwards.

### ■ REALITY CHECK

To help reduce fever and discomfort from shots, it's okay to give your baby acetaminophen (Tylenol) as long as you wait at least four hours after vaccinations are given. The dose is not listed on the package. It says to "consult a doctor." That's because doctors don't want you giving this medicine to a baby three months or younger with a fever without checking in first. Other than with shots, you need to call your doctor about fevers in this age group.

## What are the worst reactions to vaccination?

These are called adverse reactions. This is the equivalent of an allergic reaction to a medication – and fortunately, they are all quite rare. With each generation of newer vaccinations, the risk of serious reactions is almost eliminated.

Adverse reactions include:

1. Death.
2. Anaphylactic reaction.
3. Encephalitis.
4. Fever-related seizure (convulsions).

Both the CDC and FDA keep close tabs on adverse reactions to vaccines via a Vaccine Adverse Event Reporting System (VAERS). Both doctors and patient families may submit a VAERS form if any adverse reaction occurs.

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Keep in mind that medical illness reports do not prove an association of a particular illness with a specific vaccination. The job of both the CDC and FDA is to review each report that occurs and see if there is a pattern of subsequent illness after vaccination. VAERS data is publicly available at [vaers.hhs.gov](http://vaers.hhs.gov). To report a possible reaction, you can download a form at the same site. There is also a Clinical Immunization Safety Assessment Project comprised of six U.S. academic medical centers that evaluates adverse reactions to vaccines.

While we would be remiss if we didn't tell you that vaccinations have some risks associated with them, we want you to remember that the risk of adverse reaction is significantly lower than leaving your baby unprotected.

In 1988, recognizing that there are rare, serious reactions that occur as a result of vaccinating children, the U.S. Department of Health and Human Services created the Vaccine Injury Compensation Program. This program attempts to determine whether adverse reactions from vaccines are responsible for injuries or death and then to provide the victim with compensation. Since 1988 there have been about 15,000 claimants. Considering there are four million babies born each year and most have been vaccinated, the odds of an injury are staggeringly tiny.

Another statistic to mull over: 1.9 billion doses of vaccine were given in the U.S. from 1991 to 2001. Only 2,281 cases of allergic reactions were reported.<sup>6</sup> (Compare that statistic to one in 50 adults who have a food allergy!)

We agree that an adverse reaction only has to happen to one child for it to be heartbreaking. But if we look at the big picture, we can point to the millions of children who might have experienced illness, chronic disability, and death if diseases like smallpox or polio were not controlled by vaccinations.

### Are there any reasons I should not vaccinate my child?

There are several very specific medical reasons to discontinue or hold off on certain vaccinations. These include:

1. Patient or family member is immune-compromised.
2. Patient had disease (for example, if you've had chickenpox, you don't need the vaccine).
3. Patient has encephalitis or degenerative brain disorder.
4. Patient has allergy to vaccine or to an additive in the vaccine.

If your baby has a food allergy to eggs or gelatin, or an allergy to antibiotics (such as neomycin, streptomycin, polymyxin B), notify your doctor before any vaccinations are given. Several vaccines are grown in chick embryo cells and therefore contain a small amount of egg protein: flu vaccine, MMR, rabies, and yellow fever vaccine. The MMR vaccine also includes gelatin.

Rabies, MMR, chickenpox, and polio vaccines include several different kinds of antibiotics to prevent contamination of the vaccine itself. Check with your doctor if your child is allergic to any antibiotics.

While there is a scant amount of egg protein in the MMR vaccine, it is still safe to give to a person with an egg allergy in your pediatrician's office. And, although the flu vaccine contains trace amounts of egg protein, beginning with the 2016–17 vaccination season, it is recommended that patients with an egg allergy of any severity can safely be vaccinated with any influenza vaccine product.

### Who keeps a record of my child's vaccinations?

You and your doctor. Your doctor keeps a record of vaccinations in your child's records. And some states have an immunization registry that also keeps records of vaccinations.

But ultimately, YOU need to have a copy of these in your personal medical record file. You will need proof of vaccinations for many things. Any childcare or school program requires this information. Summer camps and athletic programs want the records, too. If your child becomes a healthcare professional, joins the military, or is a food handler, he will also need this information.

#### ▶ HELPFUL HINT

It's a good idea to have a medical passport for your child. This should include an immunization record, growth chart, list of medical problems, list of surgeries, drug allergies, and name and dosage of any medications that are used regularly (such as asthma medicine). Some medical practices now offer a patient portal that allows you to keep track of your own records. If so, we encourage you to take advantage of it!

### How do I know when my child needs booster shots?

Your doctor will remind you at each well child visit. We wish pediatricians were more like dentists or veterinarians, who long ago figured out how to send out reminders of needed visits. Sadly, only a minority of pediatric practices have electronic reminder or recall systems. Most do not usually send out reminder cards to let you know your child is due for shots. What most practices do is provide the schedule in an information packet at your child's first visit. Your doctor will tell you at each well check when to return. This system works pretty well unless you start missing well-child visits. Then your child gets behind on his vaccination series. You can try to catch your child up on shots when he is in for a sick visit if this happens.

#### ■ REALITY CHECK

**Wanted: A National Immunization Registry** – There is no uniform system of tracking immunization status and sending reminder cards to patients' families. One solution: a national immunization registry. Advocates of this plan feel it will improve our country's immunization rates. Those opposed to the plan think it invades personal privacy and creates a government health care tracking system. So, like most governmental decisions, it may take years to resolve.

### What vaccines are required and which ones are optional?

The answer varies state to state. It also varies depending on the frequency of disease in particular counties within a state. We have provided a table of the most recent requirements in the U.S. on our website, [Baby411.com](http://Baby411.com) (click on "Bonus Material").

### Can I take my baby out before she gets her first set of shots?

Yes, just be smart about it. Pediatricians usually recommend limiting human contact with babies under four weeks of life. Why? Because if your newborn gets any fever (of 100.4 or greater), that is an automatic

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ticket to the hospital for two days. Even if your baby has the cold that the rest of the household has, we still need to rule out a serious infection.

That said, you aren't quarantined, but use discretion when planning your outings. In cold and flu season, avoid crowded places for the first three months of life.

With respect to an unvaccinated baby, the biggest threat these days is whooping cough. Whooping cough is spread by cough and sneeze droplets of an infected person. Babies get a series of four shots over the first two years of life to protect them from whooping cough. To keep everyone inside that long is crazy! But being cautious until she gets her first shot at two months isn't a bad idea.

### **I have a friend who does not vaccinate her child. Is it okay for our babies to play together?**

Awkward, right? Well, the most politically correct thing to do would be to cancel a playdate when either child is ill. This is not a foolproof solution, however. A person with measles, for instance, is contagious for three to four days before the rash erupts.

If you want to make a statement (and potentially lose the friendship), be honest and explain to her that you feel uncomfortable with your kids being together – it may give her pause to consider her choices.

## **Controversies**

Let's face it, controversy drives TV ratings and web traffic. No one is interested in hearing about things that work as they should – and vaccines are a good example. Vaccines have been a hot topic for the last decade or so. Unfortunately, rare adverse events and theoretical concerns tend to make more headlines than the remarkable success story of vaccinations. These problems are then seized on by vaccine opponents and spread online through the web like a, well, virus.

So, let's address this head on. Here are the controversies you might hear about with vaccines:

### **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 AIDS. None of these are caused by vaccination. The government operates a safety monitoring system (VAERS, FDA, 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 MMR vaccine might cause autism.<sup>7</sup> But don't try to find the article online because the journal that published the article later retracted it when a former member of the research lab revealed that the data reported in the study was fabricated! 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 replicate 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 both in England and the U.S. 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 reports! Talk to your child's doctor about any vaccine safety concerns.

### **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.

### **I've heard there is mercury preservative in the vaccines. Is this true?**

Not anymore. It was removed from all required childhood vaccines by 2001. This deserves repeating: YOUR baby will not be getting required vaccines that contain mercury (thimerosal) as a preservative.

Despite the fact that vaccines have been mercury preservative-free for over a decade 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.<sup>8</sup> (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.)

Bottom line: Thimerosal will remain on blogs and anti-vaccine websites forever, but the preservative does not remain in any of the required childhood vaccines that YOUR baby will get.

**Because of ongoing concerns, the next two Q&As should provide you with more than you ever wanted to know about thimerosal.**

### **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, the entire childhood vaccine series went thimerosal (mercury) preservative-free. If your doctor has a 2001 vintage vaccine vial sitting on the shelf (which would be long expired by now), I'd have bigger concerns about your doc than his vaccine supply.

Here is the specific rule regarding thimerosal use in vaccines: the FDA requires manufacturers of routine childhood immunizations to no longer use thimerosal as a preservative. This rule does NOT apply to flu vaccine because (technically) this vaccination is optional (except in New Jersey) and not "routine."

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

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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.

What about other vaccines? Do they contain thimerosal? There are four vaccines that use thimerosal in the production process – but it is extracted before the final product is bottled. As such, these vaccines must list that TRACE amounts of thimerosal (less than 0.003mg) may exist in the vaccine. There is probably little or no thimerosal in the finished product, but the manufacturer must declare it.

We have no concerns about these vaccines, but if you are completely freaked out about the thimerosal thing (despite the proof that they are safe), there are other alternatives to these specific vaccines made without any thimerosal: Pediarix (one brand combo of DTaP/HepB/IPV), Engerix-B (one brand of HepB).

The FDA has a chart online that tracks any thimerosal content in vaccines: [vaccinesafety.edu/thi-table.htm](http://vaccinesafety.edu/thi-table.htm) We have a link to the chart on our website [Baby411.com](http://Baby411.com) (click on "Links").

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

### Does thimerosal cause autism?

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

Thimerosal has been removed from 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 three years of age. By now, any reduction in autism should have been obvious if thimerosal caused the disorder.<sup>9</sup>

### Are there other additives in the vaccines?

Yes. And you should know about them.

As we have already discussed, 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.<sup>10</sup>

- **Preservatives:** Prevent vaccine contamination with germs (bacteria, fungus). Example: 2-phenoxyethanol, phenol, (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 ([Baby411.com](http://Baby411.com), click on "Bonus Material") for a list of ingredients for the routine childhood vaccination series.

### 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.

### 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, that ever-present smell wafting from the anatomy lab in high school comes to mind. 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.<sup>11</sup>

### 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 eyedrops, and various skin care creams. Polyethylene glycol is used in the production process to purify vaccines.

### 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 study children whose vaccinations were delayed and found there was absolutely no difference in their development to children who'd received their shots on time (Smith). A 2013 study showed further evidence that giving numerous shots at the same

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time and giving the recommended vaccination schedule has no impact on a child's risk of autism.<sup>12</sup>

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 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.

With the 2015 measles outbreak on everyone's minds, more pediatricians are increasingly adamant about protecting their littlest patients. Many refuse to deviate from the recommended schedule just to appease a nervous parent. It may be difficult to find a board-certified pediatrician willing to modify or delay shots. It's our job to protect kids. Following the recommended schedule is the best way to do that.

### How do I know that the CDC and FDA are on "our" side?

Ah, the government conspiracy theory – the belief by some that the government is part of a vast conspiracy to hurt children with bad vaccines... and enrich pharmaceutical makers who make vaccines.

Yes, years ago, some members of vaccine advisory committees had ties with vaccine producers. These people were invited to the table because they brought a wealth of knowledge with them (example: vaccine research scientists).

Today, no one working for the vaccine watchdogs (CDC, FDA, AAP, ACIP, or AAFP) receives any grant or research money from pharmaceutical companies. So there is no real or perceived financial incentive to allow a bad vaccine to stay on the market. If there is concern about a vaccine, it will be pulled from the market immediately.

To further ensure unbiased recommendations, the National Immunization Program (NIP) and the Vaccine Injury Compensation Program (VICP) parted ways in 2005 so there would be no perceived "conflict of interest."

Here is another consideration: why would these groups want our nation's children to suffer chronic illness, pain, or even death? Think about it. It is in nobody's interest to increase infant morbidity and mortality rates.

### ▶ HELPFUL HINTS – Where to get more information

Our advice: don't type in "vaccinations" in a Google search. You will end up with inaccurate information from concerned groups who do a great job of creating parental anxiety. The following sites will provide accurate information:

- Centers for Disease Control and Prevention: [www.cdc.gov/vaccines/parents](http://www.cdc.gov/vaccines/parents), (800) CDC-INFO or (800) 232-4636
- American Academy of Pediatrics: [www.aap.org/immunization](http://www.aap.org/immunization), (800) 433-9016
- Immunization Action Coalition at [www.immunize.org](http://www.immunize.org) and [www.vaccineinformation.org](http://www.vaccineinformation.org)
- Vaccine Education Center, Children's Hospital of Philadelphia [www.vaccine.chop.edu](http://www.vaccine.chop.edu)

Here is an excellent reference book written for parents: *Vaccines and Your Child. Separating Fact from Fiction*. Offit, P. and Moser C. New York: Columbia University Press. 2011.

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