As a parent, one of your most difficult tasks is making decisions for your children that may forever impact their lives. How many hours did you spend narrowing down lists until you chose the perfect name? And imagine the hours that you will soon commit to finding the right school for your child. We understand that the decision to immunize your child can be very daunting, and often this decision becomes a source of fear, stress and disagreement between parents. With a wealth of misinformation offered by books, news stories, television, Internet and even well-meaning friends and family, the "evidence" becomes very unclear. My goal is to help you to wade through this information and to point you toward the true science behind vaccine safety and efficacy.

Vaccines are medicine's bright and shining stars. Before vaccines, parents in the United States could expect that ever year:

- Polio would paralyze 10,000 children.
- Rubella "German Measles" would cause birth defects and mental retardation in as many as 20,000 newborns.
- Measles would infect about 4 million children, killing 3,000.
- Diphtheria would be one of the most common causes of death in school-aged children.
- A bacterium called Hib would cause meningitis in 15,000 children, leaving many who survived with permanent brain damage.
- Pertussis "whooping cough" would kill 8,000 children, most of whom were less than 1 year of age.

I believe that often the reason that people choose not to vaccinate is because it is harder to knowingly choose to do something to your baby that could potentially be harmful, than it is do nothing and just hope that the great odd's work out in your favor. They are choosing to avoid a "seen risk" (nobody likes to sign a consent form which lists potentially serious side effects). Fortunately, for our generation of young parents we see many more cases of autism than we do polio. Therefore, the benefit of protecting children against diseases like polio, rubella, and diphtheria is not quite as clear as it may have been to generations past who lost family and friends to these illnesses. The unseen risks that they are taking are thousands of different kinds of potentially harmful viruses and bacteria that are part of our daily environment. Whether we realize it or not, we're all gamblers. There are risks in even the most routine activities:

- We take a bath, even though every year in the United States about 350 people are killed in bathrelated activities.
- We eat breakfast, even though every year about 200 people die from choking.
- We walk outside on rainy days, even though every year about 100 people are struck and killed by lightning.

And vaccines don't even come with statistics as scary as these.

So, how do we answer the question "Are vaccines safe?" It depends on how you define the word *safe*. If you define safe as completely free from any possible negative effects, then the answer is no. The better question is "Do the benefits of vaccines outweigh the risks?" To answer these questions, you need three pieces of information:

1. What are the chances of catching a particular infection?

- 2. What are the side effects from a particular vaccine and what is the chance of these side effects occurring?
- 3. How effective is the vaccine in preventing disease?

To answer these questions, I recommend the website <a href="www.chop.edu">www.chop.edu</a>. Under the tab "Vaccine Education Center", choose "A Look at Each Vaccine" and click through each one. After reading this, you will have a better understanding of each disease, how your child could be exposed to that particular illness, how each individual vaccine is made and the possible side effects from the vaccine.

(Who are these "CHOP" people anyway?? They are physicians, they are researchers, they are scientists. They are mothers and fathers. They are very highly trained in infectious diseases, immunology and vaccine research. They are funded by the Children's Hospital of Philadelphia. THEY DO NOT RECEIVE SUPPORT FROM VACCINE MANUFACTURERS. This is science, It's not a blog or a story about a few lucky kids who survived vaccines.)

### Frequently asked questions

### Why do we still need vaccines? Is there actually a risk of my child getting diseases like polio or diphtheria?

The only vaccine discontinued because the disease was eliminated was the smallpox vaccine. That's it – just one. All other vaccine-preventable diseases still cause suffering and death in the United States or the rest of the world or both. Chickenpox, pertussis, pneumococcus, Hepatitis A and B, rotavirus, influenza, and HPV still occur commonly in the United States. Measles, mumps, rubella, Hib and meningococcus still occur in the US, but less frequently. Although these disease are uncommon, they are very contagious and can be devastating. A good example of this is measles. Measles is still common in many parts of the world including some countries in Europe, Asia, the Pacific, and Africa. Travelers with measles continue to bring the disease into the United States. Measles can spread when it reaches a community in the U.S. where groups of people are unvaccinated. If one person with measles is sitting in a small room with 10 other people, 9 of those people will be infected. This year the United States is experiencing a record number of measles cases. From January 1 to July 18, 2014, there have been 580 confirmed measles cases reported. This is the highest number of cases since measles elimination was documented in the U.S. in 2000. This number will continue to climb as more and more parents choose not to immunize. And lastly, some diseases have been virtually eliminated from the United States, but still occur in other parts of the world (diphtheria and polio). The world is not a big as it used to be. International travel is common and history has repeatedly shown that if immunization rates drop, these diseases return. (For one example, read about the Soviet Union in the early 1990's when, because of a severe drop in immunization rates, tens of thousands of children suffered diphtheria and thousands died).

#### Why should I trust a system that makes money for drug companies?

The pharmaceutical industry doesn't have a very good reputation. Indeed, the term "Big Pharma" is meant to be derogatory. And to some extent, the reputation is deserved. In marketing their products, pharmaceutical companies have acted aggressively, unethically and sometimes even illegally. However, vaccines are not drugs. They are made differently, tested differently, regulated differently, promoted differently, and used differently. Did you know the Rotavirus vaccine took 16 years and cost \$1 billion to develop? At that point, they submitted paperwork to the FDA (a Biologics License Application) that filled the back of a small U-Haul truck. Vaccines are not nearly the moneymaker that drugs are. For example,

annual sales from a single lipid-lowering agent can exceed those for the entire worldwide vaccine industry. So the pressure to sell drugs, which can be huge blockbusters for companies, are great. There is no such thing as a blockbuster vaccine. Because the CDC and AAP recommend vaccines (and therefore your pediatrician), companies rarely have to convince people of their value. So, the marketing dollars spent on vaccines are trivial compared with those spent on drugs. And if you are ever concerned that your pediatrician is making a big profit off of these vaccines, I am happy to show you the data. (I should have gone into anesthesiology!).

If people are concerned that vaccines can't be trusted because vaccine makers have misrepresented or falsified data, it would be justified if there were at least one example of this actually happening. But there isn't. Safety and efficacy data generated before licensure is invariably repeated in testing after licensure, and vaccines continue to prove themselves safe over many years.

### Do too many vaccines overwhelm my baby's immune system?

In our generation (kids born in the 80's), children received seven vaccines – MMR, DTP and polio. In our parent's generation (kids born in the 50's), children received 5 vaccines – DTP, polio and smallpox. At the turn of the century, children only received one vaccine – smallpox. Many people would be surprised to know that the number of immunological components contained in that one vaccine given a hundred years ago was greater than the 14 vaccines given today combined. Immunological components are the proteins or sugars from the viruses or bacteria that induce an immune response. The smallpox vaccine contained 200 proteins. The 14 vaccines given to young children today contain 160. Fortunately, thanks to advances in protein chemistry, protein purification, and recombinant DNA technology, we can make vaccines today that are much purer (and consequently safer) than those in the past. So, although there is no denying that 14 is greater than one, it's what is in the number of vaccines that counts.

Second, compare vaccines to other immunological challenges in the environment. The womb is sterile, so babies' immune systems aren't required to do much. As the baby passes through the birth canal and enters the outside world, that changes quickly. (Vaginal births can be very messy, just think about it). The baby is immediately confronted with literally TRILLIONS of bacteria. These bacteria immediately line the nose, throat, skin and intestines. They have the capacity to invade the bloodstream and cause harm. Each bacterium contains between 2,000 and 6,000 immunological components. Therefore, babies are making huge quantities of antibodies every single day. In addition, soon after they are born, babies encounter a variety of viruses that aren't prevented by vaccines. Studies show that healthy children experience between 6 and 10 viral infections every year in the first few years of life. And unlike vaccine viruses, which reproduce poorly or not at all, these natural vaccines reproduce thousands of times, causing an intense immune response. As you can see, even for a newborn' immune system, the task of responding to vaccines is trivial compared to their daily job description. Susumu Tonegawa, a molecular biologist who won a Nobel Prize for his work, showed that people have the capacity to make between 1 billion and 100 billion different types of antibodies. Given the number of immunological components contained in modern vaccines, a conservative estimate would be that babies have the capacity to respond to about 100,000 different vaccines at once. (But don't worry... we're not going to try!)

#### Do Vaccines Cause Autism?

In 1998, a British researcher named Andrew Wakefield raised the notion that the MMR vaccine might cause autism. In the medical journal The Lancet, he reported the stories of eight children who developed autism and intestinal problems soon after receiving the MMR vaccine. This study was flawed and unethical for many reasons, and in fact Wakefield was in the process of creating his own MMR vaccine when his study was published. Many contributors to the study later admitted to this, and Andrew Wakefield lost his medical license. To determine whether Wakefield's suspicion was correct, researchers performed a series of studies comparing *hundreds of thousands* of children who had received the MMR vaccine with *hundreds of thousands* who had never received the vaccine. They found that the risk of autism was the same in both groups. The MMR vaccine did not cause autism. To learn more about autism and the details of the above studies, I recommend the book <u>Autism's False Prophets</u> by Paul A Offit.

Are we sure? Are there enough studies out there to be sure that there is not a link? Epidemiological studies have shown that a rotavirus vaccine used between 1998 and 1999 in the United States caused intestinal blockage in one out of every 10,000 vaccine recipients; that measles vaccine caused a reduction in the number of cells needed to stop bleeding (platelets) in one out of every 25,000 recipients; and that an influenza (swine flu) vaccine used in the United States in 1976 caused a type of paralysis called Guillain-Barré syndrome in one out of every 100,000 recipients. So these studies are very sensitive, meaning they pick up very rare side effects. About one out of every 100 children in the United States is diagnosed with an autism spectrum disorder. Even if vaccines caused autism in only 1 percent of autistic children, the problem would have easily been detected by epidemiological studies.

#### Do preservatives in vaccines cause harm?

The preservative in vaccines that has caused the most concern among parents is thimerosol. That's because thimerosal contains mercury, and large quantities of mercury can be toxic to the nervous system. In 1999, the AAP and the U.S Public Health Service, asked that thimerosal, an ethylmercury-contaning preservative, be removed from all vaccines given to young children. These two groups had become concerned that as more and more vaccines containing thimerosal were added to the schedule, babies might be exposed to harmful quantities of mercury. Those who favored removal of thimerosal argued that they were exercising caution in the absence of data, because at the time, no studies had determined whether thimerosal in multiple vaccines was toxic. Unfortunately, the removal was done in such a precipitous manner that parents became concerned. They reasoned that maybe it was thimerosal, not MMR, that was causing autism. But as had been the case during the MMR scare, the science quickly followed. Six studies examined the risk of autism in those who had or hadn't received vaccines containing thimerosal; the chances of getting autism were the same in both groups. Consistent with these findings, the incidence of autism has only continued to increase even though thimerosal has been removed from all vaccines given to young infants.

An interesting point — a typical breast-fed child will ingest almost 400 mcg of methylmercury during the first 6 months of life. That's more than twice the amount of mercury that was ever contained in all childhood vaccines combined. And because methylmercury is excreted from the body much more slowly than ethylmercury (the kind in vaccines), breast milk mercury is much more likely to accumulate.

#### Do vaccines contain harmful adjuvants like aluminum?

Adjuvants, which have been used in vaccines since the 1930's, were added to vaccines to enhance the immune response, allowing for lesser quantities of vaccine and fewer doses. For the past 80 years, vaccines have contained only one type of adjuvant: aluminum salts. So the safety of aluminum in vaccines has been

assessed for more than eight decades. Aluminum, the third most abundant element on earth, is in our air, food and water. Breastfed babies will ingest 10 mg by 6 months, formula fed babies will ingest 30 mg by 6 months. Babies who get all of the recommended vaccines will receive 4 mg of aluminum in the first 6 months of life. Researchers have studied whether vaccines containing aluminum increase the amount of aluminum in the blood. They don't. The quantity of aluminum in vaccines is so small that the amount in blood is unchanged after vaccination.

# "I know I should believe in vaccines but my neighbor told me..."

Anecdotal experiences can be very powerful. For example, a professor emeritus at Duke University School of Medicine tells the story about a friend's four month old child who was taken to a clinic to get a DTP vaccine. The father waited and waited in line. Finally, he tired and took the baby home without getting the vaccine. At home, the father put the child to bed. Several hours later, the child was found dead in his crib, the victim of SIDS. Had the father actually given his child the vaccine, no amount of statistical evidence in the world would likely have convinced him that anything other than the vaccine was the cause. We hear these stories often. Children receive shots very frequently and sometimes unexplainable tragedies can happen in the hours, days or weeks following vaccines. Thankfully, there are systems in place to report these events so further research can be done to look for a link. As mentioned above, there are epidemiologic studies constantly looking for a link between these associations. Read about the Vaccine Adverse Events Reporting System and the Vaccine Safety Datalink to learn more.

## Is there any harm in using an alternate schedule?

The biggest problem with an alternative schedule is that it increases the time during which children are susceptible to vaccine-preventable diseases. If immunization rates across the US were about 95%, this wouldn't be a problem. But that's not the case. Population (or herd) immunity – the ability of a vaccinated community to protect those who can't or won't be vaccinated – has broken down. Delaying vaccines until your child is older is analogous to wearing a bicycle helmet while you are sleeping. Babies and young children are the most susceptible to severe disease from these illnesses, so holding off on vaccines when they are infants is leaving them unprotected at the most critical time. Another problem with the alternative vaccine schedule is that it's untested. Every time a new vaccine is added to the recommended schedule, it's tested to make sure that it doesn't interfere with the immune response or safety of the existing vaccines and vice versa. By creating your own schedule (or following Dr. Sears), you are experimenting with your own child.

Another reasonable argument for spacing out vaccines is that it would mean fewer shots at one time, and therefore less pain for the child. Interestingly, researchers have found that children experience similar amounts of stress — measured by secretion of a hormone called cortisol — whether they are getting one shot or two shots at the same visit. In fact, more visits to the doctor created by separating or spacing out vaccines will likely only increase the trauma of getting shots.

### Final Thoughts

The fact is that every year vaccine-preventable diseases still kill children in the United States. Influenza still kills about a hundred children and pneumococcus and meningococcus a few hundred, permanently disabling more than that. Chickenpox is still common enough that a handful of children die every year, and HPV is a long-range killer, causing fatal cervical cancer twenty to twenty-five years after infection. And if the trend of not vaccinating or delaying vaccination continues, other disease – like polio and diphtheria – will be back. Probably those best suited to explain why vaccines are important are parents who belong to advocacy organizations like Families Fighting Flu or Meningitis Angels. All of these parents tell similar stories. Their children were healthy and active until they were killed by a vaccine-preventable disease that none of them thought could happen to them – until it did. Choosing not to vaccinate is like playing Russian roulette, except instead of having a gun with five empty chambers and one bullet, it's a gun with a million empty chambers and one bullet. But why take the chance? Why play the game at all if you don't have to? Vaccines have very known, rare and not life threatening risks associated with them. The research is there. They have proven to be safe repeatedly. The most dangerous aspect of vaccines is driving to the doctor's office to get them. Every year about 30,000 people die in car accidents.

So why won't we accept patients who wish to delay or refuse vaccines? It is our social and professional responsibility to protect our patients. Some people can't be vaccinated for medical reasons, and some children are too young to receive certain vaccines. These people depend on living in a highly vaccinated community to protect them. It is not fair for them to be in danger in their own doctor's waiting room.

### **Resources and Further Education**

Paul A. Offit, M.D. and Charlotte A. Moser. *Vaccines and Your Child: Separating Facts From Fiction*. New York: Columbia, 2011.

Paul A. Offit, M.D. and Louis M. Bell, M.D. Vaccines: What Every Parent Should Know. New York: IDG Books, 1999.

Paul A. Offit, M.D. Autism's False Prophets. New York: Columbia, 2008.

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Smith, M. and L. Bouck. The Complete Idiot's Guide to Vaccinations. New York: Alpha, 2009.

#### www.chop.edu

Vaccine Education Center tab

Online videos – Vaccines and Your Baby, Separating Fact From Fiction