

Little things

that matter

Addressing Vaccine Safety

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Over the last several years, no issue in pediatrics has caused more confusion and frustration for care providers and fear for parents than the reported concerns regarding safety of vaccines and the possible causal link between the vaccines, specifically between MMR and autism. We have spent hundreds of hours discussing this issue during office visits. Due to two recent events -- the high profile federal settlement case that many of you recently read about, as well as high visibility vaccine opponents like Jenny McCarthy speaking out against vaccines in the media, we felt that it might be best to address the current state of affairs surrounding this volatile issue.

The issue first arose in 1998 when an article published in the medical journal *The Lancet* revealed the finding that a series of twelve autistic children had intestinal lymphoid hyperplasia (somewhat like swollen "neck glands" in the intestines) and that measles RNA was also found in autistic children's intestines. The authors used this link to claim that it was the MMR vaccine that was the causative agent of autism. An enormous outcry arose in the scientific and medical communities, rejecting this shaky link as real. Since that publication, ten of the thirteen authors of that paper have issued retractions discounting the finding. Some of the same researchers who authored that paper assisted in the publication of a September 2008 article that showed no link between the MMR vaccine and autism. Also, around 1998 many parents of autistic children first began reporting on the Internet that they noticed differences in their children's behavior shortly after receiving their fifteen-month vaccines. That series typically includes several vaccines that children have previously received, in addition to the MMR (Measles-Mumps-Rubella) vaccine. It is clearly natural to explore any changes in a child's routine, diet, or health care that may have led to the changes seen in their development and/or behavior when a condition as severe as autism begins to rear its head. Since the MMR is typically the only

(Continued on page 2)

IN THIS ISSUE

Vaccine Study 4

Welcome & Welcome Back 4

Influenza (Flu) Vaccines

Remember to sign up for flu vaccines. Flu vaccine clinics are scheduled for October and November. Those patients who are at highest risk for complications from the flu include the following: children 6 months to 2 years of age, children with asthma, diabetes, organ transplant, or any chronic illness.

The 2008 recommendations for flu vaccines include children 6 months to 18 years of age due to the fact that children and teenagers are twice as likely than adults to contract the flu. Yearly influenza causes 32,000 deaths in the United States as well as 200,000 hospitalizations, not to mention the countless number of days lost in work and school. For children less than 9 years of age who have never received a flu vaccine or only received one the previous year due to shortages of vaccine, 2 flu vaccines are recommended to be given one month apart.

We can only provide flu vaccines for patients of Pediatric Associates. We cannot provide flu vaccines for parents nor for non-patients of Pediatric Associates. Currently, we are not aware of any shortage of flu vaccines. However, if there were to be a shortage, flu vaccines will be distributed based on risk factors.

(Continued from page 1)

vaccine that is given for the first time at the 15-month visit, it is natural to suspect that it may play a causative role in the development of autism. It should also be noted that there are clearly specific abdominal disorders that children with autism experience at a higher rate than the general population, e.g., gastroesophageal reflux, constipation, lactose intolerance, and diarrhea. To date there have been no papers published linking these gastrointestinal disorders with the MMR vaccine.

Another concern that arose was that the mercury-containing preservative thimerosal (often used in the MMR and other vaccines) may be causing toxicity to children's developing brains and causing an increased incidence of autism. Thimerosal contains a non-absorbable form of mercury known as ethyl mercury. Due to this concern, thimerosal was removed from most vaccines in 2001 (the primary exception to this is the flu vaccine). Despite that, the reported incidence of autism continues to rise. In fact, in some areas the incidence has again doubled since 2004. A form of mercury that is found in tuna, known as methyl mercury, is absorbable by humans. In populations where there is high intake of seafood, in particularly tuna, there has been no increase in developmental disorders including autism incidence seen, with the exception of one population where exceptionally high levels of whale meat is consumed. In that population a higher incidence of developmental disorders and birth defects was seen. Studies have shown that there was more mercury in a can of commercially produced tuna than in the MMR vaccine before thimerosal was removed. A recent large study done in California showed no differences in the blood levels of mercury or other heavy metals seen in autistic children versus typically developing control children. Numerous other studies have been performed, and these have failed to show a link between autism and thimerosal as well.

Chelation therapy is related to this topic. This involves administering medications to a child or adult with the goal of removing toxins, such as mercury, in order to "cure" conditions such as autism or reduce a child's risk of developing it. The previous discussion should show why this is not helpful. The main point to be made here is that chelation was designed to be used under the careful observation of a physician for removing toxins, such as lead, from children. When this is done by reputable physicians, these children are admitted to the hospital and monitored carefully with frequent blood work. Recently, care providers, including some in our area, and others on the Internet have sold chelating agents for parents to use at home. This is an exceptionally dangerous practice, and one that we advise against in the strongest of terms. A child from Pittsburgh died doing just this type of therapy in recent years, and its risk cannot be overemphasized.

This entire discussion leads to the obvious question: What causes autism? The amount of research on this topic has exploded in recent years and focuses on a variety of possible causative mechanisms. Genetic studies have shown a higher incidence of gene markers in "proband" families (families that have numerous individuals affected by autism). Numerous theories propose the cause of autism: that the increased incidence involves abnormalities in the developing immune systems of young children, that increased exposure to environmental toxins or germs, or that there are other prenatal agents damaging to a child's sensitive brain early in its development. What most people don't understand is that the majority of children who develop autism begin to show signs of the condition between the ages of 18 and 24 months. Two other smaller groups make up the remainder of the majority of the children who are eventually diagnosed as autistic. One group is children who show signs as early as 6 months and another group who only develop signs of autism at around four years of age. If these two structures in the brain fail to develop normally, autism may result. These structures are the amygdala (involved with how emotions influence our ability to learn) and the hippocampus (involved in how we determine what life experiences will be saved in long-term memory). Both structures become active in young children's brains between the ages of 18 and 20 months. Two researchers, Jocelyn Bachevalier, MD from Emory University and Margaret Baumen, MD from Harvard have looked at this issue extensively. (Their work is very interesting to study if you have further interest in this question.) These two researchers have shown that the failure to develop normal amygdala and/or hippocampal structures leads to different behaviors typically seen on the autism spectrum. If these structures fail to develop normally at 18 to 20 months, and the MMR is given between 15 and 18 months, might that not show a link? Dr. Baumen's research has shown that whatever happens to cause this abnormal development appears to be the result of some event that occurs at around 27 weeks of prenatal development. There-

fore, although the timing of MMR administration and development of autism occur close together, there again appears to be no link between the two events.

Vaccines are truly one of the greatest medical advances of the last century. Their success has in large part led to the current problem that we have today. If, for example, there were no vaccines against diseases such as polio and measles and children were dying or being crippled by the thousands as they were just a century ago, the public outcry for prevention measures for these diseases would be deafening. Several of us in the office can tell you horror stories from our residency years of watching children with meningitis die within twenty four hours of being diagnosed, despite the fact that they received the most advanced medical care possible. Because of the success of the Hib and Prevnar vaccines, which were introduced in the late 1980's and 2000 respectively, we rarely see these diseases anymore. The CDC has followed the incidence of morbidity of diseases that we now vaccinate against both prior to the introduction of the vaccine and after. Diphtheria, measles, mumps, polio, rubella, congenital rubella, and Haemophilus influenzae type b have all seen decreases in morbidity of over 99%, whereas for tetanus the decrease is 98% and for pertussis is 95%.

An increase in the incidence of autism cases nationally over the last ten to fifteen years is clear. It is not necessarily true that there is some new causative agent present in our environment or from medical therapy that accounts for this increase. There are several theories regarding why this increase may have occurred. The first is that awareness of primary care physicians has clearly increased; therefore far more children have been referred to specialists and diagnosed. This is due to large public awareness campaigns and increased efforts to educate physicians about the various forms of autism. Second, many children who were diagnosed as being cognitively challenged (commonly referred to as mentally retarded) or learning disabled in the past have now been re-diagnosed as being autistic. This is primarily due to the fact that the two main diagnostic instruments for the disorder (the ADOS and the ADI) are very inclusive, and include many of these children under the autism diagnosis. Similarly, other children with severe neurological problems, such as cerebral palsy, have also been co-labeled as autistic if they have behavioral characteristics of the syndrome. In all, data from the Individuals with Disabilities Act shows that there has been an 871% increase in the number of children aged six to twenty-one years who have been diagnosed as autistic between the years 1992 to 2002. The CDC puts the national incidence of autism at 1:142 children affected, while many state educational agencies quote an incidence of 1:300. In any case, the incidence is clearly increasing.

The Hippocratic Oath, the creed that all physicians pledge to honor before entering practice, holds that we "First, do no harm" as the primary guiding principle by which we deliver care. This is something that we take very seriously and is the first consideration that we make when deciding on a course of treatment for any given child. When I mentioned at the beginning that this issue is frustrating, it is because we do not yet know what causes autism and why the rates seem to have increased markedly over the last 15 years. All of the scientific evidence points to the fact that vaccines do not play a causative role. Yet with the media hype that has surrounded this issue many parents have decided to forego vaccinating their children. If this trend continues we will see a recurrence in disease like polio that most of us should never see in our careers. Already in the first half of 2008 there were more measles cases diagnosed in the U.S. than there were in any entire year in over ten years. We are happy to answer your questions regarding vaccine safety as best we can, but we also realize that we are not always privy to the latest data. The CDC has set up a help line and an e-mail address to answer parents' questions regarding vaccines: 1-800-CDC-INFO or cdcinfo@cdc.gov. You may also want to turn to the following web sites before coming for your next checkup visit in order that you may know the facts behind this thorny issue:

<http://www.cdc.gov/ncbddd/autism/vaccines.htm>

<http://www.aap.org/advocacy/releases/vaccinesafety-May08.htm>

Other links to references regarding articles on this subject and to the case mentioned at the beginning of the article are also contained on our web site.

We are honored by the trust that you show in us by allowing us to aid you in the care of your children and we look forward to taking every measure to keep your children healthy and safe.

Vaccine Study

In conjunction with Sanofi-Aventis pharmaceuticals, Pediatric Associates is conducting an immunization study on **four-year booster vaccines**. The study, based on similar studies completed in Canada, expects to see less soreness, redness, pain and fever with the diphtheria, tetanus, and pertussis immunization components (DTaP vs. Tdap) while continuing to confer excellent protection. Compensation is provided for study time and for two blood draws after immunizations. If interested, please speak with your child's provider. This study will be closed to enrollment 12/5/08.

Welcome & Welcome Back

In an effort to provide more appointments to desired office locations, Pediatric Associates would like to announce and welcome **Dr. Kerri Sobolewski, MD** and Physician Assistant **Stacey Shadix** to the practice. We are very excited about these additions and know you will enjoy getting to know them. Many of you may have met **Dr. Sobolewski** as she has worked with Dr. Spicker for the past three years. Dr. Sobolewski grew up on the West Side of Cincinnati and completed her undergraduate studies and medical school at the University of Cincinnati. She then completed her pediatric residency at Cincinnati Children's Hospital. Kerri is married to her husband, Brad, who is an Emergency Room physician at Cincinnati Children's Hospital. **Stacey Shadix** hails from Anderson Township and attended Midwest University in Chicago. Stacey spent several weeks with Pediatric Associates while she shadowed Dr. Brokaw during her training years. Stacey has much experience from working in the Emergency Departments at University and Jewish Hospitals. Stacey is married to her husband, Steve, a civil engineer.

Welcome back to **Dr. Chris Bolling, MD!** Many of you know Dr. Bolling. Pediatric Associates welcomes him back after he spent some time in the General Pediatrics Department at Cincinnati Children's Hospital. We have missed you, Dr. Bolling, and cannot wait to have you back in the office. For those who may not have met Dr. Bolling, Chris is from Northern Kentucky and completed his undergraduate and medical school at the University of Cincinnati followed by his residency and Chief Residency at Cincinnati Children's Hospital.

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