

# Vaccine Safety Update

Concerns about vaccine safety have been a part of public discourse since the advent of immunizations. Widespread skepticism about Salk's polio vaccine circulated in the 1950s, and concerns about pertussis vaccine in the 1970s and 1980s led to declines in immunization rates in Britain and the United States. Most recently, a proposed link between vaccines and autism spectrum disorders (ASD) has ignited contentious debate.

Families of affected children, as well as other advocates and health care professionals seeking to find a mutable cause of these disorders, have raised questions regarding possible associations between vaccines and ASD. As healthcare providers and educators, it is important that we are sensitive to parents' concerns; take the time to answer their questions; and clearly communicate the message that there is no reliable evidence to support the claim that vaccines cause autism.

Within the last decade, two theories positing a link between autism and vaccines have been popularized. One focuses on the MMR (measles, mumps, and rubella) vaccine; the other identifies thimerosal as a primary cause. Additional concerns include the safety of other vaccine ingredients as well as the idea that multiple vaccinations result in an immune system overload. While there is no reliable scientific evidence supporting these hypotheses, it is important to understand these theories in order to effectively address parents' concerns.

## The MMR Vaccine

Concerns about a potential link between MMR vaccination and ASD incidence were initially sparked by a 1998 publication in *The Lancet*. Wakefield et al argued that the MMR vaccine, which contains live virus, could cause a chronic measles infection. This infection could lead to "leaky gut" syndrome where toxins and chemicals normally broken down by the gut enter the bloodstream and damage the brain, causing ASD-like behaviors. Wakefield et al asserted that findings from a follow-up study in 2002 supported this hypothesis. Results indicated that 75 of 90 children with autism had measles virus genome in intestinal biopsy tissue, versus only 5 of 70 control patients. While results have caused concern, the study methodologies were critically flawed and the results have been called into question by subsequent analysis. In fact, in 2004, 10 of the 13 authors of the 1998 study retracted its interpretation, stating that the data were not able to establish a causal link between MMR vaccine and autism.

Various studies have since failed to confirm a link between MMR vaccine and autism. Early ecological studies in the United Kingdom and California suggest a lack of association, and several controlled epidemiological studies have independently refuted the hypothesis. Perhaps most convincingly, Madsen et al performed a large-scale study in Denmark between 1991 and 1998, finding that the

risk of autism in the group of vaccinated children was the same as that in the unvaccinated group. Additionally, no relationships were found between the age at vaccination, time since vaccination, or vaccination date and the appearance of ASD symptoms. Finally, the Institute of Medicine's 2004 comprehensive "Immunization Safety Review: Vaccines and Autism" concluded that the evidence favors rejection of the causal relationship between MMR vaccine and ASD.

When speaking with parents about their concerns, it is important to remember that although a causal connection between MMR and ASD has been invalidated, temporal associations are powerful. Symptoms of autism often become evident during the second year of life, which corresponds to a time period of vaccination. Some mistake this temporal association for causation.

## Thimerosal-containing Vaccines

In use since the 1930s, thimerosal is a preservative that prevents bacterial contamination of multi-dose vaccine vials. The compound is 49.6% ethylmercury by weight. Concerns have been raised that this preservative leads to ASD. However, there is no convincing scientific evidence of harm caused by the low doses of thimerosal in vaccines.

Most information about the toxicity of mercury compounds relates to methylmercury, which has been found to cause central nervous disorders, birth defects, and epilepsy. Methylmercury and ethylmercury are often mentioned interchangeably in the press, but the ethylmercury that is in vaccines is more rapidly broken down and eliminated from the body than methylmercury. While the levels of mercury in childhood vaccines before 1999 did exceed recommended guidelines for mercury in general, the exposure levels from vaccines did not constitute direct evidence of harm. Furthermore, clinical signs of autism are inconsistent with those of mercury toxicity; both conditions affect central nervous system function, but manifest differently.

A number of peer-reviewed studies have been published showing no correlation between thimerosal in vaccines and ASD. The IOM report cited above also concluded that the evidence is sufficient to reject this association. Despite the lack of evidence, the US Public Health Services and American Academy of Pediatrics issued a joint statement in 1999 recommending the removal of thimerosal from most childhood vaccines. Although precautionary, removal was merited given the goal of reducing exposure to mercury from all sources and the priority of ensuring public confidence in vaccine safety. With the exception of some flu vaccines, thimerosal has been removed from all childhood vaccines since 2001. In California, by law, no flu vaccine containing more than trace amounts of thimerosal can be provided to pregnant women or children under the age of three.

*Continued on page 6*

## Vaccine Safety Update...from page 5

Recent data do not support an association between thimerosal-containing vaccines and autism. In California, Schecter and Grether's 2008 review found continuing increases in autism levels statewide, following the exclusion of more than trace levels of thimerosal from all childhood vaccines given in the state. This is the latest in a series of studies that do not support the hypothesis that thimerosal exposure from vaccines is a primary cause of autism.

### Emerging Vaccine Safety Concerns

Doubts about vaccines and autism are expanding beyond the MMR vaccine and thimerosal to include concerns about other vaccine ingredients (e.g. aluminum), the number of shots, and the recommended childhood immunization schedule. Some parents fear that the number of childhood vaccines will result in an "overload" of the immune system, though vaccines given today actually expose children to fewer antigens than in the past.

The Immunization schedule is developed and continually updated based on a combination of FDA licensure requirements and ACIP (Advisory Committee on Immunization Practices) recommendations. It is important to adhere to the recommended schedule so that children are protected from these diseases by the time the benefit from maternally acquired antibodies has waned. Vaccines are given early and at the recommended intervals to:

- Protect against diseases that can seriously harm infants and young children.
- Prevent complications that can be much more severe in young children.
- Ensure that children are protected by the time they have the greatest risk of exposure.

To facilitate adherence to the recommended schedule, children may often receive multiple vaccinations at the same visit. Although children receive more vaccinations today than in the past, the total amount of antigens in current vaccines is

*Use every visit to address parents' concerns and emphasize the benefits of on-time vaccination.*

much less than that in vaccines given years ago. For example, the acellular pertussis vaccine used today contains only 2 to 5 antigens, as opposed to the 3,000 distinct antigens that were in the whole cell pertussis vaccine that most adults today received when they were children. Available data show no adverse effects from administering all of the routinely recommended vaccines in one visit. Also, it is important to remember that the immune systems of infants and children respond to many different antigens on a daily basis, as infants and children explore and interact with their biological and physical environments.

### Conclusion

Dramatic decreases in morbidity and mortality as a result of vaccinations are among public health's greatest achievements. While coverage rates in Los Angeles County have exceeded national averages and Healthy People 2010 goals in recent years, media attention and advocacy continue to fuel questions about the safety of childhood vaccinations. Ultimately, these concerns—though repeatedly refuted—have the potential to translate into significant changes in parental behavior. Reservations may cause parents to utilize extended schedules or refuse vaccinations completely. In fact, the number of parents declining to vaccinate their children due to Personal Belief Exemptions (PBEs) has increased statewide.

Declines in vaccination rates can lead to increases in vaccine-preventable diseases. The increased potential for outbreaks is underscored by the recent measles outbreaks across the nation and in Southern California. In San Diego, nine out of twelve children infected through contact with an unvaccinated child who contracted measles outside of the US were not vaccinated because of PBEs. In Los Angeles, an unvaccinated child was hospitalized with measles in April 2008.

*There are no valid studies that show a link between MMR vaccine or thimerosal and autism.*

Persisting misconceptions are likely to lead to decreased coverage, possibly undermining the significant advances in the prevention of vaccine-preventable diseases. It is incumbent upon the healthcare community to be sensitive to parents' concerns and to help them understand that:

- Immunizations are the best way to protect against serious vaccine-preventable diseases.
- We have the safest, most effective vaccine supply in history.
- There is no reliable evidence that vaccines cause autism.
- A decision not to vaccinate has a significant impact on children, families, and communities.

### Kim Harrison-Eowan, MPH, CHES

Health Communications Coordinator

Los Angeles County Immunization Program

*For More Information, visit the following links:*

*LAC Immunization Program at [www.publichealth.lacounty.gov](http://www.publichealth.lacounty.gov), CDC Vaccine Information Center at [www.cdc.gov/ncbddd/autism/vaccines.htm](http://www.cdc.gov/ncbddd/autism/vaccines.htm), American Academy of Pediatrics at [www.aap.org](http://www.aap.org) or the Immunization Action Coalition at [www.immunize.org](http://www.immunize.org)*