

UPDATE ON VACCINE SAFETY WHY ARE THEY MORE IMPORTANT THAN EVER

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Vaccine Safety Concerns

- Past of vaccines
- Now most parents have never seen a case of diphtheria, measles, or other once-common diseases .
- They therefore wonder why their children must receive shots for diseases that do not seem to exist.
- Myths and misinformation confuse parents more.



Vaccination

- Vaccination is a common, memorable event, and association of events in time often signals cause and effect...
- **Some** of the sickness or reactions post vaccination may be caused by the vaccine, **many** are unrelated.
- Scientific research attempts to distinguish true vaccine side effects from unrelated.
- *Now more than ever we need to dispel the misconceptions regarding vaccines because of recent outbreaks of measles and Pertussis and more and more parents refusing to vaccinate.*

Is there a relationship between vaccines and autism?



- Many studies have been done so far.
- The weight of the evidence indicates that *vaccines are not associated with autism*.
- CDC is committed to protecting the health of children and identifying the **biological** and **environmental** causes of autism and other **developmental disabilities**, so they will continue to study the role of vaccines.

Measles, Mumps, and Rubella (MMR) Vaccine

- MMR Vaccine? 1st dose 12-15 mo, 2nd 4-6Yr.
- In 1998, a study of autistic children raised the question of this relation however the study has a number of limitations. For example, the study was very small, only 12 children.
- In 2004 researchers withdrew this study.

MMR and Autism Cont.

- Larger study by researchers in **UK involved 498** children with autism born between **1979 and 1998**. They found:
 - There was no difference in the age of diagnosis of autism in vaccinated and unvaccinated children.
 - The onset of "regressive" symptoms of autism did not occur within 2, 4, or 6 months of receiving the MMR .

No Link Between MMR and Autism

- Groups of experts, including the **American Academy of Pediatrics**, agree that MMR vaccine is not responsible for recent increases in the number of children with autism.
- In 2004, a report by the **Institute of Medicine (IOM)** concluded that there is no association between autism and MMR vaccine, or the vaccines that contain thimerosal as a preservative.
- There is no published scientific evidence showing that there is any benefit to **separating the combination** MMR vaccine into three individual shots.
- CDC continues to recommend two doses of MMR vaccine for all children.

MMR and Autism

- A prominent British medical journal on Tuesday retracted a 1998 research paper that set off a sharp decline in vaccinations in Britain after the paper's lead author suggested that vaccines could cause autism.
- By GARDINER HARRIS Feb. 3rd 2010

Mitochondrial Disease and Autism

- The **United Mitochondrial Disease Foundation**, in collaboration with our Scientific and Medical Advisory Board stated;
- **“There are no scientific studies documenting that childhood vaccinations cause mitochondrial diseases or worsen mitochondrial disease symptoms. In the absence of scientific evidence, the **UMDF** cannot confirm any association between mitochondrial diseases and vaccines.”**

Mercury and Vaccines (Thimerosal)

- Thimerosal is a mercury-containing preservative used in some vaccines and other products since the 1930s.
- There is no convincing scientific evidence of harm caused by the low doses of thimerosal in vaccines, except minor reactions like **redness and swelling** at the injection site.
- However, in **July 1999**, the Public Health Service agencies, the AAP, and vaccine manufacturers agreed that thimerosal should be **reduced or eliminated** in vaccines as a precautionary measure.

Thimerosal

- Since 2001, with the exception of some influenza (flu) vaccines, thimerosal is not used as a preservative in routinely recommended childhood vaccines.
- Recent estimates from CDC's [Autism and Developmental Disabilities Monitoring network](#) found that about **1 in 150 children have an ASD**.
- It is higher than 1990's, so it was linked to Thimerosal
- However, evidence does not support such an association.

Scientific Review by Institute of Medicine

- “The evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism.”
- CDC supports the IOM conclusion.

RotaTeq Vaccine & Kawasaki Syndrome

- The known benefits of the RotaTeq vaccine in preventing rotavirus disease- a cause of potentially very serious illness in our children, outweighs any known risks to date.
- Approximately 6 million doses of RotaTeq have been distributed in the United States through June 8, 2007.

RotaTeq Vaccine

- The RotaTeq label has been updated to include 6 *specific cases of Kawasaki syndrome* that were observed **during the clinical trials** conducted before the vaccine was licensed.
- There were 5 cases among the 36,150 recipients of RotaTeq.
- One case among the 35,536 placebo recipients. It is *not known* if RotaTeq played a role in these cases.

Kawasaki Syndrome and VAERS

- Additionally, the label has been revised to include information that VAERS has received reports of Kawasaki syndrome.
- In the VAERS reports, children had received other childhood vaccines in addition to RotaTeq.
- **The three Kawasaki syndrome reports submitted to VAERS since the vaccine's licensure on February 3, 2006 do not exceed the number of cases we expect to see based on the usual occurrence of Kawasaki syndrome in children.**

Monitoring RotaTeq

- CDC continues to support the [\(ACIP\)](#) for routine immunization of all U.S. infants with three doses of RotaTeq administered orally at ages **2, 4, and 6** months.
- CDC and FDA continue to monitor the safety of RotaTeq and all vaccines, and **encourage health** care providers and other individuals **to report** cases of Kawasaki syndrome or other severe medical problems following vaccination to VAERS.

Syncope After Vaccinations

- Syncope, also called fainting, has been reported after vaccination and serious injuries have occurred.
- Advisory Committee on Immunization Practice currently recommends that, "vaccine providers should strongly consider observing patients for **15 minutes** after they are vaccinated.
- **If syncope develops**, patients should be observed until the symptoms resolve.

Syncope Reports

- Since 2005, VAERS detected a trend of increasing syncope reports.
- VAERS received **463 syncope reports** during January 1, 2005 – July 31, 2007.
- There were only **203 syncope reports** during January 1, 2002 – December 31, 2004.
- This increase coincides with the licensure and recommendation of three vaccines for adolescents:
 - Meningococcal conjugate vaccine (MCV₄)
 - Tetanus toxoid, reduced diphtheria toxoid acellular pertussis vaccine (Tdap)
 - Human papillomavirus (HPV) vaccine

What We Know

- Among post-vaccination syncope reports in persons aged ≥ 5 years, **49%** were adolescent females aged **11 to 18 years**. At least one of the three adolescent vaccines (HPV, MCV₄, and Tdap) were received in 60% of reports involving a single vaccine.
- HPV was the most frequently reported associated vaccine type (52% of single vaccine reports).

What We Know Cont.

- Among the 41 syncope reports with secondary injuries, 76% - 11 to 18 years.
- It occurred Within 5 -15 minutes.
- Ten of the 41 (24%) sustained injuries that were classified as serious in nature.

Guillian-Barre' Syndrome and Menactra Meningococcal Vaccine

- The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), in partnership are *investigating cases of Guillain-Barré syndrome (GBS) among adolescents who recently received tetravalent (A, C, Y, W135) meningococcal conjugate vaccine.*

(Meningococcal Polysaccharide Diphtheria Toxoid Conjugate Vaccine, Menactra[®], Sanofi Pasteur [MCV₄]).

Menactra and GBS

- As of **February 25, 2008**, more than **15 million** doses of Menactra have been distributed.
- **VAERS** has received **26 confirmed** case reports of GBS within 6 weeks of receipt of MCV₄ Menactra meningococcal vaccination.
- **24 people, 11 to 19 years of age,**
- **2 reports of GBS among people aged 20 years and older also have been confirmed.**

Menactra and GBS Cont.

- Onset was 2 to 33 days after vaccination.
- While this data suggests a small increased risk of GBS following Menactra immunization, there are a number of limitations in the data.
- CDC is unable to determine if Menactra increases a risk of GBS in people who receive the vaccine.

Menactra and GBS Cont.

- CDC recommends to continue vaccination strategies.
- Caregivers be informed of this ongoing investigation as part of the consent process for vaccination with MCV₄.
- People with a history of GBS who are not in a high-risk group for invasive meningococcal disease should not receive MCV₄.

Reporting Cases to VAERS

- FDA and CDC request that providers report any known cases to VAERS [online](#) or by telephone at 1-800-822-7967.
- CDC further requests that health care providers report other cases of **GBS** (even those not associated with MCV₄ or other vaccination) that occur among people aged 11 to 19 years to state health departments in accordance with state or local disease-reporting guidelines.

Administration of Multiple Vaccines Simultaneously & SIDS

- The Institute of Medicine (**IOM**) released a report on Immunization Safety Review:
 - * Vaccination and **Sudden Unexpected Death in Infancy** in 2003 was reviewed.
 - *The committee reviewed **epidemiologic** evidence focusing on **SIDS, during the first 4 weeks** of life.
 - *The committee also looked for possible relationships between **SIDS and the individual vaccines (DTP), DTaP, HepB, Hib, and polio**; and specific combinations of vaccines or any combination of vaccines.

No Link Between Vaccines and SIDS

- The committee did not find enough evidence to show vaccines cause SIDS.
- A study using [Vaccine Safety Datalink \(VSD\)](#) data, found no association between immunization and deaths in young children.
- The **Vaccine Safety Datalink (VSD)** project is a collaborative effort between CDC's **Immunization Safety Office** and eight **managed care organizations (MCOs)**. The VSD project was established in 1990 to monitor immunization safety and address the gaps in scientific knowledge about rare and serious events following immunization.

The Study

- It Focused on children who died **one month to 7 years of age between 1991 and 1995.**
- It Looked at **the week and month prior** to the date of death for each child.
- **517** deaths occurred between **1991–1995,**
- **59%** during the first year of life.
- Of these deaths, the results did not show an association between immunizations and childhood deaths.

How Vaccines Are Tested and Monitored?

- Vaccines are one of the greatest success stories in public health. Vaccines have:
 - Ended smallpox.
 - Nearly ended polio.
 - Reduced outbreaks of measles, pertussis, and other illnesses to an all-time low.
- Vaccines are our best defense against infectious diseases, but no vaccine is 100% safe or effective.

Testing Vaccines Before Licensing

- Licensed by the [U.S. Food and Drug Administration \(FDA\)](#) before they can be used in the United States.
- Before the FDA approval:
- Tested on **animals**.
- When the vaccine completes these laboratory tests successfully, the FDA allows it to be tested on **people** during "clinical trials."
- Although vaccines are tested extensively before they are licensed for use in the United States, not enough people are included in the tests to detect reactions that happen only rarely. If there is a serious reaction the vaccine is withdrawn.

Monitoring Vaccines After Licensing

- After a vaccine is licensed for public use, its safety is monitored.
- The FDA requires **all manufacturers** to submit samples from each vaccine lot before its release.
- Manufacturers must give the FDA their test results for vaccine **safety, potency, and purity**.

Vaccine Adverse Event Reporting System (VAERS)

- Rare side effects and delayed reactions may not happen until the vaccine is given to millions of people.
- VAERS takes reports of health problems that happen after vaccination so scientists can find out if a vaccine is causing a health problem.
- Only scientific research can determine if a vaccine really caused the health problem, or if it was just a coincidence.

VAERS Reporting System

- People who report a health problem to VAERS are asked if the problem led to hospitalization, life-threatening illness, disability, or death.
- These events are classified as "serious," and are often subject to further study.

The Future

- Monitoring vaccine safety will become more important as new vaccines are developed and added to complicated immunization schedules.
- Scientists may also find **new ways** of giving vaccines, such as edible vaccines and needle-free injections.
- Vaccines will remain **our best tool** for preventing disease in the future...Best Use of Science...
- Reporting systems like VAERS will continue to be used to monitor health problems, so vaccines can continue to be held to very high standards of safety.

Immunization Safety Office

- ISO has a three-part mission that supports CDC's leadership role:
- To perform high-quality vaccine safety research.
- To assess causality and preventable risk factors.
- To identify adverse events following immunization (AEFIs) through public health surveillance.

