THE OFFICIAL NEWSMAGAZINE OF THE AMERICAN ACADEMY OF PEDIATRICS
AAP News
DEDICATED TO THE HEALTH OF ALL CHILDREN
Breaking News
July 1, 2014
www.aapnews.org

Evidence report: Serious adverse events from childhood vaccines 'extremely rare'

by **Alyson Sulaski Wyckoff** • *Associate Editor*

A new systematic review of adverse events linked to routine childhood vaccines has found that vaccines associated with serious adverse events are "extremely rare and must be weighed against the protective benefits that vaccines provide."

The following are among the findings of the review commissioned by the Agency for Healthcare Research and Quality (AHRQ):

- Measles-mumps-rubella (MMR) vaccine was *not* associated with the onset of autism (based on evidence with high confidence).
- There was no association with leukemia among the following vaccines: MMR, diphtheria toxoid, tetanus toxoid and acellular pertussis (DTaP), *Haemophilus influenzae* type B (Hib) and hepatitis B (high strength evidence).
- Rotavirus vaccines were linked to intussusception (moderate evidence), but the occurrence was extremely rare.

The report, *Safety of Vaccines Used for Routine Immunization of U.S. Children: A Systematic Review*," released July 1, will be published in the August *Pediatrics* (http://bit.ly/1rTonMn).

Part of a larger effort analyzing reports on the safety of vaccines for all ages, this review looked at studies on vaccines recommended for children 6 years and younger. Authors Margaret A. Maglione, M.P.P., and others from RAND Corp., a nonprofit research organization, updated the evidence from a 2011 Institute of Medicine (IOM) report (http://tinyurl.com/3dgyrcr) on the safety of vaccines and broadened the scope to include additional childhood vaccines.

The literature search began a year before and extended a couple of years after the IOM report. Of 20,478 relevant titles published from 2010-'13, 67 studies were accepted for review.

Here is a snapshot of the AHRQ findings:

- **DTaP** – No new studies met inclusion criteria.
- **Hib** – One study showed associated redness and swelling.
- **Hepatitis A** – moderate association with purpura in youths 7-17 years old
- **Hepatitis B** – Evidence favored acceptance of a causal relationship between vaccine and anaphylaxis in yeast-sensitive individuals.
- **Inactivated polio virus** – insufficient evidence of adverse events
- **Influenza** vaccines – Live attenuated vaccine (LAIV) and trivalent inactivated vaccine (TIV) forms were associated with mild gastrointestinal events (moderate evidence). TIV was associated with febrile seizures (increased when pneumococcal vaccine was given at the same time; about 44.9 cases per 100,000 doses in highest risk age group of 16 months).
- **MMR** – associated with febrile seizures but not autism (high confidence); anaphylaxis in allergic children (high confidence); association with thrombocytopenic purpura in children in the short term after vaccination (moderate but consistent evidence); transient arthralgia (moderate evidence)
- **Meningococcal** – could cause anaphylaxis in children allergic to its ingredients (moderate evidence)
- **Pneumococcal conjugate vaccine (PCV13)** – associated with febrile seizures (moderate evidence), with escalated risk when co-administered with influenza (TIV) vaccine
- **Rotavirus** vaccines – associated with intussusception (moderate evidence), though extremely rare (about 1-5 cases per 100,000 doses)
- **Varicella** – associated with thrombocytopenic purpura in youths 11-17 years (moderate evidence)

The authors concluded that the findings may allay some patient, caregiver and health care provider concerns.

In a companion commentary in *Pediatrics* ("Vaccines: Can Transparency Increase Confidence and Reduce Hesitancy?", http://bit.ly/1qupfcQ), Carrie Byington, M.D., FAAP, chair of the AAP Committee on Infectious Diseases (COID), notes that the adverse events listed in the review were not unexpected, and clinicians may have encountered them in practice, especially seizures associated with fever. Fortunately, they are rare and in most cases expected to resolve after the acute event in contrast to what can be life-threatening infections vaccines are designed to prevent.

Michael T. Brady, M.D., FAAP, immediate past chair of COID, agreed the study did not identify any adverse events that were not already known to providers who immunize.

"Adverse events and even serious adverse events following immunizations need to be put in context with the benefit of disease reduction that occurs in children who have been immunized," Dr. Brady emphasized. "It is disappointing that even in the face of evidence, there are still children who are underimmunized and vulnerable to significant and even life-threatening diseases because certain families choose to ignore the evidence that is not consistent with their own beliefs."

If parents are not convinced by the safety data in the review, Dr. Byington wrote in her commentary, perhaps the data can be used to increase clinicians' confidence in the vaccine schedule. Because physicians' recommendations carry so much weight with families, the increased confidence could help boost vaccination rates. Overall, Dr. Byington concludes, the two reports' findings "should be reassuring to parents of young children and to the clinicians who care for them."