Flu At@Glance®

• There is no increased risk of adverse events when trivalent inactivated influenza vaccine (TIV) is administered to pregnant women.

• Adverse events in pregnant women following administration of trivalent inactivated influenza vaccine and live attenuated influenza vaccine in the Vaccine Adverse Event Reporting System, 1990-2009.


Abstract:

OBJECTIVE: The objective of the study was to characterize reports to the Vaccine Adverse Event Reporting System (VAERS) in pregnant women who received seasonal influenza vaccines to assess for potential vaccine safety concerns.

STUDY DESIGN: We searched VAERS for reports of adverse events (AEs) in pregnant women who received trivalent inactivated influenza vaccine (TIV) from July 1, 1990 through June 30, 2009, or live attenuated influenza vaccine (LAIV) from July 1, 2003, through June 30, 2009.

RESULTS: A total of 148 reports after TIV and 27 reports after LAIV were identified. Twenty TIV (13.5%) and 1 LAIV (4%) reports were classified as serious. No specific AEs were reported in 30 TIV (20.3%) and 16 LAIV (59%) reports. The most common pregnancy-specific AE was spontaneous abortion: 17 after TIV (11.5%) and 3 after LAIV (11%). The reporting rate of spontaneous abortion was 1.9 per million pregnant women vaccinated.

CONCLUSION: No unusual patterns of pregnancy complications or fetal outcomes were observed in the VAERS reports of pregnant women after the administration of TIV or LAIV.

Safety of trivalent inactivated influenza vaccine in children 6 to 23 months old.


Abstract:

CONTEXT: Beginning with the winter season of 2004-2005, influenza vaccination has been recommended for all children 6 to 23 months old in the United States. However, its safety in young children has not been adequately studied in large populations.

OBJECTIVE: To screen for medically attended events in the clinic, emergency department, or hospital after administration of trivalent inactivated influenza vaccine in children 6 to 23 months old.

DESIGN, SETTING, AND PARTICIPANTS: Retrospective cohort using self-control analysis, with chart review of significant medically attended events at 8 managed care organizations in the United States that comprise the Vaccine Safety Datalink. Participants were all children in the Vaccine Safety Datalink cohort 6 to 23 months old who received trivalent inactivated influenza vaccine between January 1, 1991, and May 31, 2003 (45,356 children with 69,359 vaccinations).

MAIN OUTCOME MEASURE: Any medically attended event significantly associated with trivalent inactivated influenza vaccine in risk windows 0 to 3 days, 1 to 14 days (primary analysis), 1 to 42
days, or 15 to 42 days after vaccination, compared with 2 control periods, one before vaccination and the second after the risk window. All individual ICD-9 codes as well as predefined aggregate codes were examined.

RESULTS: Before chart review, only 1 diagnosis, gastritis/duodenitis, was more likely to occur in the 14 days after trivalent inactivated influenza vaccine (matched odds ratio [OR], 5.50; 95% confidence interval [CI], 1.22-24.81 for control period 1, and matched OR, 4.33; 95% CI, 1.23-15.21 for control period 2). Thirteen medically attended events were less likely to occur after trivalent inactivated influenza vaccine, including acute upper respiratory tract infection, asthma, bronchiolitis, and otitis media. After chart review, gastritis/duodenitis was not significantly associated with trivalent inactivated influenza vaccine (matched OR, 4.00; 95% CI, 0.85-18.84 for control period 1; matched OR, 3.34; 95% CI, 0.92-12.11 for control period 2).

CONCLUSIONS: In the largest population-based study to date of the safety of trivalent inactivated influenza vaccine in young children, there were very few medically attended events, none of which were serious, significantly associated with the vaccine. This study provides additional evidence supporting the safety of universally immunizing all children 6 to 23 months old with influenza vaccine.

Absence of associations between influenza vaccines and increased risks of seizures, Guillain-Barré syndrome, encephalitis, or anaphylaxis in the 2012-2013 season.


Abstract:

PURPOSE: We conducted weekly surveillance for pre-specified adverse events following receipt of the 2012-2013 influenza vaccines in the Vaccine Safety Datalink (VSD).

METHODS: For each outcome, risk intervals (i.e., period after vaccination with a potentially increased risk) were defined on the basis of biologic plausibility and prior literature. Seizures following inactivated influenza vaccine (IIV) were monitored in children in three age groups (6-23 months, 24-59 months, and 5-17 years) using a self-controlled risk interval design. We also monitored for Guillain-Barré syndrome, encephalitis, and anaphylaxis following IIV in patients ≥6 months of age using a cohort design with historical controls. In the risk intervals following live attenuated influenza vaccine (LAIV), we collected weekly counts of Guillain-Barré syndrome, encephalitis, and anaphylaxis in patients ages 2-49. Among LAIV vaccinees, numbers of expected events based on rates in historical controls were calculated, adjusted for age and site.

RESULTS: At the end of surveillance, approximately 3.6 million first doses of IIV and 250,000 first doses of LAIV had been administered in the VSD. No elevated risks were identified in risk intervals following 2012-2013 IIV, as compared with a self-matched control interval or to historical controls. For each outcome, fewer than three events occurred in the risk interval following 2012-2013 LAIV, and we thus were unable to estimate measures of relative risks.

CONCLUSIONS: No increased risk was identified for any of the pre-specified outcomes following 2012-2013 influenza vaccinations in the VSD. Published 2014. This article is a U.S. Government work and is in the public domain in the USA.