Comparative safety of two recombinant hepatitis B vaccines in children: data from the Vaccine Adverse Event Reporting System (VAERS) and Vaccine Safety Datalink (VSD).

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Source

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Abstract

BACKGROUND:

Preliminary review of data from the Vaccine Adverse Event Reporting System (VAERS), 1991-1994, revealed that more serious adverse events were reported in children who received a specific brand of recombinant hepatitis B (HepB) vaccine.

OBJECTIVE:

To compare the post-marketing safety experience of the two recombinant HepB vaccines licensed for use in infants and children in the United States.

DESIGN:

Review of a case series derived from passive surveillance data in the national VAERS. A retrospective cohort study using data from one health maintenance organization participating in Vaccine Safety Datalink (VSD), a computerized record linkage system. POPULATIONS STUDIED: U.S. children, ages birth-10 years for
whom adverse events after HepB vaccine were reported to VAERS, 1991-1994. Children, ages birth-6 years, who received HepB vaccine at Kaiser Permanente Medical Care Program, Northern California, 1991-1994. Main

OUTCOME MEASURES:

VAERS reporting rates for each vaccine by manufacturer were calculated from the numbers of reported events occurring within 30 days of HepB vaccination and the number of doses distributed by the manufacturers. VSD event rates for each vaccine were calculated from the numbers of hospitalization or emergency room visits within 30 days of HepB vaccination and the number of vaccine doses administered to the cohort.

RESULTS:

In VAERS, higher rates of serious events (i.e., life threatening or resulting in hospitalization or permanent disability) were reported in children who received Vaccine A vs. Vaccine B (relative risk [RR]: 3.13-8.18, P < 0.01), particularly by those vaccinated in the private (RR: 7.62-28.58, P < 0.01), but not public sector (RR: 2.12, P = 0.19). Similar types of events were reported in recipients of both vaccines. In contrast, analysis of VSD data showed no significant difference in rates of hospitalization or ER visits in children who received either HepB vaccine (RR: 0.96-1.25, P > 0.05).

CONCLUSIONS:

Our investigation reveals that it is unlikely there is a true difference between rates of serious events temporally associated with the two HepB vaccines in children. This study demonstrates the dual roles played by VAERS and VSD in providing a more complete picture of the post-marketing safety profile of childhood vaccines, and underscores the importance of using other analytic studies to evaluate findings from passive surveillance systems of adverse events.

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