Reporting Adverse Events after Vaccination

Modern vaccines are safe and effective; however, adverse events have been reported after administration of all vaccines. These events range from frequent, minor, local reactions to extremely rare, severe, systemic illness (e.g., anaphylaxis). Establishing evidence for cause-and-effect relations on the basis of case reports and case series alone is impossible because temporal association alone does not necessarily indicate causation. Unless the symptom or syndrome that occurs after vaccination is clinically or pathologically distinctive, more detailed epidemiologic studies to compare the incidence of the event among vaccinees with the incidence among unvaccinated persons are necessary. Reporting adverse events to public health authorities, including serious events, is a key stimulus to developing studies to confirm or refute a causal association with vaccination. More complete information about adverse reactions to a specific vaccine is available in the ACIP recommendations for that vaccine and in a specific statement on vaccine adverse reactions.

The National Childhood Vaccine Injury Act requires healthcare providers to report selected events occurring after vaccination to VAERS. Events for which reporting is required appear in the Reportable Events Table (http://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf). Persons other than health-care providers also can report adverse events to VAERS. All clinically significant adverse events other than those that must be reported or that occur after administration of vaccines not covered by the Act also should be reported to VAERS, even if the physician or other health-care provider is uncertain they are related causally to vaccination. VAERS forms and instructions are available in the FDA Drug Bulletin by contacting VAERS (800-822-7967), or from the VAERS website (http://vaers.hhs.gov/index).

National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program, established by the National Childhood Vaccine Injury Act, is a no-fault system in which persons thought to have suffered an injury or death as a result of administration of a covered vaccine can seek compensation. The program became operational on October 1, 1988, and is intended as an alternative to civil litigation under the traditional tort system in that negligence need not be proven. Claims arising from covered vaccines must first be adjudicated through the program before civil litigation can be pursued.

The program relies on a Reportable Events Table listing the vaccines covered by the program and the injuries, disabilities, illnesses, and conditions (including death) for which compensation might be awarded. The table defines the time during which the first symptom or substantial aggravation of an injury must appear after vaccination (http://www.hrsa.gov/vaccinecompensation/vaccinetable.html). Successful claimants receive a legal presumption of causation if a condition listed in the table is proven, thus avoiding the need to prove actual causation in an individual case. Claimants also can prevail for conditions not listed in the table if they prove causation. Injuries after administration of vaccines not listed in the legislation authorizing the program are not eligible for compensation through the program. Additional information is available from the

- National Vaccine Injury Compensation Program
- Health Resources and Services Administration
- Parklawn Building, Room 11C-26, 5600 Fishers Lane
- Rockville, MD 20857
- telephone: 800-338-2382
- Website: http://www.hrsa.gov/vaccinecompensation/