Chapter 18: Surveillance for Adverse Events Following Vaccination

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I. Public health importance

Immunizations have reduced the incidence of many vaccine-preventable diseases in the United States (and many other countries) by more than 95% compared with the prevaccine era (**Table 1**). For example, paralytic poliomyelitis has been eliminated from the Western Hemisphere and there has been cessation of indigenous measles virus transmission in the U.S. As the proportion of the vaccinated population increases, however, the number of persons who experience an adverse event following vaccination also increases—due either to reactions caused by the vaccination or coincidental events not caused by the vaccination (e.g., sudden infant death syndrome after diphtheria-tetanus-pertussis [DTP] vaccination). In recent years, the annual number of reports to the national adverse event reporting system has exceeded the total number of reports of routine childhood vaccine-preventable diseases, excluding varicella (**Table 1**). In the absence of disease, benefits of vaccination may be overshadowed by reports of vaccine adverse events (VAEs), and media attention may result in loss of public confidence in the vaccine and resurgence of vaccine-preventable diseases as experienced by several countries for pertussis.[1-3]

Vaccinations are usually administered to healthy persons and often are mandated; therefore, they are held to a higher standard of safety than other medications.[4] However, as with all medications, no vaccine is perfectly safe or effective. Vaccines can induce minor adverse events such as local reaction or fever. Very rarely, they can induce serious adverse events such as seizures, intussusception, or severe allergic reactions. However, until vaccine-preventable diseases are eradicated, vaccines must continue to be used. To ensure that vaccines are as safe as possible and to maintain public confidence in vaccines, close monitoring of the reporting of adverse events, adequate scientific evaluation of possible associations, and appropriate responses to newly identified risks of vaccines are essential.

To reduce the occurrence of vaccine adverse events, it is important to improve the understanding of vaccine safety, and, thereby, foster the development and use of safer vaccines.[5] One of the best ways to enhance our understanding of vaccine safety is to improve surveillance for vaccine adverse events (VAEs).

II. Background

Vaccines, like other pharmaceutical products, undergo extensive testing and review for safety, immunogenicity, and efficacy in trials with animals and humans before they are licensed. Because these trials usually include a placebo control or comparison group, it is possible to ascertain which local or systemic reactions were actually caused by the vaccine. However, prelicensure trials are relatively small, usually limited to a few thousand subjects, and usually last no longer than a few years. In addition, they may be conducted in populations more homogeneous than those in which the vaccine is ultimately used. The sensitivity for detection of uncommon or rare adverse reactions or events with delayed onset before licensure is low. As a result, postlicensure or postmarketing surveillance—the continuous monitoring of vaccine safety in the general population after licensure—is needed to identify and evaluate such adverse events.[4]

The history of such postmarketing surveillance for VAEs in the United States has been reviewed elsewhere.[5] From 1978 through 1990, CDC and the Food and Drug Administration (FDA) divided the responsibility for postmarketing surveillance of vaccines in the United States. Reports of adverse events occurring following the administration of vaccines purchased with public funds were reported to CDC's Monitoring System for Adverse Events Following Immunization (MSAEFI); the FDA received reports of adverse events after the administration of vaccine purchased with private funds. Most reports to the CDC were from public health clinics operated by state and county health departments, while reports to the FDA were mainly from private physicians and vaccine manufacturers. Even though collaboration was maintained between the two agencies, the use of different reporting forms and reporting requirements made combined analysis difficult. The passage of the National Childhood Vaccine Injury Act of 1986 (NCVIA) and its mandatory reporting requirement was an opportunity to correct these shortcomings.

With enactment of the NCVIA, health-care providers who administer vaccines and vaccine manufacturers licensed in the United States are required by law to report certain serious adverse events following specific vaccinations.[6] The NCVIA was an attempt to reduce threats (liability concerns, inadequate supply of vaccine, rising vaccine costs) to the stability of the immunization program and to compensate persons who may have been injured by vaccines.[7] The NCVIA stipulates the vaccines, the adverse events, and the time of occurrence after vaccination for which reporting is required (**Table 2**). The NCVIA also requires that any event listed in the manufacturer's package insert as a contraindication to subsequent doses of the vaccine be reported. The Department of Health and Human Services (DHHS) determined that the Vaccine Adverse Event Reporting System (VAERS), a passive surveillance system that monitors vaccine safety, be established to provide a single system for the collection and analysis of reports of adverse events following vaccination.[8] The CDC and FDA work together to implement VAERS. Programs such as VAERS exist in many countries? some monitor vaccines separately from other drug products, but most are joint

programs. These programs form the cornerstone of drug safety monitoring efforts around the world.

III. Reporting to VAERS

The VAERS form (see **Appendix 23**) has been sent annually to approximately 200,000 primary care physicians in the specialties of pediatrics, family practice, general practice, internal medicine, and school or college health. Copies are also sent to state health departments and to public health clinics that administer vaccines. Orders for additional printed report forms, assistance in completing the form, or answers to other questions about VAERS are available via a toll-free telephone helpline (1-800-822-7967) that is staffed during normal business hours. VAERS reports can be entered and submitted online by accessing VAERS at www.vaers.org; report forms and instructions can also be downloaded and printed from the internet site. A sample copy of the VAERS form, which can be copied for reporting purposes, is available in the American Academy of Pediatrics' Red Book. The Vaccine Information Statements developed by DHHS also contain instructions on how to report adverse events to VAERS.

The VAERS form is preaddressed and postage paid and can be sent directly to VAERS, P.O. Box 1100, Rockville, Maryland 20849-1100 or faxed toll-free to 1-877-721-0366. Local health departments should follow the reporting instructions provided by their state immunization program.

Upon receipt, reports are entered into a database, verified, and coded using a standard set of coding terms. Reporters are sent a letter verifying receipt of the form by VAERS and are sent a request for information if critical information is missing. The FDA reviews reports of death and other serious events and conducts analyses of reports by vaccine lots. CDC routinely reviews selected serious outcomes (e.g., anaphylaxis, Guillain-Barré syndrome) and conducts additional analyses as needed to address specific concerns and to evaluate trends in reporting.

Health-care providers and manufacturers are mandated by law to report certain adverse events after vaccination, but more importantly, these groups should report any clinically significant or unusual event occurring after vaccination, even if they are not certain the event is causally related. Reports are also encouraged from patients and parents or caregivers. Lay persons who report are encouraged to consult with a health-care provider to ensure that information is complete and accurate. It is by aggregating all reports that possible causal relations can be properly evaluated.

IV. Completion of VAERS form and submission of reports

About form VAERS-1

Instructions for completing the VAERS form are on the back of the form.

Adverse events can be reported to VAERS at www.vaers.org or VAERS report forms and instructions can be downloaded from the same site.

- Report adverse events associated with vaccines on Form VAERS-1. Do not use MEDWATCH or the old MSAEFI forms to report vaccine-related events.

- Do not report events associated with tuberculosis screening tests (Tine, PPD, or Mantoux) or immune globulins to VAERS. These events should be reported to the FDA's MEDWATCH program at 1-800-FDA-1088 (1-800-332-1088).

Public sector reporting

Local health departments may request reporting forms from their state immunization program or obtain them from www.vaers.org.

Local reporting responsibilities

Clinic staff at the local level are responsible for initiating the VAERS report when an adverse event is suspected or occurs. As much of the requested information as possible should be obtained. Reporting priority should be given to serious or unexpected events or unusual patterns of expected non-serious events. Each report should be reviewed for completeness, accuracy, and legibility before it is sent to the State Health Coordinator (SHC) or VAERS Coordinator, with specific attention to the following:

- **Dates**—All dates should make chronological sense. For example, the vaccine date cannot precede the birth date, the report date cannot precede the vaccine date, etc. All date fields require entry of the full month, date, and year.

- **Patient name**—Verify that the patient's first and last names are correct. This check assists in the identification of duplicate reports.

- **Reporter information** (upper right corner of form)—The reporter name and complete mailing address are required. Verification letters and requests for missing or follow-up information are sent to this address. Some SHCs prefer to receive and submit verification letters, requests for missing information, and related correspondence; they may delete or white-out the original reporter's name and address and insert the SHC name and address. If you do not receive a verification letter within a reasonable amount of time (e.g., one month) check with your SHC.

- **Critical boxes**—Certain items are crucial to the analysis of VAERS data and have been designated as critical boxes. If all critical boxes are complete, no missing data will be requested and the report is considered complete. Critical boxes are differentiated by a square around their respective item numbers on the form as follows:

  - **Box 3:** Date of birth
  - **Box 4:** Age of patient at the time of vaccination
  - **Box 7:** Narrative description of adverse events, symptoms, etc.
  - **Box 8:** Indicates whether a report is regarded as serious or non-serious, and identifies the most serious reports for 60-day and annual follow-up

    - **Serious**
      - Patient died and date of death
      - Life-threatening illness
      - Resulted in permanent disability
      - Required hospitalization and number of days hospitalized
      - Resulted in prolongation of hospitalization

    - **Non-serious**
      - Required emergency room or doctor's visit
      - None of the above

  - **Box 10:** Date of vaccination (and time, if known)
  - **Box 11:** Date of onset of adverse event (and time, if known)
  - **Box 13:** All vaccines given on the date listed in Box 10, including name of vaccine, vaccine manufacturer, vaccine lot number, route and site of administration and number of previous doses given. Accurate lot information is needed to examine events occurring within specific vaccine lots.
  - **Boxes 15 and 16:** Identify potential public health reports; VAERS will request the immunization report number if not supplied.
  - **Box 24:** NCVIA requires tracking of vaccines administered; the immunization project report number is assigned by the SHC and is an identifier linking the SHC and the VAERS ID.

- **Timely reporting—**All reports are to be sent to the SHC as they occur, especially any serious report. Do not send batches of reports. VAERS data is downloaded on a daily basis to the FDA. Timely reporting is essential to timely follow-up investigation.

State health coordinator responsibilities

The SHC receives VAERS reports from local health departments or immunization projects and is responsible for the following activities:

- Reviews the report for completeness (especially the critical boxes), obtains any other necessary information, and clarifies any questions about the report.

- Assigns an identifying immunization project number using the two-letter state postal abbreviation, two-digit representation for year, and the state numbering sequence. For example, the 57th report received in Arizona in 1995 begins with AZ, followed by 95, followed by 057, and should look like this: AZ95057.

- When the immunization project number has been assigned, the SHC sends the original report to VAERS and keeps a copy. As for local reporting, the cases should be forwarded rapidly to VAERS and not batched for sending.

- The VAERS office frequently receives reports from other sources that should have been sent to the SHC first. These reports usually indicate that the vaccine or vaccines were given in a health department and do not have a state immunization project number assigned. Copies of these reports will be faxed to the appropriate SHC, along with a cover sheet that indicates the VAERS ID number and a place to indicate whether the SHC claims the report. If the SHC claims the report, he or she assigns an immunization project number to that report. The SHC enters the appropriate information on the cover sheet and should fax the information to VAERS.

- Any correspondence about a report must include the VAERS ID number. Reports are entered into the VAERS database under the unique ID number. It is also helpful to have the patient's name and date of birth, if available, to help identify the specific report.

- VAERS sends a monthly report of missing information to the SHC; the SHC submits to VAERS the requested missing information, as well as follow-ups for each report at 60 days and 1 year.

- The SHC updates VAERS with any personnel, fax, phone, or address changes.

State health coordinator monthly reports

Reports are generated by VAERS and sent to SHCs each month to request missing data, as well as 60-day and annual follow-up reports. Monthly reports list VAERS reports by VAERS ID number and SHC project number. Although these follow-up requests are sent monthly, the case reports are scanned upon receipt at VAERS and available to CDC and FDA for evaluation.

- **Missing data?** Missing data is requested if information is missing from critical boxes (see this section, "Local reporting responsibilities"). The specific information needed is indicated on the monthly report. Missing or corrected information may be submitted to VAERS by fax or mail as follows:

  - **Fax:** Using a blank VAERS form, record the following information in the appropriate boxes and fax to 1-877-721-0366:
    - VAERS ID
    - SHC immunization project number
    - Patient's name and date of birth
    - Missing or corrected information you are providing
    - Reporter's name and phone number

  - **Mail:** Using a blank VAERS form, record the following information in the appropriate boxes:
    - VAERS ID
    - SHC immunization project number
    - Patient's name and date of birth
    - Missing or corrected information you are providing
    - Reporter's name and phone number

- **60-day and annual follow-up:** The SHC provides information about the patient's status at 60 days and 1 year after serious events. The SHC may also provide additional information for critical boxes if not originally available.

  - Submit 60-day and annual follow-up using a blank VAERS form. Include the following information in the appropriate boxes:

    - VAERS ID Number
    - Patient name
    - Reporter's name and phone number
    - **Box 3:** Patient date of birth
    - **Box 7 or 9:** Patient status. Indicate the date that the follow-up information was obtained.

      - **Recovered:** Patient health condition is the same as it was prior to the vaccine.
      - **Not recovered:** Patient health condition has not returned to pre-vaccination state of health.
      - **Unknown:** Patient condition or whereabouts are unknown.
      - **Died:** Patient has expired since initial report. Include date of death and supporting documentation (copies of hospital records, autopsy report, death certificate, etc.) as available.

- **Box 24:** Immunization project number
- **Box 27:** Check box as "Follow-up"

The SHC should send the 60-day or annual follow-up reports to the VAERS office by fax or mail.

V. System operation

Objectives of VAERS

The objectives of VAERS are:

- To detect previously unrecognized reactions in current and future vaccines.
- To detect unusual increases in previously reported events.
- To detect preexisting conditions that may promote reactions and be contraindications to additional doses.
- To detect vaccine lots with unusual numbers and types of reported events.
- To trigger further clinical, epidemiologic, or laboratory investigations regarding the causal relation between a vaccine and adverse event.
- To provide data on national numbers of reported adverse events following vaccination.

Scope of reports sought

The Table of Reportable Events (**Table 2**) lists the events mandated for reporting to DHHS. However, more importantly, reports should be submitted to VAERS for all serious and unusual events occurring after vaccination, in all age groups, even if the causal relationship to vaccination is uncertain. Such events include all deaths, any life-threatening illness, an illness requiring an emergency room visit or hospitalization, prolongation of a hospital stay, or any illness resulting in a permanent disability, as well as less serious but previously unrecognized adverse events attributable to vaccination.

The VAERS form allows description of the adverse event in narrative form by the reporter. Unlike other public health disease surveillance systems for which a distinct case definition exists, many adverse events reported to VAERS are clinical syndromes that may be poorly defined or poorly understood or are diagnoses of exclusion. The Brighton Collaboration (http://brightoncollaboration.org) is an international voluntary collaboration whose primary aim is to develop globally accepted standardized case definitions of adverse events following immunization. The term *adverse event* rather than *reaction* is used because attribution of causality to the vaccine usually is not possible. The VAERS form is designed to permit description of the adverse event, the type of vaccine(s) received, the timing of vaccination and the adverse

event, demographic information about the recipient, concurrent medical illness or medications, and prior history of adverse events following vaccination (see **Appendix 23**). Adverse events should be described as clearly as possible, with accurate timing with respect to vaccination. Additional medical records or discharge summaries are encouraged if they assist in clarifying any aspects of the report.

VI. Evaluation of VAERS

Approximately 11,000–12,000 reports of adverse events following vaccination are received by VAERS each year. All reports are accepted and entered without determining whether or not the adverse event could have been caused by the vaccine in question. To put the number of reports of adverse events in perspective, it should be noted that each year over 100 million doses of vaccine are distributed in the United States. Additionally, the type and severity of event reported varies from minor local reactions or fever to death. Of the reports received between 1991 and 1998, 1.5% reported death as the outcome; 9.9% reported a serious non-fatal adverse event, and 88.6% reported less serious events.

From 1991 through mid-2001, vaccine manufacturers submitted 42% of the VAERS reports; 30% were from private health care providers. State and local health departments accounted for 12% of the reports, patients and their parents submitted 7% of the reports, and 9% came from other sources. Direct reporting to VAERS or to the SHC by health-care providers is encouraged, as these reports arrive on a more timely basis than those submitted to manufacturers. Manufacturers are not required to provide these reports to VAERS immediately upon receipt unless serious and unexpected events have occurred. As a result, evaluation for less serious associated events is delayed.

Usefulness

The data from VAERS have been used by the FDA, CDC, and the Division of Vaccine Injury Compensation (although reporting to VAERS does not constitute filing a claim and VAERS is a separate program from the Vaccine Injury Compensation Program). The FDA investigates all deaths, reports classified as serious, and certain non-serious events that have unusual characteristics. Assessments of lot-specific reporting rates are conducted weekly, using manufacturer-supplied data on lot size. The FDA has the authority to withdraw a vaccine lot if it is determined that the rate of reported vaccine-associated adverse events is unusually high. Since VAERS inception, no vaccine lot has been recalled for safety reasons.

CDC has used VAERS data in the analyses of the safety of acellular pertussis vaccine versus whole-cell pertussis vaccine; the rates of allergic reactions after first and second doses of measles-containing vaccines; intussuception occurring after rotavirus vaccine; the safety of newly licensed vaccines such as varicella, pneumococcal conjugate, and hepatitis A vaccines; the association between influenza vaccinations and Guillain-Barré syndrome; evaluation of reporting

efficiency; and use of safety profiles and similarity indices as tools for assessing vaccine safety. Further, VAERS data, without identifying information, are available to the public through the VAERS website (www.vaers.org) and are updated quarterly.

VAERS data have also been used by the Institute of Medicine (IOM) Vaccine Safety Committee in an extensive assessment of the causal relations between common childhood vaccines and adverse events.[9,10] IOM has recently established a new independent expert committee to review hypotheses about existing and emerging immunization safety concerns. A focused report will be published regarding each hypothesis addressed, which will summarize the current epidemiologic evidence for causality between an immunization and a hypothesized health effect (including information obtained from VAERS), the biologic mechanisms relevant to the adverse event hypothesis, and the significance of the issue in a broader societal context. These references may be useful to providers who are called on to answer the public's questions on vaccine safety and the occurrence of adverse events.

Completeness of case reporting

The sensitivity of VAERS is affected by the likelihood that parents and/or vaccinees detect an adverse event, parents and/or vaccinees bring the event to the attention of their health-care provider(s), parents and/or health-care providers suspect an event is related to prior vaccination, parents and/or health-care providers are aware of VAERS, and that parents and/or health-care providers report the event. The reporting of adverse events known to be associated with certain vaccines varies according to the severity of the event and the specificity of the clinical syndrome to the vaccine.[11,12]

The reporting efficiency for paralytic poliomyelitis following oral polio vaccine (severe event, very specific vaccine association, and very rare) is 68%, yet the reporting efficiency for rash following MMR is < 1% (mild event, many causes).

Event	Reporting efficiency %
OPV and vaccine-associated paralytic polio	68%
Rotavirus vaccine and intussusception	47%
MMR + MR and seizures	37%
DTP and seizures	24%
MMR and thrombocytopenia	4%
DTP and hypotonic hyporesponsive episodes	3%
MMR and rash	<1%

Limitations of VAERS

The limitations of VAERS, consistent with many passive reporting systems, should be considered in interpreting VAERS data.

Dose distribution data. A significant limitation is that vaccine dose distribution data are not readily available to calculate reporting rates. This means that often only numerator information is available. To illustrate the difficulty this limitation presents, consider that if an increase in the number of reported events following a certain vaccine is noted during one year, it may not be obvious whether this increase is the result of increased reporting, increased use of the vaccine, or an actual increase in the rate of events.

Quality of information. Since there are no formal guidelines for reporting, and because anyone may submit reports to VAERS, the accuracy and amount of information varies significantly between reports.

Underreporting. Underreporting may occur for several reasons. These include limitations in detection of an event, lack of recognition of association between vaccine and event, or failure to submit a report. Underreporting can affect the ability of VAERS to detect very rare events.

Biased reporting. Reports to VAERS may not be representative of all adverse events that occur. Events that occur within a few days to weeks of vaccine administration are more likely to be submitted to VAERS than events with a longer onset interval. Media attention to particular types of medical outcomes can stimulate reporting; this occurred after the initial 1999 MMWR publication describing reports of intussusception associated with rotavirus vaccine.

Confounding by drug and disease. Many reports describe events that are not exclusively the result of a vaccine(s) but may also be caused by medications or various diseases. Many adverse event reports may encompass clinical syndromes that are poorly defined, not clearly understood, or a diagnosis of exclusion (e.g., SIDS). Often multiple vaccines are administered at the same visit, making attribution of causation to a single vaccine or antigen difficult.

Inability to determine causation. VAERS reports are usually not helpful in assessing whether a vaccine actually caused the reported adverse events because they lack either unique laboratory findings or clinical syndromes necessary to draw such conclusions.[4] VAERS reports also constitute less than 25% of the information necessary for an epidemiologic assessment of vaccine causality (i.e., just cell “a” of the 2 x 2 table of vaccination and adverse event). Reports to VAERS are useful for generating hypotheses, but controlled studies are necessary to confirm any hypotheses generated by VAERS observations.[4,13-15]

VII. Enhancing surveillance

Several activities can be undertaken to improve the usefulness and quality of VAERS as a surveillance system.

Improving quality of information reported

At the state and local level, VAERS forms should be reviewed for completeness and accuracy. The reporter should be contacted if any information is missing. For death and serious outcomes after vaccination, efforts should be made to obtain additional documentation (e.g., hospital discharge summaries, laboratory reports, death certificates, and autopsy reports). As of January 1999, the VAERS staff contacts reporters and parents or vaccine recipients routinely to obtain missing information or to correct inaccurate information for all reports of deaths, serious adverse events, and for selected clinically significant events.

Evaluation of system attributes

The VAERS program should consider evaluating the acceptability and representativeness of the VAERS data and should examine the possibility of simplifying the reporting process. Knowledge, attitudes, and beliefs of both private and military health-care providers about reporting to VAERS will be surveyed in the near future. A review of the data quality and timeliness of reporting has been conducted by the VAERS program. The review indicated that improvement was needed in the areas of quality control and quality assurance. Revision and simplification of the reporting form is underway, with release of a revised VAERS report form scheduled for early 2003.

Promoting awareness

Current outreach and education efforts include online availability of both continuing medical education (CME) credits (www.vaers.org/ce.htm) and an online public use data set (www.vaers.org/info.htm). Surveillance reports have not been published since VAERS began accepting reports on November 1, 1990. An MMWR Surveillance Summary for VAERS covering 1991–2001 is in preparation. Publication and dissemination of periodic reports by CDC and FDA could stimulate interest in VAERS, decrease underreporting, and provide information to health departments and health-care providers about adverse events following vaccination. The VAERS contact information is provided on all Vaccine Information Statements (VISs) that are to be handed out at each vaccination visit.

To complement VAERS' role in hypothesis generation, CDC created the Vaccine Safety Datalink (VSD) project in 1990 to test and validate hypothesized VAEs.[16] The VSD links computerized vaccination and medical records for more than 3 million children and 6 million adults at 8 health maintenance organizations (HMOs). Because the databases are usually generated during routine administration of the HMO, the problems of underreporting or recall bias are

minimized. Because these programs have enrollees numbering from thousands to millions, large cohorts may be assembled to examine less frequent adverse events. Denominator data and control groups are also readily available. Hence the VSD provides an economical and rapid means of detecting as well as evaluating new hypothesized vaccine adverse events.

Despite the limitations of VAERS, currently there are no alternatives for a population-based post-marketing surveillance system for vaccines. VAERS is useful in that it generates signals that trigger further investigations. VAERS can detect unusual increases in previously reported events and it indicates the number of adverse reactions reported nationwide. The sentinel role of VAERS is particularly significant for newly licensed vaccines, as evidenced by the detection of intussusception following the newly licensed rotavirus vaccine, or changes in the schedule of administration for currently licensed vaccines. Although manufacturers are now routinely asked to conduct "Phase 4" studies designed to collect additional safety data in large numbers of vaccine recipients, the need for a national post-marketing surveillance system remains.

VIII. The National Vaccine Injury Child Compensation Program (VICP)

The NCVIA established the VICP to provide compensation for certain adverse events following immunization. VICP is not related to VAERS and is a separate government "no-fault" system directed to compensate individuals whose injuries may have been caused by vaccines recommended by the CDC for routine use in children. Reporting an event to VAERS does not constitute filing a claim with the VICP. The Vaccine Injury Table (http://www.hrsa.gov/osp/vicp/table.htm) lists specific injuries or conditions and time frames following vaccination that may be compensated under the VICP.[6,17] Intervals for reporting post-vaccination adverse events in the Table of Reportable Events (**Table 2**) vary slightly from the timeframes for compensation listed in the Vaccine Injury Table.

The toll-free number for the Vaccine Injury Compensation Program is 1-800-338-2382. Further information can be obtained by writing to: National Vaccine Injury Compensation Program, Parklawn Building, Room 8A-46, 5600 Fishers Lane, Rockville, MD 20857.

Table 1. For vaccine-preventable diseases, comparison of maximum annual cases and current reported morbidity with known vaccine adverse events

Disease	Maximum cases	Year	2001* provisional	% Decrease
Diphtheria	206,939	1921	2	99.99
Measles	894,134	1941	108	99.99
Mumps	152,209	1968	226	99.85
Pertussis	265,269	1934	5,420	97.96
Polio (paralytic)	21,269	1952	0	100.00
Rubella	57,686	1969	22	99.99
Cong. Rubella Synd.	20,000	1964-5¶	2	99.99
Tetanus	601	1948	27	95.50
H. Influenzae type b and unknown (<5 yrs)	20,000	1984¶	290	98.55
Vaccine adverse events	0		13,526§	

* 2001 data are provisional.

¶Estimated because no national reporting existed in the prevaccine era

§Adverse events after vaccines against diseases shown in Table = 6,766

Table 2. VAERS Table of Reportable Events Following Vaccination*

Vaccine/Toxoid	Event	Interval from Vaccination
Tetanus in any combination; DTaP, DTP, DTP-Hib, DT, Td, or TT	A. Anaphylaxis or anaphylactic shock	7 days
	B. Brachial neuritis	28 days
	C. Any sequelae (including death) of above events	Not applicable
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.
Pertussis in any combination; DTaP, DTP-HIB, P	A. Anaphylaxis or anaphylactic shock	7 days
	B. Encephalopathy (or encephalitis)	28 days
	C. Any sequelae (including death) of above events	Not applicable
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.
Measles, mumps and rubella in any combination; MMR, MR, M, or R	A. Anaphylaxis or anaphylactic shock	7 days
	B. Encephalopathy (or encephalitis)	28 days
	C. Any sequelae (including death) of above events	Not applicable
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.
Rubella in any combination; MMR, MR, or R	A. Chronic arthritis	42 days
	B. Any sequelae (including death) of above events	Not applicable
	C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.
Measles in any combination; MMR, MR, or M	A. Thrombocytopenia purpura	7 – 30 days
	B. Vaccine-strain measles viral infection in an immunodeficient recipient	6 months
	C. Any sequelae (including death) of above events	Not applicable
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.

Oral Polio (**OPV**)	A. Paralytic polio	30 days, 6 months
	B. Vaccine-strain polio viral infection	30 days, 6 months
	C. any sequelae (including death) of above events	Not applicable
	D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.
Inactivated Polio (**IPV**)	A. Anaphylaxis or anaphylactic shock	7 days
	B. Any sequelae (including death) of above events	Not applicable
	C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.
Hepatitis B	A. Anaphylaxis or anaphylactic shock	7 days
	B. Any sequelae (including death) of above events	Not applicable
	C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.
Haemophilus influenzae type b polysaccharide (**Hib**)	A. Early-onset Hib disease	7 days
	B. Any sequelae (including death) of above events	Not applicable
	C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.
Haemophilus influenzae type b, conjugate (**Hib**)	A. Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.
Varicella	Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.
Rotavirus	Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.
Pneumococcal conjugate	Events described in manufacturer's package insert as contraindications to additional doses of vaccine	See package insert.

** The Reportable Events Table (RET) reflects what is reportable by law (42U.S.C. 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturer's package insert. In addition, individuals are encouraged to report ANY clinically significant or unexpected events (even if you are not certain the vaccine caused the event) for ANY vaccine, whether or not it is listed on the RET. Manufacturers are also required by regulation (21 CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine. Effective December 18, 1999*.

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