Chapter 21: Surveillance for Adverse Events Following Immunization Using the Vaccine Adverse Event Reporting System (VAERS)

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I. Public Health Importance

Vaccination is one of the ten great public health achievements of the 20th century.[1] Vaccines have reduced the incidence of many vaccine-preventable diseases in the United States by more than 98% compared to the prevaccine era.[2,3] This historic decrease in disease rates is shown in Table 1.

Table 1. Decline in vaccine-preventable disease morbidity in the United States during the 20th century[2,3]

Disease	Baseline 20th century annual morbidity	2014 reported cases	% Decrease
Smallpox	48,164*	0	100
Diphtheria	175,885†	1	>99
Pertussis	147,271‡	32,971	>77
Tetanus	1,314§	25	>98
Poliomyelitis (paralytic)	16,316¶	0	100
Measles	503,282#	667	>99
Mumps	152,209**	1,223	>99
Rubella	47,745††	6	>99
Congenital rubella	823 (estimated)‡‡	1	>99
Haemophilus influenzae, type b	20,000 (estimated)§§	306 (serotype b or unknown serotype, age <5 years)	>98

* *Average annual number of cases during 1900–1904.*

† *Average annual number of reported cases during 1920–1922, 3 years before vaccine development.*

‡ *Average annual number of reported cases during 1922–1925, 4 years before vaccine development.*

§ *Estimated number of cases based on reported number of deaths during 1922–1926 assuming a case-fatality rate of 90%.*

¶ *Average annual number of reported cases during 1951–1954, 4 years before vaccine licensure.*

Average annual number of reported cases during 1958–1962, 5 years before vaccine licensure.

** *Number of reported cases in 1968, the first year reporting began and the first year after vaccine licensure.*

†† *Average annual number of reported cases during 1966–1968, 3 years before vaccine licensure.*

‡‡ *Estimated number of cases based on seroprevalence data in the population and on the risk that women infected during a childbearing year would have a fetus with congenital rubella syndrome.*

§§ *Estimated number of cases from population-based surveillance studies before vaccine licensure in 1985.*

Vaccinations are usually administered to healthy persons and often are mandated by states as a condition for school attendance (with certain exemptions allowed); therefore, they are held to a higher standard of safety than other medical products.[4] However, as with all medical products, no vaccine is perfectly safe or effective. Vaccines can cause minor adverse events (AEs) such as fever or local reactions at the injection site. Rarely, they can cause serious AEs such as anaphylaxis. Adverse events can also occur coincidentally after vaccines (i.e., they would have occurred in the absence of vaccination). Improving our understanding of vaccine safety is important to reduce the occurrence of vaccine AEs and maintain public confidence in vaccines. One way to enhance our understanding of vaccine safety is to improve surveillance for vaccine AEs. Robust vaccine safety monitoring may foster the discovery of adverse events associated with vaccination, and thus the development and use of safer vaccines and recommendations to minimize the risk of AE after vaccination (e.g., creating new recommendations, contraindications, and precautions).[5]

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 in the United States. Because these trials generally 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—generally limited to a few thousand subjects— and usually last no longer than a few years. In addition, they may be conducted in populations less demographically, racially, and ethnically diverse than those in which the vaccine is ultimately used. Persons with certain health conditions, such as pregnancy, may be excluded from the trials. Prelicensure trials usually do not have the ability to detect rare AE or an AE with delayed onset. The continuous monitoring of vaccine safety in the general population after licensure (known as postlicensure or postmarketing surveillance) is needed to identify and evaluate risk for such AEs after vaccination.[4]

The National Childhood Vaccine Injury Act of 1986 (NCVIA) mandates that healthcare providers who administer vaccines and vaccine manufacturers report certain AEs following specific vaccination.[6] The NCVIA's purposes are to compensate persons who may have been injured by vaccines and to reduce threats to the stability of the immunization program (e.g., liability concerns, inadequate supply of vaccine, rising vaccine costs).[7] The NCVIA requires that healthcare providers report to VAERS specific AEs which are listed on the Vaccine Adverse Event Reporting System (VAERS) Table of Reportable Events Following Vaccination. (Note that this table was revised as of March, 2017 and is available at https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf.)[8] VAERS, co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA), was established in 1990 for the collection and analysis of reports of AEs following vaccination.[9] Spontaneous reporting systems for AEs similar to VAERS exist in many countries; some monitor vaccines separately from other drug products, but many are joint programs. These programs form the cornerstone of drug and vaccine safety monitoring efforts around the world.

III. Objectives of VAERS

The objectives of VAERS are to

- monitor increases in known side effects, like arm soreness where a shot was given;
- identify potential patient risk factors for particular types of health problems related to vaccines;
- assess the safety of newly licensed vaccines;
- watch for unexpected or unusual patterns in adverse event reports; and
- serve as a monitoring system for vaccinations administered in public health emergencies.

Scope of reports sought

Anyone can report any vaccine AEs to VAERS. Reports are accepted from healthcare providers, vaccine manufacturers, patients, parents and anyone else who cares to report. Persons who are not healthcare providers are encouraged to consult with a healthcare provider to ensure that information is complete and accurate and that their provider is aware of the AE. Manufacturers are required to report to VAERS all AEs made known to them for any US-licensed vaccine. Reports of vaccination errors are also accepted by VAERS.

The VAERS Table of Reportable Events Following Vaccination (available at https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf) lists the events mandated for healthcare providers to report to VAERS. In addition, healthcare providers should submit reports to VAERS for all clinically significant AEs occurring after vaccination, in all age groups, even if the causal relationship to vaccination is uncertain. Such events include (but may not be limited to) all deaths, any life-threatening illness; an illness requiring a hospitalization, prolongation of a hospital stay, or any illness resulting in a permanent disability; and congenital anomalies, as well as less serious AEs of concern. The VAERS form requests information about the AE, the vaccine(s) received, the timing of vaccination before the AE, demographic information about the recipient, concurrent medical illness or medications, and prior medical history and history of prior AEs. The VAERS form allows description of the AE in a narrative format by the reporter. The VAERS form has been updated and the new form (VAERS-2.0) has been in use since

June 2017. The VAERS-2.0 form is available on the VAERS website at https://vaers.hhs.gov/index. The AE should be described on the VAERS form as clearly as possible, with accurate timing with respect to vaccination. Additional medical records or discharge summaries may be requested by the VAERS staff during follow-up for reports of a serious AE.

Reporting to VAERS
Reporting to VAERS online (i.e., web-based reporting) is strongly encouraged since it allows for quicker receipt and processing of the information. The option to report on a downloadable pdf was made available in June 2017. If someone is unable to report online or via the writable pdf, they can contact VAERS by phone at 1-800-822-7967 or email at info@vaers.org for assistance.

A VAERS reporting form, which can be copied for reporting purposes, is available online at https://vaers.hhs.gov/pdf/vaers_form.pdf. The form can also be requested by telephone at 800-822-7967. The Vaccine Information Statements (VIS) (http://www.cdc.gov/vaccines/hcp/vis/index.html) developed by CDC for all US-licensed vaccines and given to patients at the time of vaccination also contain instructions on how to report an AE to VAERS. Detailed instructions for completing the reporting form are provided below. Local health departments should follow the reporting instructions provided by their State Immunization Program.

Completion of VAERS form and submission of reports

Instructions for completing the VAERS form are on the VAERS website (https://vaers.hhs.gov/index).

***Note:** Report AEs associated with vaccines on the VAERS form. Do not use the FDA's MEDWATCH forms to report vaccine AEs.*

Do not report events associated with tuberculosis screening tests (Tine, PPD [purified protein derivative], or Mantoux), immune globulins, or other non-vaccine medical products to VAERS. These events should be reported to the 1-MedWatch program http://www.fda.gov/Safety/MedWatch/ or by calling 800-FDA-1088 (800-332-1088).

Reporting responsibilities
Clinic staff at the local level are responsible for completing a VAERS report when an AE is suspected or occurs following immunization. As much of the requested information as possible should be included. Although reporting priority may be given to serious or unexpected events or unusual patterns of expected non serious events, all clinically significant AEs should be reported. Each report should be reviewed for completeness and accuracy before it is sent to VAERS with specific attention to the following sections.

- *Dates*—All dates should make chronological sense. For example, the vaccine date cannot precede the birth date, or the report date cannot precede the vaccine date. All date fields should include the month, day, and year.
- *Patient name*—Verify that the patient's first and last names are correct. This check assists in identification of duplicate reports.
- *Reporter information*—The reporter's name and complete mailing address are requested. Verification letters and requests for missing or follow-up information are sent to this address. VAERS sends any reporter other than a manufacturer or State Immunization Program staff member (see below) a letter or email (based on the reporter's preference) verifying receipt of the form and requesting any critical information that was missing from the VAERS report (if necessary).
- *Critical boxes*—Certain items on the VAERS form are crucial to the analysis of VAERS data and have been designated as critical boxes (data fields). Persons reporting will be asked to supply this information later if it is missing. Critical boxes are differentiated by a square around their respective item numbers on the form as follows and are highlighted on the pdf:

Critical boxes	VAERS 2.0 Form box number
Date of birth	Box 2
Age of patient at the time of vaccination	Box 6
Sex	Box 3
Date of vaccination (and time if known)	Box 4
Date of onset of AE (and time, if known)	Box 5
Narrative description of AE, symptoms, etc.	Box 18
Indicates whether a report is regarded as serious or non-serious, and identifies the serious reports for follow-up Serious (serious status is based on the Code of Federal Regulations) • Patient died and date of death • Life-threatening illness (based on the judgment of the reporter) • Required hospitalization and number of days hospitalized • Resulted in prolongation of hospitalization • Resulted in permanent disability Non-serious • Required emergency department or doctor visit • None of the above	Box 21
All vaccines given on the date listed in box 4 of the VAERS-2.0 form, including name of vaccine, manufacturer, vaccine lot number, route and site of administration and number of previous doses given.	Box 17

- *Timely reporting*—Reporters are encouraged to send reports to VAERS as AEs occur, especially reports of any serious event. Programs are discouraged from sending batches of reports. Timely reporting is essential for rapid assessment of vaccine safety concerns and follow-up investigation.

  States may have VAERS reports sent directly to VAERS from providers without being first sent to the State Immunization Program staff. If VAERS reports are sent directly from healthcare providers and do not include an immunization project number [box 24 or 26 completed on the VAERS report-see below], the provider, instead of the State Immunization Program staff, will be contacted for notification of report receipt and for follow-up information.

State Immunization Program staff activities

The State Immunization Program staff member designates a VAERS Coordinator or Vaccine Safety Coordinator with overall responsibility for VAERS-related activities including the following specific responsibilities.

- Serving as CDC's main point-of-contact for vaccine safety in the awardee's jurisdiction.
- Alerting CDC to vaccine safety concerns in awardee's jurisdiction and responding to vaccine safety emergencies.
- Reporting vaccine safety emergencies and events of concern requiring vaccine safety responses to the CDC Immunization Safety Office (404-498-0680) or the CDC Emergency Operations Center (770-488-7100).
- Collaborating with CDC and other partners (e.g., FDA, local health departments, healthcare facilities, providers) to respond to and investigate reports of serious adverse events in accordance with state health department policy.
- Identifying and responding to vaccine safety issues of concern in respective jurisdiction.

Activities required of state immunization program staff who chose to submit reports from local health departments or immunization projects

The State Immunization Program staff member (VAERS Coordinator or Vaccine Safety Coordinator) who chooses to submit VAERS reports from local health departments or immunization projects (rather than having the healthcare provider caring for the patient submit it) is responsible for the following activities.

- Registering with Epi-X—CDC's secure communications network for public health professionals (https://www.cdc.gov/epix/) at the email address: epiXhelp@cdc.gov so that they can receive quarterly report summaries of the VAERS reports that they submitted.
- Reviewing each report for completeness (especially the critical boxes), obtaining any other necessary information, and clarifying any questions about the report.
- Assigning an identifying immunization project number using the 2-letter state postal abbreviation, 2- or 4-digit representation for year, and the state numbering sequence. For example, the 57th report received in Arizona in 2016 begins with AZ, followed by 16, followed by 057, and should look like this: AZ16057. This number is entered into box 26 of the VAERS 2.0 form.
- Uploading or sending the original report with the identifying number to VAERS and keeping a copy. As with local reporting, the cases should be forwarded rapidly to VAERS and not sent in a batch. Any further correspondence about a report must include the 6-digit VAERS ID number, which is assigned by the VAERS system. Reports are entered into the VAERS database under this number. It is also helpful to have the patient's name and date of birth, if available, to help identify the specific report. VAERS maintains the confidentiality of patients' personal identifying information, consistent with the requirements of the NCVIA.
- Completing the quarterly update report that is sent by VAERS via Epi-X (https://www.cdc.gov/epix/). (Although these follow-up requests are sent quarterly, the case reports are scanned upon receipt at VAERS and available to CDC and FDA for evaluation in near real time upon request.) This quarterly report contains a list of all initial reports received during the quarter, by VAERS ID number and state immunization project number, and serves as an acknowledgment of those reports. Specific missing or incomplete information for these reports is noted and completed in the appropriate boxes. The quarterly update report also lists reports for which VAERS requests recovery status at 60 days postvaccination and at 1-year postvaccination. The State Immunization Program staff submits to VAERS any requested missing information, as well as follow-up recovery status information for each listed report at 60 days and 1-year postvaccination. The State Immunization Program staff may update any other pertinent information about these individuals, such as vaccination information or date of birth. Reponses to quarterly report questions can be submitted to VAERS by mail, fax, or email.

States are asked to update VAERS with any personnel, fax, phone, or address changes. This is done by means of a quarterly e-mail request from VAERS to the state health department.

IV. Evaluation of VAERS Data

VAERS contract site staff receive and process reports, which are entered into a database using a standard set of coding terms from the Medical Dictionary for Regulatory Affairs (MedDRA) to code the AEs; a report may include more than one AE. FDA and CDC medical officers and vaccine safety experts review reports of deaths and other serious events and conduct other analyses to address specific safety concerns and to evaluate trends in reporting. Although all serious reports are reviewed, it is primarily by analyzing all reports in aggregate that possible safety concerns (or "signals") between vaccines and AEs can be properly detected and assessed.[10] When vaccine safety concerns are detected in VAERS they almost always require further assessment such as the Vaccine Safety Datalink (VSD) (see below).

Approximately 40,588 US reports of AEs following immunization are now received by VAERS each year (CDC, unpublished data). All reports are accepted and entered without case-by-case determination of whether the AEs could have been caused by the vaccine in question. To put the number of reports of AEs in perspective, it should be noted that each year over 317 million doses of vaccine are distributed in the United States (CDC unpublished data). Additionally, the type and severity of events reported vary from minor local reactions to death. Of the US primary reports received between 2012 and 2016, 0.4% reported death as the outcome; 5% reported a serious nonfatal adverse event (as defined above), and 94.6% reported non-serious events (CDC, unpublished data).

From 2012 through 2016, vaccine providers submitted 32% of U.S. VAERS reports; vaccine manufacturers submitted 41%; patients or parents submitted 13%; and 14% came from other or unknown sources (CDC, unpublished data).

Direct reporting to VAERS by healthcare providers or by State Immunization Program staff is strongly encouraged, as these reports usually arrive on a timelier basis than those submitted first to manufacturers. Manufacturers are not required to provide these reports to VAERS immediately upon receipt unless serious or unexpected events have occurred. As a result, evaluation of non-serious vaccine-associated events may be delayed.

Usefulness

The data from VAERS have been used by FDA, CDC, and the National Vaccine Injury Compensation Program at the Health Resources and Services Administration (HRSA); vaccine policy bodies, including the Advisory Committee on Immunization Practices (https://www.cdc.gov/vaccines/acip/); and other stakeholders. Below are some recent examples of how VAERS data have contributed to public health, listed by some of the major objectives of VAERS.

Detect new or rare AEs. Detection of an unexpected number of intussusception reports after introduction of the first rotavirus vaccine Rotashield is the classic example.[11] Further investigation in other systems verified this association, and the Rotashield vaccine is no longer licensed in the United States.[12–14]

A more recent example was when VAERS found a small increased risk for febrile seizures among young children after influenza vaccine (Fluzone) during the 2010–2011 season.[15] Additional studies covering influenza seasons from 2006–2007 through 2011–2012 confirmed this signal; simultaneous administration of flu vaccine with certain other vaccines (PCV and/or DTaP) appears to be associated with an increased risk for febrile seizures in young children on the day of and day after vaccination.[16, 17] However, this finding did not change the ACIP recommendations to give flu vaccine with other recommended vaccines since the benefits of on-time vaccinations outweigh the risk of febrile seizures.[18] In addition, most children most children who have febrile seizures recover quickly and have no long-term adverse effects.[19]

Assess the safety of newly licensed vaccines. VAERS has been used to assess the safety profile of the high-dose trivalent inactivated influenza vaccine; these findings have supported the vaccine's indications and recommendations.[20]

Identify potential risk factors in vaccinees for particular types of AEs. VAERS contributed data to support severe combined immunodeficiency syndrome (SCID) as a new contraindication for rotavirus vaccine.[21, 22]

Rapidly respond to vaccine safety concerns or public health emergencies. VAERS provided the first national data during 2009–10 H1N1 pandemic response. The first 2 months of data were published 3 months after the start of the program.[23] VAERS has also identified a number of preventable vaccination errors that once brought to attention of the public health community have been addressed in training materials and other prevention strategies.[24–27]

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 AE. IOM established an independent expert committee that conducted comprehensive reviews of 158 vaccine-AE pairs to study existing and emerging immunization safety concerns among eight different vaccines. In 2012, Adverse Effects of Vaccines: Evidence and Causality was published and included causality conclusions for each vaccine-AE pair addressed.[28] The IOM report summarizes the current epidemiologic evidence (including information obtained from VAERS) for causality between an immunization and a hypothesized health effect, the biologic mechanisms relevant to the adverse event hypothesis, and the significance of the issue in a broader societal context. The entire report can be downloaded free of charge or purchased at https://www.nap.edu/catalog/13164/adverse-effects-of-vaccines-evidence-and-causality. This reference may be useful to providers or public health officials who are called on to answer the public's questions on vaccine safety and the occurrence of AEs.

Reporting sensitivity

Like all passive surveillance systems, VAERS is subject to varying degrees of underreporting. The sensitivity of VAERS is affected by the likelihood that parents and/or vaccinees detect an AE; that parents and/or vaccinees bring the event to the attention of their healthcare provider(s); that parents and/or healthcare providers suspect an event is related to prior vaccination; that parents and/or healthcare

providers are aware of VAERS; and that parents and/or healthcare providers report the event. The completeness of reporting of AEs associated with certain vaccines varies according to the severity of the event and the specificity of the clinical syndrome to the vaccine.[29, 30] Reporting can also be stimulated by media attention on specific AEs.[31]

VAERS major strengths are:

- scale: VAERS is national in scope and therefore can be used during public health emergencies
- timeliness
- capacity to detect new AEs (in addition to monitoring prespecified AEs found in the prelicensure trials)
- accessibility: anyone can submit a report

V. Limitations of VAERS

The limitations of VAERS, which are common to many passive reporting systems, should be considered in interpreting VAERS data.

Dose distribution data. Vaccine dose distribution data are used to calculate reporting rates. However, these data are not age or state-specific. In addition, dose distribution information, derived from biologics surveillance data provided by vaccine manufacturers, does not track the actual amount of vaccine administered. These biologics surveillance data are proprietary and not available to the public. The only exception is for annual influenza vaccine. Data on the number of doses of influenza vaccine distributed are calculated by CDC and made available to the public but are not product specific by brand or manufacturer.

Quality of information. Since all reports, even incomplete ones, are accepted by VAERS, and because anyone may submit reports to VAERS, the accuracy and amount of information vary 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, although this may less of a concern for clinically serious events as they are more likely to be reported than non-serious events.[29]

Biased and stimulated reporting. Reports to VAERS may not be representative of all AEs 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.[31]

Confounding by drug and disease. Many reports to VAERS describe events that may have been caused by medications or underlying disease processes. Other reports to VAERS encompass clinical syndromes that are poorly defined, not clearly understood, or represent diagnoses of exclusion (e.g., sudden infant death syndrome).

Inability to determine causation. Because VAERS reports lack either unique laboratory findings or other information necessary to draw such conclusions, they are usually not helpful in assessing whether a vaccine actually caused a reported AE. Often multiple vaccines are administered at the same visit, making attribution of causation to a single vaccine or antigen difficult. Additionally, there is lack of an unvaccinated group for comparison in VAERS. Therefore, reports to VAERS are useful for generating hypotheses, but studies with vaccinated and unvaccinated subjects are necessary to confirm any hypotheses generated by VAERS observations.[5]

VI. Enhancing Surveillance

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

Improving quality of information reported

At the state and local levels, VAERS forms (including the web-based reporting form) should be reviewed for completeness and accuracy prior to submission. The reporter should be contacted if any information is missing. For death and serious outcomes after vaccination, the VAERS staff will attempt to obtain

additional documentation (e.g., hospital discharge summaries, laboratory reports, death certificates, autopsy reports). The VAERS staff routinely contacts reporters—healthcare providers and parents or vaccine recipients—to obtain missing information or to correct inaccurate information for all reports of deaths, serious AEs, and other selected clinically significant events.

Evaluation of system attributes

A survey was conducted in 2005 to assess the knowledge, attitudes, and practices among healthcare providers about reporting to VAERS.[32] Data indicated that although 71% of respondents were familiar with VAERS, only 17% said they were very familiar with it. Approximately 37% of healthcare providers had identified at least one adverse event after immunization, but only 17% stated that they had ever reported to VAERS. Vaccine Information Statements (VIS) were the most common source used to learn about VAERS. CDC is continuing to support efforts to further evaluate providers' perceptions and behaviors about VAERS and about reporting AEs after vaccination.

Promoting awareness

Current outreach and education efforts to promote VAERS include online print and web material, general information brochures in English and Spanish at https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/print-material.html and CDC vaccine safety publications available at https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/publications.html

VAERS contact information is provided on all VISs, which are required to be handed out at each vaccination visit to persons receiving a vaccine that is covered by the Vaccine Injury Compensation Program (VICP)—(i.e., listed on the Vaccine Injury Table). VIS use is strongly encouraged for all vaccines, including those not covered by the VICP.

VAERS data, without identifying information, are available to the public through the VAERS website for downloading raw data files or via search engine on the CDC WONDER site (https://wonder.cdc.gov/vaers.html) and are updated monthly.

Despite its limitations, VAERS is useful in that it generates signals that trigger further investigations. VAERS can detect unusual increases in previously reported events. As noted earlier, the sentinel role of VAERS is particularly significant for newly licensed vaccines, as evidenced in 2009 by the VAERS publication of the first summary of postlicensure H1N1 pandemic influenza safety data.[23] Although manufacturers are now routinely asked to conduct or sponsor postlicensure studies designed to collect additional safety data for large numbers of vaccine recipients, the need for a national postlicensure surveillance system remains. Like prelicensure studies, postlicensure studies may not be large enough to detect novel very rare AEs or may take several years to accumulate enough data to assess a rare occurrence.

VII. The National Vaccine Injury Compensation Program

The National Childhood Vaccine Injury Act of 1986 established the National VICP to provide compensation for AEs following immunization. VICP is a "no-fault" system to compensate individuals whose injuries may have been caused by covered vaccines. VICP is separate from VAERS and managed by HRSA. Reporting an event to VAERS does not result in the filing of a claim to the VICP. A claim for compensation must be filed directly with VICP. Any individual, of any age, who received a covered vaccine and believes he or she was injured as a result, can file a petition with VICP. The VCIP website lists specific injuries or conditions and time frames following vaccination that may be compensated under the VICP. If an injury and/or condition does not meet the requirements in the vaccine injury table, a petitioner must prove through evidence such as expert witness testimony, medical records, or medical opinion that the vaccine caused the injury and/or condition.[6, 33]

The toll-free number for the VCIP is 800-338-2382. Further information can be obtained by visiting their VICP website (https://www.hrsa.gov/vaccinecompensation/ or by writing to National Vaccine Injury Compensation Program, Parklawn Building, 5600 Fishers Lane, 8N146B, Rockville, MD 20857.

VIII. Other Vaccine Safety Monitoring Activities

In addition to VAERS, several other systems exist to monitor the safety of vaccines. The systems maintained by CDC are listed below.

The Vaccine Safety Datalink project (http://www.cdc.gov/vaccinesafety/activities/vsd.html) is a collaborative effort between CDC's Immunization Safety Office and several integrated healthcare systems to monitor immunization safety and address the gaps in scientific knowledge about AEs following immunization.[34] The VSD links computerized vaccination and medical records for approximately 10 million persons (3% of the total U.S. population) enabling evaluation of less frequent AEs. Denominator data and control groups are also readily available. The VSD thus provides a way of testing hypotheses related to vaccine safety. VSD has also implemented a system to conduct near real-time monitoring for specific AEs after vaccines in the VSD population.

The Clinical Immunization Safety Assessment (CISA) Network (http://www.cdc.gov/vaccinesafety/Activities/CISA.html) consists of six academic centers with vaccine safety expertise working in partnership with CDC and is designed to improve scientific understanding of vaccine safety issues at the individual patient level. The CISA Network's goals are to study mechanisms of vaccine AEs, study individual risk factors for AEs, serve as a resource to provide consultation for difficult vaccine safety issues, and to assist in developing vaccine safety guidance.

In summary, ongoing postlicensure safety monitoring is necessary for all US-licensed vaccines. Well-established systems are in places to accomplish that monitoring and State Immunization Program staff have a key role to play in helping to keep vaccines safe.

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