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Epidemiology and Surveillance

Overview

Effective vaccine-preventable disease (VPD) surveillance at national, state and local levels serves to document the impact of vaccination programs, evaluate the effectiveness of current vaccines and vaccination policies, and identify needed changes in program strategies. It also tracks trends in disease over time, monitors progress toward disease reduction and elimination goals, and serves to signal the need for public health responses.

Surveillance is used to measure the impact of changes in immunization policies. Surveillance is especially critical following the introduction of a new vaccine to monitor post-licensure vaccine safety, coverage, and decline in disease. Surveillance must be very complete for those diseases with extremely low incidence, especially those for which there is a target of elimination. For many diseases, particularly those for which testing is required for diagnosis and/or case confirmation, surveillance may rely heavily on laboratory-based reporting to increase the completeness of case reporting.

The Council of State and Territorial Epidemiologists (CSTE) has the responsibility to decide which diseases should be reported nationally. Priority areas of concern for CSTE are surveillance and epidemiology of infectious diseases, chronic diseases and conditions, and environmental health concerns. CSTE promotes the effective use of epidemiologic data to guide public health practices and improve health. This is accomplished by supporting the use of effective public health surveillance and good epidemiologic practice through training, capacity development, peer consultation, developing standards for practice, and advocating for resources and scientifically based policy.

The role of immunization programs in VPD surveillance varies considerably from state to state, with many immunization programs sharing this responsibility to a greater or lesser degree with other organizational sections, branches, or divisions responsible for general communicable disease control or epidemiology. However, to meet the national disease elimination objectives established for VPD surveillance, activities will need to be intensified and enhanced. With many VPDs at all-time low levels, the involvement of immunization program management and staff will be essential to assure complete case identification and thorough case investigation.

Monitoring adverse events and addressing vaccine safety concerns is an essential part of an immunization program. The National Childhood Vaccine Injury Act (NCVIA) of 1986 mandated the reporting of certain adverse events following immunization. This act led to the establishment of the Vaccine Adverse Event Reporting System (VAERS), a passive reporting system for adverse events following receipt of any U.S. licensed vaccine. VAERS is operated jointly by the CDC and the Food and Drug Administration (FDA). VAERS is the cornerstone of a comprehensive vaccine safety monitoring program to maintain public confidence in vaccines and vaccination programs.

Public and private immunization programs perform a critical role in vaccine safety by ensuring that their providers report suspected adverse events following vaccination through VAERS. Because VAERS is a passive surveillance system, there may be underreporting or biased reporting. Furthermore, VAERS usually cannot determine if an adverse event was actually caused by a vaccine. By collating and analyzing VAERS data nationwide, FDA and CDC are able to identify and respond to vaccine-associated risks potentially not identified in pre-licensure assessments. In addition, VAERS can detect unusual increases in recognized events, vaccine lots with unusual numbers or types of reported events, and, by collecting and following up additional case information, may detect pre-existing conditions that may be contraindications to vaccination. Results of VAERS analyses are used to trigger investigations of hypothesized relationships between a vaccine and adverse events.

VAERS data are available via the VAERS website (<http://www.vaers.hhs.gov>). Routine updates and/or custom searches are available to grantees on request from the VAERS program. Adverse events designated as “serious” require additional follow-up by the VAERS program to obtain more complete medical information with which to evaluate the case. These and other enhancements to CDC’s vaccine safety efforts will add to the knowledge regarding vaccine safety and help maintain confidence in our vaccination programs.

Currently the NCVIA specifies vaccines/toxoids and types of events that must be reported. However, healthcare providers are encouraged to report all clinically significant events to VAERS. Reporting forms and instructions are available from the VAERS website (<http://www.vaers.hhs.gov>) or by calling 1-800-822-7967 or sending an e-mail to info@vaers.org.

To modernize and enhance public health surveillance and information systems, CDC and its public health partners are implementing the National Electronic Disease Surveillance System (NEDSS). NEDSS implementation strategies include ensuring that the relevant activities of state and local immunization programs are consistent with the functional and technical specifications of the NEDSS information architecture. State and local immunization programs should evaluate current activities with respect to the NEDSS information system architecture and modify these activities, if necessary, so that they are consistent with NEDSS specifications. Information describing these specifications can be found on the internet at <http://www.cdc.gov/nedss/BaseSystem/NEDSSRequirements.pdf>.

References

- CDC. Manual for the Surveillance of Vaccine-Preventable Diseases <http://www.cdc.gov/vaccines/pubs/surv-manual>
- Information about nationally notifiable events (NNDSS) is available at <http://www.cdc.gov/ncphi/diss/nndss/phs/infdis.htm>
- Information about the event condition/code list with MMWR print criteria is available at http://www.cdc.gov/ncphi/diss/nndss/phs/files/NNDSS_event_code_list_January_2010.pdf
- Information about the National Electronic Disease Surveillance System is available at <http://www.cdc.gov/nedss>
- Healthy People 2010 National Objectives, (DHHS) <http://www.healthypeople.gov/Document/HTML/Volume1/14Immunization.htm>

- Information about the Vaccine Adverse Events Reporting System (VAERS) is available at <http://www.vaers.hhs.gov>, telephone 800-822-7967; fax 877-721-0366, info@VAERS.org.
- Information about the National Childhood Vaccine Injury Act is available at http://www.cdc.gov/od/science/iso/about_iso.htm
Information about the Council of State and Territorial Epidemiologists is available at <http://www.cste.org>
- CDC. Morbidity and Mortality Weekly Report website: <http://www.cdc.gov/mmwr>

Program Requirements

9.1 Case Investigation

Implement and maintain surveillance systems to investigate and document cases and outbreaks of vaccine-preventable diseases designated as nationally notifiable by the Council of State and Territorial Epidemiologists (CSTE, <http://www.cste.org/dnn/LinkClick.aspx?fileticket=7CCxM20JUGg%3d&tabid=36&mid=1496>), including cases as described in the case status print criteria approved by CSTE (<http://www.cdc.gov/nepi/diss/nndss/phs/infdis.htm>), applying guidance as provided in the “Manual for Surveillance of Vaccine-Preventable Diseases” (<http://www.cdc.gov/vaccines/pubs/surv-manual>).

Required objectives

VPD surveillance

- 9.1a. Investigate cases, implement appropriate public health activities, and ensure that appropriate clinical specimens are tested and relevant epidemiologic information is collected for Congenital Rubella Syndrome (CRS), diphtheria, *Haemophilus influenzae*, measles, meningococcal disease, mumps, pertussis, polio, invasive pneumococcal disease, rubella, tetanus, pediatric (< 18 years of age) influenza deaths, and varicella.

Performance measure: Percent of case reports with complete information submitted to CDC within one month of diagnosis for the following:

Congenital Rubella Syndrome (CRS)

Diphtheria

Haemophilus influenzae

Measles

Meningococcal disease

Mumps

Pertussis

Polio

Invasive pneumococcal disease

Rubella

Tetanus

Pediatric (< 18 years of age) influenza deaths

Varicella

Recommended objectives

- 9.1b. Develop administrative policies and procedures to assure the systematic, institutionalized reporting of cases and suspected cases of VPDs by providers, healthcare institutions, schools, child care centers, universities, and laboratories.
- 9.1c. Obtain the authority for health department staff to review medical records of persons who are cases or suspected cases of all VPDs.
- 9.1d. Ensure availability of written up-to-date guidelines for case investigation, outbreak investigation, and outbreak control of all VPDs. In program areas where an immunization information system (IIS) is operational, incorporate the use of IIS into case investigation guidelines when documenting the vaccination status of cases and controls.
- 9.1e. Ensure that health department staff responsible for VPD surveillance and response is trained to perform VPD case and suspect case investigations, outbreak investigations, and outbreak control.
- 9.1f. Initiate VPD case investigations and outbreak investigations promptly and implement outbreak control measures and other necessary public health interventions in a timely manner.
- 9.1g. Develop and distribute written up-to-date laboratory guidelines for each VPD detailing the appropriate clinical specimens for testing, the recommended laboratory tests and laboratories, appropriate specimen handling, and expected timelines for laboratory results. Ensure that laboratory capacity is available for testing clinical specimens for VPDs.
- 9.1h. Ensure that clinics, schools, child care facilities, hospitals and other VPD reporting sites routinely submit surveillance reports to health departments.
- 9.1i. Conduct enhanced, active surveillance in communities where a VPD is prevalent, or where there is increased incidence.
- 9.1j. Pursue unreported cases of VPDs by searching laboratory, hospital and/or death certificate data, especially for VPDs which are rare or uncommon.
- 9.1k. Investigate outbreaks occurring in schools, child care and institutional facilities, and offer control efforts either through provision of vaccine in public clinics or by referrals to primary healthcare providers. In outbreak settings, obtain clinical specimens from at least one case for laboratory confirmation.

9.2 Electronic Data Submission to CDC

For routine surveillance, collaborate with appropriate staff to submit timely and complete electronic case and/or death notifications to CDC for cases of VPDs designated as nationally notifiable by the Council of State and Territorial Epidemiologists (CSTE, <http://www.cste.org/dnn/LinkClick.aspx?fileticket=7CCxM20JUGg%3d&tabid=36&mid=1496>), including cases as described in the case status print criteria approved by CSTE (<http://www.cdc.gov/ncphi/diss/nndss/phs/infdis.htm>), applying guidance as provided in the “Manual for Surveillance of Vaccine-Preventable Diseases” (<http://www.cdc.gov/vaccines/pubs/surv-manual>).

Note: Outbreaks may require additional notification elements as agreed upon by CSTE and CDC.

Required objectives

Case reports to NNDSS

- 9.2a. Notify CDC about cases immediately by phone, and electronically transmit complete case reports and supplemental surveillance information to CDC via the National Notifiable Diseases Surveillance System (NNDSS) within one month of diagnosis for Congenital Rubella Syndrome (CRS), diphtheria, measles, polio, rubella, and pediatric (<18 years of age) influenza deaths. Collect and transmit complete case reports and supplemental surveillance information to CDC via the National Notifiable Diseases Surveillance System (NNDSS) within one month of diagnosis for *Haemophilus influenzae*, meningococcal disease, mumps, pertussis, invasive pneumococcal disease, tetanus, and varicella.

Performance measure: Percent of case reports with complete information submitted electronically to CDC within one month of diagnosis for the following:

Congenital Rubella Syndrome (CRS)

Diphtheria

Haemophilus influenzae

Measles

Meningococcal disease

Mumps

Pertussis

Polio

Invasive pneumococcal disease

Rubella

Tetanus

Pediatric (< 18 years of age) influenza deaths

Varicella

- 9.2b. Comply with the Nationwide Health Information Network (NHIN) standards and specifications for surveillance systems funded through CDC grants, contract and cooperative agreements. The NHIN is a set of standards, services and policies that enable secure health information exchange over the Internet. The NHIN will provide a foundation for the exchange of health IT across diverse entities, within communities

across the country, helping to achieve the goals of the Health Information Technology for Economic and Clinical Health Act.

Performance measure: Grantee is in compliance with NHIN standards.

Recommended objectives

- 9.2c. Assure that laboratories report all results which indicate need for public health action, as described in CDC's "Manual for Surveillance of Vaccine-Preventable Diseases."
- 9.2d. Ensure that appropriate procedures exist and are followed for entering, analyzing, and reporting surveillance, investigation and outbreak data in a timely fashion.
- 9.2e. Analyze, review, and interpret surveillance data regularly and outbreak data as needed.
- 9.2f. Disseminate surveillance morbidity and mortality data regularly to surveillance partners, network participants, providers, policy makers, and the public.

9.3 Evaluate timeliness and completeness of case/death investigation and reporting for cases of VPDs designated as nationally notifiable by the Council of State and Territorial Epidemiologists (CSTE, <http://www.cste.org/dnn/LinkClick.aspx?fileticket=7CCxM20JUGg%3d&tabid=36&mid=1496>), including cases as described in the case confirmation status print criteria approved by CSTE (<http://www.cdc.gov/ncphi/diss/nndss/phs/infdis.htm>), applying guidance as provided in the "Manual for Surveillance of Vaccine-Preventable Diseases" (<http://www.cdc.gov/vaccines/pubs/surv-manual>).

Required objectives

Quality of VPD surveillance

- 9.3a. *Haemophilus influenzae*: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of *Haemophilus influenzae* invasive disease cases among children <5 years of age with complete vaccination history

- 9.3b. *Haemophilus influenzae*: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of *Haemophilus influenzae* isolates from cases <5 years of age that were serotyped

- 9.3c. Measles: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of measles cases with complete vaccination history

- 9.3d. Measles: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of measles cases or chains of transmission that have an imported source

- 9.3e. Meningococcal disease: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of cases with complete vaccination history

- 9.3f. Meningococcal disease: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of meningococcal cases with known serogroup

- 9.3g. Mumps: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of mumps cases for which appropriate clinical specimens were obtained and submitted to the laboratory

- 9.3h. Mumps: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of cases with complete vaccination history

- 9.3i. Pertussis: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of cases from which clinical specimens are obtained

- 9.3j. Pertussis: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of probable and confirmed pertussis cases meeting the clinical case definition that is laboratory confirmed

- 9.3k. Pertussis: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of cases confirmed by isolation of *B. pertussis* by culture

- 9.3l. Pertussis: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of probable and confirmed pertussis cases with a complete vaccination history

- 9.3m. Pneumococcal invasive disease: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of pneumococcal invasive disease cases among children <5 years of age with complete vaccination history

- 9.3n. Pneumococcal invasive disease: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of pneumococcal isolates from cases of invasive disease <5 years of age that are serotyped and tested for antibiotic resistance

- 9.3o. Rubella: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of confirmed rubella cases among women of child-bearing age with known pregnancy status

- 9.3p. Rubella: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: The proportion of confirmed rubella cases that are laboratory confirmed

- 9.3q. Varicella: Monitor the quality of VPD surveillance by reviewing surveillance data and surveillance indicators to identify problems and strategies to resolve the problems.

Performance measure: Percentage of cases with complete information for age, vaccination history, and severity of disease

Recommended objectives

- 9.3r. Monitor the quality of surveillance by applying surveillance indicators to additional VPDs.
- 9.3s. Monitor the quality of additional aspects of VPD surveillance by applying other surveillance indicators, as described in CDC's "Manual for Surveillance of Vaccine-Preventable Diseases."

9.4 Coordinate reporting and monitor the Vaccine Adverse Event Reporting System (VAERS) mandated by the National Childhood Vaccine Injury Act of 1986. The VAERS website now accepts adverse event reports in an encrypted and secure electronic transmission format and can be found at <http://www.vaers.hhs.gov>.

Required objectives

VAERS reporting

- 9.4a. Ensure at least one employee is designated with overall responsibility for vaccine safety and VAERS reporting. Duties should include completing VAERS reports electronically and/or in hard copy form, promptly reviewing all VAERS reports received, submitting reports to VAERS contractor within 7 days of receipt, requesting, collecting and forwarding supplemental medical information, answering provider and parent inquiries regarding VAERS and vaccine safety, and coordinating communication with and from media. Use state and local policies and procedures for VAERS reporting.

Performance measure: Name of person with overall responsibility for vaccine safety and VAERS reporting

Local VAERS

- 9.4b. Ensure all local health departments and public health clinics know how to report and do report adverse events to the grantee using the VAERS form and/or secure web-based reporting.

Performance measure: Date by which communication will occur

Recommended objectives

- 9.4c. Establish/maintain protocols and systems to accept reports of adverse events following immunization; VAERS reports may be submitted by public and private healthcare providers, parents, vaccinees, and other concerned individuals.

Performance measure: Increase the number of adverse events reported to the immunization program office (by vaccine type and reporting source) and increase the timeliness of reporting (measured by date of report minus date of symptom onset)

- 9.4d. Provide all immunization providers (public and private) with a copy of state policies on VAERS reporting, copies of the VAERS reporting form, instructions on which adverse events must be reported and which can be reported, instructions on completing and submitting the form, and updates on VAERS reporting as they arise.

Performance measure: Number of immunization service providers (e.g., pediatricians, family practitioners, general practitioners, clinics) receiving initial VAERS and other safety information and training

- 9.4e. Encourage providers to voluntarily submit VAERS reports on adverse events not listed in the National Vaccine Injury Table.

- 9.4f. Communicate information on vaccine safety in a timely way to all healthcare providers, public health officials, state professional associations, and the public, using tools including media interviews, press releases, information kits, etc.

9.5 Follow up on all reports of serious adverse events received by the state agency (e.g., death, life-threatening illness, hospitalization and permanent disability) following immunization.

Required objectives

Supplemental information

- 9.5a. Submit supplemental medical information requested by the national VAERS program within 10 working days of receipt of request.

Performance measure: Percentage of requested supplemental reports submitted within 10 working days of receipt of request

Recommended objectives

- 9.5b. Review all VAERS reports that are sent to the state agency upon receipt; verify accuracy of key information designated with “boxes” on form, attempt to complete critical fields, and assign an immunization project number. If all critical information

cannot be obtained by the grantee, the report should be forwarded to VAERS if it contains at least the following: a patient identifier (nominal or non-nominal); a vaccine; an adverse event description; and an identifiable reporter (of the adverse event).

Performance measure: Percentage of VAERS reports submitted to the contractor within 5 working days of receipt

9.6 Additional Objectives

Recommended objectives

9.6a. Collaborate with local/state influenza surveillance coordinators to ensure adequate local and state influenza surveillance, including virologic surveillance and outpatient surveillance for influenza-like illness. Develop plans for timely and coordinated dissemination of influenza vaccination promotions. Ensure that state and local influenza virus surveillance data are disseminated to providers and the public during each influenza season.

9.6b. Assure prenatal screening of all pregnant women for rubella antibody and documentation of results in provider and birthing hospital chart.

Performance measure: Number and percent of pregnant women with documentation of rubella status in pre-delivery hospital record

9.6c. Assure rubella antibody-negative mothers are made aware of benefits and risks of rubella vaccine, offered rubella vaccine following delivery, and acceptors receive the vaccine before hospital discharge.

Performance measure: Number and percent of rubella antibody-negative pregnant women receiving rubella vaccine following delivery and prior to discharge

9.6d. Maintain a registry of persons with HBsAg-positive results.

This document can be found on the cdc website at:
<http://www.cdc.gov/vaccines/vac-gen/policies/ipom/downloads/chp-09-epi-surv.pdf>