9 Epidemiology and Surveillance

Overview

Effective vaccine-preventable disease (VPD) surveillance at national, state and local levels serves to document the impact of vaccination programs, to evaluate the effectiveness of current vaccines and vaccination policies, and to 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 evaluate 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, especially 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 what 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 (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 (www.vaers.hhs.gov), or by calling 1-800-822-7967, or by 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/nip/publications/surv-manual/default.htm
- Healthy People 2010 National Objectives, (DHHS) http://www.healthypeople.gov/Document/HTML/Volume1/14Immunization.htm
- CDC. Managing a Hepatitis B Prevention Program: A Guide to Life as a Program Coordinator http://www.cdc.gov/ncidod/diseases/hepatitis/resource/perinatalhepB.htm
- Hepatitis Surveillance Report No. 51, Sept. 2006 http://www.cdc.gov/ncidod/diseases/hepatitis/resource/PDFs/hep_surveillance_61.pdf
- Information about the Vaccine Adverse Events Reporting System (VAERS) is available at 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/nip/vacsafe/#NCVIA
- Information about the Council of State and Territorial Epidemiologists is available at http://www.cste.org
- Information about the National Electronic Disease Surveillance System is available at http://www.cdc.gov/nedss
- CDC. Morbidity and Mortality Weekly Report website: http://www.cdc.gov/mmwr
- CDC. Revised Standards for Child and Adolescent Immunization Practices. Available at http://www.cdc.gov/nip/recs/rev-immz-stds.htm
- CDC. Revised Standards for Adult Immunization Practices. Available at http://www.cdc.gov/nip/recs/rev-immz-stds.htm
- 2008-2012 Immunization Program Operations Manual (IPOM) Chapters 1, 5, 6, 7 and 8

Program Requirements

9.1 Implement and maintain surveillance systems to investigate and document cases and outbreaks of vaccine-preventable diseases, in accordance with CDC's "Manual for Surveillance of Vaccine-Preventable Diseases."

Required activities

9.1a. For Congenital Rubella Syndrome (CRS), diphtheria, *Haemophilus influenzae*, hepatitis A, hepatitis B, measles, meningococcal disease, mumps, pertussis, polio, invasive pneumococcal disease, rubella, tetanus, pediatric (<18 years of age) influenza deaths, and varicella:

- Investigate each suspected case and implement public health activities, as appropriate.
- In accordance with guidance in CDC's "Manual for Surveillance of Vaccine-Preventable Diseases," ensure that appropriate clinical specimens are tested and relevant epidemiologic information is collected.

Recommended activities

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, day 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 complete 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, day 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 For routine reporting, collaborate with appropriate staff to submit timely and complete electronic case/death reports to CDC for cases of VPDs designated as reportable by the Council of State and Territorial Epidemiologists (CSTE) http://www.cdc.gov/epo/dphsi/nndsshis.htm, including cases as described in the case confirmation status print criteria approved by CSTE http://www.cdc.gov/epo/dphsi/phs/infdis.htm, applying guidance as provided in the "Manual for Surveillance of Vaccine-Preventable Diseases." http://www.cdc.gov/nip/publications/surv-manual/default.htm Outbreaks may require additional reporting elements as deemed necessary by CDC.

Required activities

9.2a. Collect and transmit both case reports and supplemental surveillance information to CDC via the National Notifiable Diseases Surveillance System (NNDSS). Complete case reports and supplemental surveillance information should be submitted for all reported cases within one month of diagnosis. Cases of CRS, diphtheria, polio, rubella, measles, and pediatric (<18 years of age) influenza deaths should be reported to CDC immediately by phone, with complete information submitted within one month. The total number of varicella outbreaks, defined as ≥5 cases related in place

within at least one incubation period (i.e., 21 days), should be reported to CDC on a quarterly basis. For each varicella outbreak, the information to report should include: size of outbreak, age distribution, length of outbreak, vaccination coverage, and laboratory confirmation of cases, if obtained.
Performance Measure: Percent of case reports submitted to CDC within one month of diagnosis
Target: Set by individual program; progress toward 100%
Performance Measure: Proportion of confirmed cases (measles, rubella, tetanus) or confirmed and probable cases (pertussis, mumps, diphtheria, varicella, varicella deaths, polio, Haemophilus influenzae <5 years old, invasive Streptococcus pneumoniae <5 years old, meningococcal disease, congenital rubella syndrome) that are reported through NNDSS with complete information, as indicated in CDC's "Manual for Surveillance of Vaccine-Preventable Diseases."
Target: 90%

Recommended activities

9.2b. Assure that laboratories report all results that indicate need for public health action, as described in CDC's "Manual for Surveillance of Vaccine-Preventable Diseases."

9.2c. Ensure that appropriate procedures exist and are followed for entering, analyzing, and reporting surveillance, investigation and outbreak data in a timely fashion.

9.2d. Analyze, review, and interpret surveillance data regularly and outbreak data as needed.

9.2e. 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, in accordance with CDC's "Manual for Surveillance of Vaccine-Preventable Diseases."
http://www.cdc.gov/nip/publications/surv-manual/default.htm

Required activities

9.3a. Monitor the quality of VPD surveillance by reviewing surveillance indicators, problems identified, and strategies developed and implemented to address them.

- For Haemophilus influenzae
  Performance Measure: The proportion of Haemophilus influenzae invasive disease cases among children <5 years of age with complete vaccination history
  Target: 95%
  Performance Measure: The proportion of Haemophilus influenzae isolates from cases <5 years of age that were serotyped
  Target: 95%

- For measles
  Performance Measure: The proportion of measles cases with complete vaccination history

Target: 100%
Performance Measure: The proportion of measles cases or chains of transmission that have an imported source
Target: 100%

- For meningococcal disease
  Performance Measure: The proportion of cases with complete vaccination history
  Target: 95%
  Performance Measure: The proportion of meningococcal cases with known serogroup
  Target: 95%

- For mumps
  Performance Measure: The proportion of mumps cases for which appropriate clinical specimens were obtained and submitted to the laboratory
  Target: 90%
  Performance Measure: The proportion of cases with complete vaccination history
  Target: 90%

- For pertussis
  Performance Measure: The proportion of cases from which clinical specimens are obtained
  Target: 90%
  Performance Measure: The proportion of probable and confirmed pertussis cases meeting the clinical case definition that is laboratory confirmed
  Target: 90%
  Performance Measure: The proportion of cases confirmed by isolation of B pertussis by culture
  Target: At least 10%
  Performance Measure: The proportion of probable and confirmed pertussis cases with a complete vaccination history
  Target: 90%

- For pneumococcal invasive disease
  Performance Measure: The proportion of pneumococcal invasive disease cases among children <5 years of age with complete vaccination history
  Target: 95%
  Performance Measure: The proportion of pneumococcal isolates from cases of invasive disease <5 years of age that are serotyped and tested for antibiotic resistance
  Target: 90%

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

Target: 100%
Performance Measure: The proportion of confirmed rubella cases that are laboratory confirmed
Target: 95%

- For varicella
  Performance Measure: Percentage of cases with complete information for age, vaccination history, and severity of disease
  Target: 90% (contingent on availability of mechanism for reporting these data electronically through NNDSS)

Recommended activities

9.3b. Monitor the quality of surveillance by applying surveillance indicators to additional VPDs.

9.3c. Monitor the quality of additional aspects of VPD surveillance by applying surveillance other indicators, as included 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 www.vaers.hhs.gov.

Required activities

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.

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

Recommended activities

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 in the number of adverse events reported to the immunization program office, by vaccine type and reporting source
Target: Set by individual program

Performance measure: Increase in the timeliness of reporting, measured by date of report minus date of symptom onset
Target: Set by individual program

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 newly licensed providers (e.g., pediatricians, family practitioners, general practitioners, clinics) and percentage of those provided VAERS and other safety information and training
Target: >90%; set by individual program

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 activities

9.5a. Routinely obtain supplemental medical information (e.g., autopsy reports, death certificates, hospital discharge summaries) related to every serious adverse event reported (e.g., reports involving death, life-threatening illness, hospitalization, permanent disability).
Performance measure: Number and percentage of serious adverse event reports for which supplemental medical information was collected
Target: >90%; set by individual program

9.5b. Submit supplemental medical information requested by the national VAERS program within 10 working days of receipt of request.
Performance measure: Number and percentage of requested supplemental reports submitted within 10 working days of receipt of request
Target: >90%; set by individual program

Recommended activities

9.5c. 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: Number and percentage of VAERS reports submitted to the contractor within 5 working days of receipt
Target: >90%; set by individual program

9.6 Additional Activities

Recommended activities

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. Surveillance Information Systems funded through the Immunization Services Division (ISD), like all systems funded through CDC grants, contracts, and cooperative agreements, must comply with the Public Health Information Network (PHIN) standards and specifications. http://www.cdc.gov/phin/overview.html

9.6c. 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
Target: Set by individual program; progress toward 100%

9.6d. 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
Target: Set by individual program; progress toward 100%

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