

Smallpox Vaccination Adverse Events Reporting, Monitoring and Management System

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State Health Department Training

Smallpox Vaccine Adverse Event Workshop

January 22-23, 2002

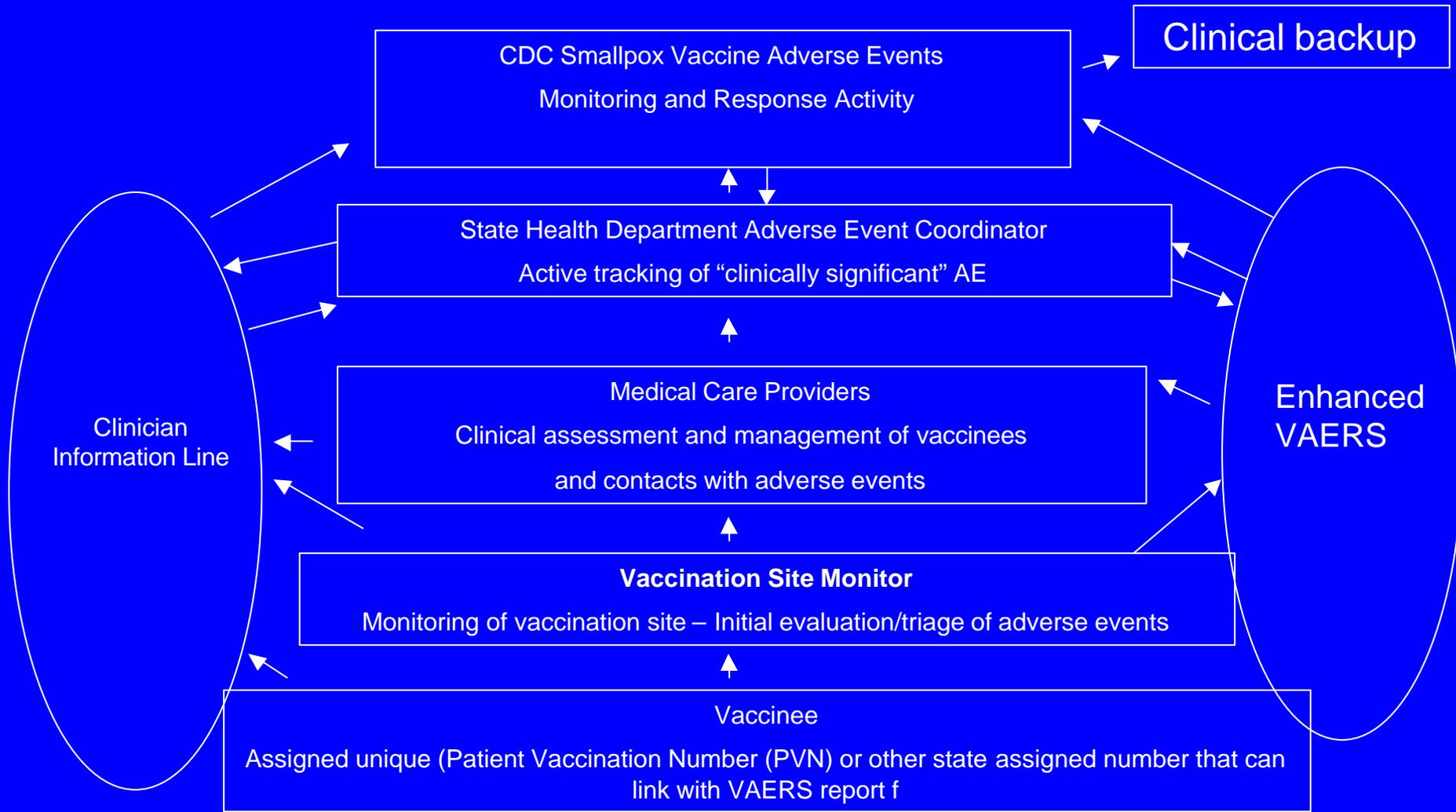
Program Oversight

- Institute of Medicine
 - Every few weeks
- Data Safety Monitoring Board
 - 1st meeting January 24; Weekly
- ASTHO, NACCHO, AE Coordinators
 - Weekly
- Internal CDC review
 - Daily

System Objectives

- Monitor the occurrence of clinically significant adverse events
- Identify unexpected adverse events
- Facilitate timely and appropriate distribution of VIG/cidofovir
- Monitor application of contraindication screening and identify need for new contraindications
- Build state capacity for assessment of AEs

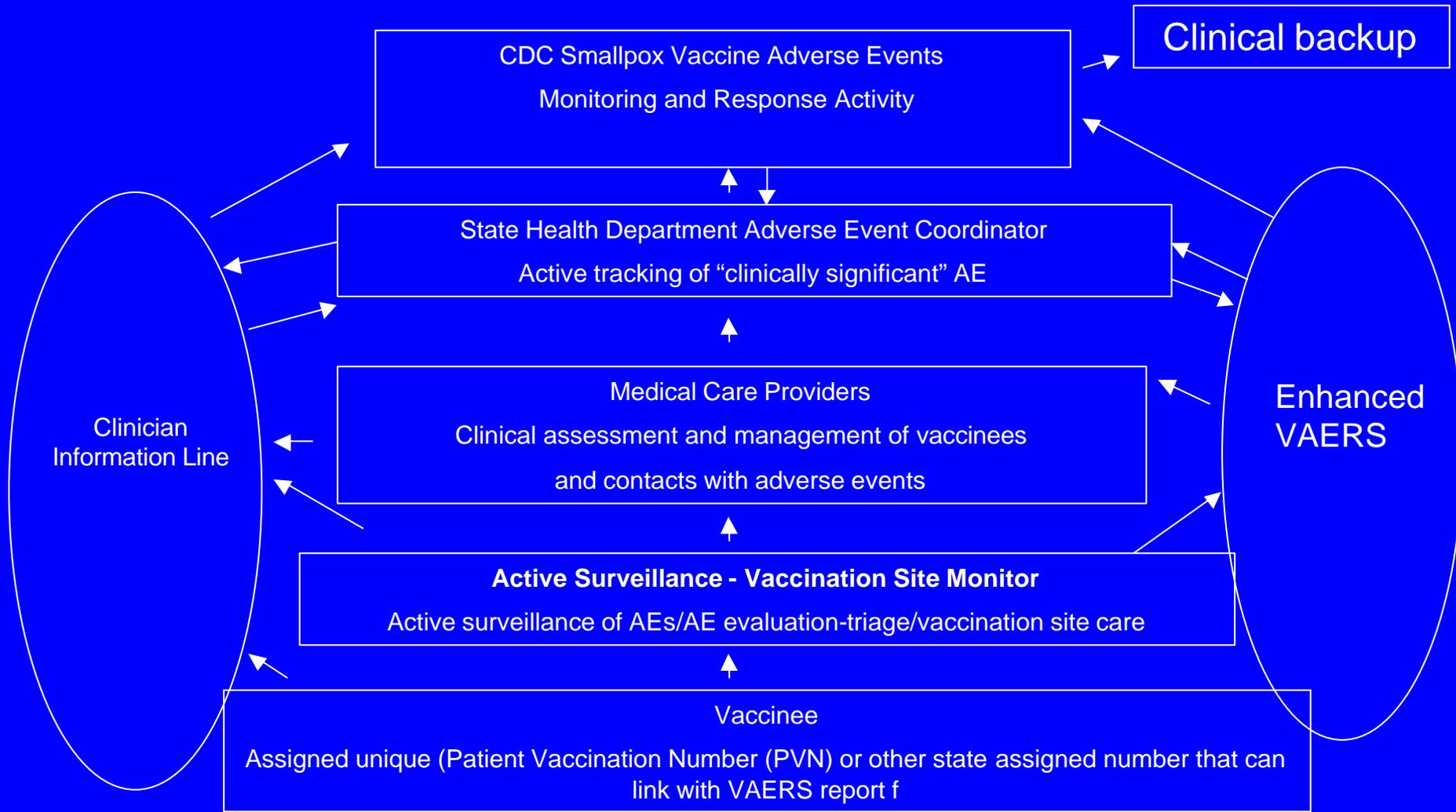
Smallpox Vaccination Adverse Events Reporting, Monitoring and Management System – 01/17/03



Institute of Medicine Committee on Smallpox Vaccination Program Implementation

- 1st report to CDC - January 22, 2003
- The committee strongly recommends that active surveillance for adverse reactions be employed, rather than relying exclusively on the passive surveillance systems that already exist.

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Telephone Lines

- Public Response Service
 - 888-246-2675
- Clinician Information Line
 - 877-554-4625
 - Not operational yet!!
- State HD Line
 - Phone # 404-639-8215

Vaccine Clinic

Roles and Responsibilities

- Conduct screening to identify persons with contraindications
- Treat immediate AEs (i.e., anaphylaxis, syncope)
- Educate vaccinees on vaccination site care
- Assure vaccinees have follow up instructions and contact information
- Know reporting process for AEs

Vaccine Clinic Roles and Responsibilities

- Document demographic and vaccination information
- Conduct take response checks
 - Enter take response into PVS

Hospital Roles and Responsibilities

- Provide 24/7 coverage for follow-up of vaccinees
- Perform vaccination site care
- Monitor vaccination response
- Conduct take response checks
 - Forward take response data to clinics for data entry into PVS

Hospital Roles and Responsibilities

- Identify and assess suspected adverse events
- Promptly report clinically significant or unexpected AEs to state health departments
- Conduct active surveillance for AEs

Individual Provider Roles and Responsibilities

- Become educated about the smallpox vaccination program and smallpox vaccine AEs
- Recognize, refer and manage AEs
- Report AEs as directed by SHD
- Comply with VIG and Cidofovir IND protocol requirements

Smallpox Vaccine AE Coordinator Roles and Responsibilities

- Establish and coordinate state smallpox adverse events reporting, monitoring and tracking system
- Facilitate training and communication with persons and organizations responsible for AE reporting and management
- Identify and track clinically significant AEs in collaboration with CDC
- Facilitate VIG/cidofovir release as appropriate
- Assist with submission of VAERS reports

State Health Department Roles and Responsibilities

- Communicate with medical organizations
- Communicate with the media
- Inform medical providers about smallpox vaccination program
 - Where to obtain information
 - What and where to report

CDC Roles and Responsibilities

Smallpox Vaccine Adverse Events Monitoring and Response Activity

Clinical Consultation

Technical Assistance

AE Surveillance

CDC Clinical Consultation

- Provide clinical consultation to healthcare providers in diagnosis and management of smallpox vaccine adverse events
 - 24/7 clinical consultation for AE calls
 - Expert clinical backup to the clinical team
 - Active tracking of clinically significant AEs in collaboration with SHDs
 - VIG and Cidofovir release
 - Clinical Evaluation Tools for dx and mgt

State Technical Assistance

- Provide technical assistance to state health departments through adverse event coordinators
- Designated telephone for SHDs for non-clinical questions
- Clinician Information Line for clinical questions
- Regular conference calls with the AE coordinators

CDC Adverse Event Surveillance

- Enhanced surveillance for AEs
 - Notification by states and providers
 - VIG/Cidofovir requests
 - Active surveillance at vaccination care sites
 - “Enhanced” VAERS

Proposed Active Surveillance for Clinically Significant AEs

- Goal – To detect and document the occurrence of clinically significant AEs by conducting active surveillance on all vaccinees by the vaccination site monitors
- Surveillance Questions
 - Time lost from work because of vaccination
 - If yes, number of days
 - Health care visit
 - If yes, determine if hospitalization or outpatient visit
 - Did patient have a clinically significant AE?
 - If yes, was a VAERS report filed
- Track negative and positive responses

Proposed Active Surveillance Process for Common AEs

- Post vaccination survey
 - Objectives
 - Determine rates of common AEs
 - Evaluate vaccinee satisfaction with immunization program
 - Assess AEs in household contacts
 - Time lost from work
 - Methods
 - Telephone survey at days 10 and 21
 - Stratified sample of <10,000
 - Selected states

CDC Adverse Event (passive) Surveillance

- Enhanced VAERS
 - Accelerated processing of VAERS reports
 - Rapid review and tracking of reports
 - Electronic submission of reports
 - Daily summary reports of state and national data

Reporting Adverse Events Following Smallpox Vaccine

- Report – clinically significant or unexpected AEs
- When – clinically significant/unexpected AEs within 48 hours and other AEs within 7 days
- Who can report – SHDs, providers, vaccinees, manufacturers
- How to report
 - <http://secure.vaers.org/VaersDataEntry.cfm>
 - Fax: 877-721-0366
 - Telephone: 800-822-7967 for form

CDC Adverse Event Surveillance

- Data analysis
 - Calculate rates of AEs
 - Clinically significant; comparison with historical rates
 - Common AEs
 - Monitor for unexpected adverse events
 - Monitor for AE clusters or trends
 - Monitor for serious AEs in persons with contraindications
 - Inadvertent exposure registry
- Conduct special studies of AEs

Summary

- CDC, SHDs, healthcare providers, and medical facilities all have important roles in smallpox vaccine adverse event monitoring, reporting and management.
- Much more detail to follow...