Smallpox Vaccine Safety and Reporting Adverse Events

Department of Health and Human Services
Centers for Disease Control and Prevention
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Smallpox Vaccine Safety and Reporting Adverse Events

- Learning Objectives:
  - Describe the overall process for reporting clinically significant or unexpected adverse events (AEs)
  - Describe the process for obtaining clinical information on adverse events (AEs)

Hello. I appreciate the opportunity to speak to you today. To complete the vaccine safety discussions today, I intend to give you an overview of smallpox vaccine safety monitoring and reporting.

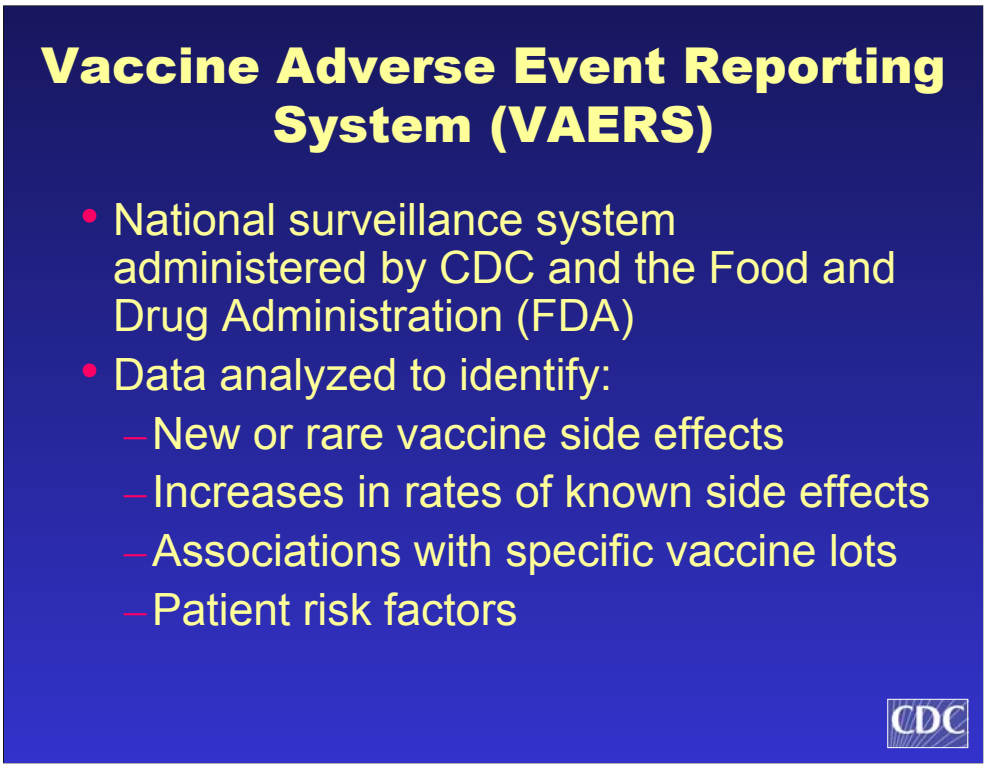
In this segment I'll describe the overall process for reporting clinically significant or unexpected adverse events.

I will also describe the process for obtaining clinical information on adverse events.

Smallpox Vaccine Safety and Reporting Adverse Events

- Learning Objectives:
  - List the steps for obtaining Vaccinia Immune Globulin (VIG) or cidofovir for treatment of AEs

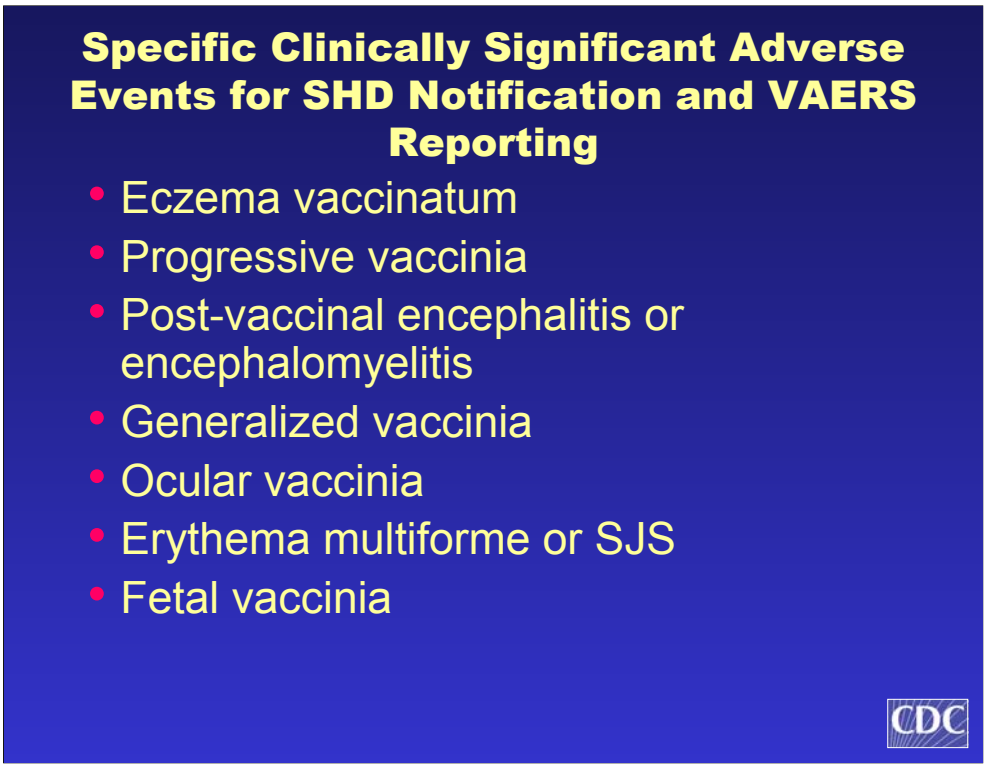
Finally we will list the steps for obtaining VIG or cidofovir for treatment of adverse events.



Some of you might be unfamiliar with the usual reporting of vaccine adverse events through a system called VAERS, so let me take a moment to explain

VAERS is the national surveillance system for adverse events following immunization. VAERS data are routinely analyzed by CDC and the FDA to identify: new or rare vaccine side effects; increases in rates of known side effects; associations with specific vaccine lots; and patient risk factors.

Although any adverse event can be reported to VAERS, for smallpox vaccine it is most important to report the *clinically significant or unexpected* adverse events, ideally within 48 hours. Healthcare providers should remember to first notify their state health department and then file a VAERS report.



What is meant by clinically significant? Of course, serious adverse events, events that are life-threatening or result in death, hospitalization, or permanent disability are considered clinically significant. Adverse events that prompt a visit to a health care provider may also be considered clinically significant; however, that is left up to the judgment of the healthcare provider.

The known clinically significant adverse Events for State Health Department Notification and VAERS Reporting are:

Eczema vaccinatum

Progressive vaccinia

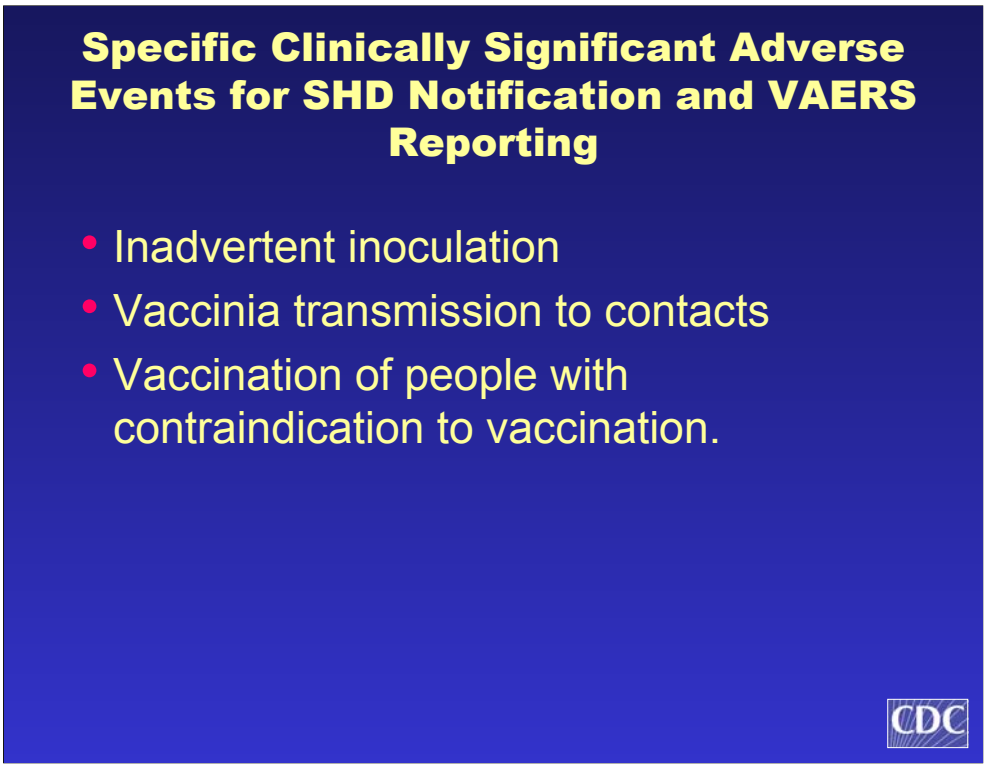
Post-vaccinal encephalitis or encephalomyelitis

Generalized vaccinia

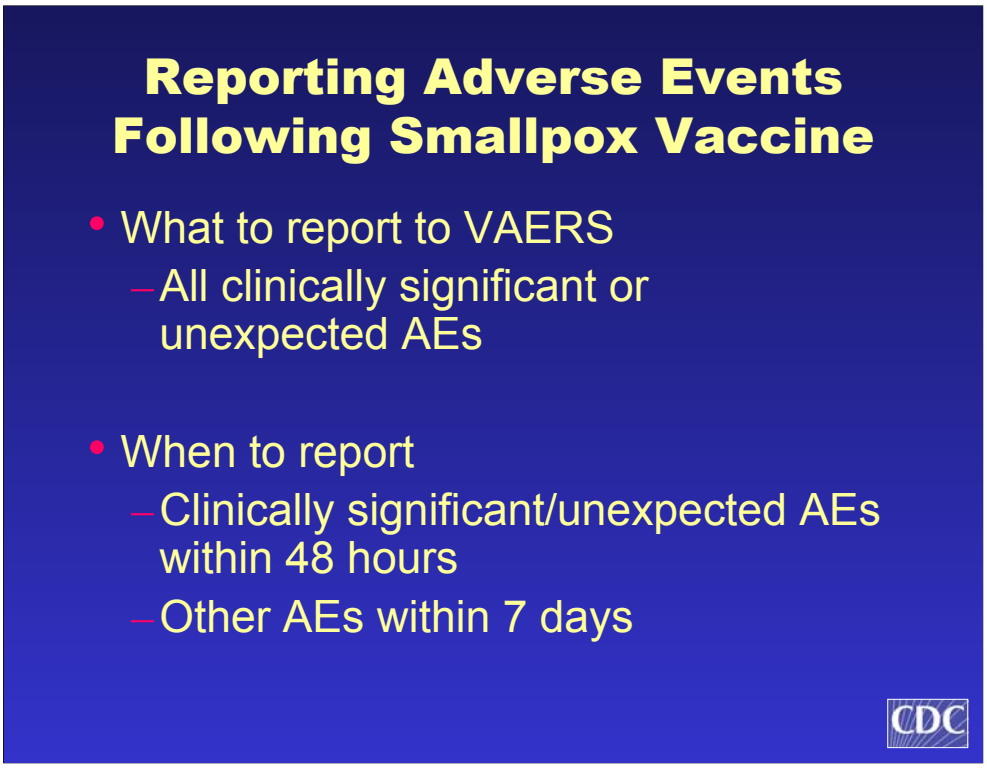
Ocular vaccinia

Erythema multiforme major or SJS and

Fetal vaccinia



Inadvertent inoculation
Vaccinia transmission to contacts
Vaccination of persons with a contraindication to vaccination

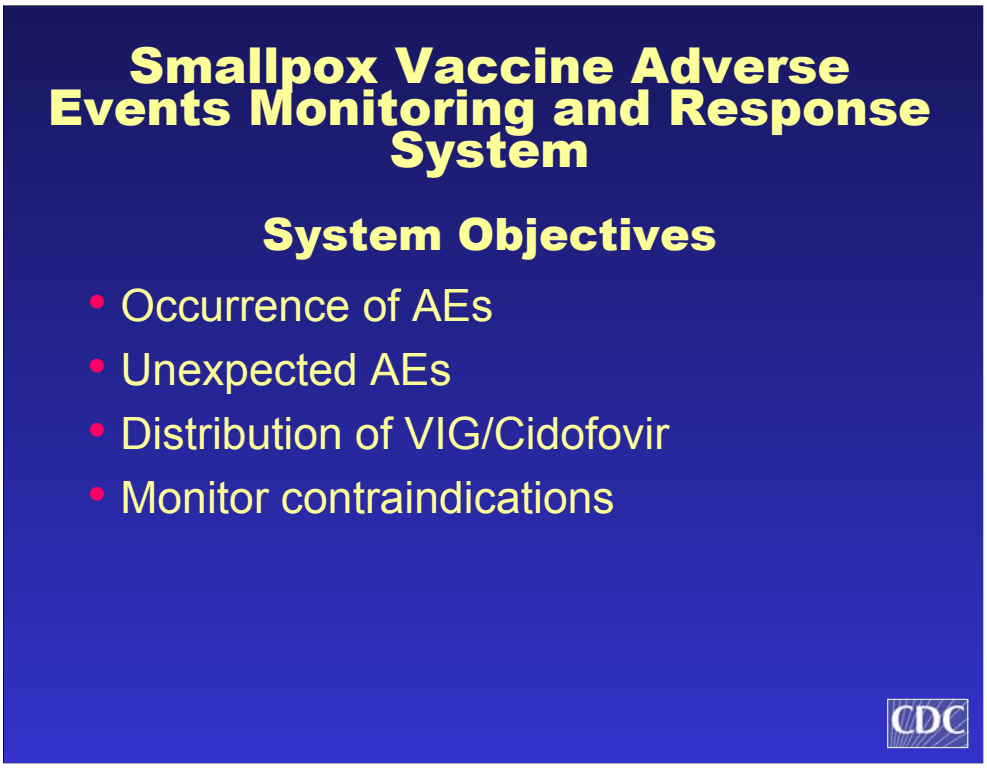


Anyone can report to VAERS: healthcare providers, health departments, vaccinees, and vaccine manufacturers. Reports can be sent to VAERS via the web, FAX, or mail.

The VAERS contact information is listed on the screen.

Although VAERS is an essential tool for detecting smallpox vaccine adverse events, it is just one component of a system – the Smallpox Vaccine Adverse Events Monitoring and Response System.

The State Health Departments, in collaboration with CDC and largely hospital-based vaccination site monitors, will track the number of vaccinations given, the vaccination take response, and the occurrence of adverse events – through both active and passive surveillance.



This system is intended to monitor the occurrence of clinically significant adverse events, identify unexpected adverse events, facilitate the timely and appropriate distribution of VIG or Cidofovir, and monitor the application of contraindication screening and identify the need for new contraindications. Through this system we will provide assistance to the states as they implement the smallpox vaccination program.

Although VAERS is an essential tool for detecting smallpox vaccine adverse events, it is just one component of a system – the Smallpox Vaccine Adverse Events Monitoring and Response System - intended to monitor the occurrence of clinically significant adverse events, identify unexpected adverse events, facilitate the timely and appropriate distribution of VIG or Cidofovir, as well as to monitor the application of contraindication screening and identify the need for new contraindications.

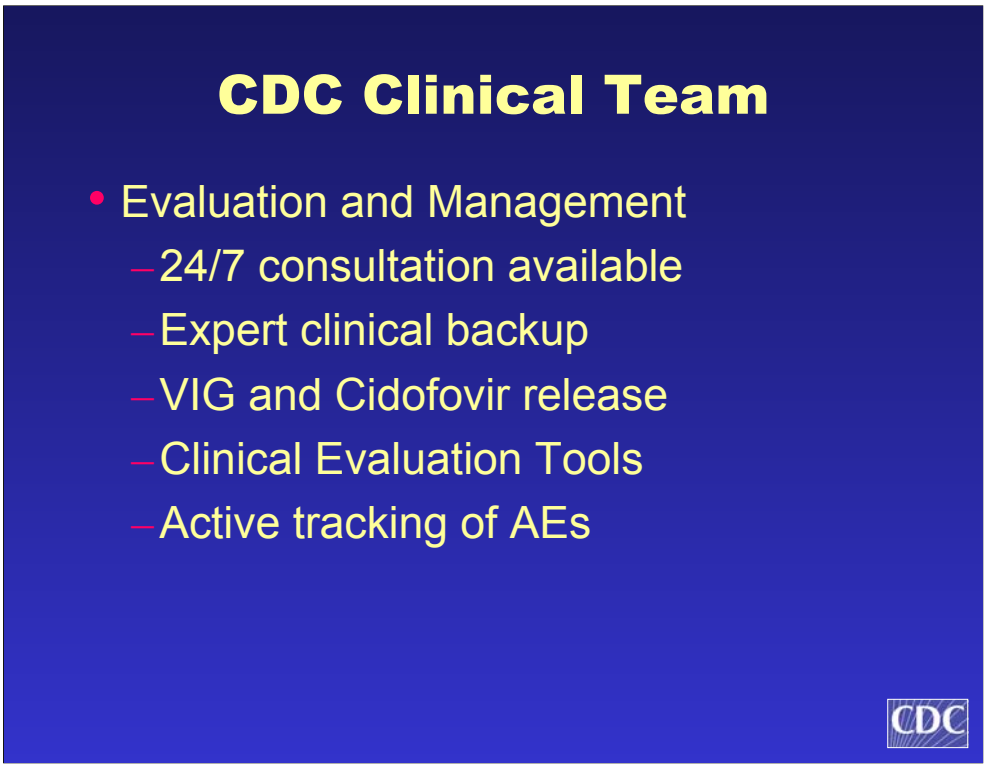
Telephone Lines

- Clinician Information Line
  - 877-554-4625
- Public Response Service
  - 888-246-2675

Several resources are available to you as we begin this vaccination program.

A Clinician Information Line, at 877-554-4625, is staffed with medical personnel who can assist clinicians in evaluating adverse events. This resource line is available 24 hours a day, 7 days a week.

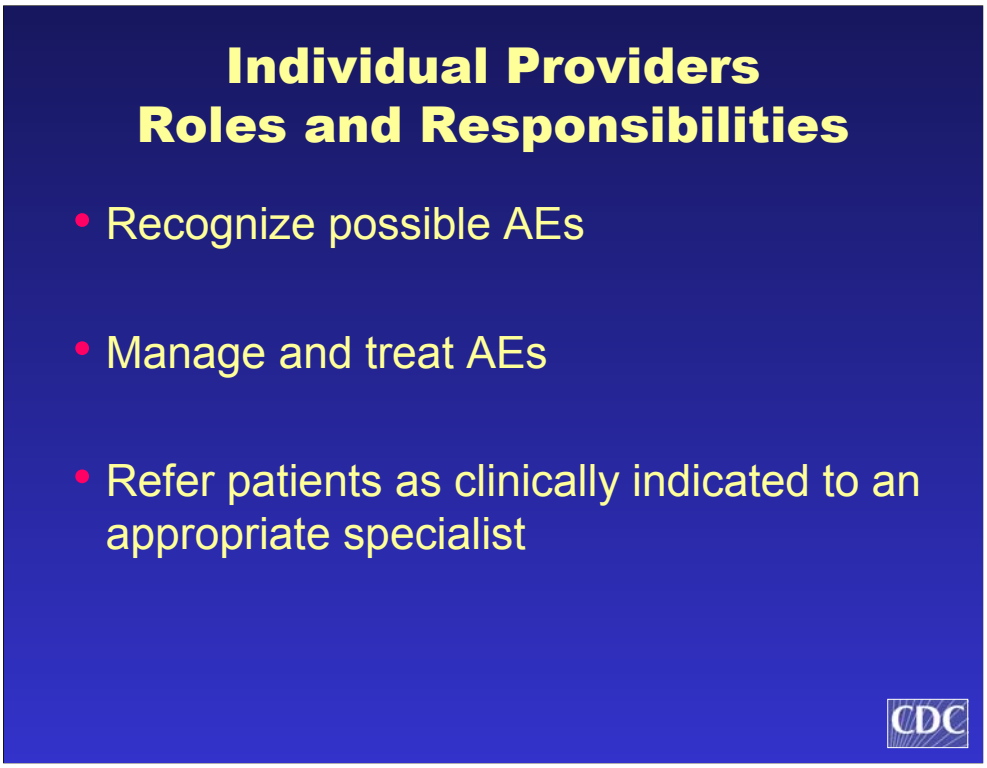
Some state health departments are also establishing assistance and will be notifying clinicians of the services available in your area. The Public Response Service, at 888-246-2675, is available to answer general questions regarding recommendations for use of the vaccine, contraindications, and recommended vaccination site care.



If a healthcare provider needs assistance beyond that offered by the Clinician Information Line, CDC's Clinical Consultation Team will be available, 24 hours a day, 7 days a week, to provide clinical consultation to healthcare providers in the diagnosis and management of smallpox vaccine adverse events.

The team consists of CDC infectious disease specialists, with backup from neurology, ophthalmology, and smallpox experts.

It is through the CDC Clinical Team that clinicians will request the release of VIG and Cidofovir. The Clinical Team has also developed clinical evaluation tools to assist in the diagnosis and management of adverse events. The tools will be posted on the CDC smallpox website.



What are the roles and responsibilities of the individual providers? The providers should be able to recognize and manage possible adverse events, and refer patients. Many of the adverse events will be mild and can be managed by primary care physicians. However, for moderate, severe, or unusual adverse events, healthcare providers should know how to refer patients as clinically indicated to an appropriate specialist.

Individual Providers Roles and Responsibilities

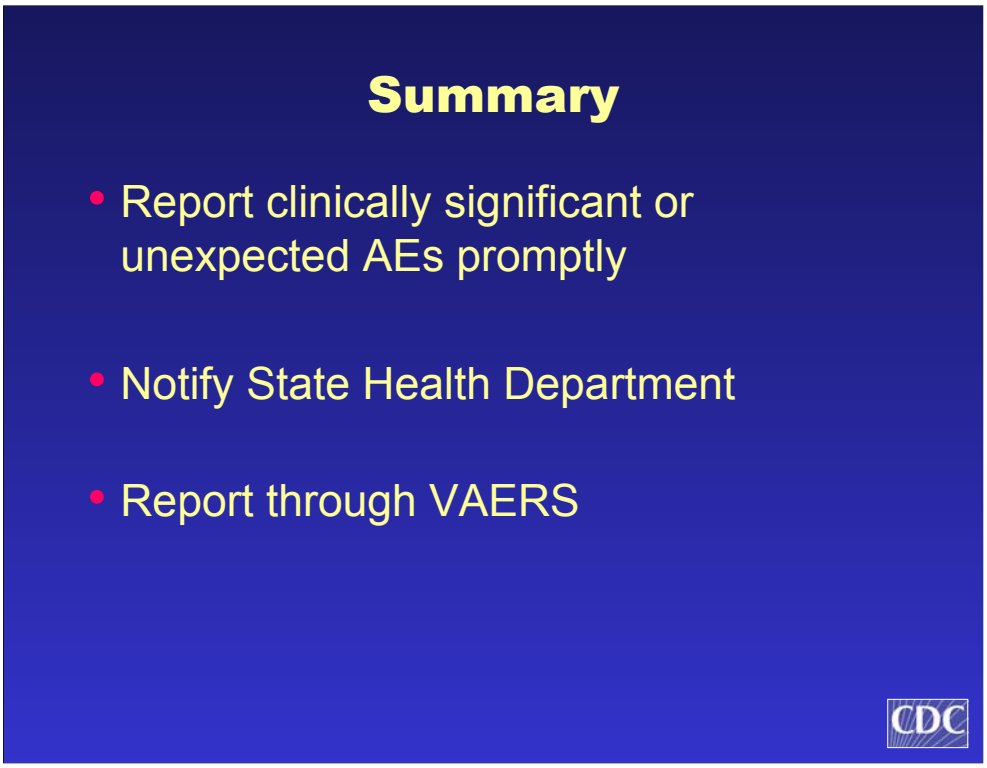
- Report AEs to state health department and VAERS
- Comply with IND protocol requirements if VIG and Cidofovir used for treatment of AEs

For clinically significant and unexpected adverse events, the provider must notify their state health department and submit a report to VAERS. If a provider needs to treat a vaccinee or contact with VIG or Cidofovir, the provider must comply with the IND protocol requirements.

Obtaining VIG and Cidofovir

- Treating physician contacts designated state official
- State informs CDC of VIG and/or Cidofovir request by contacting the Clinician Information Line
- Clinician Information Line links to the CDC Clinical Team
- Upon CDC Clinical Team approval, NPS releases VIG or Cidofovir to the treating physician

To obtain VIG or Cidofovir, the treating physician should contact their designated state official. The State will contact CDC through the Clinician Information Line and inform CDC of the request for VIG and/or cidofovir. After review of the case by the CDC Clinical Team, CDC, through the National Pharmaceutical Stockpile will release the requested treatment product to the treating physician.

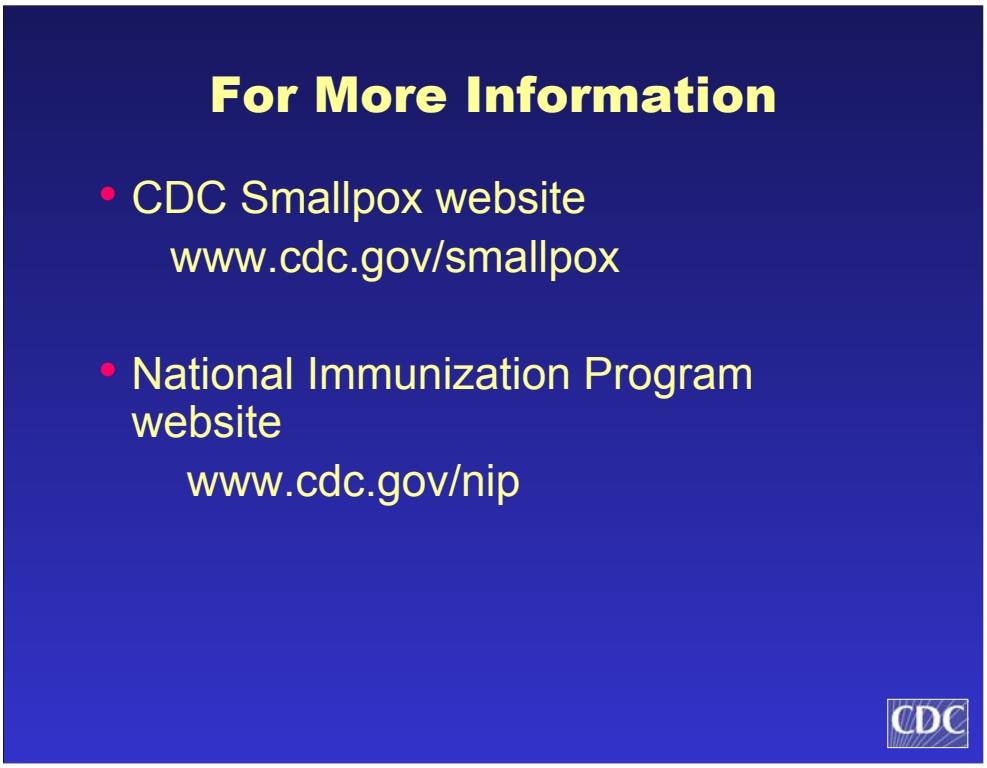


In summary, CDC, the states, and individual healthcare providers and medical facilities all have important roles and responsibilities in the monitoring and reporting of adverse events. State health departments should be promptly notified of clinically significant adverse events and a VAERS report should be filed.

Summary

- CDC will monitor these reports and provide information to assist the states
- Some AEs will benefit from treatment with VIG or Cidofovir, which are available from CDC under IND protocols

CDC will monitor these reports and provide information to assist the states in the operation of their vaccination program. Some adverse events will benefit from treatment with VIG or Cidofovir, which are available from CDC under IND protocols.



Finally, as mentioned earlier in this broadcast, there are additional resources available.

We hope that these services will prove useful to you as we all step into the modern era of smallpox vaccination. Thank you.