WEBCAST TRANSCRIPT

Transcript of "Smallpox Vaccine Safety and Reporting Adverse Events"

Presented by Dr. Gina Mootrey, 6 December 2002, on the satellite broadcast of "CDC Bioterrorism Update: Smallpox Preparedness"

(Associated graphics can be found at www.bt.cdc.gov/agent/smallpox/training/webcast/dec2002/files/safety.ppt and www.bt.cdc.gov/agent/smallpox/training/webcast/dec2002/files/safety.pdf.)

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(Slides 1 and 2-3 are title and objectives, respectively)

MOOTREY:
I appreciate the opportunity to speak to you today. From the previous presentations it should be apparent why vaccine safety is so important. To complete the vaccine safety discussions, I intend to give you a programmatic overview of smallpox vaccine safety monitoring and reporting.

Slide 4
I will begin with an overview of the process for reporting smallpox vaccine adverse events. Vaccination clinics and healthcare providers should report clinically significant and unexpected adverse events to their state health department. The state health department will, in turn, report such adverse events to the CDC. A VAERS report should also be filed for clinically significant and unexpected adverse events; the VAERS report can be submitted by the clinic, provider, vaccinee, or state health department.

Slide 5
Some of you might be unfamiliar with VAERS, so let me take a moment to explain. VAERS is the national surveillance system for adverse events following the administration of U.S. licensed vaccines. VAERS is administered by CDC and the Food and Drug Administration. 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

Slide 6
Although any adverse event can be reported to VAERS, it is most important to report the clinically significant or unexpected adverse events, ideally within 48 hours. What is meant by clinically significant? Of course, serious adverse events, events that result in death, hospitalization, permanent disability or are life-threatening are considered clinically significant. Adverse events that prompt a visit to a healthcare provider may also be considered clinically significant; however, that is left up to the judgment of the healthcare provider. Adverse events other than unexpected or clinically significant can be reported to VAERS within 7 days.

Slide 7
Anyone can report to VAERS: vaccinees, healthcare providers, vaccine manufacturers, and, of course state health departments. For smallpox vaccine, state health departments should make sure that VAERS reports have been filed for the clinically significant and unexpected adverse events. Reports can be sent to VAERS

via the web, FAX, or mail. The VAERS contact information is listed on the screen. The website is http://secure.vaers.org/VaersDataEntry.cfm. The FAX number is 877-721-0366. Call 800-822-7967 for a report form.

Slide 8
So much for the reporting of adverse events. Let's spend some time considering the vaccine safety roles and responsibilities of the different participants in the vaccination program. At the federal level, CDC will be responsible for tabulating the reported adverse events, by number and type of adverse event. We will determine the reported frequency of known serious adverse events to estimate whether the reported rates are consistent with the historically reported rates. CDC will review VAERS reports and information from the states and providers on a daily basis to monitor for unexpected adverse events. If there are any unusual adverse events, such as type of event, geographic location, or population distribution, CDC will conduct special studies to further investigate any risk factors. CDC will make Vaccinia Immune Globulin or VIG and cidofovir available under Investigational New Drug (IND) protocols for selected adverse events. This was stated in an earlier presentation, but the conditions for which VIG is clearly indicated are eczema vaccinatum, progressive vaccinia, and severe generalized vaccinia.

Slide 9
CDC will also provide technical assistance to state health departments to support the safest possible use of smallpox vaccine. For example, CDC will provide assistance for questions regarding screening, contraindications, vaccination technique, and adverse events. CDC will provide technical consultation to clinicians in the diagnosis and management of adverse events after smallpox vaccination, especially if the adverse events are moderate to severe, unexpected, or are not following an expected clinical course. And CDC will work with the Food and Drug Administration to monitor VAERS reports.

Slide 10
State Health Departments should develop a plan to assure monitoring of adverse events among smallpox response teams. As part of that plan, State Health Departments need to identify an individual to oversee, establish, and coordinate vaccine safety monitoring.

Slide 11
They should be prepared to communicate with medical organizations within their state, and to communicate with media on vaccine safety issues before, during and after the vaccination program. Although states may designate or recommend certain medical facilities for the assessment of adverse events, in practice, vaccinees could enter the healthcare system at many points. Therefore, the state should make sure their healthcare providers are aware of the vaccination program and know who to contact if they need to assess, refer, or treat a person with a potential vaccine adverse event.

Slide 12
As part of the State Health Department plan for vaccine safety monitoring, there should be a system developed for rapid reporting and assessment of adverse events in vaccinees or their contacts. This system should provide coverage for answering questions posed by vaccinees and clinicians 24 hours a day, 7 days a week. This system should assure prompt reporting to CDC for clinically significant and unexpected adverse events; VIG or cidofovir requests; and for the clinical outcome following treatment.

Slide 13
I just mentioned that there should be prompt reporting to CDC for VIG or Cidofovir requests. However, I'd like to stress that not only is reporting essential, but discussion of the case with CDC is needed. So, let me reiterate, CDC MUST be contacted for VIG or Cidofovir requests. And, the system should assure that all of the reporting and regulatory requirements for the VIG and Cidofovir INDs are fulfilled.

Slide 14
Hospitals are major participants in this vaccination program since many of them will have staff vaccinated as part of smallpox response teams. The hospitals with smallpox response teams must provide follow-up of vaccinees, including 24/7 coverage for vaccine adverse event assessment. It is recommended that hospitals perform daily vaccination site care to reduce the possibility of contact transmission of the vaccine virus from the healthcare worker to any patients. Hospitals should identify subspecialists to assist with assessment of suspected adverse events. Subspecialty categories would ideally include dermatology, infectious diseases, neurology, ophthalmology, and allergy/immunology.

Slide 15
Hospitals should promptly notify their state health department of any clinically significant or unexpected adverse events and should submit a case report to the health department.

Slide 16
As might be expected, vaccination clinics have a number of vaccine safety responsibilities. Vaccine clinics should be prepared to treat rare, immediate adverse events, such as anaphylaxis or syncope. The clinics should be able to educate vaccinees on vaccination site care, such as with written instructions. Vaccine clinics should assure that vaccinees have instructions for follow up, such as for vaccine take checks.

Slide 17
Not only should the clinics know the reporting process for adverse events for their own reporting purposes, but they should also be able to provide vaccinees with information on who to contact for suspected adverse events. Clinics should tabulate the number of persons vaccinated. This is helpful for evaluating clinic operations, monitoring vaccine use, and, for vaccine safety purposes, it facilitates calculating the rate of reported adverse events. In an earlier presentation you heard about the Pre-Event Vaccination System or PVS. One plus of the PVS is that a report of those vaccinated can be easily generated for each clinic.

Slide 18
Last in my presentation, but not least among the participants in the vaccination program, are the individual health care providers. We acknowledge that most healthcare providers have never seen smallpox vaccination adverse events. However, with educational programs such as this broadcast and others, we would anticipate that most providers would be able to recognize possible adverse events. 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.

Slide 19 – Individual Providers' Roles and Responsibilities
For clinically significant and unexpected adverse events, the provider must report to the state health department and 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.

Slide 20
To obtain VIG or Cidofovir, the treating physician should contact their designated state official. The State will inform CDC of the request for VIG and/or cidofovir. After review of the case and indications for use of VIG or Cidofovir, CDC will release the requested treatment product.

Slide 21
In summary, CDC, the states, and individual healthcare providers and medical facilities all have important roles and responsibilities in the surveillance and reporting of clinically significant or unexpected AEs. Clinically significant or unexpected adverse events should be reported promptly to the state health

department, which will, in turn, report to CDC. Clinically significant or unexpected adverse events should also be reported through VAERS.

Slide 22
CDC will monitor these reports and provide information to assist the states in the operation of their vaccination program. Some AEs will benefit from treatment with VIG or Cidofovir, which are available from CDC under IND protocols.

Slide 23
Everyone's participation in this process will be critical to ensure we learn as much as possible about smallpox vaccine in today's world. Finally, as mentioned multiple times during the various presentations in this broadcast, information and resources for smallpox surveillance and reporting, including vaccine safety, can be found at www.cdc.gov/smallpox

MOOTREY
I hope the information presented today has given you an understanding of the need for, and the steps involved in smallpox vaccine safety monitoring and reporting. Thank you.

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