Update on ASTHO/CSTE/NACCHO/APHL Conf Calls (questions from Jan. 29, 2003)

Centers for Disease Control and Prevention

Frequently Asked Questions supporting the National Smallpox Vaccination Program – To be posted on Member-only websites of ASTHO, NACCHO, CSTE, and APHL

What is the ACIP recommending for the number of needle sticks? (1/29/03)
On January 29, 2003, the ACIP met by conference call to finalize supplemental recommendations for use of smallpox vaccine. The Committee recommended that smallpox vaccine be given in accordance with the package insert, with 3 insertions of the bifurcated needle for primary vaccination and 15 insertions for revaccination. A trace of blood should appear at the site of vaccination within 15-20 seconds; if no trace of blood is visible, an additional 3 insertions should be made using the same bifurcated needle without reinserting the needle into the vaccine vial. (Note: Approved by Dixie, David, Kevin, and Julie)

Is the medication information collected on the Patient Medical History and Consent Form tracked in the PVS system? (1/29/03)
No, these are not captured in the PVS system. States may want to capture this information on separate forms so that the data entry personnel never see it.

Where are states required to put the PVN sticker (what forms)? (1/29/03)
On the Patient Medical History and Consent Form, vaccination card, and 1 sticker should be given to the vaccinee so it can be put on the VAERS form, if that is needed later – the vaccinee needs the keep the sticker for post-vaccination follow up.

Is it required to put PVN stickers on each page of the Patient Medical History and Consent Form? (1/29/03)
There is space on the top of each page for the PVN sticker.

What is the turnaround on granting security certificates? Have the states that are currently vaccinating been approved for their security certificates? (1/29/03)
Some of these states have it set up, but not all. Several states have their certifications submitted, but have additional steps to complete the process. Then approval time can be as short as 48 hours.

Will user logins define access to the different systems? (1/29/03)
Yes, logins will limit the systems a user can access on the first page.

If a state is using their own systems in lieu of PVS, can the systems be integrated with VAERS so that clinicians' data entry burden is limited? (1/29/03)
This is unfortunately not a possibility due to federal limitations on data interfaces. Anyone can fill out a VAERS report even if the state is using their own system for PVS.

If a state has trouble using PVS when they start their vaccinations, how should they capture the necessary information and report back? (1/29/03)
PVS is only used to facilitate state's reporting of their information. An email has/will be sent with information on the bi-weekly reporting requirements (e.g., number vaccinated, number with takes, number of participating hospitals).

Are the Monday, Wednesday, Friday calls enough? Should these be expanded to occur every day? (1/29/03)
For now, we will continue with the M-W-F frequency.

Can states have a copy of IND protocols for VIG and Cidofovir for their IRB? (1/29/03)
These forms are not yet available.

If someone doesn't check yes that they can be contacted on the Medical History and Consent form, can they be vaccinated? (1/29/03)
They cannot be vaccinated.

What if the Patient Medical History and Consent Form is not fully completed regarding some questions (e.g., race/ethnicity, SSN)—does this mean the person is disqualified from being vaccinated? (1/29/03)
A potential vaccinee must provide complete all the information on the Patient Medical History and Consent Form as part of the vaccination process. If an individual refuses to complete the information, he/she cannot be vaccinated.

What is the process of communication between military installations and the local/state health departments? (1/29/03)
The public notice of military smallpox vaccination has been out since 12/13/02, so state and local health departments with nearby military installation can expect to have vaccinated military personnel in their state. The installations' preventive-medicine/public-health departments will be reminded to call the state health department, but given the current increased demands on the military the communications bridge needs to operate in both directions.

How do military personnel who may happen to be treated at civilian hospitals get access to VIG? (1/29/03)
For DoD beneficiaries and families of Reserve Component personnel, DoD will work diligently with civilian institutions to assist. This could involve moving the patient to a military hospital or arranging for VIG at the civilian hospital. Physicians treating personnel vaccinated through the DOD can obtain VIG through the DOD system after completing documents required by the FDA. An employee vaccinated through the hospital's program who requires VIG would probably obtain it through the CDC, even if he or she was a Reservist or in the National Guard.

How do civilian physicians treating military vaccinees access VIG? (1/29/03)
Civilian physicians can begin the process of requesting VIG according to instructions at the DOD website at www.smallpox.army.mil/resource/pdf/PRTemplate.pdf <http://www.smallpox.army.mil/resource/pdf/PRTemplate.pdf>
Civilian physicians who first call the CDC hotline will be provided the information they need.

On the Patient Medical History and Consent Form, to what does the term "medical screener" refer? (1/29/03)
This term is based on requirements for other immunization programs. A "medical screener" is a witness; anyone can be a witness. Future revisions of this form may remove this section.

How do you designate between a "primary" versus "secondary" vaccinee? (1/29/03)
A person is determined to be a primary vaccinee based on their medical history. If they don't know or did not receive the smallpox vaccine previously, then they should be treated as a primary vaccinee. If they were born prior to 1972, they were most likely vaccinated, although this is not guaranteed. The vaccinator should err on the side of revaccination, as this requires 15 punctures, and has a higher probability of a take.