Lessons Learned / Tips on Running a Pre-Event Smallpox Vaccination Clinic

(From WVDHHR Clinics Held 2/14/03 and 2/19/03)

Site Issues:

- Where necessary, clinics can be effectively run in one large room with stations, including the informational video. The background noise from the informational video running helped assure confidentiality of individual screening when privacy screens between screening stations were not available. This set up does require a fairly large room and well-labeled stations to direct flow. It also takes thinking about confidentiality issues when setting up the room (e.g., don't put a screening station near where folks sit waiting for vaccination, etc.)
- Assure strong lighting in the vaccination station (to verify droplet picked up on bifurcated needle). If strong lighting not already in place, you may want to add a floor lamp to assist with this.
- Copy machine on site is very useful.

Overall:

- Be certain to have provided CDC packet of informational materials to persons considering vaccine in advance with time for questions, applicable testing, etc. Referring agencies should also provide potential vaccinees, in advance, info on how they will handle need for time off as well as what is and is not available in terms of compensation in the rare instance of a serious adverse event in the vaccinee or a contact.
- Remind people in advance to bring a photo ID, their completed self screening form, info on their trained vaccine safety monitor / HAP, and any other materials you request in advance.
- Before the clinic, the clinic manager or other designated individual should call and verify that all VSM and HAPs for those you are about to vaccinate have completed medical follow up training prior to running your clinics. Training for these individuals includes completion of one or more of the following (These and other applicable material can be found at http://www.bt.cdc.gov/agent/smallpox/vaccination/index.asp):
  - "Smallpox Vaccination and Adverse Reactions: Guidance for Clinicians": (MMWR initially published 1/24/03; republished 2/21 as Recommendations and Reports): http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm
  - "Smallpox Vaccination and Adverse Events Training Module" (On-line: CME provided): http://www.bt.cdc.gov/training/smallpoxvaccine/reactions/default.htm
  - "Clinical Management of Adverse Events Following Smallpox Vaccination: A National Training Initiative" (Webcast of 2/4/03 Satellite Broadcast): http://www.bt.cdc.gov/agent/smallpox/training/webcast/04feb2003/index.asp
- Your screening process (before vaccination) should include verifying that each potential vaccinee has a trained vaccine safety monitor (VSM) in place and at least one trained local physician supporting that VSM. Do not vaccinate anyone who does not have a trained VSM expecting to see them the next work day (or earlier if there are problems) and at least one trained HAP identified in advance!

- Besides site checks every work day, make certain individuals know that they must see the VSM (or someone else identified by you) on day 6-8 post vaccination. If take is not documented on day 6-8, there is no way to be certain they are immune! Put in place tickler or other systems to assure vaccinated individuals are seen and take documented on day 6-8.
- Be certain all are aware who is in charge at the clinic and use them for guidance / organization.
- Security: Have one or more individuals whose job is to constantly watch and have clear control of who comes in and out of the clinic. This person should not have additional tasks that could side track him/her from this job. You should know exactly who comes and goes and assure they are supposed to be on site. Early am and lunch time are easy times for this to lapse.
- Have either a mock patient or run one of yourselves through the clinic first to identify missing items / problem areas (forms missing, copy of material missing a page, etc.). Give yourself 30-40 minutes between this person and your full cadre of patients to correct any problems identified.
- Have staff cross trained so you can juggle staffing on site if needed to maintain flow. Natural roles to cross train include: 1) screeners, vaccinators, exit monitors (mostly nurses or other health care professionals). May also be able to cross train these with vaccinator assistants (depending on who you use for this role);
  2) registration staff and data check staff
- Found it very useful to have a physician on site–screening questions, evaluate severity of current rash, verify 3 vs 15 pricks for an individual vaccinee, etc.
- Found having a PDR available was useful (look up meds to help in screening).
- Review how and when to use epi-pen (for anaphylaxis) with all clinical staff prior to starting and be certain all know where this will be kept.
- Medical screening and Exit Interviews (site care, follow up, etc.) are the stations that took the most time. Staff them adequately and spend time on them to assure all questions are answered–both are very important parts. Generally need ratio of at least 2 screeners : 1 vaccinator : 2 exit interviewers. May find 3:1:3 works better.

Station Specific Items:

Stations at DHHR clinic included:

- Registration (welcome, check id, mark arrival on appointment list, provide clipboard with info to read / review, forms to fill in, etc.)
- Informational Video (CDC 11 minute video)
- Medical Screening (review self screening, complete clinic screening, address questions, verify VSM and HAP in place for follow up, sign consent, put together chart)
- Vaccination (Complete paperwork, vaccinate)
- Exit Interview (Review site care, review follow up plans, assure chart put together and complete, answer questions).
- Data Check and Data Entry (if done on site): Reviewed Medical History and Consent Form to verify all information complete. Verified “initial” vs “revaccination” marked correctly in upper left corner (these apply to initial vs revacc during the current pre-event effort; not whether or not they’ve been vaccinated in years past–that is elsewhere on the record).

Registration:

- Pre-scheduling was very useful.
- Useful to have phone numbers of vaccinees on appointment list (to call and reschedule if running ahead or behind schedule).
- Have patient fill out name and demographics on all parts of forms (they are listed multiple times and this helps with flow as they move through; or use pre-prepared name labels).

Informational Video:

- Found a TV and VCR worked better than a large screen projector, at least in the single room set up.

Medical Screening:

- Include in screening verification that the individual has (and knows) who their Vaccine Safety Monitor is and that there is at least one nearby physician who can serve as a back up to that VSM. If you cannot verify there is a trained VSM and at least one trained physician in place to support that VSM, do not vaccinate.
- Have extra copies of the self screening form available to go over with individuals if they did not bring in a completed one for you to review with them. This is in addition to the screening on the Medical History and Patient Consent Form.
- Useful to use laminated card with HIV risk factors on it. "Please review these risk factors. Do any of them apply to you (no need to say which) or do you have any question about your HIV status? If so, have you recently had an HIV test or would you like to have HIV testing done prior to vaccination?"
- Useful to build patient chart here if not already built. May be useful to color code charts for different referring agencies.
- Found it useful to color code papers (e.g., all those individual takes with them are colored; all remaining in chart are white).

Vaccination:

- Takes almost 40 minutes to reconstitute vaccine.
- Vaccine is a yellow color.
- Vaccinator Assistant is a critical role. Really need one assistant with each vaccinator, rather than one assistant covering 2 vaccinators.
- Vaccinator assistant handles all papers in vaccination station.
- Have a nearby table top separate from vaccination work surface for vaccinator assistants to use (adding PVN numbers, filling out paper work, etc.).
- On the vaccinator assistant work surface, have a paper for reference that notes the common info for all they are completing: e.g, vaccination lot #, batch #, date.
- Make certain, on the vaccination work surface, that there is no room to lay down purses, papers, etc.-- to minimize risk of spilling vaccine.
- There are 6 PVN stickers for each vaccinee. We put five on the paper work (where PVN noted) and one on the chart folder.
- Need something to store vial stopper in when vaccine vial is open (e.g., top to sterile cup, etc.).

- When packing up vaccine, will need a bigger cooler than need when all is packed in original box. Found it useful to put paper tape over vial stopper once vial reclosed (just to make certain it stays on). Once carry opened smallpox vaccine in a specific cooler, may want to designate and label that cooler for smallpox vaccine transport and not use for transport of other vaccines.
- On the diluent is a date of manufacture (a date in the past). This is the "Batch Date".
- Mark whether you gave 3 or 15 pricks, though not listed on form. Would put where you note the arm vaccine is given in: e.g., Left arm-15; Left arm–3)

Exit Interviews:

- Provide and review interim vaccination documentation, instructions on site care, follow up information (paper with VSM info, number to call 24/7 with problems / questions), pictures of normal vaccination takes, 21 day diary.
- Helps to date day 0 on diary as date of vaccination. Also point out site to mark with date when scab separates.
- Useful to have a handout with a short list of supplies vaccinee will need to obtain for own site care (2x2 gauze pads, paper tape, waterproof bandages, zip lock bags, large plastic bag for laundry, etc.) These supplies are available at most drug stores, and, depending on where you go, run $5-10.
- Reiterate importance of regularly seeing VSM–especially on day 6-8 to verify take–this is a must, as well as if there is any problem or concern. In direct patient care settings, it's also a must to see VSM at the beginning of any work day.
- Be consistent providing site care and follow up information for everyone. Do not skip over or rush through this just because you have highly trained medical personnel (ID docs, experienced nurses, etc.) coming through. "You may know this information, but I hope you don't mind if I review it with you to make sure. We're going over this with everybody...."

Data Checks / Data Entry:

- Verify where noted on upper left corner of medical history and consent form whether the section labeled "initial" or "revacc" is correct (all in this part refer to the current pre-event vaccination effort–a "revacc" here is the follow up vaccination you give if their was no take). This does not refer to whether or not the person was vaccinated years ago–that's elsewhere on the form.
- Use provided PVN bar code scanner–significant room for data entry errors otherwise.

Vaccination Site Checks / Follow up:

The following are lessons learned to date in our site checks / take evaluations:

- Maintain a line list of those for whom you need to assure follow up.
- Digital or other cameras are useful during site care / follow up. Photos can be useful for training / learning purposes. If digital, they can also be sent to consultants electronically for review if needed.
- Activities at the site check include: checking site, changing dressing if needed, asking about symptoms in self or contacts, reminding to complete diary, reminding about hand washing, documenting take, assuring take and other adverse event info gets back into First Responder System (however arranged locally), linking into additional care if needed, answering questions.

- We have seen a variety of tape reactions. No need to overbandage or overtape site. One or at most two pieces of paper tape and a gauze pad (covered by a semi-permeable dressing only when in a direct patient care or other increased risk of transmission setting) is usually adequate and results in fewer tape reactions.
- We have seen, as expected, some staff with systemic aches, fever, and malaise. Treatment should include lots of fluids, NSAIDs (e.g., ibuprofen) or acetaminophen, and rest. Avoid aspirin products. Fluids are important--dehydration can make it significantly worse. If individuals are sick enough to stay home, they still need to see the VSM if at all possible. If not, they at least need to call.
- A site check form used at each visit to include in the individual's chart can be useful.
- Use some form of tickler system to assure you see folks on day 6-8 to verify take. You may want to remind the VSMs for others you vaccinated of the need to verify and document "take" as well (unless you verify "take" yourself for all you vaccinated.).
- Start "take" documentation on day 6. If you haven't seen someone by day 7, call them to assure you see them by day 8. <u>"Take" must be documented on day 6 - 8.</u>

Commonly Asked Questions that arose:

Is there an upper age limit for vaccination? Under "Precautions," the package insert recommends not using the vaccine in the geriatric age group in a non-emergency setting. "Geriatric" is typically defined elsewhere as 65 and older. While there is no evidence of increased risk in otherwise healthy, older individuals, there is simply no data on it.

The person gives a history of prior vaccination, but I can't find a scar. Assume previously vaccinated and use 15 pricks to administer vaccine.

Can I take aspirin products after vaccination? No, this is not recommended because of the theoretical risk of Reye's syndrome–an illness associated with aspirin use with other viral infections. Acetaminophen and ibuprofen (or other NSAIDs) are better used for pain, aches, or fever post vaccination.

What if I need to travel during the vaccination period. Do I need to take any special precautions regarding the hotel? First, the vaccination site should be covered by gauze and then by long sleeves at all times, including sleeping. Dressing changes in a hotel should be done just as at home and potentially contaminated items put in a sealed plastic bag. Waterproof dressings should be used in the shower, so the site should not contact towels, etc. (plus you can blot this area off with tissue and put that in the baggie (or use a hair dryer to gently dry the area.) So, the site really should not have any contact with the sheets, towels, etc., and therefore should not pose any risk to housekeeping staff.

If you are concerned about your ability to do this, you could certainly bring along a sheet and a towel to use instead of using the facility ones. These, you could take home and wash yourself.

Finally, if for any reason, clear or visible contamination of hotel sheets or towels occur, you should discuss it with the hotel management -- to calmly inform them and provide some education on washing it separately in hot water and soap, using gloves to handle the materials. Or, you could offer to take them home yourself to wash and return.

What about wearing contacts? Remember, your most important action to prevent transmission to yourself and others is good hand washing with soap and hot water and/or use of an alcohol based hand rub. Do not insert contacts immediately after handling the vaccine site or materials that may have been in contact with the site. Be certain to wash hands very, very well prior to handling eyes and contacts. If you are concerned about your ability to practice good hand hygiene during this time period, use glasses instead.