

Massachusetts Department of Public Health  
Division of Epidemiology and Immunization

**Smallpox Vaccination Clinic SOP**

Pre-Vaccination Screening

1. At least 2 weeks prior to the clinic, provide all potential vaccinees with CDC's Smallpox Pre-Vaccination Information Packet to ensure that potential candidates have the time for further medical consultation and/or HIV and/or pregnancy testing, as indicated.

The web site to obtain the CDC's Smallpox Pre-Vaccination Information Packet is <http://www.bt.cdc.gov/agent/smallpox/vaccination/infopacket.asp>.

- Review the Contents and Instructions document.
- Prior to each clinic, make sure all the documents in the packets are the most recent versions. The date of the latest version of each document is found at the website above.

Contents of the CDC's Smallpox Pre-Vaccination Information Packet are:

- Cover Letter
- Smallpox Vaccine Information Statement (VIS)
  - Supplement A: Reactions After Vaccination
  - Supplement B: Vaccination Site Appearance and Care
  - Supplement C: Skin Conditions That Mean You Should Not Get Smallpox Vaccine
  - Supplement D: A Weakened Immune System Means You Should Not Get Smallpox Vaccine
  - Supplement E: Pregnancy and Breastfeeding Mean You Should Not Get Smallpox Vaccine
- Pre-Event Screening Worksheet for Smallpox Vaccine
- Fact Sheet: Someone You are Close to May Get the Smallpox Vaccine: What You Should Know and Do
- Fact Sheet: Investigational Vaccinia Immune Globulin (VIG) Information
- Fact Sheet: Investigational Vistide (Cidofovir) Information

Also include in the Smallpox Pre-Vaccination Information Packet:

- MDPH's *Protecting Pets and Other Animals After You Get the Smallpox Vaccine* document.
- The *Massachusetts HIV Counseling and Testing Fact Sheet*.

2. Optional: Provide opportunity for vaccination candidates to view the 45-minute CDC video: “Considerations for Response Team Volunteers”.
3. All vaccination candidates should complete the *Pre-Event Screening Worksheet for Smallpox Vaccine*.
4. Review the *Pre-Event Screening Form for Smallpox Vaccine* with each potential vaccinee. If the potential vaccinee answered “**Yes**” to any of the questions, vaccination should be deferred at this time. If the potential vaccinee answered “**No**” to all questions, provide appointment for vaccination clinic.
5. Provide all potential vaccinees the opportunity to obtain a referral for laboratory testing for medical conditions that may increase their risk for adverse events from the vaccine, including anonymous and confidential HIV testing and, if appropriate, pregnancy testing.
6. Provide all potential vaccinees the opportunity to discuss their medical conditions with their health care provider and household or close intimate contacts.
7. Provide vaccination candidates with information about the date, time and location of the vaccination clinic.
8. Instruct vaccination candidates to bring with them to the clinic:
  - The *Pre-Event Screening Worksheet*.
  - Documentation of prior smallpox vaccination, if available.
  - Remind vaccination candidate to wear a short-sleeved garment with easy access to their upper arms.

#### Pre-Vaccination Clinic Preparation

1. Establish a list of vaccination candidates who have been prescreened and referred for vaccination.
2. Have a Take Clinic pre-arranged in order to provide the vaccination candidate with date, time, and location of f/u visit.
3. Assemble Vaccination Clinic Packets for all vaccination candidates. The packets should include all the documents included in the Pre-Vaccination Information Packet, as well as:
  - *Patient Medical History and Consent Form*
    - Fill out in advance the clinic information and vaccine batch information on P. 3
  - *Post-Vaccination and Follow-Up Information Sheet*
    - Fill out in advance the Take Clinic information and 24-hour telephone number
4. Place PVN stickers on the 4 pages of the *Medical History and Consent Form*

5. Staple 2 remaining PVN stickers to the *Post-Vaccination and Follow-up Information Sheet*.
6. Attach the *Massachusetts Supplemental Screening Form* and the *Screener's Note Page* to the *Medical History and Consent Form*.
7. Ensure that there will be a VCR and TV available at the clinic for viewing of the mandatory 11-minute CDC video: "Smallpox Vaccine: Decision Point for the Smallpox Vaccination Candidate."
8. Ensure that emergency medications and equipment are available.
9. Ensure that room is equipped with a phone for emergency use.
10. Ensure that all clinic workers understand their role.

### The Day of the Clinic

#### **Registration Station**

1. Check vaccinee's name off of the Vaccination List
2. Provide the vaccination candidate with the Vaccination Clinic Packet.
  - Make sure all the documents in the packets are the most recent versions. The date of the latest version of each document is found at the website above.
3. Inform vaccinee regarding the procedure for the clinic:
  - They will view CDC video titled, "Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate"
  - They will complete Sections A & B of the *Patient Medical History and Consent Form*
  - They will meet with a medical screener and have an opportunity to have any remaining questions answered
  - If, after viewing the video and meeting with a medical screener, the potential vaccinee still wants to proceed with vaccination, they will be referred for vaccination
  - Finally, after the vaccination they will meet with a nurse for an exit interview, where they will receive instructions on site care and receive a site care kit. They will also be provided with a 24/7 number to call if they have any questions about their vaccination and an appointment for the Take Clinic
2. Ask the vaccinee to review the materials in the Smallpox Pre-Vaccination Information Packet and to complete Sections A & B of the *Patient Medical History and Consent Form* while they are waiting to view the video and to meet with a medical screener.

3. Direct the vaccinee to the video viewing area.
4. The vaccinee will view the CDC video, “Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate”.

### **Screening Station**

1. Review the *Pre-Event Screening Worksheet for Smallpox Vaccine* with each potential vaccinee. If the vaccinee answered “**Yes**” to any of the questions, make a note on the *Screener’s Notes Page* and staple to the *Patient Medical History and Consent Form*. If the vaccinee has already received further medical evaluation and has received their provider’s approval for vaccination, document on the *Screener’s Notes Page* and staple to the *Patient Medical History and Consent Form* and review the *Patient medical History and consent Form*. If the vaccinee answered “**No**” to all questions, review the *Patient medical History and consent Form*.
2. Review the *Patient Medical History and Consent Form* with the vaccinee. Enter the date and the vaccinee’s name on each page of *Patient Medical History and Consent Form*. Ensure that the vaccinee completed Sections A and B. Finish completing the *Patient Medical History and Consent Form* with the vaccinee. If the vaccinee answered “**Yes**” to any of the screening questions, do not refer for vaccination, unless they have already received further medical evaluation and have received their provider’s approval for vaccination. Make sure there is a note on the *Screener’s Notes Page* and staple it to the *Patient Medical History and Consent Form*. If the vaccinee answered “**No**” to all questions, review the *Massachusetts Supplemental Screening Form*.
3. Complete *Massachusetts Supplemental Screening Form*. Staple to *Patient Medical History and Consent Form*.
4. Ask candidates if they are prepared to sign the consent form. If they are, have the candidate sign the consent form. The screener will also sign the consent form.
5. Check the appropriate box under “Disposition” on page 3 of the *Patient Medical History and Consent Form* (“referred for vaccination”, “deferred due to medical contraindications”, or “vaccination refused”). If the vaccinee is referred for vaccination, guide the vaccinee to a vaccination station when there is a vaccinator ready. Hold candidate at the screening table until there is a vaccinator ready.
6. If vaccination is deferred due to medical contraindications or vaccination is refused, collect all forms (except the *Pre-Event Screening Worksheet for Smallpox Vaccine*) and thank candidate for considering vaccination.

### **Vaccination Station**

1. Ensure that the vaccinee has signed the *Patient Medical History and Consent Form*.

2. Change gloves and wash hands between each vaccination.
3. Administer the smallpox vaccine according to the package insert and CDC protocol.
4. If vaccinee is returning immediately to direct patient care, cover vaccination site with gauze and semi-permeable dressing. If vaccinee is not going to be involved in direct patient care, cover vaccination site with gauze and hypoallergenic tape.
5. Complete the vaccination documentation section of page 3 of the *Patient Medical History and Consent Form*. Include date of vaccination, arm inoculated, and the number of punctures (write this in by hand). Print your name and sign the line, "Vaccine administered by".
6. Return the *Patient Medical History and Consent Form* to the vaccinee's Smallpox Vaccination Clinic Packet.
7. Direct the vaccinee to the exit interview table if there is a nurse exit interviewer available. Hold vaccinee at vaccination table until an exit interviewer is available.

#### **Exit interview**

1. Exit interviewer should ensure that *Patient Medical History and Consent Form* is signed and completed.
2. Collect the *Patient Medical History and Consent Form*, and any additional forms, such as the *Massachusetts Supplemental Screening Form* and the  *Screener's Notes Page* (both additional forms should be stapled to the *Patient Medical History and Consent Form*).
3. DO NOT collect the *Pre-Event Screening Worksheet for Smallpox Vaccine* or the *Post-Vaccination and Follow-Up Information Sheet*. Return these forms to the vaccinee.
4. Remind the vaccinee to return to the Take Clinic. Ensure that the date, time, and location of the Take Clinic are written on the *Post-Vaccination and Follow-Up Information Sheet*. Also ensure that the 2 remaining PVN stickers are stapled to the form.
5. Provide the vaccinee with adequate supplies to conduct dressing changes for 7 days (until the Take Clinic). Supplies include: gauze (non-sterile or sterile), gloves of correct size, tape, alcohol-based waterless antiseptic, Ziploc bags, and semi-permeable dressings (if vaccinee will be involved in direct patient care), CDC's Smallpox VIS *Supplement B: Vaccination Site Appearance and Care*.
6. Review Site Care Instructions – Refer to CDC's Smallpox VIS *Supplement B: Vaccination Site Appearance and Care*.
7. Emphasize:

- Handwashing, handwashing, handwashing.
  - Keep site covered while showering/bathing to avoid contaminating towel while drying.
8. Review the Post-Vaccination and Follow-up Information Sheet with the 2 PVN stickers stapled to it and tell them to bring it with them when they go to the Take Evaluation appointment. Tell them they will get a permanent smallpox vaccination card at that appointment.
  9. Ask the vaccinee if they have any final questions.
  10. Review the 24/7 number to call if they have questions or concerns after leaving the clinic.

#### Follow-up

1. Create a file for each vaccinee. Keep *Patient Medical History and Consent Form*, and any additional forms, such as the *Massachusetts Supplemental Screening Form* and the *Screener's Notes Page* in this file. A copy of any VAERS report should also be kept with the patient's file.
2. Maintain a Vaccination Clinic log. Include clinic date, location, vaccinee name, PVN, vaccination disposition (vaccinated, deferred, refused), take response (major, equivocal, no take), and Adverse Event Active Surveillance worksheet completion.
3. Conduct a Take Clinic 6-8 days after the vaccination clinic.
4. Conduct Adverse Event Active Surveillance for each vaccinee 21 - 28 days after the vaccination clinic.
5. Enter all data into the Prophylaxis and Vaccination Management System (PVMS), once system is available.