

# Smallpox

Clinical Description &  
Recommendations for a Vaccination Program

## **Smallpox Vaccine Administration**

The first step is to gather the necessary supplies. The following supplies are needed for the administration of the smallpox vaccine: vaccine, bifurcated needles, diluent, a syringe for drawing up the diluent (if it does not arrive in an ampule with a vented needle), gloves, a sharps container, a Chux® pad, alcohol pads and dressing supplies. In some settings you may receive a vaccine package, which includes the smallpox vaccine, diluent with attached needle, and a bifurcated needle or needles. The dressing supplies will vary depending on whether you are performing pre-event vaccination or mass vaccination in response to identified smallpox cases. This will be discussed in greater detail later in this program.

The next step is to prepare the smallpox vaccine. Put on a pair of gloves before you begin. Gloves should be worn at all times when handling or administering the smallpox vaccine. In addition, due to recent problems encountered while reconstituting the vaccine, it is now recommended that persons involved in this process wear a face shield to guard against any accidental “splattering” of vaccine.

Please note, we are showing the contents of a smallpox vaccine kit for educational purposes and we were not reconstituting vaccine when we took these pictures. You should always wear gloves when actually handling the live vaccine.

In the vaccine packaging you will find two vials and either individually wrapped needles or a needle dispenser with many needles. The first vial contains the smallpox vaccine. The second container is an ampule which contains the diluent for reconstituting the vaccine.

To prepare the vaccine, first lift up the aluminum seal on the vaccine vial. Do not break off or tear the tab on the seal. This step is very important as recent events are documented where persons have experienced problems with the top of the vaccine vial becoming compromised and rendering the vaccine unusable. The aluminum seal needs to be in place to keep the rubber stopper properly secured on the vaccine vial during the reconstitution process.

Next, swab the rubber stopper with an alcohol pad and allow it to dry.

Place the vaccine vial upright on a hard, flat surface. Next, insert a sterile 21 gauge or smaller needle into the rubber stopper to release the vacuum from the vaccine vial. The needle should be discarded into a sharps container. This needle is not included in the kit you receive from the CDC.

The diluent should be at room temperature to reduce its viscosity. If necessary, you can warm up the cartridge by holding it in the palm of your hand for a minute or so.

Peel open the vented needle package, which will be provided with the kit, and aseptically remove the vented needle. Remove the rubber cover from the end of the diluent syringe.

With a twisting motion, aseptically attach the vented needle to the hub of the diluent syringe.

Remove the protective cover from the vented needle and expel the air from the diluent syringe.

Aseptically insert the needle through the rubber stopper into the vaccine vial up to the first hub.

Depress the plunger to ensure the entire volume of diluent is delivered into the vial.

Once the diluent has been successfully transferred, withdraw the diluent syringe/vented needle and dispose in an appropriate sharps container. Allow the vaccine vial to stand undisturbed for three to five minutes. Then, if necessary, swirl the vial gently to ensure complete reconstitution of the vaccine.

Please refer to the package insert inside your vaccine for further instructions if your vaccine does not arrive to you in this form.

This process will yield approximately 100 doses of vaccinia virus vaccine.

The vaccine is now ready to be administered.

Remove the aluminum seal from the vaccine vial by pulling the tear off tab down. Discard the seal in a biohazard container. Next, remove the rubber stopper from the vaccine vial. If you choose to retain the stopper for resealing, it is important to maintain its sterility. When removing either the white vinyl cap or the rubber stopper, place it topside down. Make sure that nothing comes in contact with the portion of the cap or stopper that goes inside the vaccine vial. This ensures the cap or stopper will remain sterile.

A special bifurcated needle is used to administer the smallpox vaccine. No other vaccine uses this type of needle. The bifurcated needle is shaped like a two-pronged pitchfork. When the bifurcated needle is dipped into the vaccine vial and withdrawn, the tiny amount of vaccine required for a single dose is captured between the two prongs of the needle.

New safety devices for bifurcated needles are available, but have some disadvantages when used. Some available prototypes contain needles with necks too short to reach the bottom of the smallpox vaccine vial. This results in a wastage of vaccine dosages. In addition, some safety devices utilize a sheath that does not lock in place except for disposal, which results in sheath and needle sliding. This makes administration of the vaccine more difficult. If efficient safety devices are available that are cost effective, their use may be considered in order to decrease the risk of needlesticks.

We will now demonstrate the vaccine administration technique.

In general, no skin preparation, including use of alcohol or other chemical agents, is required, unless the skin of the arm is grossly contaminated. If alcohol is used to clean the skin, the skin must be allowed to dry thoroughly in order to prevent inactivation of the vaccine.

Gently shake one sterile bifurcated needle from the needle dispenser, or remove the bifurcated needle from its packaging if individually wrapped needles are provided.

Dip the bifurcated point of the needle into the vaccine solution so that the needle is perpendicular to the floor. The needle will pick up a drop of the vaccine in the space between the two prongs. Do not re-dip the needle into the vaccine solution once it has touched the patient's skin. Doing so will contaminate the vaccine vial and render that vaccine unusable.

The vaccine should be administered in the deltoid muscle of the patient's non-dominant arm. Pull the skin on the arm taut.

On January 29<sup>th</sup>, 2003, the Advisory Committee on Immunization Practices recommended that smallpox vaccine be given in accordance with the package insert, with three insertions of the bifurcated needle for primary vaccination and 15 insertions for revaccination. A trace of blood should appear at the site of the vaccination within 10 to 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.

This should be done rapidly in a perpendicular fashion within a five-millimeter diameter area. You need to effectively puncture the skin in order to introduce the vaccine into the skin. This method allows the vaccine to penetrate the superficial layers of the skin so that viral multiplication can take place and immunity to smallpox can develop.

Once the vaccine is administered, the bifurcated needle should be disposed of in a sharps container.

Using a 2X2 or other size gauze pad, blot the inoculation site to remove any excess blood before applying a dressing.

Next you will need to cover the inoculation site with a dressing. The type of dressing used will depend on whether you are performing pre-event vaccination or mass vaccination in response to confirmed cases.

As of January, 2003, all vaccinations provided are considered pre-event since smallpox does not occur naturally and any confirmed case would be assumed to result from a bioterrorism attack. Pre-event vaccinations do not have the same urgency and time requirements as post-event immunization. Post-event vaccinations have an urgency not present in pre-event situations because there is a short, 3-4 day window of opportunity to vaccinate exposed individuals in order to decrease the risk of morbidity and mortality related to smallpox exposure.

At this time, pre-event vaccinations are recommended for select occupations only, in order to provide a protected team of primary responders in the event of an initial suspected case of smallpox. This team would be responsible for patient care until the diagnosis is confirmed, at which time mass prophylactic vaccinations would be given to the affected community. Since we do not know if, when or where a case of smallpox may occur, pre-event vaccinations do not have a deadline or time frame other than that recommended by public health authorities.

In a mass vaccination setting, response time will be critical. The earlier vaccination is provided after exposure, the less likely additional smallpox cases will develop. Therefore, it will be crucial to provide prophylactic vaccination to those at risk in the shortest period of time. Because of this, there may not be enough time to provide the same thorough dressing that may be used during pre-event vaccinations when time is less critical. Whenever possible, it is best to use a full three-layer dressing in order to decrease the risk of viral shedding which may result from the inoculation site.

After the skin is inoculated with smallpox vaccine, the site should be covered with an appropriate dressing. Gloves should be worn when applying the dressing. A 2 X 2 inch gauze pad should be folded into quarters and applied to the inoculation site. The gauze should be covered with a small, occlusive dressing, such as a 6 X 7 cm Tegaderm®. Next, a larger occlusive dressing, such as a 10 X 12 cm Tegaderm®, should be applied. In addition, the wearing of long sleeved shirts further reduces the risk of secondary transmission.

The dressing and inoculation site should be evaluated daily. A new dressing should be applied at least daily or immediately if it becomes soiled, loosened or dislodged. Gloves should always be worn when evaluating the inoculation site and handling dressing

materials. It is best to place your finger on the middle of the dressing when removing the edges in order to stabilize the dressing and prevent it from falling.

All dressing materials are considered to be potentially infectious and should be put into a baggie, sealed and then placed in a biohazard bag for disposal.

If a dressing is accidentally removed and the vaccinee is not at the evaluation clinic site, vaccinees should double-bag the dressing materials using sealed plastic baggies, place a large band-aid or other covering over the inoculation site, and then immediately wash their hands. This should be reported to the evaluation site clinic immediately, and a new full dressing should be applied as soon as possible. The removed double-bagged dressing materials should be disposed of in a red biohazard bag at the site evaluation clinic, not placed in a trash can at home or work.

For the duration of the vaccination period requiring an inoculation site dressing, which is until scab development, patients should avoid swimming. All other activities, including bathing and showering, are allowed and do not generally dislodge the dressing. According to the CDC, if proper follow-up procedures are followed, healthcare workers receiving the vaccine do not need to be furloughed or reassigned to non-patient care areas as the risk of secondary inoculation to others is small when the full three-layer dressing is used. However, facilities may choose to furlough or reassign healthcare workers if the risk of employee compliance with infection control and inoculation site management is questionable.

Due to the critical time frame implicit during mass prophylaxis, use of a full three-layer dressing may not be feasible due to the time needed to apply such a dressing. At the very least, gauze should be placed over the inoculation site and should then be covered with tape. If possible, it is best to use an occlusive dressing, such as Tegaderm® rather than tape because it provides a better barrier and does not become dislodged as easily. Viral shedding studies, however, have not been performed on tape and gauze dressings.

During post-event mass vaccinations, daily site visits will most likely not be performed due to staffing and time limitations. If feasible, dressing materials will be sent home with vaccinees or they may be purchased at drug or discount stores.

When dressings become soiled, loosened or dislodged in a mass vaccination situation, vaccinees may dispose of the dressing materials at home rather than returning to the vaccination clinic. Dressing materials should be double-bagged and sealed before being placed in a trashcan. Vaccinees should wash their hands immediately after the handling and disposal of dressing materials. A new dressing should be applied as soon as possible to reduce the risk of vaccinia transmission.