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**CDC Interim Protocol for Investigating and Reporting Blood and/or
Vaccinia Virus Exposures During Smallpox Vaccination**

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CDC Protocol for Investigating and Reporting Blood and/or Vaccinia Virus Exposures During Smallpox Vaccination

There exists a risk of blood or vaccinia virus exposure to vaccinators when administering vaccinia vaccine. Therefore, CDC has established a voluntary sentinel event reporting system for blood and/or vaccinia virus exposure to vaccinators, including injuries with bifurcated needles, during smallpox vaccination.

Reporting and Investigation Protocol

1. State and county health departments and other entities that provide smallpox vaccinations should institute (or update existing) exposure control plans (ECP) consistent with the Bloodborne Pathogens Standard of the Occupational Safety and Health Administration (OSHA) (1). If the institution providing vaccinations is required to maintain OSHA illness and injury records under 29 CFR 1904, then the ECP should include establishment of a sharps injury log. The Smallpox Vaccination Clinic Blood and Body Fluid Exposure Report Form (Attachment A) may be used for this purpose or to supplement an existing sharps injury log.
2. If a vaccinator or other employee sustains a blood or vaccinia virus exposure during smallpox vaccination, the following steps should be taken:
 - The exposed vaccinator should report the exposure to the appropriate authority designated by the employer.
 - Management of the exposure should follow current CDC recommendations for immediate and follow-up treatment (2).
 - A designated authority (e.g., supervisor) should complete exposure report (Attachment A). Relevant information should be added to the sharps injury log unless the institution is exempt from OSHA record keeping under 29 CFR 1904.
 - The designated authority should perform a root cause analysis (Attachment B) to identify factors contributing to the injury/exposure and preventive measures that should be implemented to avoid a similar occurrence in the future. Both the exposed vaccinator and the supervisor should have input into this analysis.
 - Copies of the exposure report (Attachment A) and the root cause analysis (Attachment B) should be delivered expeditiously to the individual designated by the employer to receive information on exposure incidents.
 - Within 48 hours of the exposure event, a copy of the completed exposure report (Attachment A), root cause analysis (Attachment B) and cover sheet with contact information (Attachment C) should be faxed to:

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Smallpox Vaccination Sentinel Event Exposure Reporting System
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
FAX: 404-498-1244

The exposed employee's name and that of other individuals included on the blood exposure form and root cause analysis form must be obscured/blacked out before they are transmitted to CDC. Questions about how to fill out these forms or how to manage the exposure may be addressed to DHQP staff at:
800-893-0485 or 404-498-1250.

3. CDC will summarize and communicate information gathered through the Smallpox Vaccination Sentinel Event Exposure Reporting System electronically such as through the Health Alert Network or EPI-X. The purpose of these communications will be to alert all sites to preventive measures that can be taken to avoid future blood and body fluid exposures.

References.

1. Occupational Safety and Health Administration, Department of Labor. 29 CFR Part 1910.1030, Occupational exposure to bloodborne pathogens; final rule. Federal Register 2001;66:5325.
2. CDC. Updated Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Postexposure Prophylaxis. Morbid Mortal Wkly Rep 2001;50 (RR-11).

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Attachment A

Smallpox Vaccination Clinic Blood and Body Fluid Exposure Report Form

The purpose of this form is to document blood or vaccinia virus exposure events during smallpox vaccination. If the clinic is required to report occupational injury and illness by the Occupational Safety and Health Administration's Recordkeeping standard (29CFR 1904) then the clinic must maintain a Sharps Injury Log .

This form has been specifically designed to meet the dual purposes of keeping a OSHA sharps injury log and reporting exposures to the CDC Smallpox Vaccination Sentinel Event Exposure Reporting System.

The vaccination clinic supervisor together with the exposed vaccinator or other employee should provide the information requested on this form. Completion of the form should not take precedence over seeking appropriate postexposure care. Once completed, the form, with the exposed individual's name obscured/blacked out, should be faxed to the CDC in accordance with the reporting protocol (404-498-1244). For questions about completing this form, call CDC at 800-893-0485 or 404-498-1240.

Exposure Event Number _____
(Assigned for and by CDC)

Smallpox Vaccination Clinic Blood and/or Vaccinia Virus Exposure Report Form

Clinic ID: _____

Name of exposed worker: Last _____ First : _____ ID #: _____

Date of exposure: _____ / _____ / _____ Time of exposure: _____ : _____ AM PM (Circle)

Location in clinic where exposure occurred: _____

Name of person completing form: _____

A. Type of Exposure *(Check all that apply.)*

Percutaneous (Used Bifurcated Needle)

Mucocutaneous: ___ Mucous Membrane ___ Skin

___ Substance involved in exposure ___ Blood ___ Vaccinia virus (vaccine)

B. Exposure Information

1. Body site of exposure. *(Check all that apply.)*

Hand/finger

Eye

Mouth/nose

Face

Arm

Leg

Other (Describe: _____)

2. If percutaneous exposure:

Depth of injury *(Check only one.)*

Superficial (e.g., scratch, no or little blood)

Moderate (e.g., penetrated through skin, wound bled)

Deep (e.g., intramuscular penetration)

Unsure/Unknown

Was blood visible on device before exposure?

Yes

No

Unsure/Unknown

3. If mucous membrane or skin exposure: *(Check only one.)*

Approximate volume of material

Small (e.g., few drops)

Large (e.g., major blood splash)

If skin exposure, was skin intact?

Yes

No

Unsure/Unknown

C. Employee Narrative

Describe how the exposure occurred and, in the employee's opinion how it might have been prevented:

D. Bifurcated Needle Injury Circumstances

When and how did the injury occur? (From the left hand side of page, select the point during or after use that most closely represents when the injury occurred. In the corresponding right hand box, select one or two circumstances that reflect how the injury happened.)

During vaccination

Select one or two choices:

- Patient moved and jarred device
- While puncturing skin during vaccination
- Collided with co-worker or other during procedure
- Sharp object dropped during procedure
- Other circumstance during use

After vaccination, before disposal

Select one or two choices:

- During clean-up
- In transit to disposal
- Collided with co-worker or other person
- Sharp object dropped after procedure

During or after disposal

Select one or two choices:

- Placing sharp in container:
 - Injured by sharp being disposed
 - Injured by sharp already in container
- While manipulating container
- Over-filled sharps container
- Punctured sharps container
- Sharp protruding from open container
- Sharp in unusual location:
 - In trash
 - Left on table/tray
 - On floor
 - Other unusual location
- Collided with co-worker or other person
- Sharp object dropped

Other (Describe): _____

E. Bifurcated Needle Information

Brand _____

Manufacturer _____

Did the bifurcated needle have a sharps injury prevention feature, i.e., a "safety device"?

No (Go to F)

Yes (Answer the following questions)

If yes, when did the injury occur?

Before activation of safety feature was appropriate

Safety feature failed after activation

During activation of the safety feature

Safety feature not activated

Safety feature improperly activated

Other: _____

Describe what happened with the safety feature, e.g., why it failed or why it was not activated: _____

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F. Employer/Supervisor Narrative

Describe what occurred and how, from the employer/supervisor's perspective, what could have been done to prevent this event. If another person witnessed this event, include his/her perspective.

Attachment B

Smallpox Vaccination Clinic Form for Performing a Root Cause Analysis of a Blood and/or Vaccinia Virus Exposure

This form was developed to assist vaccination clinics determine the factors that may have contributed to a blood and/or vaccinia virus exposure event. **Root cause analysis** (RCA) is a process for identifying the basic or causal factors that underlie variations in expected performance. This process is being used widely in healthcare to identify factors that lead to adverse patient outcomes or are associated with a “sentinel event” (e.g., medication errors, laboratory errors, falls). Because exposures in smallpox vaccination clinics are expected to be rare, they have been designated a sentinel event.

The key to the RCA process is asking the question “why?” as many times as it takes to get down to the “root” cause(s) of an event.

- What happened?
- How did it happen?
- Why did it happen?
- What can be done to prevent it from happening in the future?

Use of this form and the trigger questions provided will help determine whether and how one or more of the following was a contributing factor: assessment of the vaccinee, vaccinator training or competency, equipment (e.g., bifurcated needle), lack of or misinterpretation of information, communication, availability and use of specific policies or procedures, and/ or vaccinator issues.

The vaccination clinic supervisor or a designee should complete this form. The exposed vaccinator and any witnesses to the event should provide relevant information that will assist in identifying the root cause. Once the root cause determination has been made and an action plan created, the form should be faxed to the CDC Smallpox Vaccination Sentinel Event Reporting System for Blood and/or Vaccinia Virus Exposures to Vaccinators as specified in the reporting protocol (404-498-1244). All individual identifiers should be deleted or blacked out before faxing to CDC. The vaccination clinic supervisor should retain the form for recording the outcome of improvement measures.

Questions regarding completion of this form should be directed to CDC personnel at

800-893-0485 or 404-498-1240

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Exposure Event Number _____
(Assigned for and by CDC)

**Smallpox Vaccination Clinic
Form for Performing a Root Cause Analysis of a Blood or Vaccinia Virus Exposure Event**

Event: Date ___/___/___ Time ___ AM ___ PM Location in Clinic Where Exposure Occurred: _____ Person completing this form: _____ Details of how the event occurred: _____				
Contributing Factors (See list of trigger questions)	If "YES", what contributed to this factor being an issue?		Is this a root cause of the event?	If YES, is an action plan indicated?
	YES	NO		
1. Issues related to vaccinee assessment?	YES	NO	YES NO	YES NO
2. Issues related to staff training or staff competency?	YES	NO	YES NO	YES NO
3. Bifurcated needle or gloves?	YES	NO	YES NO	YES NO

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4. Work environment?	YES NO		YES NO	YES NO
5. Lack of or misinterpretation of information?	YES NO		YES NO	YES NO
6. Communication?	YES NO		YES NO	YES NO
7. Appropriate policies/ procedures or lack thereof?	YES NO		YES NO	YES NO
8. Worker issues?	YES NO		YES NO	YES NO

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Root Cause Analysis Action Plan

Risk Reduction Strategies	Measure(s) of Effectiveness	Responsible Person(s)
Action item #1		
Action item #2		

**Trigger Questions for Performing a Root Cause Analysis
of a Blood or Vaccinia Virus Exposure**

1. Issues related to vaccinee assessment
 - Was the vaccinee agitated before the procedure?
 - Was the vaccinee cooperative before the procedure?
 - Did the vaccinee contribute in any way toward the event?
2. Issues related to staff training or staff competency
 - Did the vaccinator receive training on proper vaccination technique?
 - Was the vaccinator's technique observed during the training?
 - Are there training or competency factors that contributed to this event?
 - Approximately how many vaccinations had this individual administered on the day of the injury?
3. Bifurcated needle or gloves
 - Did the bifurcated needle contribute in any way to this event?
 - Was a "safety" bifurcated needle used?
 - If not, is it likely that a safety bifurcated needle could have prevented this event?
 - Were gloves a factor in this event?
4. Work environment
 - Did the location, fullness or lack of a sharps container contribute?
 - Did the organization of the work environment (e.g., placement of supplies, position of vaccinee) influence the risk of injury?
- Was there sufficient lighting?
- Was crowding a factor?
- Was there a sense of urgency to complete the vaccination?
- Was there a back-log of people waiting?
5. Lack of or misinterpretation of information
 - Did the vaccinator misinterpret any information about the procedure that could have contributed to the event?
6. Communication
 - Were there any communication barriers that contributed to this event (e.g., language)
 - Was communication in any way a contributing factor in this event?
7. Appropriate policies/procedures
 - Are there existing policies or procedures that describe how this event should be prevented?
 - Were the appropriate policies or procedures followed?
 - If they were not followed, why not?
8. Worker issues
 - Did being right or left handed influence the risk?
 - On the day of the exposure, how long had the worker been working before the exposure occurred?
 - At the time of the exposure, could factors such as worker fatigue, hunger, illness, etc. have contributed?

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Attachment C

FACSIMILE TRANSMISSION

DATE: _____ **TIME:** _____

FROM: _____

TO: **Smallpox Vaccination Sentinel Event Reporting System ***
 Division of Healthcare Quality Promotion
 Centers for Disease Control and Prevention

PHONE: **404-498-1240**

FAX: **404-498-1244**

FOLLOW-UP CONTACT INFORMATION:

NAME: _____

TITLE: _____

PHONE: _____

E-MAIL: _____

COMMENTS:

*To protect confidentiality, delete or black out any information that could identify an exposed vaccinator or other individual.