New York City Department of Health and Mental Hygiene
Smallpox Vaccination Adverse Events Reporting Form

IMM-60 (2/03)

Affix PVN sticker or note PVN here if known:
PVN: _____

PATIENT INFORMATION

LAST NAME: | FIRST NAME: | MIDDLE NAME: | SUFFIX:

SSN: ☐☐☐-☐☐-☐☐☐☐ | GENDER: ☐ MALE ☐ FEMALE | DATE OF BIRTH: ____/____/____ (MM DD YYYY)

HOME ADDRESS: *STREET NUMBER* *STREET* *APARTMENT NUMBER*

CITY | STATE | ZIP | HOME PHONE: ( ) - | CELL/PAGER ( ) -

Is the patient a *(check one):* ☐ Smallpox vaccine recipient ☐ Household or close contact of smallpox vaccine recipient ☐ Other non- vaccine recipient

If patient is a recent smallpox vaccine recipient, date of vaccination ____/____/200___ (MM DD YYYY) Name of hospital or agency where patient was vaccinated: _____

Was patient vaccinated again since the date listed above? ☐ Yes ☐ No Date of revaccination ____/____/200___ (MM DD YYYY)

Name of hospital or agency where patient was revaccinated: _____

REPORTING INFORMATION

REPORTER LAST NAME: | FIRST NAME: | TITLE MD RN OTHER:

NAME OF FACILITY | DATE FORM COMPLETED ____/____/____ (MM DD YYYY)

ADDRESS: *STREET NUMBER* *STREET* | CITY | STATE | ZIP

PHONE NUMBER: ( ) - | CELL/PAGER ( ) - | E-MAIL ADDRESS

Are you seeing patient for a routine vaccination site check as part of the smallpox vaccination program? ☐ Yes ☐ No

ADVERSE REACTION

DATE OF ADVERSE EVENT ONSET: ____/____/____ (MM DD YYYY)

COMPLETE EITHER SECTION A (Severe or moderate) or SECTION B (mild).
Please refer to "Guidance on Reporting Adverse Events following Smallpox Vaccination" on back or attached.

SECTION A: Severe or Moderate Reactions *(Check all that apply)*

- ☐ Bacterial superinfection
- ☐ Eczema Vaccinatum
- ☐ Fetal Vaccinia or Spontaneous Abortion
- ☐ Generalized Vaccinia
- ☐ Inadvertent inoculation (Accidental implantation):
  ○ Vaccine recipient ○ Contact
- ☐ Ocular Vaccinia (including Vaccinia Keratitis)
- ☐ Post-vaccinial encephalitis
- ☐ Progressive Vaccinia (Vaccinia Necrosum)
- ☐ Severe allergic reaction (Anaphylaxis)
- ☐ Stevens-Johnson Syndrome or Erythema Multiforme
- ☐ Other *(Specify):* _____
- ☐ Suspected vaccinia in a non-vaccine recipient *(Describe):* _____

SECTION B: Mild Reactions *(Check all that apply)*

- ☐ Itching at injection site (○ Mild ○ Moderate ○ Severe)
- ☐ Lymphadenopathy *(measure diameter* _____ cm)
- ☐ Pain at injection site (○ Mild ○ Moderate ○ Severe)
- ☐ Rash (non-Urticaria)
- ☐ Robust local reaction (erythema _____ cm, induration _____ cm)
- ☐ Satellite lesions
- ☐ Urticaria (hives) (○ Mild ○ Moderate ○ Severe)
- ☐ Fever >101.0° F (38.3° C)
- ☐ Other systemic symptoms *(Check all that apply)*
  ○ Myalgia ○ Headache ○ Chills ○ Fatigue ○ Nausea

OUTCOME *(CHECK ALL THAT APPLY)*

- ☐ Patient has life threatening illness
- ☐ Patient sought care in Emergency Room or at MD office *(Facility Name):* _____ Date of visit: ____/____/____ (MM DD YYYY)
- ☐ Patient was hospitalized *(Hospital Name):* _____ MR Number _____ Admit Date ____/____/____
- ☐ Patient recovered Discharge Date ____/____/____
- ☐ Patient died *(Date):* ____/____/____ (MM DD YYYY)

FOR NYC DOHMH USE ONLY: *(Check one)*

- ☐ Referred to DOHMH MD for immediate consultation *(Name of MD):* _____
- ☐ Referred to MD/RN/Epi for follow-up *(Name of MD/RN/Epi):* _____
- ☐ Information given, no follow-up needed.
- ☐ Other *(Specify):* _____

DOHMH Staff completing form *(First name/Last Name):* _____

LAST DOHMH FOLLOW-UP: ____/____/____ (MM DD YYYY)

☐ CASE CLOSED

TO REPORT, PLEASE FAX FORM TO NYC DOHMH AT 1-212-227-3842 OR 1-212-227-3843.

For any condition listed in Section A (Severe or Moderate reactions), call 1-866-NYC-DOH1. For any life-threatening illness, call 1-866-NYC-DOH1 immediately for assistance with patient management and acquisition of VIG or cidofovir.

For more information about smallpox and to download the NYC DOHMH Smallpox Vaccination Adverse Events Reporting Form, visit www.nyc.gov/health/smallpox

Guidance on Reporting Adverse Events following Smallpox Vaccination

Progressive Vaccinia

Clinical: Rapid, progressive, and painless enlargement of primary vaccination site OR progression without apparent healing after 15 days. Usually occurs in persons with impaired immune function (especially T-cell deficiency). Ulcerative or vesiculopustular lesion with central necrosis; expands circumferentially. Minimal or absent local inflammation. Systemic signs initially absent. Metastatic lesions may appear at other sites of the body, usually at later stages, and also exhibit progressive necrosis. *Laboratory*: Skin specimens for culture and PCR/DFA for vaccinia. Evaluation of immune status by immunoglobulin and T cell work-up. *Treatment/referral*: Prompt hospitalization and immediate consultation with CDC via NYC DOHMH to determine if Vaccinia Immune Globulin (VIG) or antiviral medications (cidofovir second line agent) are indicated. Surgical debridement used in past with variable success. **Lesions may contain vaccinia virus—use infection control precautions.**

Eczema Vaccinatum

Clinical: Person with a history of eczema or atopic dermatitis presenting with localized or generalized papular, vesicular, or pustular rash with onset concurrent with or shortly after vaccinial lesion at vaccination site. In contacts, onset ~5-19 days following suspected exposure. Lesions have predilection for site of atopic dermatitis eruptions and follow the same course as the vaccination site. Severity independent of the activity of the underlying eczema. Untreated patients may develop systemic symptoms that can be severe leading to septic shock and possibly death. *Laboratory*: Skin specimens for culture and PCR/DFA for vaccinia. *Treatment/referral*: Most patients require hospitalization and urgent treatment with VIG (mortality has been prevented in persons treated promptly and adequately). Consultation with CDC via NYC DOHMH. **Lesions may contain vaccinia virus—use infection control precautions.**

Postvaccinial Encephalitis

Clinical: Initial symptoms: headache, vomiting, drowsiness, fever. Severe cases: paralysis, incontinence, urinary retention, convulsions. Symptom onset 10-14 days post-vaccination. Death may occur suddenly, usually within one week of symptom onset. *Laboratory*: CSF: normal or nonspecific (increased mononuclear cells, slightly increased protein and glucose). Rule-out other infectious or toxic causes. Use of imaging studies has not been evaluated. *Treatment/referral*: Hospitalization. No specific therapy available. Supportive care, anticonvulsants. VIG is ***not*** effective and not recommended.

Generalized Vaccinia

Clinical: Vesicles or pustules appearing on normal skin distant from the vaccination site (usually trunk and abdomen) resulting from viremia. Lesions can be few or numerous and occur 6-9 days following vaccination. Rarely, lesions may recur at 4-6 week intervals for up to a year. Often accompanied by fever, headache, and myalgias. Illness is typically minor in healthy host but may be severe in immunocompromised persons. *Laboratory*: virologic diagnosis is seldom needed. *Treatment/referral*: Rash is generally self-limited in immunocompetent persons with no underlying illnesses and requires no treatment. VIG is indicated for patients with severe or recurrent disease or immune deficiency—consult CDC via NYC DOHMH. **Lesions may contain vaccinia virus–use infection control precautions.**

Inadvertent Inoculation (Accidental Implantation)

Clinical: Transfer of vaccinia virus from vaccination site to another site on the body, or to a close contact. Most common sites are periocular/ocular, face, nose, mouth, genitalia, rectum. Lesions contain vaccinia virus and follow same course as the primary vaccination lesion. Risk factors: disruption of epidermis or very young age. *Laboratory*: If in a vaccinee or close contact, diagnosis by clinical presentation and history. If in person without history of contact with vaccinee, then skin biopsy specimens for culture and PCR/DFA for vaccinia. *Treatment/referral:* If there are only one or a few lesions, no specific treatment is required. Multiple lesions, especially if widespread or confluent, or significant pain warrant treatment with VIG—consult CDC. **Lesions may contain vaccinia virus—use infection control precautions.**

Ocular Vaccinia including Keratitis, Blepharitis and Conjunctivitis

Clinical: Inadvertent periocular or ocular implantation with vaccinia virus. Clinical signs of keratitis include central, grayish, disciform corneal lesion. *Laboratory:* none specified. *Treatment/referral*: Immediate consultation with an ophthalmologist, slit-lamp exam needed. Topical antiviral agents are the treatment of choice for keratitis. VIG may be of value, except in isolated keratitis due to increased risk of scarring and corneal clouding.

Fetal Vaccinia or Spontaneous Abortion

Clinical: Vaccinial infection of fetus. Can occur in all trimesters, but greatest risk in third trimester. Outcomes: premature birth, fetal loss, high mortality. Death usually before birth or in perinatal period. No known pattern of congenital malformations. *Laboratory:* No known reliable intrauterine test. *Treatment/referral:* VIG may be considered if infant born alive with lesions. Consult with CDC via NYC DOHMH. Antivirals not recommended.

Severe Allergic Reaction (Anaphylaxis)

Clinical: Acute mucocutaneous signs (pruritis, flushing, urticaria, angioedema) occurring almost immediately following vaccination. Additional symptoms: respiratory obstructive symptoms or bronchospasm; hypotension, syncope, orthostatic hypotension; gastrointestinal symptoms: nausea, vomiting, diarrhea or cramps. *Laboratory:* Diagnosis based on clinical presentation. *Treatment/referral:* Airway management, epinephrine, supportive care.

Other Dermatologic Conditions

ERYTHEMA MULTIFORME/STEVENS-JOHNSON SYNDROME

Clinical: Hypersensitivity reaction with skin lesions including macules, papules, urticaria, and typical bulls-eye (targetoid) lesions (central, dark papule, surrounded by pale zone and a halo of erythema) occurring ~10 days after vaccination. Rarely, desquamating Stevens-Johnson Syndrome occurs with involvement of >10% of body surface area and more than two mucosal surfaces. Constitutional symptoms may occur and can be severe. *Laboratory*: Lesions are not thought to contain virus. *Treatment/referral*: Symptomatic care (e.g. antihistamines). Hospitalization and supportive care for Stevens-Johnson may be needed depending on degree of body surface and mucosal involvement. VIG not indicated. Role of steroids controversial—consult immunologist, dermatologist, or ID.

BACTERIAL SUPERINFECTION

Clinical: Usually caused by *Staph. aureus* or *Strep. pyogenes*, occasionally anaerobes or mixed infections. *S. aureus*: vesiculopustular lesion at the site of vaccination often spreading peripherally in circumferential fashion, with clearing behind the advancing border. *S. pyogenes*: piled up eschar, heaping at the vaccination site. Bacterial lymphangitis and regional lymphadenitis may occur. *Laboratory*: swab purulent lesions for bacterial culture; aspirate vesicular or pustular lesions for culture. If sepsis symptoms present, send blood culture. *Treatment*: Appropriate antibiotic therapy. **Lesions may contain vaccinia virus—use infection control precautions.**

Laboratory testing: consider use of licensed diagnostic tests to rule out etiologies not related to vaccinia virus contained in smallpox vaccine. For more detailed information, please refer to the CDC website:www.bt.cdc.gov/training/smallpoxvaccine/reactions/adverse.html