




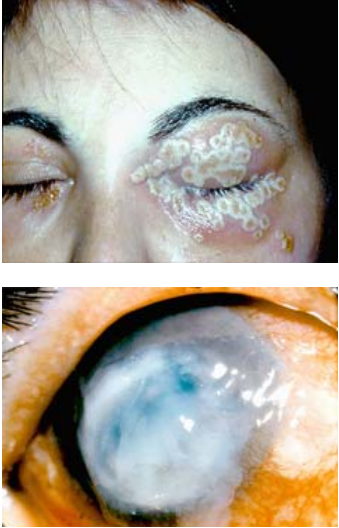




NYC DOHMH CLINICAL GUIDELINES ON RECOGNITION, EVALUATION AND TREATMENT OF MODERATE OR SEVERE ADVERSE REACTIONS FOLLOWING SMALLPOX VACCINATION

ALL MODERATE OR SEVERE ADVERSE REACTIONS SHOULD BE REPORTED TO THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE IMMEDIATELY!
(SEE PAGE 3 FOR REPORTING INSTRUCTIONS)

DISEASE	EXPECTED INCIDENCE†	CLINICAL SIGNS & SYMPTOMS	DIAGNOSIS	TREATMENT/REFERRAL
<p>INADVERTENT INOCULATION (ACCIDENTAL IMPLANTATION)</p> 	<p>Primary Vaccinee: 27-532 per million</p> <p>Re-Vaccinee: ~40 per million</p>	<p>Physical transfer of vaccinia virus from a vaccination site to one or more secondary sites on the vaccinee or to a close contact of a vaccinee.</p> <p>Most common sites</p> <ul style="list-style-type: none"> • Face, eyelids, nose, mouth, lips, genitalia and anus. <p>Usually self-limited with resolution in 3 weeks.</p>	<p>If occurs in vaccinee or close contact of vaccinee, the diagnosis is based on clinical history and presentation.</p> <p>If occurs in unvaccinated individual, skin specimens[‡] should be obtained for:</p> <ul style="list-style-type: none"> • Viral culture. • PCR/DFA for vaccinia. 	<ul style="list-style-type: none"> • Infection control – standard and contact precautions. <p>Single or few uncomplicated lesions:</p> <ul style="list-style-type: none"> • No specific treatment required. <p>Extensive lesions or if eye affected:</p> <ul style="list-style-type: none"> • Immediate consultation with DOHMH and CDC to determine if VIG* or antiviral meds indicated.
<p>GENERALIZED VACCINIA</p> 	<p>Primary Vaccinee: 18-223 per million</p> <p>Re-Vaccinee: ~10 per million</p>	<ul style="list-style-type: none"> • Disseminated maculopapular or vesicular lesions (usually trunk and abdomen). • Non-toxic, +/- fever. • More severe disease occurs in persons with known immunodeficiency. • Lesions occur 6-9 days following vaccination. 	<p>Diagnosis based on clinical presentation and history.</p>	<ul style="list-style-type: none"> • Infection control – standard and contact precautions. • Anti-inflammatory, anti-pruritic meds, as needed. <p>If few lesions:</p> <ul style="list-style-type: none"> • No specific treatment required. <p>If lesions extensive, recurrent disease, or person with immune deficiency:</p> <ul style="list-style-type: none"> • Immediate consultation with DOHMH and CDC to determine if VIG* or antiviral meds are indicated.
<p>STEVENS-JOHNSON SYNDROME (SJS)</p>  <p>ERYTHEMA MULTIFORME (No Image)</p>	<p>Primary Vaccinee: ~131/million</p>	<p>Hypersensitivity reaction with range in severity of skin lesions occurring 1-2 weeks post-vaccination:</p> <ul style="list-style-type: none"> • Stevens-Johnson Syndrome: In more severe cases, desquamating SJS (rare) with full body involvement, conjunctival/ corneal inflammation, and mucous membrane involvement; vaccinee may have severe constitutional symptoms. • Erythema Multiforme: Erythematous or urticarial macules or papules, bull's eye lesions; vaccinee usually afebrile with resolution within 2-4 days. 	<p>Diagnosis based on clinical presentation and history.</p>	<ul style="list-style-type: none"> • Symptomatic care (e.g. antihistamines, antipruritics). • Hospitalization and supportive care for SJS depending on severity. • Steroid use for SJS is controversial. • VIG not indicated.

DISEASE	EXPECTED INCIDENCE†	CLINICAL SIGNS & SYMPTOMS	DIAGNOSIS	TREATMENT/REFERRAL
<p>POST-VACCINIAL ENCEPHALITIS OR ENCEPHALOMYELITIS</p>	<p>Primary Vaccinee: 2-9 per million</p> <p>Re-Vaccinee: ~2 per million</p>	<p>Range of neurological symptoms:</p> <ul style="list-style-type: none"> Fever, headache, malaise, lethargy, vomiting, meningeal signs, seizures, paralysis, drowsiness, altered mental status, coma. Acute onset 6-15 days after vaccination. 	<ul style="list-style-type: none"> Diagnosis of exclusion. CSF: normal or non-specific; monocytosis, lymphocytosis, or elevated protein. 	<ul style="list-style-type: none"> Intensive supportive care. No specific therapy available. Anticonvulsants as needed. <p>VIG and anti-virals are <u>not</u> effective and not recommended.</p>
<p>PROGRESSIVE VACCINIA (VACCINIA NECROSUM, VACCINIA GANGRENOsum)</p> 	<p>Primary Vaccinee: ~1-1.5 per million</p> <p>Re-Vaccinee: ~2-3 per million</p>	<ul style="list-style-type: none"> Non-healing vaccination site with painless, progressive (central) necrosis at the vaccination site. Progression of ulcer with minimal inflammation after 15 days should suggest progressive vaccinia. Metastatic lesions occasionally in skin, bones, viscera. No inflammation initially but can occur several weeks later. Usually seen in individuals with T-cell deficiency. 	<p>Obtain skin specimens‡:</p> <ul style="list-style-type: none"> Viral culture. PCR/DFA for vaccinia. 	<ul style="list-style-type: none"> Prompt hospitalization. Infection control – standard and contact precautions. Surgical debridement of progressive necrotic lesions not proven useful. Immediate consultation with DOHMH and CDC to determine if VIG* or antiviral medications are indicated.
<p>ECZEMA VACCINATUM</p> 	<p>Primary Vaccinee: 11-42 per million</p> <p>Re-Vaccinee: ~3 per million</p>	<ul style="list-style-type: none"> Extensive vesicular/pustular eruption anywhere OR occurring in sites typically affected by atopic dermatitis (inner elbow folds, back of knees, face). Signs of moderate to severe systemic illness: high fever, generalized lymphadenopathy. Usually seen in individuals with history of eczema or atopic dermatitis. <p>Occurs:</p> <ul style="list-style-type: none"> Concurrent with or shortly after the local vaccinal lesion in a vaccinee. 5-19 days after exposure in a contact. 	<p>Obtain skin lesion specimens‡:</p> <ul style="list-style-type: none"> Viral culture. PCR/DFA for vaccinia. <p>Consider dermatology consultation.</p>	<ul style="list-style-type: none"> Immediate consultation with DOHMH and CDC to determine if VIG* or antiviral medications are indicated. Hospitalization if severe. Infection control – standard and contact precautions. Hemodynamic support Volume and electrolyte repletion. Observe for secondary skin infections.
<p>OCULAR VACCINIA (including VACCINIA KERATITIS)</p> 	<p>Rare, exact incidence not known.</p>	<p>Usually caused by touching vaccination site followed by rubbing of the eye.</p> <ul style="list-style-type: none"> <u>Keratitis</u>: marginal inflammation and/or ulceration with or without stromal haze/infiltration. <u>Conjunctivitis</u>: Hyperemia, edema, membranes, focal lesions, fever, lymphadenopathy. <u>Blepharitis</u>: Lid pustules on or near lid margin, edema, hyperemia, lymphadenopathy, cellulitis, fever. <p>Symptoms occur 7-10 days after implantation of vaccinia virus.</p>	<p>Diagnosis requires ophthalmology consultation.</p>	<ul style="list-style-type: none"> Immediate ophthalmology consultation. Off-label topical antiviral agents may be considered, in consultation with ophthalmologist. Topical prophylactic antibacterial meds for keratitis. Immediate consultation with DOHMH and CDC to determine if VIG* or antiviral medications are indicated. <p>VIG* may be indicated for:</p> <ul style="list-style-type: none"> Severe blepharitis or blepharoconjunctivitis (without keratitis). Keratitis with vision-threatening or life threatening complications. <p>VIG NOT indicated:</p> <ul style="list-style-type: none"> Isolated keratitis

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SEVERE ALLERGIC REACTION (ANAPHYLAXIS)	Incidence not known	Hypotension, tachycardia, nausea, vomiting, collapse in the first hours after smallpox vaccination.	Diagnosis based on clinical presentation and history.	<ul style="list-style-type: none"> Epinephrine. Airway management. Supportive care, as needed.
FETAL VACCINIA	Very rare	<ul style="list-style-type: none"> Generalized vaccinia type rash (vesicular, pustular, or ulcerative) in newborn. Spontaneous abortion in an inadvertently vaccinated pregnant woman. 	Diagnosis based on clinical history of vaccination during pregnancy and typical lesions on infant.	If infant born with lesions, then immediate DOHMH and CDC consultation to determine if VIG* or antiviral medications are indicated.
BACTERIAL SUPERINFECTION	Uncommon	<ul style="list-style-type: none"> <i>S. aureus</i>: vesiculopustular lesion at vaccination site; often spreads circumferentially, clearing behind the advancing border. <i>S. pyogenes</i>: piled up eschar, heaping at vaccination site. Bacterial lymphangitis and regional lymphadenitis may occur. 	<ul style="list-style-type: none"> Gram stain. Bacterial culture. 	<ul style="list-style-type: none"> Appropriate antibiotic therapy, if needed. No topical medications.

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* VIG (Vaccinia Immune Globulin) may be indicated – Call [1-866-NYC-DOH1](tel:1-866-NYC-DOH1) immediately for advice.

† The expected incidence of smallpox vaccine-associated adverse events has been extrapolated from studies of the 1960's (CDC. Smallpox adverse event rates, 1968. Atlanta, GA: US DHHS, 2002; available at <http://www.bt.cdc.gov/agent/smallpox/vaccine-safety/adverse-events-chart.asp>). The frequency of adverse events may be different in today's environment, with changes in the prevalence of risk factors among the US population.

‡ Vaccinia, herpes simplex and varicella viral testing is available at the New York City DOHMH Public Health Laboratory (455 First Avenue). Call [1-866-NYC-DOH1](tel:1-866-NYC-DOH1) for immediate consultation. Additional information on the collection and submission of specimens will be provided at the time of the consultation.

For more detailed information and additional images of clinical presentations, please refer to the CDC website: www.bt.cdc.gov/training/smallpoxvaccine/reactions/adverse.html

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Moderate or severe adverse reactions include:

Bacterial superinfection, eczema vaccinatum, fetal vaccinia (including spontaneous abortion), generalized vaccinia, inadvertent inoculation (accidental implantation) in a vaccine recipient or close contact, ocular vaccinia (including vaccinia keratitis), post-vaccinia encephalitis or encephalomyelitis, progressive vaccinia (vaccinia necrosum), severe allergic reaction (anaphylaxis), Stevens-Johnson syndrome or erythema multiforme, or suspected vaccinia in a non-vaccinee.

Reports should be submitted on a New York City Department of Health and Mental Hygiene Smallpox Vaccination Adverse Events Reporting Form. Reporting forms will be made available at vaccination clinic sites, and can also be downloaded at <http://www.nyc.gov/health/smallpox> or requested by calling **1-866-NYC-DOH1**. Completed forms should be faxed to 212-227-3842 or 212-227-3843.

For any severe or life-threatening illness in a smallpox vaccine recipient or close contact of a vaccine recipient, please call 1-866-NYC-DOH1 immediately for assistance with patient management and possible treatment including Vaccinia Immune Globulin (VIG) or cidofovir.