

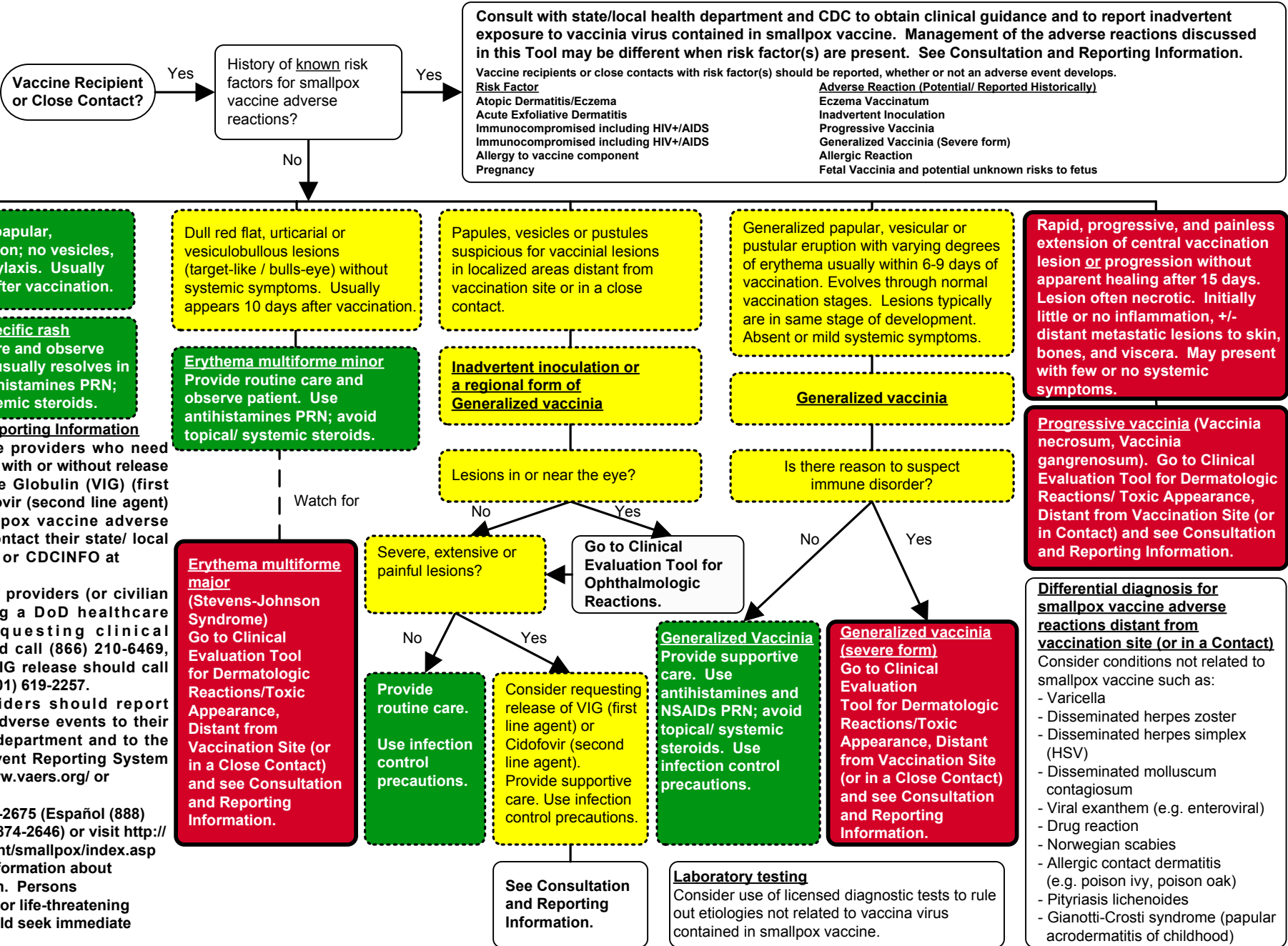
Clinical Evaluation Tool for Smallpox Vaccine Adverse Reactions

Dermatologic Reactions/Nontoxic Appearance, Distant from Vaccination Site (or in a Close Contact)

www.bt.cdc.gov/agent/smallpox/vaccination/clineval (01-19-2011 Version)

Legend
Morbidity and Mortality
Risk based on
clinical preseool 2n.

Low
Moderate
High



Consult with state/local health department and CDC to obtain clinical guidance and to report inadvertent exposure to vaccinia virus contained in smallpox vaccine. Management of the adverse reactions discussed in this Tool may be different when risk factor(s) are present. See Consultation and Reporting Information.

Vaccine recipients or close contacts with risk factor(s) should be reported, whether or not an adverse event develops.

Risk Factor	Adverse Reaction (Potential/ Reported Historically)
Atopic Dermatitis/Eczema	Eczema Vaccinatum
Acute Exfoliative Dermatitis	Inadvertent Inoculation
Immunocompromised including HIV+/AIDS	Progressive Vaccinia
Immunocompromised including HIV+/AIDS	Generalized Vaccinia (Severe form)
Allergy to vaccine component	Allergic Reaction
Pregnancy	Fetal Vaccinia and potential unknown risks to fetus

Urticarial, maculopapular, or acneiform eruption; or acneiform eruption; no vesicles, no signs of anaphylaxis. Usually appears 10 days after vaccination.

Urticaria or nonspecific rash
Provide routine care and observe patient. The rash usually resolves in 2-4 days. Use antihistamines PRN; avoid topical/ systemic steroids.

Consultation and Reporting Information
Civilian health care providers who need clinical consultation with or without release of Vaccinia Immune Globulin (VIG) (first line agent) or Cidofovir (second line agent) for potential smallpox vaccine adverse reactions should contact their state/ local health department or CDCINFO at (800) 232-4636.
Military health care providers (or civilian providers treating a DoD healthcare beneficiary) requesting clinical consultation should call (866) 210-6469, and if requesting VIG release should call (888) USA-RIID or (301) 619-2257.
Health care providers should report smallpox vaccine adverse events to their state/ local health department and to the Vaccine Adverse Event Reporting System (VAERS) at <http://www.vaers.org/> or (800) 822-7967.
Please call (888) 246-2675 (Español (888) 246-2857, TTY (866) 874-2646) or visit <http://www.bt.cdc.gov/agent/smallpox/index.asp> for general public information about smallpox vaccination. Persons experiencing urgent or life-threatening medical events should seek immediate medical assistance.

Dull red flat, urticarial or vesiculobullous lesions (target-like / bulls-eye) without systemic symptoms. Usually appears 10 days after vaccination.

Erythema multiforme minor
Provide routine care and observe patient. Use antihistamines PRN; avoid topical/ systemic steroids.

Erythema multiforme major (Stevens-Johnson Syndrome)
Go to Clinical Evaluation Tool for Dermatologic Reactions/Toxic Appearance, Distant from Vaccination Site (or in a Close Contact) and see Consultation and Reporting Information.

Papules, vesicles or pustules suspicious for vaccinia lesions in localized areas distant from vaccination site or in a close contact.

Inadvertent inoculation or a regional form of Generalized vaccinia

Lesions in or near the eye?

No

Severe, extensive or painful lesions?

No

Provide routine care. Use infection control precautions.

Yes

Consider requesting release of VIG (first line agent) or Cidofovir (second line agent). Provide supportive care. Use infection control precautions.

See Consultation and Reporting Information.

Generalized papular, vesicular or pustular eruption with varying degrees of erythema usually within 6-9 days of vaccination. Evolves through normal vaccination stages. Lesions typically are in same stage of development. Absent or mild systemic symptoms.

Generalized vaccinia

Is there reason to suspect immune disorder?

No

Go to Clinical Evaluation Tool for Ophthalmologic Reactions.

Generalized Vaccinia
Provide supportive care. Use antihistamines and NSAIDs PRN; avoid topical/ systemic steroids. 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.

Rapid, progressive, and painless extension of central vaccination lesion or progression without apparent healing after 15 days. Lesion often necrotic. Initially little or no inflammation, +/- distant metastatic lesions to skin, bones, and viscera. May present with few or no systemic symptoms.

Progressive vaccinia (Vaccinia necrosum, Vaccinia gangrenosum). Go to Clinical Evaluation Tool for Dermatologic Reactions/ Toxic Appearance, Distant from Vaccination Site (or in Contact) and see Consultation and Reporting Information.

Differential diagnosis for smallpox vaccine adverse reactions distant from vaccination site (or in a Contact)
Consider conditions not related to smallpox vaccine such as:
- Varicella
- Disseminated herpes zoster
- Disseminated herpes simplex (HSV)
- Disseminated molluscum contagiosum
- Viral exanthem (e.g. enteroviral)
- Drug reaction
- Norwegian scabies
- Allergic contact dermatitis (e.g. poison ivy, poison oak)
- Pityriasis lichenoides
- Gianotti-Crosti syndrome (papular acrodermatitis of childhood)

Disclaimer The CDC and its partners in the Clinical Immunization Safety Assessment (CISA) network have developed Clinical Evaluation Tools to help health care providers manage patients with potential adverse reactions from smallpox vaccination in the absence of circulating smallpox virus (pre-event setting). These Tools are based on studies conducted before routine US childhood smallpox vaccination was discontinued in 1972 and on expert opinion; they are not entirely evidence-based. The Tools may not apply to all patients with smallpox vaccine adverse reactions and are not intended to substitute for evaluation by a trained clinician. This Tool was last updated on 1-19-11. Please direct feedback on these Tools to spoxtool@cdc.gov.