Legend Morbidity and Mortality Risk based on clinical presentation.

Clinical Evaluation Tool for Smallpox Vaccine Adverse Reactions Dermatologic Reactions/Toxic Appearance, Distant from Vaccination Site (or in a Close Contact)

www.bt.cdc.gov/agent/smallpox/vaccination/clineval (03-12-2003 Version)

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. History of known risk Vaccine recipients or close contacts with risk factor(s) should be reported, whether or not an adverse event develops. Yes Yes Vaccine Recipient Adverse Reaction (Potential/ Reported Historically) Risk Factor factors for smallpox

vaccine adverse reactions?

No

Atopic Dermatitis/Eczema **Acute Exfoliative Dermatitis** Immunocompromised including HIV+/AIDS

Immunocompromised including HIV+/AIDS Allergy to vaccine component

Pregnancy

Eczema Vaccinatum Inadvertent Inoculation Progressive Vaccinia

Generalized Vaccinia (Severe form)

Allergic Reaction

Fetal Vaccinia and potential unknown risks to fetus

Widespread, extensive bullae and erosions with involvement of two or more mucosal surfaces. Systemic symptoms present.

or Close Contact?

Erythema multiforme major (Stevens-Johnson Syndrome)

- NOT recommended VIG (first line agent) or
- Cidofovir (second line agent). Hospitalize and provide
- supportive care. Role of steroids unclear: consult with dermatologist as indicated.

See Consultation and Reporting Information

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 the CDC Clinician Information Line at (877) 554-4625. 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 lifethreatening medical events should seek immediate medical assistance.

Large contiguous patches of skin with vesicles and pustules (may be umbilicated and coalescing) that are suspicious for vaccinial lesions. Predilection for sites typical for eczema/ atopic dermatitis eruptions. Lesions often erupt over intact skin and are usually seen in vaccine recipients or contacts (especially young children) with history of atopic dermatitis/ eczema, irrespective of disease activity or severity. Systemic toxicity with worsening disease may occur.

Eczema vaccinatum

- Request release of VIG (first line agent) or Cidofovir (second line agent).
- Contact state health department for quidance.
- Hospitalize and provide supportive care with attention to hemodynamic support, secondary infections and meticulous skin care (severe cases may require burn unit).
- Use infection control precautions.

Generalized papular, vesicular or pustular eruption with varying degrees of erythema (typical lesion size > 5 mm). Lesions typically appear within 6-9 days of vaccination, evolve through normal vaccination stages and are in the same stage of development. Severe systemic symptoms present.

Generalized vaccinia (severe form)

- Request release of VIG (first line agent) or Cidofovir (second line
- Contact state health department for quidance.
- Hospitalize and provide supportive care.
- Conduct immunologic work-up. Use infection control precautions.

See Consultation and Reporting Information. Rapid, progressive, and painless extension of central vaccination lesion or progression without apparent healing after 15 days. Lesion often necrotic. Initially little to no inflammation, +/- distant metastatic lesions to skin, bones, and viscera.

Progressive vaccinia (Vaccinia necrosum, Vaccinia gangrenosum).

- Request release of VIG (first line agent) or Cidofovir (second line
- Contact state health department for
- Hospitalize and provide supportive care with attention to secondary infections.
- Conduct immunologic work-up. Use infection control precautions.

See Consultation and Reporting Information.

See Consultation and Reporting Information.

Laboratory testing

Consider use of licensed diagnostic tests to rule out etiologies not related to vaccina virus contained in smallpox vaccine.

Differential diagnosis for smallpox vaccine adverse reactions distant from vaccination site (or in a close contact)

Consider conditions not related to smallpox vaccine such as:

- Varicella
- Disseminated herpes zoster
- Disseminated herpes simplex virus (HSV)
- Meningococcemia

- Kawasaki syndrome
- Sweet's syndrome
- (Acute febrile neutrophilic dermatosis)
- Leukocytoclastic vasculitis
- (e.g. Henoch-Schonlein purpura)

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 3-12-03. Please direct feedback on these Tools to spoxtool@cdc.gov.