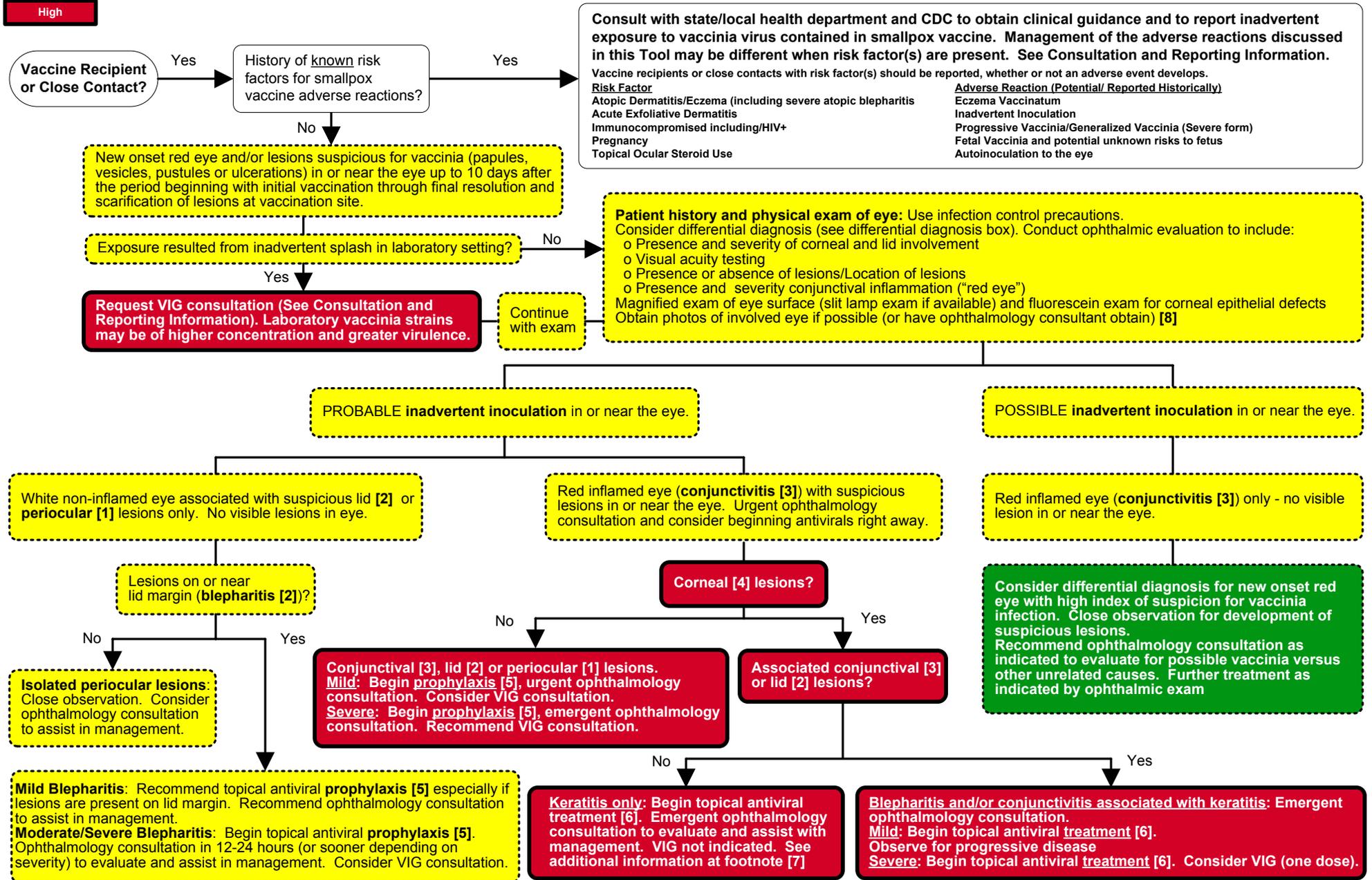


# Clinical Evaluation Tool for Smallpox Vaccine Adverse Reactions

## Ophthalmologic Reactions/Inadvertent Inoculation in a Vaccinee (or in a Close Contact)

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



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**Footnotes:**

- 1. Periocular involvement:** (generally above the brow or below the inferior orbital rim)  
Papules, vesicles or pustules not involving the ocular adnexa, lids, lid margins or canthi.
- 2. Blepharitis:** (lid involvement)  
Mild - few pustules, mild edema, no fever.  
Severe - pustules, edema, hyperemia, lymphadenopathy (preauricular and/or submandibular), cellulitis, fever.
- 3. Conjunctivitis:** (involvement of membrane that lines inner surface of the eyelid and exposed surface of the eyeball; excluding the cornea)  
Mild - mild hyperemia and/or edema, no membranes or focal lesions.  
Severe - marked hyperemia, edema, membranes, focal lesions, lymphadenopathy (preauricular and/or submandibular), fever.
- 4. Keratitis:** (corneal involvement)  
Mild - grey epitheliitis, no epithelial defect, no stromal haze or infiltrate (no cloudy cornea).  
Moderate - epithelial defect.  
Severe - ulcer, stromal haze or infiltrate (cloudy cornea).
- 5. Prophylaxis:** To prevent extension of vaccinia infection to conjunctiva and cornea: Topical trifluridine - 5 times/day (every four hours while awake) for up to 14 days or until all periocular and/or lid lesions have healed and scabs have fallen off. If no improvement or symptoms worsen after 24-48 hours consider increasing to 9 times/day (see footnote [6]). Hyperemia is an expected consequence of therapy, especially after 14 days of use. Recommend ophthalmology consultation to assist in management anytime trifluridine is used.
- 6. Treatment:** To minimize progression and begin resolution of vaccinia infection in cornea and conjunctiva: Topical trifluridine - 9 times/day (every two hours while awake) for up to 14 days or until all lesions have healed. Hyperemia is an expected consequence of therapy, especially after 14 days of use. Recommend ophthalmology consultation to assist in management anytime trifluridine is used.  
**Available topical antiviral agents:** Trifluridine (Viroptic®) and vidarabine (Vira-A®). Trifluridine and vidarabine are not approved by FDA for treatment of vaccinia disease, although the product labels for trifluridine and vidarabine state that the drugs have *in vitro* and *in vivo* activity against vaccinia virus. Vidarabine is no longer being manufactured, but supplies might be available in certain areas.
- 7. Keratitis only:** VIG should not be withheld if a co-morbid condition exists (EV or PV). Consider topical ophthalmic antibacterial prophylaxis in the presence of keratitis. After corneal epithelium has healed consider use of topical steroids (steroids should only be used under supervision of an ophthalmologist).
- 8. Photographs:** Recommend obtaining digital photos of involved eye and periocular region. Consult with ophthalmology as needed for photos (Digital photos preferred but 35mm photos or scanned images are welcome).

**Differential Diagnosis for smallpox vaccine adverse reactions\***

Consider non-smallpox vaccine related conditions, such as:

- Viral conjunctivitis (usually adenovirus)
- Bacterial conjunctivitis
- Allergic conjunctivitis
- Allergic contact dermatitis (e.g. poison ivy, poison oak)
- Contact lens-related infection
- Hordeolum (stye) or chalazion
- Subconjunctival hemorrhage
- Herpes simplex virus (HSV)
- Herpes zoster virus (varicella or shingles)
- Molluscum contagiosum
- Bacterial keratitis
- Preseptal or orbital cellulitis
- Drug reaction
- Insect bite
- Norwegian scabies
- Chemical/toxic exposure

\* List should not be regarded as comprehensive.

This clinical tool is intended to guide primary care clinicians (such as ER physician, internist, pediatrician, family practice, optometrist, physician assistant or nurse practitioner) in preliminary evaluation/treatment. Referral to ophthalmology for suspected cases as indicated is recommended.

**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 life-threatening medical events should seek immediate medical assistance.

**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 childhood US 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](mailto:spoxtool@cdc.gov).