

# Inadvertent inoculation as an adverse event following exposure to vaccinia virus: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data<sup>☆</sup>

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## 1. Preamble

### 1.1. Need for developing case definitions and guidelines for adverse events following exposure to vaccinia virus

Following a declaration by The World Health Assembly in 1980 on the worldwide eradication of smallpox [1], comprehensive smallpox vaccination programs around the world were stopped. Today, >50% of the world's population is potentially unprotected against smallpox disease

<sup>☆</sup> *Disclaimer:* The findings, opinions and assertions contained in this consensus document are those of the individual scientific professional members of the working group. They do not necessarily represent the official positions of each participant's organization (e.g., government, university, or corporation). Specifically, the findings and conclusions in this paper are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention or the Food and Drug Administration.

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<sup>1</sup> Homepage of the Brighton Collaboration: <http://www.brightoncollaboration.org>.

[2]. Recent warnings about the possible threat of using smallpox virus as a biologic weapon [3,4] prompted a resurgence of public health vaccination programs against smallpox.

In this context, and in the broader context of a need for data comparability, as discussed in the overview paper in this volume, establishing criteria for assessing adverse events following smallpox (vaccinia) vaccination is important for clinicians administering the smallpox vaccine and appropriately treating patients with adverse events following immunization (AEFI), and also for scientists collecting, analyzing, and communicating data on AEFI. Understanding the normal changes and progression of a successful vaccination site is crucial for early recognition of complications. Based on two double-blind studies [5,6], using different dilutions of smallpox vaccine in previously unimmunized adults, Frey et al. [6] noted the following descriptions about the vaccination sites (p. 1266):

“Success was defined by the presence of a primary vesicle at the inoculation site seven to nine days after scarification.

Other signs and symptoms of the replication of vaccinia virus include edema, tenderness, and erythema at the site of vaccination and regional lymphadenopathy. Subsequently, the vesicle evolves into a small ulcer over which a scab forms [2nd week post vaccination], ultimately leaving a small scar [3rd week post vaccination].”

Successful vaccination correlates with the laboratory demonstration of the development of a cytotoxic T-cell response, lymphocyte proliferation, neutralizing antibodies, and vaccinia virus-specific interferon- $\gamma$  production. This combination of clinical and laboratory response to smallpox vaccination provides long-term, and perhaps life-long immunity [7].

This paper lists, in Sections 2 and 3, respectively, the case definition and guidelines for data collection, analysis, and presentation that the Brighton Collaboration *Vaccinia Virus Vaccine Adverse Events Working Group* has developed for the standardized collection and assessment of inadvertent inoculation following exposure to vaccinia virus, with applicability in study settings with different availability of resources and access to health care. Widespread use of this definition with its guidelines will enable data comparability and lead to a better understanding of the adverse event.

### *1.2. Methods for the development of the case definition and guidelines for inadvertent inoculation following exposure to vaccinia virus*

Following the process described in the overview paper in this volume [8], a Brighton Collaboration *Vaccinia Virus Adverse Events Working Group* was formed in January 2003 with 32 members. Members volunteered for at least one of five different subgroups, each addressing adverse event following exposure to vaccinia virus. The inadvertent inoculation subgroup included nine members with a clinical or public health background. The member composition and results of the web-based survey completed by the reference group (discussed in the overview paper in this volume) with subsequent discussions in the working group can be viewed at: [http://www.brightoncollaboration.org/internet/en/index/working\\_groups.html](http://www.brightoncollaboration.org/internet/en/index/working_groups.html).

To guide decision-making for the case definition and guidelines, a literature search was performed by the coordinators of the five subgroups, with substantial input from the respective team leads for adverse events following smallpox vaccination, using as search terms eczema vaccinatum, generalized vaccinia, inadvertent inoculation, progressive vaccinia, and robust take within Medline and PubMed databases from 1966 to 2002. The search resulted in the identification of >300 references including review articles and articles focusing on at least one of the selected AEFI. Multiple general medical, pediatric and infectious disease text books were also searched as were case definitions from the Centers for Disease Control and Prevention (CDC) (<http://www.bt>

[cdc.gov/agent/smallpox/vaccination/clinicians.asp#ae](http://cdc.gov/agent/smallpox/vaccination/clinicians.asp#ae)) [9], the Advisory Committee on Immunization Practices [10], and reviews [11,12] and references employed to develop these working definitions. References predating 1966 identified by working group participants were also included. A decision was made to limit the articles to those in the English language when few foreign publications were found. We did not initiate additional literature searches through our usual contact at the Cochrane Collaboration, because it was felt that the extensive search conducted by CDC and by this working group, in conjunction with the substantial input of scientists who generated much of the data from the 1960s and 1970s, was sufficiently comprehensive for our task. The literature review for this document focused on citations mentioning inadvertent inoculation following exposure to vaccinia virus. Despite the quantity of articles discussing inadvertent inoculation following exposure to vaccinia virus, detailed clinical descriptions were found in less than 20 articles, and some of these were reports of adverse reactions that likely were misclassified based on our present understanding of this adverse event. Each article was summarized to include information on demographics of the vaccinee, the body site, and a clinical description of the inadvertent inoculation, including the timeline post exposure to vaccinia virus, the route of transmission, diagnosis, and treatment. Because of the scarcity of published literature addressing vaccinia virus AEFI case definitions and guidelines, this working group relied particularly heavily on consultations with experts, who had been involved in prior smallpox eradication activities or in the recent public health response to a possible bioterrorism threat, for reviewing selected criteria during the development of the document and for an overall review of the final draft.

### *1.3. Rationale for selected decisions about the case definition for inadvertent inoculation following exposure to vaccinia virus*

Because of the need to distinguish the clinical event of inadvertent inoculation from the inadvertent inoculation as a mode of transmission, the working groups differentiated between inadvertent inoculation from a recently vaccinated recipient of vaccinia virus to a second individual (heteroinoculation) and a defined lesion(s) that represents autoinoculation from a primary vaccine site to another cutaneous or mucus membrane site in the same individual. Inadvertent or accidental inoculation as a mode of transmission may be relevant to several different adverse events of smallpox vaccination, and therefore applicable in different Brighton Collaboration *Smallpox Vaccine Adverse Events Working Group* definitions. The Brighton Collaboration working group definition of inadvertent inoculation following exposure to vaccinia describes a specific lesion(s), not a mode of transmission. For instance, eczema vaccinatum can occur in an individual with eczema, as a result of inadvertent inoculation. The lesion(s) associated with inad-

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