



ACCESS TO MEDICINES, VACCINES AND PHARMACEUTICALS

## Identifying & responding to serious Adverse Events Following Immunization, following use of smallpox vaccine during a Public Health Emergency

A guidance document for smallpox vaccine safety surveillance



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surveillance.



**World Health  
Organization**

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Identifying and responding to serious Adverse Events Following Events following use of smallpox vaccine during a Public Health Emergency: A guidance document for smallpox vaccine safety surveillance.

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## About this guidance

This guidance document has been developed from the principles contained in *WHO's Global Manual on Surveillance of Adverse Events Following Immunization*,<sup>2</sup> the *CIOMS guide to active vaccine safety surveillance*<sup>3</sup> and from available literature on smallpox vaccines.

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<sup>2</sup> Global manual on surveillance of adverse events following immunization. WHO 2014 (revised 2016)  
[http://www.who.int/vaccine\\_safety/publications/aefi\\_surveillance/en/](http://www.who.int/vaccine_safety/publications/aefi_surveillance/en/)

<sup>3</sup> CIOMS Guide to active vaccine safety surveillance: report of CIOMS Working Group on Vaccine Safety. Geneva, Switzerland: Council for International Organizations of Medical Sciences (CIOMS), 2017  
<https://cioms.ch/shop/product/cioms-guide-to-active-vaccine-safety-surveillance/>

## Intended Audience

This document provides information to National Immunization Programmes, health care workers and immunization staff of WHO Member States and other stakeholders on how to rapidly establish vaccine monitoring and safety surveillance systems in countries introducing smallpox vaccination in a public health emergency situation following an outbreak of smallpox.

In addition, the guide may be of use for the National Crisis Management Committee as part of the overall response to a smallpox outbreak; and may also help countries to establish minimum capacity for safety monitoring when introducing new vaccines during an emergency.

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