

**Operational framework for the deployment of
the World Health Organization Smallpox Vaccine
Emergency Stockpile
in response to a smallpox event**



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List of abbreviations

DG	Director-General of the WHO
HQ	Headquarters
IHR (2005)	International Health Regulations (2005)
PHEIC	Public Health Emergency of International Concern
SAGE	Strategic Advisory Group of Experts
SOP	Standard Operating Procedure for the Release and Delivery of Smallpox Vaccine from the Donor to the WHO
SVES	Smallpox Vaccine Emergency Stockpile
WHO	World Health Organization

1. Introduction

Smallpox, one of the oldest known human diseases, was declared eradicated by WHO in 1980, following the Intensified Smallpox Eradication Programme in which mass vaccination campaigns were conducted in countries with endemic smallpox infections. However, concern remains that the variola virus, which causes smallpox and still exists in some laboratories, might be deliberately released as a biological weapon or accidentally released from a laboratory. A range of factors – the variola virus' long incubation period and highly contagious nature, coupled with greater population mobility than 40 years' ago, clinicians lacking training and familiarity with the disease, scarce laboratory confirmation capacity, limited availability of medical countermeasures, and a global population with diminishing immunity to this disease – mean that a single smallpox case in any country poses a potential threat to all countries.

Currently, a few countries have the capacity to conduct surveillance, immunization and control campaigns, if smallpox were to reappear. However, most countries do not have their own vaccine stocks or the other resources needed to respond to an outbreak. In the case of a smallpox event, WHO will assume a major role, coordinating the global response and facilitating access to emergency supplies of vaccines, expertise and other technical, logistical, and human resources, consistent with WHO's role under the revised International Health Regulations (2005), known as IHR (2005).¹ Under the IHR (2005) which entered into force in 2007 as a legally binding framework for 195 States Parties, WHO is mandated to coordinate and manage the international assessment of, and public health response to, serious international public health events, whether or not they constitute a public health emergency of international concern (PHEIC) including a release of the smallpox virus.

In 1980, when smallpox eradication was achieved, it was recognized that there was a need for WHO to maintain an emergency reserve of Smallpox Vaccine Emergency Stockpile (SVES). WHO was given a set of formal responsibilities for maintaining capacity and expertise to respond to a re-emergence of smallpox in the post-eradication era as both a preparedness strategy and a possible deterrent to intentional release.

Originally, SVES was created by combining the remaining vaccine that had been donated by WHO Member States with the Intensified Smallpox Eradication Programme. At that time, a global physical stockpile of 200 million doses, maintained by WHO, was considered an adequate safety net. In the late 1980s, the diminished risk of recurrent smallpox and the cost of sustaining the physical stockpile led the Advisory Committee on Orthopoxvirus Infections (the Committee) to recommend that the physical stockpile should be substantially reduced.

In 2002, World Health Assembly (WHA) Resolution 55.16² urged Member States to share expertise, supplies and resources to rapidly contain a public health emergency or mitigate its effects. The resolution further requested the WHO Director-General (DG) to examine the possible development of collaborative mechanisms to prepare and stockpile resources for a potential smallpox emergency for which a PHEIC is declared. In line with this WHA resolution and the IHR (2005), five WHO Member States – France,

¹ <http://www.who.int/ihr/9789241596664/en/> (accessed 1 October 2017).

² http://apps.who.int/gb/archive/pdf_files/WHA55/ewha5516.pdf?ua=1 (accessed 5 October 2017).

Germany, New Zealand, the United Kingdom, and the United States – pledged to make smallpox vaccine immediately available to the SVES upon request.

To ensure that vaccine could be rapidly deployed and administered in response to any future outbreaks, the SVES was further developed as a mechanism to store, maintain and distribute smallpox vaccine internationally during an emergency. The SVES currently consists of two components:

- **A physical stockpile of vaccine held by WHO headquarters in Switzerland.** This is composed of calf lymph smallpox vaccines from a variety of sources dating from the final years of the eradication programme. These are regularly tested for potency. It is estimated that this stockpile will provide approximately 2.4 million doses when reconstituted and delivered by bifurcated needle.
- **A pledged stockpile held by donor countries in their respective national stockpiles for use in time of international need upon request by WHO,** which currently consists of 31.01 million doses of smallpox vaccine held by France, Germany, New Zealand, the United Kingdom, and the United States. Smallpox vaccine manufacturers, and other Member States and donors may augment this with donations in the future.³

Subject to the specific circumstances of an outbreak, **the physical stockpile of the SVES will be used for rapid, short-term and limited interventions. The pledged SVES will be mobilized when it is estimated that the physical stockpile will be exhausted or when vaccine from pledged stocks can be deployed faster. The vaccines that currently make up the SVES are NOT sufficient to vaccinate the entire global population and will instead be used to facilitate the initial response to a smallpox outbreak,** to allow manufacturers to start production of additional vaccine, and for WHO and countries to implement long-term containment/control strategies. **Vaccine from the SVES will only be released to assist containment measures in situations where an outbreak of smallpox has been confirmed by a WHO reference laboratory.** The U.S. Centers for Disease Control and Prevention (CDC) and Russia's State Research Centre of Virology and Biotechnology contain the only two WHO reference laboratories able to confirm a case of smallpox. WHO continues to work to increase international laboratory capacity and will deploy reverse transcription polymerase chain reaction (RT-PCR) reagents to countries during a smallpox emergency. WHO may seek supplementary vaccine from Member States or manufacturers and/or pursue procurement of vaccine from standby production capacity in the case of a sustained, widespread smallpox outbreak.

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