



WORLD HEALTH ORGANIZATION

FIFTY-EIGHTH WORLD ASSEMBLY
Provisional agenda item 13.6

A58/9
7 April 2005

Smallpox

Global smallpox vaccine reserve

Report by the Secretariat

1. In its final report of 1979, the Global Commission for the Certification of Smallpox Eradication discussed the need to maintain reserve stocks of vaccine and concluded that it would be prudent for WHO and national authorities to be prepared for unforeseen circumstances.¹ At that time, the source of the risk of a reintroduction of smallpox was perceived to be laboratories or natural or animal reservoirs, and that likelihood was considered negligible. The Commission recommended that freeze-dried smallpox vaccine sufficient to vaccinate 200 million people should be maintained by WHO, together with stocks of bifurcated needles.
2. In 1986, the WHO Committee on Orthopoxvirus Infections concluded that an unforeseen emergency was so unlikely that WHO no longer needed to maintain a large global reserve of smallpox vaccine. The global reserve was gradually reduced to its present level of around 2.5 million doses, held in Geneva and regularly tested for potency.
3. In recent years, Member States have expressed renewed concern that smallpox might be reintroduced. While a laboratory accident remains a possible source, the greater concern is that the smallpox virus (variola virus) might be deliberately released in an act of bioterrorism. The health consequences of such an event could be especially serious for several reasons. Smallpox was a severe disease with high fatality and no cure. As most countries have not experienced endemic smallpox for several decades, lack of clinical familiarity with signs and symptoms increases the likelihood that early cases will be missed. The long incubation period and contagious nature of smallpox facilitate rapid international spread. Population immunity following mass vaccination during the eradication era has waned, leaving much of the world's population vulnerable. The greatest fear is that, in the absence of global capacity to contain an outbreak rapidly, smallpox might re-establish endemicity, undoing one of public health's greatest achievements. All these concerns have prompted consideration of rational measures for increasing global preparedness to respond to a smallpox emergency.
4. Timely administration of vaccine according to well-established epidemiological principles has historically been effective in rapidly containing smallpox outbreaks. Vaccine stocks currently held by countries are, however, unevenly distributed and of uncertain quality.

¹ *The global eradication of smallpox, Final report of the Global Commission for the Certification of Smallpox Eradication, Geneva, December 1979.* Geneva, World Health Organization, 1980.

PLANS TO ESTABLISH A GLOBAL SMALLPOX VACCINE RESERVE

5. A proposal to establish a global smallpox vaccine reserve was reviewed by the WHO Ad Hoc Committee on Orthopoxvirus Infections, which met in Geneva from 31 August to 1 September 2004. The proposal is based on the principle of the sharing of supplies and resources during epidemic emergencies, and acknowledges the leadership role of WHO, through its enhanced epidemic alert and response activities, in the direct delivery of interventions to affected areas. The Committee noted that such a vaccine reserve would be a rational way to enhance international response capacity, as most countries would not be in a position to build and maintain their own supplies of smallpox vaccine. Having such a reserve could also serve as a global deterrent against use of the smallpox virus in a biological attack.

6. The proposal, which has two components, aims to make response capacity universal by placing adequate vaccine supplies at WHO's disposal for use in any country experiencing cases of smallpox. The two components are intended to give WHO rapid and flexible access to vaccine supplies appropriate for both short-term, limited interventions and a longer-term response, if needed.

7. The first proposed component is the maintenance of a strategic vaccine stock by WHO in Geneva for emergency use after confirmation of a case of smallpox. The proposal calls for expansion of the present reserve in Geneva to at least five million doses of freeze-dried, lymph-derived or cell-culture-derived vaccines. The additional vaccines are to be acquired through donations by individual Member States of vaccine or funds to purchase vaccines and cover the costs of storage, quality control and transport. Vaccines donated or purchased for the reserve should be evaluated and authorized by the competent national authority for use in an emergency. Appropriate supplies of bifurcated needles and diluent for vaccine reconstitution should form part of the reserve.

8. The second proposed component consists of vaccine stocks pledged to WHO by countries with national stocks and amounting to at least 200 million doses, which is the same amount as the stockpile recommended following the certification of smallpox eradication. Countries committing vaccine to the WHO stockpile should also be prepared to provide adequate supplies of bifurcated needles and diluent. Until needed, pledged stocks would remain under the control of the donor country and held in its territory. Vaccines and supplies in this second reserve would be made available to WHO for use when its stockpile proved inadequate or when nationally held stocks presented a strategic or logistic advantage. On release for use in an emergency, the donated vaccines would be delivered to recipient countries by or on behalf of WHO.

9. To strengthen global preparedness for a smallpox emergency further, the Ad Hoc Committee asked WHO to encourage Member States with vaccine-production capacity to reserve standby capacity for the manufacture of smallpox vaccines. Ideally, at least two such facilities, each able to produce a minimum of 20 million doses, would be identified globally.

10. WHO is finalizing mechanisms for its acquisition and release of smallpox vaccine for emergency response, taking into consideration comments from the Ad Hoc Committee. The operational framework covers specifications for vaccines and their procurement and storage; legal issues (including liability); and procedures for release of vaccine.

11. The Executive Board discussed the proposed smallpox vaccine reserve at its 115th session. Members welcomed the initiative as a logical and immediate way to enhance global preparedness

capacity.¹ Progress has been expressed through generous pledges of contributions to the vaccine reserve by some Member States. The next steps required are clear protocols and operational plans for sharing vaccine during an emergency and ensuring its rapid and targeted distribution.

ACTION BY THE HEALTH ASSEMBLY

12. The Health Assembly is invited to note the report.

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¹ See document EB115/2005/REC/2, summary record of the twelfth meeting, section 6.