World Health Organization

SIXTY-FIRST WORLD HEALTH ASSEMBLY **A61/5**
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Poliomyelitis: mechanism for management of potential risks to eradication

Report by the Secretariat

1. On 28 February 2007 the Director-General urgently convened stakeholders for a consultation on completing eradication of poliomyelitis and to examine the collective capacity for meeting the associated operational and financial challenges. New milestones for an intensified effort towards eradication were set for end-2007 and end-2008 and issued during the Sixtieth World Health Assembly.[1]

2. As of 25 February 2008, both countries that are endemic for poliomyelitis and those in which the virus has been reintroduced had made significant progress towards interrupting transmission of wild poliovirus since the intensified eradication effort was launched in February 2007. In 2007, the number of cases of poliomyelitis was reduced by 63% compared with the previous year, and the number of cases due to type 1 wild poliovirus – the most dangerous of the two remaining serotypes – has fallen by 84%. The absence of type 1 poliovirus in the western part of Uttar Pradesh State, India, is a particularly striking development as this is the only area in India where indigenous transmission of poliovirus has never been interrupted. Other major achievements in 2007 include a 76% overall decline in cases in northern Nigeria, the further geographical restriction of wild poliovirus transmission in Afghanistan and Pakistan, and the interruption of transmission of the original imported poliovirus in 25 of the 27 countries in which it had been reintroduced between 2003 and 2007.

3. In May 2007, the Health Assembly in resolution WHA60.14, on the mechanism for management of potential risks to poliomyelitis eradication, urged Member States to strengthen active surveillance of acute flaccid paralysis and to prepare for the long-term biocontainment of polioviruses. It also requested the Director-General to submit proposals to the Sixty-first World Health Assembly for minimizing the long-term risks of reintroduction of poliovirus and re-emergence of poliomyelitis (i.e. after interruption of wild poliovirus globally).

ISSUES

4. **Interruption of transmission of all wild polioviruses globally.** Full implementation of intensified eradication activities[2] will be essential in order to vaccinate every child with multiple doses

[1] http://www.polioeradication.org/content/publications/TheCase_FINAL.pdf.

[2] Conclusions and recommendations of the Advisory Committee on Poliomyelitis Eradication, Geneva, 27–28 November 2007. *Weekly epidemiological record*, 2008, 83(3):25-36.

of the appropriate oral poliovirus vaccine, in particular in those areas where not all the end-2007 milestones were reached. Further efforts are being focused on: the Southern Region of Afghanistan; the 72 highest-risk blocks (out of a total of 433 blocks) of Bihar State, India; the high-risk local government areas that have been identified in the northern states of Nigeria where transmission of wild poliovirus has never been interrupted (especially those local government areas in Borno, Jigawa, Kano, Katsina, Kebbi and Sokoto states); and the North-West Frontier Province and large areas of Sindh and Balochistan in Pakistan. Outbreak response activities must be fully implemented in Angola and Chad, where transmission of imported viruses has continued since 2005 and 2003, respectively. To implement the intensified eradication plan for 2008–2009, the budget of US$ 1306 million must be fully financed.

5. **Protection of areas free of wild poliovirus.** Maintaining certification-standard surveillance of acute flaccid paralysis in all Member States, including the 56 that did not attain this level of performance in 2007, is essential to ensuring effective outbreak response to any wild poliovirus importation into a poliomyelitis-free area. Minimizing the consequences of an importation of poliovirus requires maintaining routine immunization coverage against poliomyelitis at greater than 80% in all Member States. The risk of inadvertent reintroduction of wild poliovirus can be further reduced by completing the measures set out under phase I (Laboratory survey and inventory) of the WHO global action plan for laboratory containment of wild polioviruses[1] in the 39 poliomyelitis-free Member States that have yet to do so.

6. **Characterization of long-term risks associated with polioviruses.** The primary risks associated with polioviruses after interruption of transmission of wild poliovirus are:

- outbreaks due to circulating vaccine-derived polioviruses as a result of the continued use of oral poliovirus vaccine; the annual risk of one such outbreak globally is currently estimated at 60% to 95%, dropping to between 1% and 3% by the third year following synchronized cessation of a vaccination with oral poliovirus vaccine

- vaccine-associated paralytic poliomyelitis resulting from continued administration of oral poliovirus vaccine to non-immune individuals: an estimated 250–500 cases currently occur each year globally

- immunodeficiency-associated excretion of vaccine-derived polioviruses: currently, at most three persons are known to be chronically excreting such a virus,[2] but in no instance has this been associated with any secondary cases

- reintroduction of a wild or Sabin-strain poliovirus from a poliovirus-retaining site (e.g. a diagnostic, research and quality-control laboratory, and poliovirus vaccine manufacturer); currently, more than 600 sites are known to contain wild poliovirus stocks, as reported by Member States that have completed activities outlined in phase I of the WHO global action plan for laboratory containment of wild polioviruses.[1]

[1] Second edition, document WHO/V&B/03.11.

[2] The working definition of chronic excretion of such virus is for more than five years.

Further study is required to characterize better the risks of circulating vaccine-derived polioviruses, those viruses whose excretion is associated with immunodeficiency and poliovirus stocks, as well as to formulate the strategies for mitigating each.

7. **Coordination of long-term poliovirus risk management strategies.** Minimizing the risk of reintroduction of poliovirus and re-emergence of poliomyelitis after interruption of wild poliovirus transmission requires Member States:

(a) to coordinate the application of appropriate safeguards and biocontainment conditions for the handling and storage of residual polioviruses (wild, Sabin-strain and vaccine-derived) and potentially poliovirus-infected materials;

(b) to synchronize the cessation of routine immunization with oral poliovirus vaccine;

(c) to adhere to internationally-agreed processes for the use of oral poliovirus vaccine (i.e. live polioviruses) in response to new outbreaks of poliomyelitis.

8. **Development of safer processes for production of inactivated poliovirus vaccines and affordable strategies for their use.** Affordable options for the use of inactivated poliovirus vaccines should be available to any country that perceives that the medium-term or long-term risks of reintroduction of poliovirus and re-emergence of poliomyelitis warrants continued routine immunization against poliomyelitis after the eventual synchronized cessation of the use of oral poliovirus vaccine. Ideally, once vaccination with all oral poliovirus vaccine has ceased, low-income countries that wanted to maintain immunization with inactivated poliovirus vaccines would be in a position to do so at a cost similar to that with oral poliovirus vaccine. Research continues on fractional dosing and schedules with fewer doses of inactivated poliovirus vaccine, the use of adjuvants and alternative seed strains for production of inactivated poliovirus vaccine, and further process optimization for manufacturing inactivated poliovirus vaccine. The results so far indicate that new "cost-neutral" options for use of inactivated poliovirus vaccine and its safe domestic production in low-income countries may soon be feasible.

9. **Concurrence on a mechanism for coordinating long-term polio risk management.** WHO's Constitution provides the Health Assembly with three categories of normative instruments with which international consensus could be negotiated on the above-mentioned elements of the overall strategy for minimizing the long-term risks of reintroduction of poliovirus or re-emergence of poliomyelitis after interruption of wild poliovirus transmission. This includes conventions and agreements, regulations and recommendations. Recognizing that the International Health Regulations (2005) are a regulation under Article 21 of the Constitution and that the Regulations require States Parties to notify any case of "poliomyelitis due to wild-type poliovirus", the drafting and negotiation of an annex to the Regulations was proposed to the Executive Board at its 122nd session in January 2008 as a potential mechanism to establish international consensus on long-term strategies for managing the risk of reintroduction of poliovirus or re-emergence of poliomyelitis. After considerable discussion, the Board adopted resolution EB122.R1 on "poliomyelitis: mechanism for management of potential risks to eradication", which recommends a draft resolution to the Health Assembly that requests the Director-General to submit "a proposal or proposals for review by the Executive Board for a mechanism to mitigate the risk of the reintroduction of poliovirus ...".

10. **Establishment of a timeline for initiating mechanisms to minimize the long-term risks of polioviruses.** Minimizing the long-term risks of polioviruses requires stopping the use of oral poliovirus vaccine in routine immunization as soon as possible after interruption of wild poliovirus

transmission globally, when the levels of population immunity and surveillance sensitivity are high. Coordinated activities to minimize the long-term risks of polioviruses should begin as soon as there is a high probability that all wild poliovirus transmission will be interrupted globally. As wild poliovirus type 1 has proven the most difficult of the serotypes to interrupt transmission and as it is unlikely to circulate undetected for more than six months in the presence of good surveillance, mechanisms for coordinating international risk-management strategies could be initiated as early as six months after detection of the last case of paralytic poliomyelitis caused by a circulating wild poliovirus type 1 globally.

ACTION BY THE HEALTH ASSEMBLY

11. The Health Assembly is invited to consider the draft resolution contained in resolution EB122.R1.

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