

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 end-2007 and end-2008 of an intensified effort towards eradication were set and issued during the Sixtieth World Health Assembly.¹
2. An interim progress report issued in October 2007 showed that the four remaining countries where indigenous transmission of wild poliovirus had not been interrupted (Afghanistan, India, Nigeria and Pakistan hereafter referred to as endemic countries) were largely on track to meet most of the end-2007 milestones.² In those four countries where the disease remains endemic, the number of districts with cases of poliomyelitis had fallen by 51% compared with 2006; immunization coverage in those areas had in general reached the same level as in poliomyelitis-free areas of these countries, with the exception of southern Afghanistan and northern Nigeria. Of the 13 countries where imported poliovirus was still circulating in 2006, 10 had stopped their outbreaks, the exceptions being Angola, Chad and the Democratic Republic of the Congo. The fourth, mid-2007, milestone, which relates to financial commitments, was not met; with a funding shortfall for the rest of 2007 of US\$ 60 million at that time.
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).

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

² <http://www.polioeradication.org/caseforpolioeradication.asp>.

ISSUES

4. Interruption of transmission of all wild polioviruses globally. Full implementation of intensified eradication activities¹ will be essential to vaccinate every child with multiple doses of the appropriate oral poliovirus vaccine and reach the end–2008 milestones in the four countries remaining endemic for the disease. Particular attention is needed in southern Afghanistan and northern Nigeria, where a substantial proportion of children continue to be missed during poliomyelitis immunization campaigns because of insecurity and suboptimal campaign operations, respectively. Outbreak response activities must be fully implemented in Chad and the Democratic Republic of the Congo, where transmission of imported viruses has continued since 2006, as well as in Niger and Sudan, which were newly re-infected in 2007. 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 which did not achieve 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 polioviruses² 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,³ 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

¹ Conclusions and recommendations of the Advisory Committee on Poliomyelitis Eradication, Geneva, 27–28 November 2007. *Weekly epidemiological record*, 2008, in press.

² Second edition, document WHO/V&B/03.11.

³ The working definition of chronic excretion of such a virus is for more than five years.

Member States that have completed activities outlined in phase I of the WHO global action plan for laboratory containment of wild polioviruses.¹

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, as well as the use of adjuvants and alternative seed strains for production of 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 regulatory 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:

- (1) **Conventions and agreements.** Article 19 gives the Health Assembly the authority to adopt international conventions and agreements on any matter within WHO’s competence. Such international agreements are legally binding for the Member States that become Parties to them and require adoption by a two-thirds majority of the Health Assembly. The WHO Framework Convention on Tobacco Control is the first international agreement adopted by the Health Assembly under Article 19.

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

(2) **Regulations.** Article 21 provides the Health Assembly with the authority to adopt regulations concerning, among other things, measures designed to prevent the international spread of disease. Such regulations require a simple majority for adoption and establish obligations that are binding under international law. The International Health Regulations (2005) are the most recent example of regulations adopted under Article 21 of WHO's Constitution.

(3) **Recommendations.** Article 23 gives the Health Assembly authority to make recommendations on all matters within the competence of the Organization. Such recommendations are normally constituted as resolutions of the Health Assembly.

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 may be the most coherent and efficient way to establish international consensus on long-term strategies for managing the risk of reintroduction of poliovirus or re-emergence of poliomyelitis.

10. Establishment of a timeline for initiating an intergovernmental process to manage 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. It should be noted that at least three years may elapse between a decision by the Health Assembly to elaborate a new annex to the International Health Regulations (2005) and the entry into force of that annex. Consequently, the necessary intergovernmental process 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 and as it is unlikely to circulate undetected for more than six months in the presence of good surveillance, the intergovernmental process could begin 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 EXECUTIVE BOARD

11. The Executive Board is invited to consider the following draft resolution:

The Executive Board,

Having considered the report on poliomyelitis: a mechanism for the management of potential risks to eradication,¹

RECOMMENDS to the Sixty-first World Health Assembly the adoption of the following resolution:²

The Sixty-first World Health Assembly,

¹ Document EB122/6.

² See document EB122/6 Add.1 for the financial and administrative implications for the Secretariat of this resolution.

Having considered the report on poliomyelitis: a mechanism for the management of potential risks to eradication;

Recalling resolution WHA60.14, which urged Member States in which wild poliovirus is still present, especially the four countries in which poliomyelitis is endemic, to intensify poliomyelitis eradication activities in order rapidly to interrupt all remaining transmission of wild poliovirus;

Recognizing the need to make rapidly available the necessary financial resources to eradicate poliomyelitis and minimize the long-term risks of reintroduction of poliovirus and re-emergence of poliomyelitis after interruption of wild poliovirus transmission;

Recognizing the need for international coordination of the strategies to minimize and manage the long-term risks of reintroduction of poliovirus and re-emergence of poliomyelitis after interruption of wild poliovirus transmission globally;

Noting that planning for such international consensus must begin as soon as possible after transmission of wild poliovirus is interrupted globally,

1. URGES all remaining poliomyelitis-affected Member States to engage all levels of political and civil society in order to ensure that every child is consistently reached and vaccinated during every supplementary immunization activity against poliomyelitis, so that all remaining transmission of wild poliovirus is interrupted rapidly;

2. URGES all Member States:

(1) to strengthen active surveillance of acute flaccid paralysis in order to detect rapidly any circulating poliovirus and prepare for certification of poliomyelitis eradication;

(2) to complete the activities outlined in phase I of the WHO global action plan for laboratory containment of wild polioviruses¹ and prepare to implement appropriate long-term safeguards and biocontainment conditions for remaining wild polioviruses within at most 12 months after detection of the last case of poliomyelitis caused by a circulating wild virus;

(3) to achieve rapidly and to maintain routine immunization coverage against poliomyelitis at a level greater than 80% of the childhood population;

(4) to make available rapidly the necessary financial resources to eradicate poliomyelitis, and to minimize the risks of reintroduction of poliovirus and re-emergence of poliomyelitis after interruption of wild poliovirus transmission;

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

3. REQUESTS the Director-General:

(1) to continue to provide technical support to the remaining countries affected by poliomyelitis in their efforts to interrupt the final chains of transmission of wild poliovirus;

(2) to assist in mobilizing the financial resources necessary for full implementation of the intensified eradication effort and for ensuring that the long-term risks of reintroduction of poliovirus and re-emergence of poliomyelitis are minimized;

(3) to undertake the necessary research to characterize fully the long-term risks of reintroduction of poliovirus and re-emergence of poliomyelitis and to develop appropriate strategies and products for managing these risks, including safer processes for production of inactivated poliovirus vaccine and affordable strategies for its use;

(4) to report to the Health Assembly when she determines that transmission of wild poliovirus type 1 is likely to have been interrupted globally, and to submit with that report a proposal for the establishment of an intergovernmental process to amend the International Health Regulations (2005) through an annex on long-term management of the risks of reintroduction of poliovirus and re-emergence of poliomyelitis.

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