

EB136/21 16 January 2015

Poliomyelitis

Report by the Secretariat

1. On 5 May 2014, the Director-General declared the international spread of wild poliovirus a public health emergency of international concern and issued temporary recommendations to reduce risk. This report provides an update on the progress made in reducing the risk of international spread of wild poliovirus and in respect of other aspects of the Polio Eradication and Endgame Strategic Plan 2013–2018, especially global readiness for the coordinated withdrawal of the type 2 component in oral poliovirus vaccine scheduled for April 2016.

INTERRUPTION OF WILD POLIOVIRUS TRANSMISSION

2. Concerned at the international spread of wild poliovirus in the first three months of 2014, the Director-General convened a meeting of the Emergency Committee under the International Health Regulations (2005) on 28 and 29 April 2014. The Committee advised that the situation could, if left unchecked, result in failure to eradicate globally one of the world's most serious vaccine-preventable diseases. On 5 May 2014, the Director-General declared the international spread of wild poliovirus a public health emergency of international concern and issued temporary recommendations.¹

3. The temporary recommendations contained advice on measures to reduce the risk of international spread of wild poliovirus, such as declaring and managing the event as a national public health emergency and vaccinating travellers from affected countries against poliomyelitis. Criteria were outlined for the classification of countries that would be subject to the recommendations. Three countries initially met the criteria for States currently exporting wild poliovirus: Cameroon, Pakistan and Syrian Arab Republic, with Equatorial Guinea meeting the criteria when the Emergency Committee met for a second time on 28 July 2014. Six countries met the criteria for States infected with wild poliovirus but not currently exporting: Afghanistan, Ethiopia, Iraq, Israel, Nigeria and Somalia.

4. On the advice of the Emergency Committee, the Director-General extended the original temporary recommendations on 3 August 2014 and again on 13 November 2014. On 13 November, the temporary recommendations were supplemented with specific measures for Pakistan because of escalating wild poliovirus transmission in that country and the ongoing cross-border exportation of the virus into Afghanistan. Concerned at the variable implementation of the temporary recommendations,

¹ WHO statement on the meeting of the International Health Regulations Emergency Committee concerning the international spread of wild poliovirus. Available at http://www.who.int/mediacentre/news/statements/2014/polio-20140505/en/ (accessed on 19 December 2014).

the Emergency Committee indicated that additional measures, such as entry screening, would be considered when it next met at the end of January 2015.

5. By 7 December 2014, 316 cases of paralytic poliomyelitis from wild poliovirus were reported globally compared to 355 for the same period in 2013. All the cases were caused by wild poliovirus type 1 and the majority (85%) were in Pakistan, where intense transmission was ongoing. Twenty-three cases were reported in Afghanistan, primarily as a result of cross-border importation. In the only other remaining country in which poliomyelitis is endemic, Nigeria, the systematic application of eradication strategies had resulted in a substantial reduction in the number of cases, with six reported to date and onset of paralysis in the most recent on 24 July 2014.

6. Progress was also reported by countries in which there had been either cases or transmission following a wild poliovirus importation in 2013 and 2014, and which had implemented outbreak response measures. In the Horn of Africa, Somalia reported five cases, with 11 August 2014 the most recent date of onset; in Ethiopia a single case was reported with onset on 5 January 2014. In central Africa, Cameroon and Equatorial Guinea each reported five cases, with onset in the most recent cases, 9 July and 3 May 2014, respectively; in the Middle East, Iraq reported two cases (most recent onset 7 April 2014) and Syrian Arab Republic one (21 January 2014); in Israel, the last positive environmental sample detected was collected in March 2014.

7. In order to complete wild poliovirus eradication in the African continent, the following actions are required: reinforcing the innovative approaches being utilized to reach all children in northern Nigeria; sustaining the current intensive outbreak response measures in central Africa and the Horn of Africa; and bolstering surveillance in areas with the highest risk of undetected transmission, particularly in Cameroon, Central African Republic, Equatorial Guinea, Gabon and Somalia. In the Middle East, multiple synchronized immunization campaigns are continuing to enhance population immunity to poliomyelitis and reduce the risk of new outbreaks, especially in areas affected by the ongoing crisis in Syrian Arab Republic, with additional attention being paid to improving surveillance sensitivity in parts of Iraq, Lebanon, Syrian Arab Republic and Turkey.

8. In Asia, the interruption of wild poliovirus transmission is increasingly dependent on the ability of Pakistan to address the chronic gaps in strategy implementation and the ongoing threats and attacks on the programme in the Federally Administered Tribal Areas, Khyber Pakhtunkhwa, Balochistan and the city of Karachi. Although important progress was made in 2014 to reach children in such areas through additional approaches, such as carefully-planned immunization campaigns with adequate security in greater Peshawar, and transit vaccination of internally displaced persons, population immunity remains below the threshold needed to stop transmission. In Afghanistan, the remaining priority is to interrupt residual endemic virus in the southern region and respond to new cross-border importations from Pakistan.

9. Preventing new international spread of wild polioviruses will require full implementation of the eradication strategies in the remaining infected areas, particularly in Pakistan; comprehensive application of the temporary recommendations issued by the Director-General; and heightened surveillance globally to facilitate a rapid response to new cases.

WITHDRAWAL OF THE TYPE 2 COMPONENT IN ORAL POLIOVIRUS VACCINE

10. In October 2014, the Strategic Advisory Group of Experts on immunization¹ reviewed the progress made on the five criteria for assessing global readiness for the coordinated withdrawal of the type 2 component in oral poliovirus vaccine, namely: introduction of at least one dose of inactivated poliovirus vaccine in all countries; licensure of bivalent oral poliovirus vaccine for routine immunization; establishment of a global stockpile of monovalent type 2 oral poliovirus vaccine and protocols for its use; appropriate containment and handling of poliovirus type 2 infectious and potentially infectious materials; and verification of eradication of wild poliovirus type 2 globally. The Strategic Advisory Group concluded that preparations were on track for the global withdrawal of the type 2 component in oral poliovirus vaccine in April 2016, and recommended that Member States accelerate their preparations.

11. By 7 December 2014, all but three Member States had either already introduced inactivated poliovirus vaccine or had a plan to do so by the end of 2015. The three countries concerned account for less than 0.05% of the global birth cohort and are not at high risk of emergence of a circulating vaccine-derived type 2 poliovirus. Of the 73 countries eligible for support from the GAVI Alliance for the introduction of inactivated poliovirus vaccine, 66 had successfully applied. The Polio Oversight Board of the Global Polio Eradication Initiative approved 12 months of financial support for a further 25 low- and low-middle-income countries in order to facilitate introduction of the vaccine by the end of 2015. Work is ongoing to facilitate technology transfer for the domestic production of inactivated poliovirus vaccine (Sabin-IPV), where requested.

12. Withdrawal of the type 2 component in oral poliovirus vaccine from routine immunization systems globally will require replacement of the trivalent formulation of the vaccine with the bivalent (types 1 and 3) formulation in all countries that continue to use oral poliovirus vaccine. Work is continuing with manufacturers of bivalent oral poliovirus vaccines and their national regulatory agencies to extend the current licence for these products to include use in routine activities. It is imperative that all countries wishing to use oral poliovirus vaccine after April 2016 complete national licensure requirements for the use of bivalent oral poliovirus vaccine in their routine immunization programme by the end of 2015. WHO recommends acceptance of the use of bivalent oral poliovirus vaccine in routine immunization on the basis of its prequalification by WHO while national registration processes are ongoing. A protocol has been drafted to facilitate national planning for the switch from trivalent to bivalent oral poliovirus vaccine in the context of the globally coordinated withdrawal of the type 2 component.²

13. The Strategic Advisory Group of Experts on immunization reinforced its previous recommendation that stockpiles of monovalent oral poliovirus vaccine type 2 should be established and maintained only at the global level to minimize the risk of inadvertent reintroduction of serotype 2 poliovirus after withdrawal of the type 2 component in oral poliovirus vaccine globally. UNICEF has contracted two manufacturers of the WHO-prequalified product to establish a global stockpile of 500 million doses of monovalent oral poliovirus vaccine type 2 by the end of 2014. The Strategic Advisory Group endorsed a protocol on the release and use of vaccine from the stockpile, which gave

¹ Meeting of the Strategic Advisory Group of Experts on immunization, 21–23 October 2014 – conclusions and recommendations. Available at http://www.who.int/wer/2014/wer8950.pdf (accessed on 29 December 2014).

² OPV Cessation: Protocol for a global coordinated switch from trivalent OPV to bivalent OPV. Available at http://www.who.int/entity/immunization/sage/meetings/2014/october/2_Switch_Protocol_SAGE_Version_9_Oct14.pdf?ua=1 (accessed on 19 December 2014).

decision-making authority to the Director-General, acting on the advice of an expert panel with the express remit of determining whether detection of a type 2 poliovirus constituted confirmed or probable transmission requiring a vaccination response.^{1, 2}

14. In 2014, the strategic approach and plan for fully aligning the containment of polioviruses with the major milestones and timelines of the Polio Eradication and Endgame Strategic Plan 2013–2018 was finalized and endorsed by the Strategic Advisory Group. The WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of OPV use³ establishes specific measures for the poliovirus type 2 containment phase of the polio endgame; differentiates the requirements for facilities holding wild versus Sabin-strain polioviruses; and sets general parameters for the long-term containment of polioviruses following the eventual cessation of vaccination with all oral poliovirus vaccines after 2019.

15. The Secretariat will request Member States to submit to their relevant regional commissions for the certification of poliomyelitis eradication, by mid-2015, formal documentation confirming that type 2 wild poliovirus transmission has been interrupted; phase 1 containment activities have been completed or will be completed by the end of 2015; and that appropriate plans are in place to contain any residual type 2 wild polioviruses as outlined in the WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of OPV use. The relevant documentation will be reviewed by the Global Commission for the Certification of Poliomyelitis Eradication and a formal decision taken on whether the eradication of type 2 poliovirus can be declared and whether the criteria for withdrawal of the type 2 component in oral poliovirus vaccine have been met.

16. Global withdrawal of the type 2 component in oral poliovirus vaccine is currently scheduled for April 2016 (during the low transmission season for polioviruses). Final confirmation of the timing will depend on whether all persistent circulating vaccine-derived type 2 polioviruses have been interrupted at least six months previously. As at December 2014, type 2 circulating vaccine-derived polioviruses had continued to persist after many years in northern Nigeria (26 cases to date in 2014) and in the Federally Administered Tribal Areas and Khyber Pakhtunkhwa province of Pakistan (20 cases to date). Both countries are working to optimize their coverage with poliovirus vaccines containing the type 2 component during upcoming supplementary immunization campaigns to stop transmission of type 2 polioviruses and thus enable the global withdrawal of oral poliovirus vaccine containing the type 2 component on schedule in 2016.

¹ Operational framework for monovalent oral poliovirus type 2 (mOPV2) deployment and replenishment (during the endgame period). Available at

http://www.who.int/entity/immunization/sage/meetings/2014/october/4_Polio_mOPV2_stockpile_v4_09_10_2014.pdf?ua=1 (accessed on 19 December 2014).

² Protocol for notification, risk assessment, and response following detection of poliovirus type 2 following globallycoordinated cessation of serotype 2-containing oral polio vaccine. Available at http://www.who.int/entity/immunization/sage/meetings/2014/october/6_Type_2_response_protocol_14_oct_clean.pdf?ua=1

http://www.who.int/entity/immunization/sage/meetings/2014/october/6_Type_2_response_protocol_14_oct_clean.pdf?ua=1 (accessed on 19 December 2014).

³ WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of OPV use. Available at

http://www.polioeradication.org/ResourceLibrary/Posteradicationpolicydocuments.aspx (accessed on 22 December 2014).

LEGACY PLANNING

17. The objective of polio legacy planning is to ensure that the investments made in the Global Polio Eradication Initiative will continue to benefit other development goals in the long term through the documentation and transition of knowledge, lessons and assets. As an example, the infrastructure used in polio eradication is helping to support the response to the Ebola virus disease outbreak in West Africa by providing staff for surge support and conducting surveillance, contact tracing, data management, logistics and supply distribution, and outbreak management. In Nigeria, the assets and experience of the dedicated polio eradication emergency operations centre and staff were instrumental in helping to stop the outbreak of Ebola virus disease in that country. In 2014, further consultations were held with Member States, major partners and stakeholders, and detailed pilot planning missions were conducted in Democratic Republic of the Congo and Nepal for ensuring legacy planning.

18. The work reinforced the conclusions of the regional committees in 2013 that legacy planning should benefit existing health priorities and be driven and led by countries, and that its success would require a formal process to be established in all countries where substantial assets for polio eradication were financed through external resources. To that end, a draft framework has been drawn up and transition guidelines are being prepared to guide legacy planning at country level through a three-phase approach comprising planning and decision-making, preparation, and execution. Specific roles and responsibilities will need to be assigned to a range of stakeholders, with national governments providing overall leadership of the process, a donor consortium facilitating the transitioning of resources, and other partners or new entities providing project management expertise and technical assistance.

19. In 2015, finalization of the global legacy framework will ensure that essential polio eradication functions continue beyond the conclusion of the Global Polio Eradication Initiative in order to facilitate the programme of work for transitioning the polio eradication infrastructure to other priorities, and to support legacy planning in specific countries.

FINANCE

20. The overall budget for the Polio Eradication and Endgame Strategic Plan 2013–2018 remained US\$ 5.5 billion at 7 December 2014. The Global Polio Eradication Initiative has received US\$ 2.23 billion in contributions and was tracking an additional US\$ 2.85 billion in pledges and projections, which, if fully realized, would result in a funding gap of US\$ 451 million. In 2014, cash flows for some budgeted activities remained tight owing to a combination of earmarking of contributions, delayed payment of pledges, and unforeseen costs associated with new outbreaks or additional activities to curtail transmission in known infected areas.

21. As at December 2014, potential risks to the overall Polio Eradication and Endgame Strategic Plan 2013–2018 budget included delays in achieving the eradication timelines, particularly in Pakistan, and additional costs associated with the introduction of inactivated poliovirus vaccine and surge support in infected areas. A detailed review of the Strategic Plan's budget will be undertaken in the first half of 2015 to provide a basis for determining whether additional financial resources will be required.

ACTION BY THE EXECUTIVE BOARD

22. The Board is invited to consider the following draft decision:

The Executive Board, having considered the report on poliomyelitis,¹ decided the following:

(1) to encourage all Member States affected by poliomyelitis to implement fully the eradication strategies and temporary recommendations issued under the International Health Regulations (2005);

(2) to call on Member States to ensure global readiness by the end of 2015 for the coordinated withdrawal of oral poliovirus vaccines containing the type 2 component by introducing at least one dose of inactivated poliovirus vaccine into routine immunization schedules, approving the use of bivalent oral poliovirus vaccine for routine immunization, implementing appropriate containment measures for type 2 polioviruses, and submitting the relevant documentation on interruption of wild poliovirus type 2 transmission to their regional certification commissions.

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¹ Document EB136/21.