World Health Organization

SIXTY-EIGHTH WORLD HEALTH ASSEMBLY **A68/21**
Provisional agenda item 15.2 **1 May 2015**

Poliomyelitis

Report by the Secretariat

1. The Executive Board at its 136th session noted an earlier version of this report[1] and expressed support for the proposals contained in the draft decision in that report concerning intensified eradication strategies and the removal of type 2 component of the oral poliovirus vaccine. Members of the Board highlighted that the only way to achieve a polio-free world was through global solidarity and international cooperation, and the Board agreed that the Secretariat would prepare a draft resolution on renewed efforts to ensure a polio-free world for consideration by the Health Assembly. In response to the Board's request, the Secretariat has organized informal consultations with Member States, including online submissions and face-to-face meetings. The final text of the draft resolution will be issued as document A68/21 Add.1 after the consultation scheduled to be held on 22 April 2015.

2. This report provides an update on the progress made in reducing the risk of international spread of wild poliovirus and on the four major objectives of the Polio Eradication and Endgame Strategic Plan 2013–2018, especially interruption of wild poliovirus transmission and global readiness for the coordinated withdrawal of the type 2 component in oral poliovirus vaccine scheduled for April 2016.

INTERRUPTION OF WILD POLIOVIRUS TRANSMISSION

3. 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.

4. These 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. On the advice of the Emergency Committee, the Director-General extended the original temporary recommendations on 3 August 2014, 14 November 2014 and 27 February 2015, at which time Pakistan was the only country that continued to export wild poliovirus internationally. At its meeting in February, the Emergency Committee provided additional advice, based on an updated risk stratification of the countries that continued to meet criteria for States exporting wild poliovirus, States infected with wild poliovirus but not currently exporting it, and States no longer infected by wild poliovirus but which remain vulnerable to international spread. The Committee advised urgent action

[1] See summary records of the 136th session of the Executive Board, seventh meeting.

to coordinate activities regionally, recognizing large-scale population movements across borders. The Emergency Committee will reconvene before the end of April in order to assess the situation of wild poliovirus transmission and determine whether the temporary recommendations should continue beyond the Health Assembly in May 2015 or whether standing recommendations would be required to reduce more effectively the risk of international spread of wild poliovirus.

5. In 2014, 359 cases of paralytic poliomyelitis due to wild poliovirus were reported globally compared to 416 in 2013. All the cases were caused by wild poliovirus type 1 and most (85%) occurred in Pakistan, where intense transmission was ongoing. In Afghanistan 28 cases were reported, primarily as a result of cross-border importation, although transmission of an indigenous wild poliovirus continued in the southern region. 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 cases in the year and onset of paralysis in the most recent case on 24 July 2014.

6. Progress was also reported by countries in which there had been either cases or transmission following an importation of wild poliovirus 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 case 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 on 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 case (onset 21 January 2014); in Israel, the last positive environmental sample detected was collected on 30 March 2014. The Middle East is considered to remain at particularly high risk of reinfection, given the intense virus transmission in Pakistan and further deterioration of immunization systems in the Syrian Arab Republic and Iraq due to the conflict and security situation.

7. To sustain the progress and complete wild poliovirus eradication in the African continent, the following actions are required: intensifying surveillance in areas with the highest risk of undetected transmission, particularly in Cameroon, Central African Republic, Equatorial Guinea, Gabon, Somalia and South Sudan; reinforcing the innovative approaches being used to reach all children in northern Nigeria; ensuring cessation of outbreaks through full implementation of intensive response measures in central Africa and the Horn of Africa. In the Middle East, synchronized immunization campaigns will need to continue in order 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 particular attention paid to improving surveillance sensitivity in parts of Iraq, Lebanon, Syrian Arab Republic and Turkey.

8. In the Eastern Mediterranean, the interruption of wild poliovirus transmission increasingly depends on Pakistan filling chronic gaps in strategy implementation and being able to vaccinate children in infected areas that have been difficult to access owing to ongoing conflict or threats and attacks on health workers in the Federally Administered Tribal Areas, Khyber Pakhtunkhwa, Balochistan and the city of Karachi. At the end of 2014, public health leaders and managers from all levels and partners prepared a robust "low season emergency plan" for the first half of 2015. This plan incorporates important lessons learnt to reach repeatedly missed children in insecure and underperforming areas, rigorous monitoring and accountability mechanisms, establishment of emergency operations centres at federal and provincial levels to coordinate and oversee implementation, and regularly reporting of status to the office of the Prime Minister. The plan is considered to have all necessary elements in place for rapid eradication of polio; its success, however, hinges on full implementation in all areas of Pakistan. In Afghanistan, the remaining priority is to

interrupt transmission of residual endemic virus in the southern region and respond to new cross-border importations from Pakistan.

9. Preventing new international spread of wild polioviruses requires 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 immunization[1] 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. At its 136th session in January 2015, the Executive Board noted this approach and members underlined the need to ensure global readiness by the end of 2015 for the coordinated withdrawal of oral poliovirus vaccines containing the type 2 component.

11. By February 2015, all but one Member State had either already introduced inactivated poliovirus vaccine or had a plan to do so by the end of 2015. The country concerned accounts for less than 0.01% of the global birth cohort and is 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 financial support for 12 months of 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 using Sabin-strain polioviruses, 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 wanting 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

[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 31 March 2015).

switch from trivalent to bivalent oral poliovirus vaccine in the context of the globally coordinated withdrawal of the type 2 component.[1] This approach was noted by the Board at its 136th session.

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 in order 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 2015. The Strategic Advisory Group also endorsed a protocol on the release and use of vaccine from the stockpile, which suggests giving 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.[2,3] This approach was noted by the Executive Board at its 136th session.

14. In 2014, the strategic approach and plan for fully aligning the containment of polioviruses with the milestones and timelines of the Polio Eradication and Endgame Strategic Plan 2013–2018 were finalized and endorsed by the Strategic Advisory Group of Experts on immunization and noted by the Executive Board. The WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of OPV use[4] 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 is requesting 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 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 which will take a formal decision on whether the eradication of wild type 2 poliovirus can be declared and whether the criteria for withdrawal of the type 2 component in oral poliovirus vaccine have been met.

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[1] Switch from tOPV to bOPV: guidelines for developing national operational plans – a handbook for national decision makers, programme managers, logisticians, and consultants on operational aspects related to nationwide switch from tOPV to bOPV. Available at http://www.who.int/entity/immunization/diseases/poliomyelitis/endgame_objective2/oral_polio_vaccine/OPVSwitch-Guidelines_nat_plans_Mar2015.pdf?ua=1 (accessed 31 March 2015).

[2] Operational framework for monovalent oral poliovirus type 2 (mOPV2) deployment and replenishment (during the endgame period). Available at http://www.polioeradication.org/Portals/0/Document/Resources/PostEradication/mOPV2_Operational_Framework.pdf (accessed 31 March 2015).

[3] Protocol for notification, risk assessment, and response following detection of poliovirus type 2 following globally-coordinated 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 (accessed 31 March 2015).

[4] WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of OPV use (GAPIII). Available at http://www.polioeradication.org/ResourceLibrary/Posteradicationpolicydocuments.aspx (accessed 31 March 2015).

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 transmission of all persistent circulating vaccine-derived type 2 polioviruses has been interrupted. As at 3 March 2015, type 2 circulating vaccine-derived polioviruses had not been detected in northern Nigeria since the most recent case which had onset of paralysis on 16 November 2014, bring the total to 30 cases in 2014. and In Pakistan, in 2014 two "old" lineages of type 2 circulating vaccine-derived polioviruses caused 21 cases of paralysis, with most detected in the Federally Administered Tribal Areas and adjacent areas of Khyber Pakhtunkhwa province. These two lineages have not been detected since June 2014. A new persistent lineage emerged in Gadaap, Karachi, in July 2014 and was last detected in January 2015 in an environmental surveillance sample. Authorities in both Nigeria and Pakistan have increased their coverage with poliovirus vaccines containing the type 2 component during the recent supplementary immunization campaigns, with encouraging results. Additional campaigns are planned in 2015 to ensure that transmission of type 2 polioviruses is stopped, thereby enabling the global withdrawal of oral poliovirus vaccine containing the type 2 component on schedule in 2016.

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 outbreak of Ebola virus disease 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 WHO's 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 approved by the Polio Oversight Board in December 2014, 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 facilitate the programme of work for transitioning the polio eradication infrastructure to other priorities. Legacy planning will be supported in specific countries including those that have already initiated transition planning and those with substantial resources for polio eradication. Plans will need to ensure that essential polio eradication functions continue beyond the conclusion of the Global Polio Eradication Initiative.

FINANCE

20. The Global Polio Eradication Initiative had by the end of 2014 received US$ 2230 million in contributions, and was tracking an additional US$ 2850 million in pledges, against the overall budget

for 2013–2018 of US$ 5500 million. Full and rapid realization of all pledges would result in a remaining funding gap of US$ 451 million against the Endgame Strategic Plan 2013–2108. Some members of the Executive Board at its 136th session expressed concern at the ongoing funding gap and the risk it posed to implementing fully the Polio Eradication and Endgame Strategic Plan 2013–2018 and called on all donors to rapidly fulfil pledges and fill the residual funding gap as urgently as possible.

21. The Global Polio Eradication Initiative underwent significant leadership and management changes at the end of 2014, following a comprehensive management review of the Initiative that was commissioned by the Polio Oversight Board on the recommendation of the Independent Monitoring Board for polio eradication. The Polio Oversight Board adopted several recommendations in order to achieve eradication more rapidly and effectively. A new finance and accountability committee has been established to ensure more rapid, comprehensive and transparent financial reporting. By mid-2015, the Global Polio Eradication Initiative will have carried out a mid-term review of the Polio Eradication and Endgame Strategic Plan 2013–2018, which will assess progress and identify adjustments as needed, including budgetary adjustments.

ACTION BY THE HEALTH ASSEMBLY

22. The Health Assembly is invited to consider the draft resolution set out in document A68/21 Add.1.

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