Summary report on the

Meeting of national coordinators for poliovirus containment on the WHO global action plan to minimize poliovirus facility-associated risk (GAPIII)

WHO-EM/POL/419/E

Tunis, Tunisia
12–13 May 2015

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1. Introduction

The intercountry meeting of the national coordinators for poliovirus containment on the WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (GAPIII) was held in Tunis, Tunisia on 12–13 May 2015. The focus of this meeting was the completion of Phase I of GAPIII. The meeting was attended by national containment coordinators for Bahrain, Djibouti, Islamic Republic of Iran, Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Palestine, Pakistan, Saudi Arabia, Somalia, Sudan, Syrian Arab Republic, Tunisia and United Arab Emirates. Participants from Afghanistan, Egypt, Qatar and Yemen could not attend. Also in attendance were representatives from the production facility for oral polio vaccine (OPV) in the Razi Institute, Islamic Republic of Iran, and the National Institute of Health, Pakistan, along with staff of WHO headquarters and the Regional Office for the Eastern Mediterranean.

The objectives of the meeting were to:

- present GAPIII in the context of the Polio Eradication and Endgame Strategic Plan;
- discuss expected timelines for implementation of GAPIII;
- discuss roles of and expectations from key stakeholders;
- identify any gaps and needs for the national implementation of GAPIII; and
- prepare draft national action plans for containment.

In line with the Polio Eradication and Endgame Strategic Plan 2013–2018, the withdrawal of OPV type 2 (the switch from trivalent to bivalent OPV) is planned for April 2016. The switch is

dependent on meeting certain readiness criteria by the end of 2015, including the completion of Phase I of containment, i.e. the destruction of unneeded wild poliovirus type 2 (WPV2), and the preparation for Phase II, i.e. the containment of needed WPV2 materials. Containment requirements for laboratories and vaccine production facilities handling poliovirus in the post-eradication era will soon be presented to the World Health Assembly for endorsement.

At the meeting, different options were discussed, including whether or not laboratories plan to continue to handle poliovirus after type-specific eradication, and if so the physical containment and biorisk management system requirements. Information was also presented on the approval, certification and verification mechanisms and associated time-frames as they are currently understood.

National containment coordinators are essential liaison officers between laboratory facilities, vaccine production facilities and national oversight bodies, three key containment stakeholders. Their understanding and appreciation of containment issues is critical and they need to be appropriately prepared to provide advice on the implementation of GAPIII.

The WHO global and regional coordinators for GAPIII started the discussions by presenting the objectives and outcomes; polio endgame; and expectations, implications and timelines associated with poliovirus containment. Participating countries made presentations on their experience with implementing the survey and inventory of Phase I of poliovirus containment of the Global Action Plan II (GAPII),

leading to recommendations for the implementation of Phase I of GAPIII.

2. Summary of discussions

Updating the Global Action Plan II

GAPII activities were started in 2000 with a letter from the Regional Director to all Ministers of Health of Member States to implement the national laboratory survey and inventory activities of Phase I of GAPII. Up to 2006, 19 countries (Bahrain, Djibouti, Egypt, Islamic Republic of Iran, Iraq, Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Morocco, Oman, Palestine, Qatar, Saudi Arabia, Syrian Arab Republic, Sudan, Tunisia, United Arab Emirates and Yemen), reported completion of the laboratory survey and inventory activities of Phase I laboratory containment of polioviruses and potential infectious material. Three countries (Afghanistan, Pakistan and Somalia) could not start the containment activities. All countries that have completed the Phase I containment activities were required to submit a quality assurance report. Documentation of the quality of Phase I containment activities was submitted by 19 countries (Bahrain, Djibouti, Egypt, Islamic Republic of Iran, Iraq, Jordan, Kuwait, Lebanon, Libyan Arab Jamahiriya, Morocco, Oman, Palestine, Qatar, Saudi Arabia, Sudan, Syrian Arab Republic, Tunisia, Untied Arab of Emirates and Yemen). The original or revised reports have not been submitted by two countries (Djibouti and Lebanon).

Polio endgame: the switch from tOPV to bOPV

The last case of WPV2 was reported in India in 1999. Since then, a number of outbreaks of vaccine-derived poliovirus (VDPV) have

occurred. Today, the risks associated with the use of the type 2 component of OPV outweigh the benefits. The type 2 components of OPV are associated with more than 90% of VDPVs and about 40% of vaccine-associated paralytic polio (VAPP) cases, and interfere with the immune response to types 1 and 3 in OPV. The decision has been made to withdraw the type 2 component of OPV vaccines, and switch from trivalent OPV (tOPV) to bivalent OPV (bOPV).

Five readiness criteria must be met by the end of 2015 in order for the Strategic Advisory Group of Experts on Immunization (SAGE) to endorse for the switch to take place in April 2016.

1. IPV: Introduction of at least one dose of inactivated poliovirus (IPV) vaccine.
2. bOPV: Access to a bOPV that is licensed for routine immunization.
3. Surveillance and stockpile: Implementation of surveillance and response protocols for type 2 poliovirus (including constitution of a stockpile of monovalent oral polio vaccine type 2).
4. Containment: Completion of Phase I poliovirus containment activities, with appropriate handling of residual type 2 materials.
5. Verification: Verification of global eradication of wild poliovirus type 2.

SAGE will meet in October to assess whether the criteria are met. If this is the case, countries will be asked to replace tOPV with bOPV globally over a 2-week period in April 2016. No use of tOPV will be permitted after this period. All remaining tOPV stocks will be recalled and disposed of, and the process will be validated. Manufacturers will not supply any more tOPV starting a short period before the switch.

The World Health Assembly will be requested to endorse the steps leading to the withdrawal of tOPV in May 2015.

GAPIII: expectations, implications and timelines

Containment considerations are relevant for three of the above criteria, including the development of IPV, the need to strengthen surveillance and analyse samples in safe laboratory environments, the maintenance of a monovalent OPV2 stockpile, and containment itself, as criterion number 4.

Since the alignment of GAPIII with the Endgame Strategic Plan 2013–2018, Member States have been requested to update and finalize their inventories of facilities holding wild and Sabin polioviruses, and be alerted about the impending requirements to contain all type 2 polioviruses, including preparations for destruction or containment of all WPV2 and vaccine-derived strains by the end of 2015, and type 2 OPV/Sabin within three months of OPV2 withdrawal, as described in GAPIII.

Phase I of GAPIII is expected to be completed by end 2015 for WPV2. At the same time, candidate essential poliovirus facilities are expected to be certified for containment by national oversight bodies, so that handling and storage of WPV2 can continue in 2016 in Phase II, and the handling and storage of OPV2/Sabin2 materials can continue after July 2016. The number of such facilities is expected to be kept to a minimum worldwide: about 23 IPV/s-IPV producers are expected to become essential poliovirus facilities. The number of expected certified essential poliovirus laboratory facilities is as yet unknown.

GAPIII implementation activities to support countries are being proposed, including Phase I workshops for national containment coordinators; and Phase II training courses for candidate essential facilities, and national authorities responsible for containment and containment certification.

In addition, WHO is developing a new draft GAPIII Containment Certification Scheme. The Scheme will provide guidance for the certification of essential facilities as compliant with the GAPIII containment requirements for prospective essential facilities such as essential polio laboratories and vaccine production facilities, national authorities responsible for containment, Regional Containment Committees, and WHO, as well as assigning roles and responsibilities to individual stakeholders.

In May 2015 the World Health Assembly will be requested to endorse the steps leading to the withdrawal of tOPV, including containment of type 2 poliovirus. Countries will then be expected to complete the new Phase I and prepare for Phase II within required timelines, as described in GAPIII.

Country experiences during GAPII implementation

Most of the countries reported that laboratories storing WPV materials found during the survey were very cooperative and agreed to transfer to poliovirus laboratories in their countries and agreed to destroy all WPV materials. There were a few countries storing WPV material after outbreak investigation but they also destroyed them. However, the Islamic Republic of Iran maintains seed OPV production viruses and neurovirulence strain for quality control of OPV, as well as a bulk quantity of OPV stock. Egypt also maintains the bulk OPV stock.

The national containment coordinators highlighted several issues which delayed the completion of Phase I of GAPII. These included lack of strong political commitment and support from ministries of health; lack of intersectoral collaboration mechanisms for national containment coordinators to liaise with other agencies; lack of resource allocation; lack of legislation for laboratory registration; unavailability of a list of laboratories at national level; difficulties in engaging with multisectoral laboratories (university, military, police, research, private); and limited capacity of containment coordinators for data management, including entry, cleaning and analysis.

Noting the tight timeline for completion of Phase I of GAPIII, national containment coordinators expressed concern over the risk of missing the target dates due to the issues highlighted above. There was consensus among participants that the laboratory survey and inventory process can effectively identify laboratories with WPV2 materials and that the documentation process serves a critical role for compiling information that will be important for subsequent phases of containment.

During the meeting, the group discussed the preparation of a national plan of action for GAPIII implementation. It was agreed that all national containment coordinators will finalize the plan by end of July 2015 and start its implementation at the same time. Deadlines for completion of specific milestones were also provided, with the goal of completing Phase I of GAPIII for WPV2 by October 2015, and for OPV2/Sabin2 by end July 2016.

3. Recommendations

1. Work in close collaboration with national commissions for certification of poliomyelitis eradication to ensure full political and Ministry of Health support.
2. Develop and implement a national action plan to complete Phase I of GAPIII for WPV2 by end October 2015 and for OPV2/Sabin2 by end July 2016.
3. Collect, collate and enter the Phase I survey and inventory data and share them with WHO.
4. Keep WHO informed about the progress and support needed to complete Phase I of GAPIII.
5. Ensure final reports are prepared on time and according to schedule, and delivered through national certification commissions to the Regional Commission for Certification of Poliomyelitis Eradication.

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