Summary report on the

Meeting on WHO Global Action Plan (GAPIII) Phase I containment activities for national certification committees and containment coordinators

WHO-EM/POL/432/E

Amman, Jordan
29–30 November 2016

World Health Organization
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1. Introduction

An intercountry meeting on the third Global Action Plan (GAPIII) Phase I containment activities for national certification committees and containment coordinators was held from 29 to 30 November 2016 in Amman, Jordan. Participants included chairpersons of national certification committees and containment committees/task forces from 20 Member States in the Region, representatives from the production facility for oral polio vaccine (OPV) at Razi Vaccine and Serum Research Institute, Islamic Republic of Iran, as well as staff from World Health Organization (WHO) headquarters and the Regional Office for the Eastern Mediterranean.

The objectives of the meeting were to:

- explain biorisk management system principles and concepts to candidate essential and non-essential poliovirus facilities;
- discuss containment requirements, and the implementation of measures appropriate to actual needs, as described in GAPIII;
- present the national and international oversight mechanisms;
- train national certification committees and containment committees on verification visits and reporting.

The expected outcomes of the meeting were for participants to gain proper understanding of containment activities and GAPIII requirements, be ready to validate data and verify Phase I findings, and form national plans for verification of poliovirus containment activities.

Dr Nima Saeed Abid, Polio Team Leader, WHO Regional Office for the Eastern Mediterranean, delivered a message on behalf of Dr Ala Alwan, WHO Regional Director for the Eastern Mediterranean. Dr Alwan noted the continued efforts by non-endemic countries to sustain their polio-free status, and highlighted the significant reduction in the number

of confirmed poliomyelitis cases in two endemic countries (Afghanistan and Pakistan). Progress in achieving the objectives laid down in the Polio Eradication and Endgame Strategic Plan 2013–2018 saw the declaration of global eradication of wild poliovirus type 2 (WPV2) in September 2015 and the global switch from trivalent OPV (tOPV) to bivalent OPV (bOPV) in April 2016. As a result, progress towards the next phase of containment was expedited with the endorsement of the third edition of the Global Action Plan (GAPIII) for containment of polioviruses by the World Health Assembly in 2015. Dr Alwan urged national certification and containment committees, as well as national public health authorities, to support for successful completion of Phase I of GAPIII. In addition, he noted that national certification committees could provide advice, technical guidance and oversight of containment activities in order to achieve the goals defined in GAPIII and develop a mechanism for the verification of completion of containment activities.

2. Summary of discussions

Status of Phase I of GAPIII poliovirus containment in the Region

No countries in the Region are storing any WPV2 and vaccine-derived poliovirus type 2 (VDPV2), thus ensuring the completion of Phase Ia of GAPIII containment activities. The VDPV2 samples identified during laboratory surveys have been destroyed with required documented proofs. Likewise, VDPV2 materials from the regional reference laboratory in Pakistan were transferred to the National Institute of Biological Standards and Control, United Kingdom, which is a global specialized polio reference laboratory and a candidate poliovirus-essential facility. Two countries – Islamic Republic of Iran and Pakistan – have opted to have designated poliovirus-essential facilities, to store wild poliovirus and Sabin-like poliovirus type 2 materials for vaccine production and poliovirus type 2 for serology testing, respectively.

The Polio Endgame: the switch from tOPV to bOPV

The landmark achievement of WPV2 eradication was successfully accomplished and certified by the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC) on 20 September 2015. Updated data on VDPV2 and Sabin-like type 2 in the post-switch period have shown no evidence of circulating VDPV2 (cVDPV2) so far. Mitigating measures to prevent re-emergence of cVDPV2 and protocols for polio outbreak response due to type 2 poliovirus have already been implemented in Member States.

Discussion focused on GAPIII containment activities, objectives and needs. Country-specific issues related to Phase Ia containment, the switch from tOPV to bOPV and the role of national certification committees in containment activities are summarized below.

- Countries need to ensure sufficient supplies of inactivated polio vaccine (IPV) and bOPV following the switch from tOPV to bOPV.
- Inadequately immunized children in conflict-affected countries, and their movement to secure areas, pose a potential risk for reintroduction and re-establishment of poliovirus circulation.
- Countries with no poliovirus testing facility should focus on non-polio, biomedical and health laboratories involved in testing stool/faecal samples for rotavirus, astrovirus, norovirus, cholera, Shigella, respiratory pathogens and any potentially infectious materials that may harbour poliovirus. These facilities should be included in the national inventory of laboratories and must be surveyed for Phase Ib of GAPIII.

Poliovirus containment: status of GAPIII and the way forward

The status of GAPIII implementation was discussed, including required outcomes under each phase and the set timelines. Phase Ib commences as soon as the criteria for global readiness of OPV2 withdrawal are met, and continues until certification of global WPV eradication. The five readiness criteria for OPV2 withdrawal include:

1. introduction of at least one dose of IPV in routine immunization;
2. access to a bOPV that is licensed for routine immunization;
3. implementation of surveillance and response protocols for type 2 poliovirus (including constitution of a stockpile of monovalent OPV2 (mOPV2));
4. completion of Phase I poliovirus containment activities, with appropriate handling of residual type 2 materials;
5. verification of global eradication of WPV2.

Phase I is categorized into Phase Ia and Ib, focusing on containment of WPV2/VDPV2 and containment of OPV2/Sabin2 poliovirus, respectively. Compliance with GAPIII requires the special attention of national authorities, including containment and certification committees, to ensure that poliovirus-infected and potentially infectious materials are kept under secure conditions meeting all three levels of primary, secondary and tertiary safeguards. With the implementation of GAPIII, poliovirus facilities are categorized into poliovirus-essential facilities and poliovirus non-essential facilities. All laboratories that intend to work with poliovirus materials must opt for the certification to be designated as poliovirus-essential facilities, as outlined in the GAPIII Containment Certification Scheme (http://polioeradication.org/wp-content/uploads/2016/10/CCS.pdf). A critical aspect of ensuring both biorisk management controls and associated confidence in these controls is the ongoing need to certify that poliovirus containment measures are effectively implemented and maintained. The oversight

mechanism for certification of poliovirus-essential facilities is executed through national authorities for containment, containment working groups, GCC and WHO. The Containment Certification Scheme was endorsed by the WHO Strategic Advisory Group of Experts on immunization in October 2016.

The role of poliovirus-essential facilities and non-essential facilities was discussed. Only two countries in the Region opted for designation of poliovirus-essential facilities: the Islamic Republic of Iran and Pakistan. These laboratories need to continue working with poliovirus materials to meet the requirements of vaccine production (Islamic Republic of Iran) and serological survey (Pakistan) within their candidate poliovirus-essential facilities. Participants raised concerns about the role of non-polio laboratories handling faecal and respiratory materials for non-polio testing. WHO reassured the development of a new document by early 2017, entitled Guidelines for the completion of Phase I of GAPIII, to facilitate countries in the identification of samples likely to be contaminated with PV2 including WPV2, VDPV2, OPV2 and Sabin2 polioviruses. Categorization of these samples will be further performed on the basis of risk level i.e. “high”, “medium”, and “low” likelihood of being contaminated with PV2. The main emphasis at the current stage of containment is to include all such laboratories handling potentially infectious materials in the national laboratory inventory and the GAPIII survey.

Rationale and strategies defined under GAPIII for poliovirus containment

It was highlighted that non- or under-immunized populations may increase after WPV eradication and cessation of OPV use; at which stage, facility-associated reintroduction of WPV would have grave consequences. The removal of the type 2 component from OPV

vaccine, therefore, has potential risk of VDPV2 re-emergence and re-establishment of transmission. This calls for facility-associated poliovirus risk reduction through the introduction of proper containment measures in compliance with GAPIII.

Risk elimination in poliovirus non-essential facilities is achieved through worldwide destruction of infectious and potentially infectious WPV materials within 18 months after WPV transmission is interrupted, and destruction of OPV/Sabin materials within 6 months of stopping routine OPV use. Risk management in designated poliovirus-essential facilities is achieved through: international standards for primary safeguards of facility containment, secondary safeguards of an immunized population and tertiary safeguards of facility location, assured through national and international accreditation. Given the significance of these measures, the national certification document has a specific section on containment of polioviruses and potentially infectious materials, in line with GAPIII, with the aim of collecting up-to-date information on the containment progress of Phase I and II.

During the discussions, participants received technical feedback on the roles and responsibilities held by national certification committees and containment committees. While emphasizing that containment is mandatory for eventual certification, it was highlighted that both committees are national entities and must work in close coordination to achieve the targets of GAPIII, involving authorities from national health ministries and relevant stakeholders. Certification committees should support/assist laboratories and containment activities through advocacy, development of national action plans and liaison between national authorities (including Expanded Programme on Immunization (EPI) and containment coordinators). National certification committees must be part of the containment process by facilitating containment committees in data verification, on-site verification visits and report-

writing on completion of Phase I activities. Certification committees should then submit a comprehensive report to the Regional Commission for Certification of Poliomyelitis Eradication (RCC), providing details on all components of the containment process. Thus, the role of national certification committees is to provide oversight and technical support in achieving the goals and objectives of GAPIII poliovirus containment. Countries may modify and delineate the roles and responsibilities of each partner based on country-specific situation, in consultation with the health sector and relevant authorities.

Islamic Republic of Iran: pilot testing of data entry into regional containment database: issues and suggestions

Use of the regional database as a computer-based tool to secure containment data was piloted in the Islamic Republic of Iran, to identify any potential gaps and challenges experienced by laboratories in making data entries and maintaining records. An important issue relates to the available variables in the database – especially those used for collection of laboratory type and specialty, which may differ due to varying laboratory systems and structures in countries. The addition of some new options under these two variables was advised. The Islamic Republic of Iran, for example, has a Deputy Minister for Health Affairs in addition to the Ministry of Health and Medical Education; and many laboratories are named after the field of pathobiology, which requires inclusion in the database. The findings were shared with WHO data team staff for review and discussion. All necessary modifications will be incorporated into the database to make it more user-friendly and to capture information essentially required for the GAPIII containment survey.

Jordan: status of GAPIII Phase I activities: new findings

Following the introduction of GAPIII in 2014–2015, poliovirus containment activities in Jordan were re-invigorated and a new survey of laboratories operational under different sectors was conducted to collect information on availability and storage of poliovirus materials. Containment activities were re-enforced with the tOPV to bOPV switch, which was implemented on 26 April 2016. Following the switch guidelines, 56 000 vials of tOPV from reserved stocks were identified and disposed of.

Jordan met the target dates for the Phase Ia survey, set to be completed by 31 December 2015. The containment report was prepared, endorsed by the national certification committee and submitted to the RCC. A national action plan for Phase Ib is under development and includes a laboratory survey on handling, processing and testing potentially infectious materials as per the guidelines defined in GAPIII.

Egypt: GAPIII Phase I data collection and analysis, and issues around OPV stocks

Data collected under the Phase Ia survey indicated a total of 18 550 laboratories handling polio and non-polio potential infectious materials. Of these, 15 076 laboratories have provided information through a standard questionnaire. Some verification visits have been done, and follow-up actions to cover the non-responding facilities are in progress.

Egypt observed the switch from tOPV to bOPV on 11 May 2016. VACSERA, the only producer of vaccine and sera in Egypt, holds 248 bottles of GlaxoSmithKline mOPV bulk with 840 ml, 132 ml and 526 ml of poliovirus type 1, 2 and 3, respectively. These virus stocks are live attenuated stocks of mOPV bulk vaccines stored at -60°C. WHO is

in discussion with VACSERA authorities for the proper disposal and containment of unneeded OPV2 stocks to fulfil the needs of GAPIII containment. Presence of OPV2 stocks in VACSERA are significant to globally achieved eradication of PV2 and the tOPV to bOPV switch.

Egypt is planning to initiate the laboratory survey for Phase Ib to target all laboratories handling and testing poliovirus Sabin-like/OPV2 materials, as well as those dealing in non-polio infectious materials (such as respiratory and faecal specimens routinely tested for bacterial and diarrheal pathogens).

Pakistan: GAPIII Phase I activities, delays and solutions

Pakistan has experienced challenges in completion of Phase Ia activities. Lack of political support at national level, as demonstrated by the absence of a legislative framework for the laboratory registration system, has been an issue. In addition, Pakistan is still endemic for poliovirus transmission thus putting the majority of resources towards eradication efforts. Phase I activities began in late 2015. The laboratory survey to establish a national inventory is in progress, and 1456 laboratories have been surveyed to date. To accelerate completion of the Phase I survey, poliovirus containment is included in the national emergency action plan for polio eradication 2016–2017.

Federal and provincial level meetings have been conducted to discuss the national action plan and accelerate completion of Phase I containment activities. The national authorities, WHO and national certification committee members were briefed on the scope, objectives and needs of GAPIII and strategies to complete Phase I. Pakistan is committed to revision of the national action plan in light of Phase Ia and Ib guidelines, and shared plans for optimizing polio eradication staff at national and subnational level for containment activities.

Libya: completing GAPIII Phase I activities in a crisis situation

Execution of poliovirus containment activities was delayed in Libya due to the prevailing political conflict. Further challenges include limited technical support and designated human resources to conduct the laboratory survey. Containment committee members requested technical and financial support from WHO, resulting in the completion of Phase I with a 100% laboratory survey response. A total of 565 laboratories were surveyed in 2016; none were found to hold any poliovirus materials. This was further verified by on-site verification visits to ensure data accuracy. The survey report was submitted to the RCC by the national certification committee. Containment authorities in Libya are confident to continue with the Phase Ib survey, in light of lessons learned from Phase Ia and the improved country situation.

Syrian Arab Republic: completing GAPIII Phase I activities in a crisis situation

The security situation during the past 5 years has adversely affected health infrastructure and caused large scale disruption of public services in the Syrian Arab Republic. No polio cases have been reported since January 2014, and two VDPV2 cases were reported in 2015. Poliovirus containment activities were initiated in 2016, and Phase Ia was successfully completed with the destruction of all polio type 2 samples following GAPIII guidelines. However, the report on completion of Phase Ia has not been submitted to WHO to date.

Yemen: completing GAPIII Phase I activities in a crisis situation

Health systems have been significantly affected by the conflict in Yemen: less than a third of the population have access to medical care. Despite the situation, polio containment activities were carried out

with the support of WHO and AFP surveillance coordinators have been appointed in each of the 22 governorates and emergency centres. In Phase Ia, 1302 laboratories were surveyed and 57 laboratories were identified with capacity for sample storage. Survey response rate was 100% with the coordination of relevant national authorities including containment and certification committees.

Group work

Country participants were divided into five groups in view of their epidemiological situation, geographical and security contexts. Groups discussed the role of national certification committees in supporting GAPIII activities, and offered suggestions for the questionnaire to be used for surveying candidate laboratories to conduct Phase Ib of poliovirus containment. WHO provided technical input to help devise comprehensive action plans to complement GAPIII activities involving relevant national authorities including containment committees, certification committees and representatives from ministries of health.

Participants outlined country-specific agendas and discussed plans in view of Phase Ib of GAPIII. The main point of discussion was the need for revision of the laboratory survey questionnaire to collect information on potentially infectious materials in addition to polio-infected materials. Additional comments pertained to: (i) revision of containment action plans to include regular liaison with certification committees; (ii) development of a coordination mechanism for synergetic efforts by all stakeholders and partners to carry out Phase Ib activities; (iii) national certification committees supporting containment authorities to help verify the survey data by on-site physical visits to laboratories with known capacity for sample storage; (iv) harmonization of the laboratory survey questionnaire and translation into different languages, while maintaining the context of

questions; and (v) outlining an agreed timeline for the completion of Phase Ib.

3. Recommendations

1. National certification committees and containment committees should collaborate to support completion of containment activities and certification documentation through:
   - advocacy with agencies/organizations and stakeholders, especially academia and research institutions;
   - expediting data collection from non-responding agencies;
   - validating the containment data in certification documentation;
   - jointly overseeing the containment process, conducting verification visits and reviewing GAPIII Phase Ib, data and report;
   - containment coordinator should be invited to certification committee meetings, and vice versa.
2. Containment coordinators should update national action plans to include GAPIII Phase Ib activities and share the updated Phase Ib report with ministries of health, national certification committees and WHO by end of March 2017. In resource-constrained countries, WHO may provide technical and financial support to complete GAPIII Phase Ib. Pakistan should submit GAPIII Phase Ia report by January 2017.
3. Laboratory lists should be updated to ensure all those holding potentially infectious materials are part of the survey. Emphasis should be on developing inventories of enteroviruses, respiratory viruses and rotavirus, and bacteriology laboratories with storage capacity. Laboratories may be surveyed or re-visited to confirm the presence/absence of potentially infectious materials. A revised questionnaire may be distributed for laboratory surveys.

4. Containment coordinators should provide certificate of destruction of Sabin2/OPV2 based on laboratory destruction certificates; this will be required to finalize the Phase Ib report.
5. In conflict-affected countries, special measures should be used to ensure completion of GAPIII Phase I activities including coordination between EPI and partners/nongovernmental organizations to access areas for mapping of laboratory facilities, and distribution and collection of questionnaire (survey form). A short summary note should be added to the final report and certification document on containment activities conducted in conflict-affected areas.
6. Islamic Republic of Iran and Pakistan should ensure measures for the designation of poliovirus-essential facilities:
    - Pakistan (SL2 poliovirus-essential facility) should initiate the Certificate of Participation process and inform WHO of designation;
    - both countries should establish national authorities for containment and communicate to RCC/GCC (through WHO);
    - both countries should work towards the issuance of a Certificate of Participation under the Containment Certification Scheme.
7. WHO should provide technical support to proposed poliovirus-essential facilities in the Islamic Republic of Iran and Pakistan for GAPIII Phase II containment activities.
8. WHO should facilitate a network of national authorities for containment to expedite poliovirus-essential-facility-related activities in a coordinated, consistent and harmonized manner.
9. VACSERA-Egypt should work with the Ministry of Health and Population in Egypt and WHO for final disposal of OPV2 stocks and provide a certificate of destruction.
10. Ministry of Health in Iraq should work with WHO to ensure timely removal of PV2-containing vaccines from national vaccines stores; vaccines should be destroyed in line with switch

principles and a certificate of destruction should be provided through the national containment coordinator.

11. EPI/polio programme should continue surveillance for any tOPV still in use and take immediate measures as per WHO guidelines, and provide complete documentation to national containment committees.
12. WHO should share terms of reference for national containment coordinator and containment committee/national task forces.
13. WHO should propose to RCC/GCC to elaborate on the role of national certification committees in containment activities and include such activities in certification committees' terms of reference.

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