Objective 3: Containment and certification

CONTAINMENT & CERTIFICATION		
Main Objectives	Outcome Indicators	Major Activities
Certify the eradication and containment of all wild polioviruses by end-2018 and enhance long-term global security from poliomyelitis	Global polio eradication certified by end-2018	1. Containing poliovirus stocks 2. Certifying the eradication of WPVs
Monitored by the GCC		

7.1 INTRODUCTION

7.1 Following interruption of WPV transmission globally, the safe handling and containment of WPV infectious and potential infectious materials in laboratory and vaccine production facilities will be essential to minimize the risk of reintroducing WPV into the population. A reintroduction of WPV from a poliovirus facility would risk the potentially serious consequences of re-establishing poliomyelitis. After the cessation of OPV use globally, the reintroduction of an OPV/Sabin virus strain from a poliovirus facility would risk the emergence of a cVDPV, and again the potentially serious consequences of re-establishing poliomyelitis. Most facility-associated poliovirus risks can be eliminated through the destruction of WPV and OPV/Sabin infectious and potentially infectious materials. However, poliovirus facilities will be necessary in a number of countries to continue essential international functions, including IPV production, OPV stockpile management, vaccine quality assurance, diagnostic reagent production, virus reference functions and research. Minimizing the number of essential facilities worldwide reduces the risk of reintroduction, facilitates national and international oversight, and ensures that global containment standards can be met.

7.2 The primary requirements for certifying a WHO region as free of WPV are:
- the absence of any WPV for a minimum of three years in all countries of the region;
- the presence of certification-standard surveillance in all countries during that three-year period;[26]
- the completion of Phase I biocontainment activities for all facility-based WPV stocks.

Certification at the regional level is assured by independent Regional Certification Commissions (RCCs) that report in turn to the Global Certification Commission (GCC). RCCs are supported by independent National Certification Committees (NCCs) that assess, verify and present the required national documentation on polio-free status to the RCC. Members of RCCs and NCCs are independent leading experts in relevant disciplines (public health, epidemiology, virology), acting in their personal capacity, without direct responsibility for polio eradication in their country or region.

UNICEF 2011/Brian Sokol

[26] *See footnote 16 for the definition of certification-standard performance.*

Following interruption of WPV transmission globally, the safe handling and containment of WPV infectious and potential infectious materials in laboratory and vaccine production facilities will be essential to minimize the risk of reintroducing WPV into the population.

7.2 THE GOAL

7.3 The goal of Objective 3 is to certify the eradication and containment of all WPVs by the end of 2018 to enhance long-term global security from poliomyelitis.

The primary requirements for certifying a WHO region as free of WPV are:

- the absence of any WPV for a minimum of three years in all countries of the region;
- the presence of certification-standard surveillance in all countries during that three-year period;
- the completion of Phase I biocontainment activities for all facility-based WPV stocks.

7.3 WHAT IS REQUIRED?

7.4 The global certification of WPV eradication – and verification of the elimination of vaccine-related viruses – will require ensuring highly sensitive poliovirus surveillance and full application of relevant poliovirus biocontainment requirements globally. Chronic gaps in surveillance sensitivity will need to be addressed in both recently infected countries and countries that have long been certified as polio-free, overcoming complacency, weak health systems, geography, insecurity and other challenges to identifying and investigating paralysed children. International consensus will need to be established on the timelines and phasing for implementation of biocontainment requirements for the safe handling of residual polioviruses (e.g. for vaccine production, research and diagnostic facilities); the necessary inventorying, destruction and containment activities will then need to be implemented and verified in all countries. In addition, international consensus will be required on the criteria and processes for reintroducing live poliovirus vaccines to respond to any reintroduced or emergent polioviruses after OPV cessation.

7.4 WHAT IS THE CURRENT SITUATION?

7.5 The first Global Action Plan (GAP) for containment of WPV was developed in 1999 with the recognition that containment needed to be addressed in advance of eradication certification. Implementation of the first GAP identified the national laboratory survey and inventory as an essential first-step towards containment. These activities were started in 2000 in the WHO Western Pacific Region and subsequently expanded to other regions. Following the outbreak of cVDPV in Hispaniola (2000-2001), the GAP was updated to include containment of VDPV in addition to WPV (GAPII). National survey and inventory activities were completed in all countries of the WHO Western Pacific, European and American Regions by 2008.

7.6 The renewed discussions on OPV cessation that were prompted by the confirmation of cVDPVs in turn prompted the development of a third edition of the GAP. The Global Action Plan to minimize post-eradication poliovirus facility-associated risks (GAPIII) outlines relevant biosafety levels and safeguards for handling wild, Sabin and Sabin-derived polioviruses following eradication and eventual OPV cessation.

A revision of GAPIII is required based on two updates to the strategic path forward: the OPV2 cessation timeline and the requirement for global access to IPV.

International agreement on the timing and implementation of containment policy will ideally be established by the end of 2014, potentially with a World Health Assembly resolution to that effect in 2015.

7.7 Containment activities have commenced in all six WHO regions. In the WHO Region of the Americas, European Region and Western Pacific Region, all Member States have completed the Phase I containment survey and inventories for WPV materials. In the three WHO regions that are not yet certified (African, Eastern Mediterranean and South-East Asia Regions), 40 Member States have completed Phase I containment activities. In total, 155 of 194 (80%) WHO Member States have collectively surveyed more than 200 000 biomedical facilities (some of which are large institutions with multiple laboratories) to identify those with WPV infectious or potentially infectious materials. To date, approximately 550 facilities with WPV infectious or potentially infectious materials have been identified in 46 countries. This includes six facilities for producing Salk Inactivated Polio Vaccine (IPV). The majority of the remaining 39 Member States to complete Phase I are located in south-east Asia and sub-Saharan Africa; the latter is thought unlikely to possess a substantial number of facilities with WPV materials due to infrastructure challenges. Nevertheless, it is planned that these countries will complete the Phase I work in the near future.

7.8 RCCs have accepted final documentation for polio-free status from 86% of Member States (167 of 194). This includes all Member States of the already certified WHO Region of the Americas (Pan American Health Organization), European Region and Western Pacific Region. The majority of the remaining countries that have not yet submitted final documentation are in Africa; in the WHO South-East Asia Region, only India remains and in the Eastern Mediterranean Region, only Afghanistan and Pakistan remain, for which the RCC has not yet accepted final documentation. The certification of the South-East Asian Region is anticipated by mid- to end-2014. If Afghanistan, Nigeria and Pakistan interrupt all WPV transmission by the end of 2014 as targeted, the remaining WHO African Region and the EasternMediterranean Region could potentially be certified by the end of 2017, with global certification occurring as early as the following year.

7.5 WHAT WILL BE DONE?

Major activities

1. Containing poliovirus stocks
2. Certifying the eradication of WPVs

Activity 1: Containing poliovirus stocks

7.9 A revision of GAPIII is required based on two updates to the strategic path forward: the OPV2 cessation timeline and the requirement for global access to IPV. The timelines and phasing of activities in GAPIII will be finalized to align appropriately with the risks and timelines of these aspects of the programme. The process for addressing these issues will begin with the development of a revised timeline, followed by broad public consultation and specific consultation with vaccine manufacturers. The final step in the process of developing a post-eradication containment policy will be its adoption by the World Health Assembly as part

WHO/Rudolf Tangermann

The first stage of bio-containment is to complete laboratory survey and inventory activities in all polio-free countries and prepare for implementation of containment activities prior to global certification.

of the comprehensive post-eradication endgame strategy. International agreement on the timing and implementation of the plan will ideally be established by the end of 2014, potentially with a World Health Assembly resolution to that effect in 2015.

7.10 The first stage of biocontainment is to complete laboratory survey and inventory activities in all polio-free countries and prepare for the implementation of containment activities prior to global certification. These activities have largely been completed globally with the exception of the persistent polio-infected countries and those that have suffered recurrent reinfections. Following confirmation that WPV transmission has been interrupted for one year, appropriate legislation and regulation will need to be initiated in all countries in preparation for the completion of all WPV containment within six months. At the time of the tOPV-bOPV switch, safe-handling requirements will be increased for all Sabin type 2 polioviruses in advance of their full containment.

7.11 Countries retaining WPVs for the purposes of Salk-IPV production and/or essential quality assurance/quality control, laboratory or research functions may constitute the greatest residual WPV risks. At the end of 2012, five countries had active Salk-IPV production sites: Belgium, Denmark, France, the Netherlands and Sweden. The number and location of countries that retain WPVs for necessary quality assurance/quality control, laboratory and research functions will be finalized with completion of Phase 1 biocontainment activities globally (i.e. inventory and destruction of viruses and infectious materials). These areas will require full application of the primary, secondary and tertiary biocontainment safeguards outlined in GAPIII to minimize the risk of inadvertent or intentional WPV reintroduction. These safeguards are good facility design and management (primary safeguards), the location of essential facilities in areas with high levels of immunity (secondary safeguards) and location in areas with good personal, domestic and environmental hygiene standards (tertiary safeguards). Essential facilities using or retaining WPV materials after eradication will be expected to meet all primary, secondary and

WHO/Christopher Black

National certification committees together with regional commissions and the Global Commission for Certification of the Eradication of Poliomyelitis are ultimately responsible for determining eradication certification of wild poliovirus.

tertiary safeguards, while those retaining only OPV materials after cessation of OPV in routine immunization will be expected to meet primary and secondary safeguards. The safeguards will need to be in place for WPV2 by 2015; those for WPV1 and WPV3 will need to be in place by 2018.

Activity 2: Certifying the eradication of WPVs

7.12 A fourth WHO Region – South-East Asia – could potentially be certified polio-free in 2014, contingent on the timely submission of full documentation by all relevant NCCs and their acceptance by the South-East Asia Region RCC.

7.13 At its meeting in mid-2012, the GCC noted that prior to OPV2 cessation it will have to formally "conclude" that WPV2 has been eradicated globally. As a first step, RCCs from all WHO regions would need to provide the GCC with evidence towards this conclusion, based on the absence of WPV2 for more than 10 years and on regional surveillance quality. The GCC could consider this evidence as early as mid-2014, provided that an appropriate complement of GCC members has been established and that fully functional RCCs exist in all six WHO regions.

7.14 In advance of the global certification of all WPV eradication, the GCC will need to finalize data requirements from the three certified polio-free regions, clarify the role of environmental surveillance as a supplemental surveillance strategy, and establish mechanisms for reviewing and verifying documentation on the containment of laboratory stocks and IPV introduction.

For the three WHO regions that have been certified polio-free – the Region of the Americas and the European and Western Pacific Regions – the immediate priority will be to again achieve and maintain certification-standard performance in all areas with an AFP surveillance policy by 2015.

For the three WHO regions yet to be certified polio-free (as of the end of 2012), the priority will be to close remaining gaps in AFP surveillance in advance of a global tOPV-bOPV switch.

7.15 For the three WHO regions that have been certified polio-free – the Region of the Americas and the European and Western Pacific Regions – the immediate priority will be to again achieve and maintain certification-standard performance in all areas with an AFP surveillance policy by 2015 to ensure the capacity to detect and respond to any cVDPV emergence following the planned tOPV-bOPV switch. This will be achieved by the ongoing work of RCCs and NCCs to monitor the polio-free status of countries in these regions, mobilizing increased support and political commitment to the global goals of the polio endgame, allocating additional resources where needed – including for laboratory capacity – and providing WHO regional office support to countries for revitalizing their AFP surveillance.

7.16 For the three WHO regions yet to be certified polio-free (as of the end of 2012), the priority will be to close remaining gaps in AFP surveillance by 2014 (particularly in northern Nigeria, in West, Central and the Horn of Africa, and in Pakistan and Afghanistan) in advance of a global tOPV-bOPV switch. Particular attention will be given to ensuring that active surveillance is conducted and documented at least monthly at all major reporting sites, expanding networks of community informants and, potentially, establishing rewards for polio-confirmed AFP cases. As in the certified regions, RCCs and NCCs are expected to play an important role in sustaining certification-standard AFP surveillance performance at the national and subnational levels.

7.6 WHO OVERSEES THIS WORK?

The Global Commission for Certification and Regional Certification Commissions

7.17 The GCC oversees the overall process of certification. RCCs provide the GCC with documentation of certification activities under their oversight.