

**POLIO ERADICATION AND ENDGAME
STRATEGIC PLAN
2013-2018**

Global Polio Eradication Initiative

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ACRONYMS

AFP	Acute Flaccid Paralysis
aVDPV	Ambiguous vaccine-derived poliovirus
BMGF	Bill and Melinda Gates Foundation
bOPV	Bivalent Oral Polio Vaccine
CSO	Civil Society Organisation
CDC	US Centers for Disease Control and Prevention
cVDPV	Circulating Vaccine-Derived Poliovirus
EB	Executive Board of the World Health Organization
FATA	Federal Administered Tribal Areas (Pakistan)
FRR	Financial Resource Requirements
GAPIII	Third edition of the Global Action Plan to minimize post eradication poliovirus facility-associated risk
GAVI	GAVI Alliance
GCC	The Global Commission for Certification of the Eradication of Poliomyelitis
GPEI	Global Polio Eradication Initiative
GPLN	Global Polio Laboratory Network
ICC	Inter-agency Coordinating Committee
IPV	Inactivated Polio Vaccine
iVDPV	Immunodeficiency-associated vaccine-derived poliovirus
LGA	Local Government Area
LQAS	Lots Quality Assurance Sampling
mOPV	Monovalent Oral Polio Vaccine
NID	National Immunization Day
OPV	Oral polio vaccine
PAG	Polio Advocacy Group
PSC	Polio Steering Committee
PPG	Global Polio Partners Group
RCC	Regional Certification Commission
SAGE	Strategic Advisory Group of Experts on Immunization
SIA	Supplementary Immunization Activity
SNID	Sub-national Immunization Day
TAG	Technical Advisory Group
tOPV	Trivalent oral polio vaccine
UNICEF	United Nations Children's Fund
VAPP	Vaccine-associated paralytic poliomyelitis
VDPV	Vaccine-derived poliovirus
VPD	Vaccine-preventable disease
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus

1. STATEMENT OF INTENT

The goal of the 2013-2018 Polio Eradication and Endgame Strategic Plan is to complete the eradication and containment of all wild, vaccine-related and Sabin polioviruses, such that no child ever again suffers paralytic poliomyelitis.

2. BACKGROUND

2.1 On 26 May 2012 the World Health Assembly (WHA) called for the development of a comprehensive polio endgame strategy.¹ This Polio Eradication and Endgame Strategic Plan (the Plan), developed in consultation with national health authorities, scientific experts, global health initiatives (e.g. GAVI Alliance), donors and other stakeholders outlines the strategic approach to the eradication of all remaining polio disease – due to both wild and vaccine-related polioviruses, the management of poliovirus risks in the post-eradication era, and the development of a process for transitioning the Global Polio Eradication Initiative (GPEI) infrastructure as the initiative comes to completion. The consultations included, among others, the Global Polio Partners Group (PPG), national and international technical advisory groups (TAGs), and the Independent Monitoring Board (IMB) of the GPEI. In November 2012, the Strategic Advisory Group of Experts on Immunization (SAGE) reviewed the plan and endorsed its major components. In January 2013, the Executive Board of the World Health Organization reviewed the document and provided further guidance for its finalization.

2.2 This Plan supersedes the GPEI *Emergency Action Plan 2012-2013* and incorporates elements of the emergency/national action plans of the three remaining endemic countries, which outline specific activities to complete wild poliovirus eradication in specific geographies.² The Plan is based on the epidemiology of polio globally at end-2012, the recent rate of oral polio vaccine (OPV) campaign quality improvements in the remaining polio-infected areas, new understanding of the risks posed by vaccine-related polioviruses, and the recent development of new strategies and tools for managing post-eradication risks. Particular attention has been given to aligning this Plan with the goals, objectives and major activities of the Global Vaccine Action Plan (GVAP).³

2.3 Beyond 2014, this Plan will be complemented by new bi-annual operational plans that will outline the specific activities and tactics needed to achieve the Plan's objectives, based on the evolving epidemiology of polio, the priorities for managing the vaccine-related and post-eradication risks, and the agreed priorities of the Polio Legacy work. With full implementation of this Plan, polio will be the first disease of humans to be eradicated from the earth in the twenty-first century.

2.4 This document is intended for the use of individuals and organizations involved in polio eradication efforts. Potential users of the document include:

- National Polio and routine immunization programme managers and staff
- Partners supporting the Global Polio Eradication Initiative
- WHO and UNICEF country and regional focal points for polio eradication efforts and UNICEF health staff
- National Interagency Coordinating Committees (ICCs)
- Polio eradication oversight and management bodies

¹ Resolution WHA65.5 'Poliomyelitis: intensification of the global eradication initiative'

² EAP available at: <http://www.polioeradication.org/resourcelibrary/strategyandwork/emergencyactionplan.aspx>

³ Resolution WHA65.17 'Global vaccine action plan'

- Polio eradication technical advisory bodies

3. OVERVIEW

WHAT'S NEW ABOUT THIS STRATEGIC PLAN

3.1 The *Polio Eradication & Endgame Strategic Plan 2013-2018* brings together for the first time a comprehensive approach to completing polio eradication. Five major elements are new in this plan and distinguish it from previous plans:

- Strategic approaches to all polio disease (wild and vaccine-related)
- An urgent emphasis on improving routine immunization systems in key geographies
- The introduction of new IPV options for managing long-term poliovirus risks and potentially accelerating wild poliovirus eradication
- Risk mitigation strategies to address the emerging importance of new risks, particularly insecurity, in some endemic areas, and contingency plans should there be a delay in interrupting transmission in such reservoirs
- A concrete timeline to complete the Global Polio Eradication Initiative

3.2 Previous plans focused primarily on interrupting wild poliovirus transmission, followed by the elimination of vaccine-derived polioviruses (VDPVs). This plan incorporates innovative tactics, strategies and tools that will enable the programme to not only interrupt wild poliovirus transmission but also to address in parallel the risks associated with VDPVs. This fundamental shift in approach makes the most of the recently-developed bivalent OPV and new inactivated polio vaccine (IPV) options at a time when immunization and surveillance performance are expected to be at their strongest – thus improving the probability of success.

3.3 In this strategic plan, strengthening of routine immunization is given the same urgency and importance as improving OPV campaign quality in areas of highest programme priority. Strengthened routine immunization will serve both as a stronger base for building population immunity to interrupt wild poliovirus transmission and as a sustainable platform for the introduction of new vaccines (i.e. IPV options) to help manage long-term poliovirus risks. This plan commits the GPEI to intensified efforts to strengthen routine immunization using polio-funded staff, assets and tools and increased collaboration with immunization partners in key geographies.

3.4 The development and introduction of new vaccines is a major development in the management of poliovirus risk. In addition to expanding the use of bOPV, this plan exploits new understanding of the impact of IPV on mucosal immunity and new, low cost options for its wide-scale use. The Plan outlines how the development and licensure of affordable IPV options will be fast-tracked. This will facilitate the withdrawal of OPV from routine immunization programmes (and thereby the elimination of VDPVs) and may also help accelerate wild poliovirus eradication key reservoirs.

3.5 Recognizing the increasing risk of delays particularly due to insecurity in some endemic reservoirs, this plan outlines a 5-pronged framework to enhance programme safety and coverage in such areas, as well as additional measures to reduce the risk of international spread.

3.6 By changing from sequential to parallel management of the WPV and VDPV risks, the GPEI is able to establish clear timelines and milestones for completing the Global Polio Eradication Initiative.

THE MAJOR OBJECTIVES

There are four major objectives and areas of work in the 2013-2018 Polio Eradication and Endgame Strategic Plan:

- 1. Poliovirus Detection and Interruption:** This objective is to stop all WPV transmission by the end of 2014 by enhancing global poliovirus surveillance, effectively implementing national emergency plans to improve OPV campaign quality in the remaining endemic countries, and ensuring rapid outbreak response. This area of work gives particular attention to addressing the risks that emerged as increasingly important in late 2012, particularly insecurity, as the programme began to reach chronically underserved places and populations more systematically. This objective also includes stopping any new polio outbreaks due to VPDVs within 6 months of the index case. The primary geographic focus of this objective is in the three endemic countries and the countries in at highest risk of importation in Africa and southern Asia.
- 2. Routine Immunization Strengthening and OPV Withdrawal:** This objective will help hasten the interruption of wild poliovirus transmission, reduce the risk of wild and vaccine-derived poliovirus importation and spread, and help build a strong system for the delivery of other lifesaving vaccines. To eliminate all vaccine-derived poliovirus risks, in the long-term all OPV must be removed from routine immunization programmes. As wild poliovirus type 2 was eradicated in 1999, and the main cause of VDPV outbreaks is currently the type 2 component of OPV, this component must be removed from the vaccine by mid-2016. Preparation for this removal entails strengthening routine immunization systems – especially in areas at highest risk, introducing at least one dose of affordable IPV into routine immunization programmes globally, and *then* replacing the trivalent OPV with bivalent OPV in all OPV-using countries. This objective affects all 144 countries worldwide which currently use OPV in their routine immunization programmes.
- 3. Containment and Certification:** This objectives encompasses the certification of the eradication and containment of all wild polioviruses in all WHO Regions by end-2018, recognizing that a small number of facilities will need to retain poliovirus stocks in the post-eradication era for the purposes of vaccine production, diagnostics and research. Criteria for the safe handling and bio-containment of such polioviruses, and processes to monitor their application, are essential to minimize the risk of poliovirus re-introduction in the post-eradication era. Consequently, this area of work includes finalizing international consensus on long-term bio-containment requirements for polioviruses and the timelines for their application. Verifying application of those requirements, under the oversight of the Global Certification Commission, will be a key aspect of the processes for certifying global eradication. All 194 Member States of the World Health Organization are affected by work towards this objective.
- 4. Legacy Planning:** As the polio programme approaches key eradication milestones, successful legacy planning will include the mainstreaming of essential polio functions into on-going public health programmes at national and international levels, ensuring the transfer of learnings to

other relevant programmes and/or initiatives, and the transition of assets and infrastructure to benefit other development goals and global health priorities. This will require thorough consultation and planning and implementation processes to ensure the investments made in polio eradication provide public health dividends for years to come. Work under this objective should produce a comprehensive legacy plan by end-2015.

As illustrated below, the four major objectives of the Plan are not sequential but will run in parallel. In 2013-2015, the main emphasis in terms of country-level implementation will be on the first and second objectives, with increasing emphasis on the operational aspects of the third and fourth objectives as key milestones are achieved.

Overview of Eradication and Endgame Strategic Plan⁴



⁴ Essential activities (e.g. surveillance, laboratory network and IPV in routine immunization) will be mainstreamed beyond 2019.

4. CONTEXT

WHERE WE ARE TODAY

2011	2012
Last case in India	Last cases in Angola and DRC
3 countries with re-established transmission	1 country with re-established transmission
11 outbreaks in 9 countries	1 outbreak
16 countries, 650 cases	5 countries, 223 cases

4.1 The World Health Assembly (WHA), the annual meeting of the Ministers of Health of all Member States of the World Health Organization (WHO), first committed to polio eradication when it adopted resolution 41.28 in 1988 calling for the worldwide eradication of the disease by the year 2000. That marked the launch of the GPEI, spearheaded by national governments, WHO, Rotary International, the US Centers for Disease Control and Prevention (CDC) and UNICEF.

4.2 At that time, there was endemic WPV transmission in more than 125 countries and each year more than 350,000 children were paralyzed for life by polio. Since 1988, the GPEI has reduced the global incidence of polio by more than 99.9%, three of six WHO Regions have been ‘certified’ polio-free (the Americas in 1994, the Western Pacific in 2000 and the European Region in 2002), and one of the three wild poliovirus serotypes (type 2) has been eradicated (last isolated in 1999).

4.3 Through the GPEI, more than 10 billion doses of oral polio vaccine (OPV) have been administered to more than 2.5 billion children worldwide; more than 10 million people are walking today who would otherwise have been paralysed; and, over 1.5 million childhood deaths have been prevented through the administration of vitamin A during polio campaigns.⁵

4.4 In January 2012, a fourth WHO Region (South East Asia) took a major step towards polio-free certification as India passed the milestone of one year without a single case. As India moved towards this milestone, however, case numbers doubled in 2011 in the three remaining polio-endemic countries: Afghanistan, Nigeria and Pakistan. Given the increasing evidence from recent outbreaks of the terrible consequences of failing to complete polio eradication⁶, but also the potential for success as shown by India, in May 2012 the WHA declared the completion of polio eradication a “programmatically emergency for global public health” and called for a marked increase in the intensity of eradication activities in the poorest performing regions.

⁵ <http://polioeradication.org/Dataandmonitoring/Poliothisweek.aspx>

⁶ Notably outbreaks in adults in DR Congo 2010-2011 caused by type 1 wild poliovirus

4.5 In all three remaining polio-endemic countries, national emergency action plans were established in 2012 to overcome remaining barriers to reaching every child with polio vaccines; in each country, oversight bodies reporting to heads of state were further extended from the national to sub-national levels to intensify political and administrative accountability for the quality of key eradication activities. The core GPEI partners intensified their activities to reflect this emergency and a massive surge of technical assistance was deployed to the highest risk areas for polio to assist governments with strategy implementation. In September 2012, the United Nations Secretary General hosted a high-level meeting on the polio eradication emergency during the 67th session of the United Nations General Assembly, in order to reinforce national and international commitment to achieving eradication and mobilizing the necessary financing. The gathering was attended by the Heads of State of the three countries where the disease is endemic, the heads of the partner agencies, donors and other stakeholders.

4.6 As a direct result of emergency actions taken by GPEI partners and national governments, 2012 witnessed the lowest number of new polio cases in fewer districts of fewer countries than at any previous time in history. Globally, 223 cases were reported in 2012, a 66% decline compared with 2011. At the end of 2012, Angola and the Democratic Republic of the Congo successfully stopped transmission of re-established poliovirus and Chad was on track to do the same. Five countries reported cases in 2012 compared with 16 in 2011. In 2 of the endemic countries, Pakistan and Afghanistan, case numbers declined by 65% and 42% relative to 2011, respectively. In Nigeria, case numbers doubled compared with the same period in 2011, but by end-2012 there was strong evidence of improving programme performance in the historically worst-performing areas.

4.7 Throughout the global eradication effort, viruses from endemic areas, particularly Nigeria and India, have regularly re-infected polio-free areas leading to importation-associated outbreaks and, in four previously polio-free countries, the re-establishment of persistent transmission. Although international spread was limited to only one event in 2012 in Niger resulting from virus genetically linked to transmission in Nigeria, importations will remain a significant and constant threat until all wild poliovirus transmission is interrupted globally.

4.8 In January 2013, the Executive Board of the World Health Organization reinforced the importance of full OPV vaccination of travellers, per recommendations of the WHO publication 'International Travel and Health'.

4.9 As the GPEI has worked to eradicate wild polioviruses globally, it has come to understand better the risks that vaccine-related polioviruses pose to a polio-free world. Vaccine-associated paralytic poliomyelitis (VAPP) was well documented prior to the launch of the eradication effort and it was understood that VAPP could eventually be eliminated by stopping the use of OPV globally after wild virus eradication. Only in 1999-2000, however, was it proven that vaccine-derived polioviruses (VDPVs) could regain the capacity to cause polio outbreaks (i.e. become circulating VDPVs or cVDPVs). It is now understood that VDPVs can also, very rarely, result in chronic infection (i.e. iVDPVs) in individuals with certain congenital immunodeficiency syndromes.

4.10 In 2012, for the first time ever, more countries suffered a polio outbreak due to a cVDPV (primarily as the result of a type 2 virus) than due to a wild poliovirus, reaffirming the importance of rapidly addressing this risk. Fortunately, the substantial body of knowledge built since the first detection of a cVDPV in 1999-2000 has now culminated in the tools and strategies needed to eliminate VDPVs in parallel with wild poliovirus eradication during the period 2013-2018.

4.11 Since the launch of the Global Polio Eradication Initiative, three major deadlines have been set out: interruption of transmission by 2000, certification of eradication in 2005 and, most recently interruption of transmission by end-2012. Consequently, as part of developing this Plan, the GPEI embarked on a critical review of the programme to assess:

- How lessons from past successes and failures should inform future strategy
- Whether the remaining endemic countries were on a trajectory to complete eradication
- The strength of the case for completing eradication, taking into account the new resources required through 2018

4.12 The combination of these evaluations has provided the GPEI with a better understanding of why past deadlines were missed, how close the remaining endemic countries are to achieving their goals, and how critical this global eradication effort continues to be.

ACKNOWLEDGING THE PAST – LESSONS LEARNED

Lesson 1: One Size Does Not Fit All

4.11 The GPEI missed its first target date of 2000 for interrupting wild poliovirus transmission globally. This was due in part to the late launch of OPV campaigns in key geographies, including some plagued by high case rates and intense transmission. At that time, interruption of transmission in any particular country was expected to occur within 2-3 years of the launch of National Immunization Days (NIDs). The launch of these campaign activities as late as 1999-2000 in countries such as the Democratic Republic of Congo and Sierra Leone meant that a 2000 deadline was poorly planned, inadequately financed, and impossible to achieve. Equipped with a better understanding of the critical importance of OPV campaigns in interrupting transmission, the GPEI doubled the number of SIAs conducted in the period 2000 to 2005. This was supported by a tenfold increase in technical support staff and the introduction of house-to-house vaccination. By 2005, six endemic countries remained – down from more than 20 in 2000. Though only six remaining endemic countries globally marked an improvement, the target of certification of eradication by 2005 had not been achieved. Moreover, the programme retained its existing approaches, merely intensifying them, thereby missing opportunities to truly innovate, to refine tactics to the specific country context or to improve routine immunization.

Lesson 2: Technological Innovation cannot overcome gaps in programme management and community engagement

4.12. In the mid-2000s, the GPEI recognized that some areas posed exceptional challenges to stopping poliovirus transmission due to high population density, poor sanitation and a very high force of infection. This complicated the situation in India and Egypt in particular, because unlike the other infected areas at that time, where the main issue was a failure to reach children, both countries had high levels of vaccination coverage but were not achieving high enough serological conversion and mucosal immunity levels to interrupt transmission.

4.13 In 2005, monovalent OPV vaccines (mOPV1, mOPV3), which provided higher per dose sero-conversion rates but tackled only one serotype of poliovirus at a time, were developed and introduced as a means to address this issue. Egypt stopped transmission within 6 months of the introduction of mOPV1, leading many to believe that intensive use of mOPV could overcome persistent transmission in other areas. India introduced mOPV1 and mOPV3 in 2005 but – over the course of the next 5 years – veered between alternating type 1 and 3 outbreaks. Other endemic countries, particularly Nigeria and Pakistan, continued to have widespread transmission. This demonstrated that in the remaining endemic countries, technological solutions alone were not sufficient. By 2010, although only four countries still remained endemic, many more had suffered major importation-associated outbreaks due to weak routine immunization systems.



The GPEI learned that:

- due to underlying factors that affect poliovirus transmission, all countries will not respond to OPV campaigns and stop transmission with similar speed
- in some contexts, it is necessary to tackle issues and focus interventions at a micro level to achieve coverage levels
- Programme performance data are often not accurate enough to guide programme planning and corrective actions
- Technical solutions cannot compensate for basic management and accountability issues
- Strong routine immunization programmes are essential to prevent reinfection and outbreaks

Lesson 3: A combination of innovations can succeed in the most challenging settings

4.13 To rapidly drive immunity levels above the thresholds needed to interrupt poliovirus transmission in the remaining 4 endemic countries, the GPEI needed to develop more effective tactics and tools both to reach the remaining missed children and to more effectively seroconvert them, especially in areas with a high enteric disease burden due to extremely poor sanitary conditions.. It was necessary to more systematically identify who these children were and how they could be reached. Furthermore, the GPEI had to consider how to more accurately monitor the success of these efforts. This represented a substantial departure from previous approaches which were mainly focused on technical solutions with insufficient attention to operational tactics or societal issues.

4.14 The GPEI built on the technical innovations that had contributed to success in Egypt and focused on improvements in operations, monitoring and social mobilization. This included the development of a set of new tactics and tools including, but not limited to: strategies for 'underserved' populations, the Short Interval Additional Dose (SIAD) strategy⁷, seroprevalence surveys and modelling, universal finger-marking, migrant and transit strategies, independent monitoring, and Lot Quality Assurance Sampling (LQAS) surveys. At the same time, the GPEI pursued the rapid development and licensure of a new bivalent formulation of OPV (bOPV), which maximized the impact of each contact with a child by tackling both of the remaining serotypes of wild poliovirus with a new vaccine that achieved an efficacy close to that of each of the monovalent vaccines.

4.15 These approaches were first and most systematically applied in India. By 2010, over 95% of children in India were being reached in OPV campaigns, but the large birth cohort (26 million children per year) meant that the small percentage of children being missed still represented a population sufficient to maintain transmission. These missed children existed mostly in underserved populations, outside the usual health systems – nomads, slum dwellers, children of construction and brick kiln workers, or other mobile and migrant groups. Armed with the new bivalent vaccine and a more thorough understanding

⁷ SIAD approach involves administering two doses of monovalent OPV over the course of one or two weeks.

of its underserved and at-risk populations, India intensively applied a range of new tactics for reaching and protecting these children. On 13 January 2011, India finally recorded its last case of polio due to an indigenous virus in a two-year-old girl near Kolkata. Translating these approaches to the remaining endemic areas and instituting the requisite accountability mechanisms to substantially enhance the quality of vaccination campaigns is a core goal of the *2013-2018 Polio Eradication and Endgame Plan*.

India was able to interrupt transmission because of its ability to apply a comprehensive set of tactics and tools to reach and immunize all children that included innovations in:

- o Microplanning
- o Operations
- o Monitoring & accountability
- o Technology (e.g. bOPV)
- o Social mobilization
- o Surge support

NEW EVIDENCE THAT TRANSMISSION CAN BE INTERRUPTED BY END-2014

4.16 Lessons learned from more than 20 years of successes and failures in polio eradication have informed the National Emergency Action Plans of the three remaining endemic countries. The full implementation of these Plans and intensification of necessary approaches to identify, access and immunize at-risk children who have been persistently missed is the key component of the GPEI's strategy to interrupt poliovirus transmission globally (outlined in detail under Objective 1). New evidence from each of the remaining endemic countries strongly suggests that their polio eradication programmes showed marked improvements in reaching and vaccinating chronically missed children in 2012 and that they are now on a trajectory to interrupt transmission by the end of 2014.

Evidence of progress

4.17 The most critical challenge to interrupting WPV transmission in the last poliovirus reservoirs is driving up OPV coverage in order to exceed the immunity levels needed to interrupt transmission. Accessing certain 'at-risk' populations – particularly those children that have persistently been missed – has been the key challenge.

4.18 The year 2012 saw major breakthroughs in both SIA quality and access to missed children in most of the key poliovirus reservoir areas of each endemic country. In Nigeria, the proportion of very-high-risk local government areas in which the vaccine coverage reached the estimated target threshold of 80% for stopping poliovirus transmission in that setting increased from 10% in February 2012 to 70% in February 2013. In Pakistan, the proportion of highest-risk districts achieving the estimated target threshold of 95% in that setting increased from 59% in January 2012 to a peak of 74% in October; increasing insecurity in late 2012 compromised the capability to collect similar monitoring data through January 2013. In the 11 districts in southern Afghanistan at highest risk for persistent transmission of

poliovirus, the number of children inaccessible during the OPV campaigns declined from more than 80 000 at the end of 2011 to some 15 000 by December 2012.

4.20 As a result of improved SIA quality, population immunity is rising. Past experience and trend line statistical evidence suggests the threshold for interrupting poliovirus transmission is 80% immunity in Nigeria and Afghanistan, and 90% immunity in Pakistan. Based on an analysis of the number of doses of OPV children were receiving in each country by end-2012, it is estimated that the proportions of immune children are approaching these benchmarks.

4.21 Most significantly, these improvements in OPV campaign performance and population immunity are resulting in a substantial decrease in the genetic diversity and geographic extent of poliovirus, particularly in Afghanistan and Pakistan. In 2012, there was a marked decrease in the number of WPV genetic clusters in these countries (Figure 11) and increasingly focused transmission concentrated in limited geographic areas, or reservoirs.

THE CASE FOR COMPLETING POLIO ERADICATION

4.22 The benefits of reaching eradication continue to substantially outweigh the costs, even if there is a delay in stopping the remaining wild poliovirus transmission in one or more countries.

Direct Benefits of Eradication and Risks of Polio Reintroduction

4.23 The public health consequences of failing to complete polio eradication are dire. Research indicates that in a world where polio control (versus eradication) was the aim – and high level population immunity waned as a result of the discontinuation of SIAs – taking into account current routine immunization levels, polio cases would be expected to increase rapidly to at least 200,000 cases annually in low-income countries, a rate comparable to the situation in 1998.⁸ Not only would this generate significant public health and individual costs, it would place enormous strain on country health systems in managing large-scale polio outbreaks and epidemics.

4.24 From an economic perspective, completing polio eradication continues to provide significant benefit. A 2010 analysis of the long-term impact of eradication estimates that achieving eradication will generate net benefits of at least US\$ 40-50 billion, for low and low-middle income countries alone, over the next two decades.⁹ This dwarfs the investment in the GPEI of some US\$ 10 billion to date. This same study also finds that GPEI efforts disproportionately benefit low-income countries, with more than 85% of the economic gains experienced in these countries. The findings hold even when taking into account rising programme costs and varying the assumptions on programme effectiveness. Other studies on the benefits of eradication have similarly found the health and economic gains to substantially exceed the financial costs of polio eradication efforts.¹⁰

Indirect and Intangible Benefits of Eradication Efforts

4.25 The impact of the GPEI extends beyond polio, benefiting other global and country health priorities. Support to measles campaigns, the distribution of vitamin A supplements and enhanced global surveillance and response capacity for epidemic prone diseases are just three areas that have benefitted from polio eradication staff and infrastructure and delivered clear public health dividends. Conservative estimates peg the value of the GPEI's coordination with other health initiatives at US\$ 17-90 billion in benefits associated with mortality reduction¹¹; the distribution of vitamin A supplements alone is

⁸ Tebbens, Thompson, *Eradication versus control for poliomyelitis: an economic analysis* (The Lancet, April 2007).

⁹ Tebbens, Pallansch, Cochi, et al, *Economic analysis of the Global Polio Eradication Initiative* (Vaccine, Oct. 2010).

¹⁰ Thompson, Tebbens, *Eradication versus control for poliomyelitis: an economic analysis* (Lancet, 2007). Musgrove, *Is polio eradication in the Americas economically justified?* (Bulletin of the Pan American Health Organization, 2007).

¹¹ Thompson, Tebbens, *Eradication versus control for poliomyelitis: an economic analysis* (Lancet, 2007). Musgrove, *Is polio eradication in the Americas economically justified?* (Bulletin of the Pan American Health Organization, 1996). Bart, Foulds, *Global eradication of poliomyelitis: benefit-cost analysis* (Bulletin of the World Health Organization, 1996). Kahn, Ehreth, *Costs and benefits of polio eradication: a long-run global perspective* (Vaccine, 2003). Aylward, Acharya, et al, *Global public goods for health: health economic and public health perspectives* (Oxford University Press, 2003).

estimated to have averted between 1.1 (conservative) and 5.4 (maximum) million childhood deaths as of end-2010.¹² Looking ahead, a well-organized and supported 'Legacy' plan that builds on relevant aspects of the polio network's lessons and infrastructure would drive gains across other health priorities. The GPEI infrastructure can provide a strong platform for addressing other vaccine preventable diseases and support national health systems. Exploring this potential which forms a core part of the Plan.

4.26 The significant and incalculable 'intangible' impact of the global eradication programme cannot be disregarded. The size and scope of the programme has required collaboration and cooperation across countries and institutions, and between the public and private sectors. New relationships, communication channels and processes have been developed that can benefit global health more broadly. Vulnerable populations, including those in insecure areas, have been reached as never before. Achieving eradication can provide further momentum for similarly ambitious mortality and morbidity reduction goals (e.g. measles elimination) and demonstrate the impact that coordinated and concentrated action can achieve.

4.27 The GPEI has developed a comprehensive *Polio Eradication & Endgame Strategic Plan* to address all aspects of polio eradication, exploit the unique opportunity to stop all polio disease once and for all, and complete the initiative. The plan builds on new tactics and progress in interrupting wild poliovirus transmission and the development of new tools and new strategies for managing the risks of vaccine-derived poliovirus. This Plan provides the best ever opportunity for completing polio eradication and capitalizing on the huge national and international investments that have been made in this initiative to date.

¹² Thompson, Tebbens, *Eradication versus control for poliomyelitis: an economic analysis* (Lancet, 2007). Musgrove, *Is polio eradication in the Americas economically justified?* (Bulletin of the Pan American Health Organization, 1996). Bart, Foulds, *Global eradication of poliomyelitis: benefit-cost analysis* (Bulletin of the World Health Organization, 1996). Kahn, Ehreth, *Costs and benefits of polio eradication: a long-run global perspective* (Vaccine, 2003). Aylward, Acharya, et al, *Global public goods for health: health economic and public health perspectives* (Oxford University Press, 2003).

5. OBJECTIVE 1: POLIOVIRUS DETECTION AND INTERRUPTION

INTRODUCTION

5.1 The *2010-2012 Strategic Plan* saw a number of breakthroughs for the GPEI. The intense focus on interrupting transmission led to success in India – widely considered the country with the most technically challenging conditions for interrupting poliovirus transmission in the world. The Plan also resulted in the lowest ever number of outbreaks caused by importations into polio-free areas and the interruption of transmission in 2 of the countries in which transmission had been re-established (i.e. Angola and the Democratic Republic of the Congo).

The launch of the Global Polio Emergency Action Plan in May 2012 put the program on an emergency footing to overcome the challenges in the remaining three endemic countries and vigorously protect polio free areas. By the end of the year, the GPEI reported the lowest number of cases ever globally in the fewest number of countries and had made major gains towards overcoming the chronic challenges to interrupting transmission in the remaining endemic countries. However, in some of the key reservoir areas, new risks were emerging to threaten these gains, particularly attacks that left polio workers dead in Pakistan and Nigeria, requiring new approaches to ensure the safety of workers while addressing the underlying issues that contributed to these attacks.

THE GOAL

5.2 With Objective 1, the GPEI aims to take advantage of this momentum, in order to complete the interruption of wild poliovirus transmission globally and to more rapidly detect and interrupt any new outbreaks due to vaccine-derived polioviruses. The key milestones on the path to this objective are to achieve interruption of WPV type 3 by end-2013 and interruption of WPV type 1 by the end of 2014; and to stop all new outbreaks due to cVDPVs within 120 days of an index case.

WHAT IS REQUIRED TO INTERRUPT TRANSMISSION?

5.3 Interruption of wild poliovirus transmission requires rapid detection of all poliovirus transmission (WPV and VDPV) anywhere in the world, overcoming the obstacles to reaching all children with OPV in the three remaining endemic countries, and protecting areas prone to outbreaks and re-importation by maintaining immunity levels above the thresholds needed to interrupt transmission and by rapidly responding to any new outbreaks.

WHAT WILL BE DONE?

MAJOR ACTIVITIES:

1. Strengthening Global Surveillance to Detect Virus Circulation
2. Maintaining an Appropriate Supplementary OPV Immunization Schedule
3. Enhancing OPV Campaign Quality to Interrupt Endemic Transmission
4. Enhancing the safety of OPV campaign operations in insecure areas
5. Preventing and Responding to Polio Outbreaks

ACTIVITY 1: Strengthening Global Surveillance to Detect Poliovirus Circulation

5.4 Global surveillance for poliovirus is fundamental to achieving and sustaining global polio eradication. Sensitive surveillance is vital for the programme to rapidly detect all circulating poliovirus and to guide activities. Acute flaccid paralysis (AFP) surveillance will remain the primary mechanism for the detection of poliovirus, with emphasis on endemic and high risk countries. In addition, environmental surveillance will be further scaled up as a complement to AFP surveillance for detecting the presence of poliovirus in infected areas and populations. This will facilitate the more rapid identification of outbreaks in high risk areas, provide additional information to validate the interruption of transmission, and help document the elimination of vaccine-related strains after OPV cessation.

Acute Flaccid Paralysis Surveillance

5.4 For the three regions not certified polio-free at end-2012, the priority will be to close remaining gaps in AFP surveillance. Based on the global epidemiology of polio at mid-2012, the areas of greatest initial focus will be northern Nigeria, FATA/KP Pakistan, southern Afghanistan and, potentially, bordering areas of neighbouring countries which regularly become re-infected due to population movements and poor routine immunization coverage (such as the countries bordering Lake Chad and west African countries bordering Nigeria). These areas will require particularly intensive AFP and possibly supplementary surveillance activities to detect and respond to any residual transmission.

5.5 In these areas, particular attention will be given to ensuring documented active (at least monthly) AFP surveillance at all major reporting sites. As hospital involvement is critical to sensitive surveillance, there is on-going review of AFP surveillance procedures at major hospitals in risk areas, with a schedule of regular refresher trainings for staff at these establishments. In areas where performance is sub-optimal, the focus will be on staff training, the institution of appropriate management and accountability structures, and in-depth analysis of surveillance data. In addition, the programme is working to institutionalize systems for modifying surveillance networks through tracking of the health care providers visited by AFP cases and updating reporting networks as needed.

Special efforts will also be made to track AFP sensitivity in marginalized and at-risk populations. For example, in Pakistan, health care providers for Pashtun, migrant, and nomadic groups will be specifically

identified and incorporated into the surveillance reporting and informant networks. There will also be a focus on expanding networks of community informants to supplement these more official channels. Finally, where orphan viruses are detected, an investigation will be conducted and surveillance procedures will be reviewed, as appropriate.

5.6 In areas at particular risk of missed transmission, in addition to the above, targeted AFP community searches, 6-monthly active case searches and case searches during vaccination campaigns will be conducted to complement existing AFP surveillance activities. Regional and national plans will elaborate specific activities and budgets, based on quarterly regional risk assessments.

5.8 In polio-free countries, regular risk analyses (quarterly for those regions not yet certified as polio free, and 6 monthly for the three certified regions) will identify areas of sub-optimal surveillance for targeted corrective actions. For the three regions that are certified polio-free - the Americas, Europe and the Western Pacific - the priority will be to sustain AFP surveillance at certification standard¹³. A similar principle will operate for those countries that have been polio-free for several years in regions that have not yet been certified. This will be achieved through mobilizing heightened political commitment to the goals of the polio endgame, allocation of additional resources where needed – including for laboratory capacity - and increased WHO Regional Office support to countries in revitalizing AFP surveillance. Oversight of surveillance quality will be reinforced by Regional Certification Commissions.

Environmental surveillance

5.9 The systematic sampling of sewage for polioviruses currently occurs in dozens of locations across four countries as part of the GPEI. This environmental surveillance will be geographically expanded to help identify any residual transmission in endemic areas, to provide early indication of new importations into recurrently re-infected areas, and to document the elimination of Sabin viruses following the tOPV-bOPV switch and eventual bOPV cessation. This is planned to include sites in Nigeria, Afghanistan and high-risk areas/routes for importation as well as selected areas where OPV cessation must be monitored particularly closely due to a history of cVDPV emergence, or the presence of a national OPV production facility. Consequently, at least 15-20 additional sampling sites will be added by end-2015 .

Special Surveillance

5.10 AFP and environmental surveillance will be complemented by special surveillance studies where needed with four specific approaches. First, there will be expanded use of serologic surveys, on at least

¹³ Certification-standard performance is defined as the achievement of a non-polio AFP rate of at least 1 case of non-polio AFP / 100.000 population < 15 yrs, with adequate stool specimens collected from at least 80% of cases; specimens are defined as 'adequate' if 2 specimens are collected within 14 days of onset of paralysis, at least 24 hours apart, arriving in the laboratory in good condition; all specimens must be analyzed in a laboratory that is accredited by WHO.

an annual basis, to more rapidly assess and validate population immunity levels, stratified by age group, in any areas with persistent poliovirus transmission on at least an annual basis. Secondly, large-scale stool surveys and expanded contact sampling, particularly from all inadequately-sampled AFP cases will be used to more rapidly rule out on-going poliovirus transmission in recently re-infected and/or endemic areas which are no longer reporting polio cases. Thirdly, special studies will be scaled-up among patients with primary immunodeficiency syndromes to more systematically detect iVDPVs in both industrialized and middle-income countries. Finally, special environmental surveillance studies will be conducted for species C enteroviruses in areas with recurrent cVDPV emergences and/or risk factors for cVDPV emergence.

ACTIVITY 2: Maintaining an Appropriate Supplementary OPV Immunization Schedule

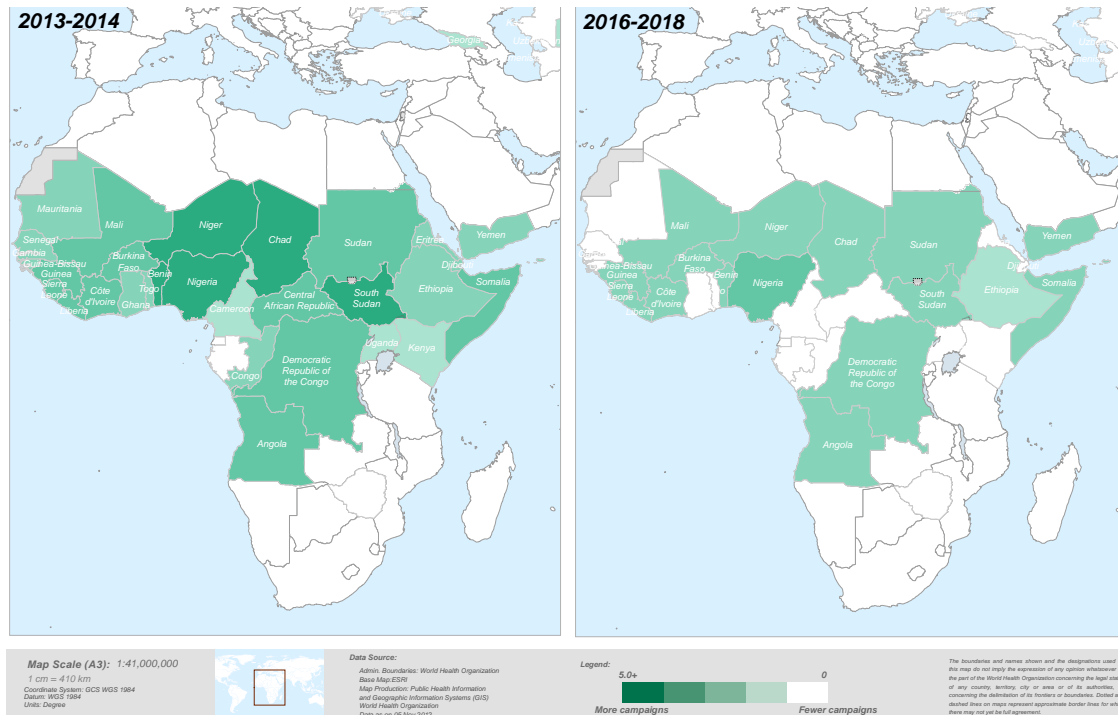
5.11 Supplementary OPV immunization activities (SIAs) are, along with AFP surveillance and routine immunization, a fundamental part of the overall strategy for polio eradication. SIAs are essential for simultaneously boosting both the humoral and intestinal immunity of infected populations to interrupt virus transmission and to maintain population immunity above the threshold for re-infection in high-risk polio-free areas. SIAs can also reduce the risk of cVDPV emergence and spread in areas at risk. Planned SIAs that are conducted on a national or sub-national basis are typically referred to as National or Subnational Immunization Days (i.e. NIDs or SNIDs). House-to-house mop-up campaigns, outbreak response campaigns and Short Interval Addition Dose (SIAD) activities are all types of SIAs.

5.12 The planning of NIDs and SNIDs is guided by a combination of risk assessments and epidemiology. The need for these SIAs in different areas will vary by risk and programme objectives. In 2013-2014, polio endemic areas of Nigeria, Pakistan and Afghanistan will require the most intensive schedules of NIDs and SNIDs to rapidly build the immunity needed to interrupt transmission. In areas at highest risk of recurrent importation from these endemic areas, particularly in west and central Africa, the objective of the continued NIDs/SNIDs during this period is to mitigate the potential for an outbreak following a wild poliovirus reintroduction. Finally, in areas with a history of cVDPVs, such as Somalia, SIAs will be conducted to reduce the conditions favoring VDPV emergence and spread. Figures 14 and 15 below illustrate the planned SIA schedules for these settings. The specific SIA plans for the entire 2013-2018 period are available in the document *GPEI Financial Resource Requirements 2013-2018*.

Figure 14. Planning framework for OPV campaign schedules

Country Status/Risks	Country/Area (examples)	Annual SIA Rounds in 2013-2018
Polio Endemic	Northern Nigeria, Pakistan, Southern Afghanistan	6-8
Recurrent Polio Importations	West Africa, Chad, Sudan, South Sudan	2-4
Recurrent cVDPV Emergence	Northern India, Somalia, Ethiopia, eastern DR Congo	2-4

Figure 15. Map of indicative SIA plans in Africa during the period 2013-2018



ACTIVITY 3: Enhancing OPV Campaign Quality to Interrupt Endemic Transmission

5.13 Interrupting polio transmission requires that population immunity reaches a level where poliovirus is unable to find sufficient numbers of susceptible individuals to sustain transmission. This has been achieved in all but the three remaining polio-endemic countries of the world. Even in these countries, the virus only persists in populations on the margins of society, in areas where health services are largely non-existent and oversight and management are weakest. Routine immunization coverage in these areas is low and repeated SIAs have fallen short of reaching enough children enough times with OPV. In order to achieve interruption of poliovirus transmission in these settings, SIA and routine immunization management and quality must be enhanced.

Enhancing SIA management and quality

5.14 Overcoming the challenges in these last pockets of poliovirus transmission requires that the full experience and strength of national governments, local leaders, and their GPEI partners to be brought to bear on these areas. The lessons learned from successes in other challenging settings, coupled with a commitment to innovative local problem solving, is essential for success. Particular emphasis and attention is needed in 6 major areas as outlined in the following sections.

Microplanning

5.15 The local microplan is the blueprint which maps out all the necessary components - the houses, the vaccination teams and their daily tasks, key influencers, social mobilizers, timings, and logistics - for ensuring vaccinators reach all children with OPV. Incomplete and poor quality microplans in these polio persistent areas are one of the primary reasons for poor campaign quality and accountability. Despite years of campaigns and guidance, microplans are still grossly inadequate in some areas in each of the remaining endemic countries. However, serious efforts are now underway to correct this root problem.

5.16 In Nigeria, the programme introduced house-based microplans for the first time in 2012, heavily informed by the success in areas of India that overcame similar issues with missed areas and missed populations. The development of house-based microplans requires a physical walk-through of all areas by local leaders and supervisors to determine daily vaccinator work areas by enumerated households. These microplans are tightly linked with vaccinator tally sheets, capturing the teams' work by household and allowing cross verification. This is in contrast to previous microplans that simply named an area, established an estimated number of children that the team should cover, and allowed the teams to simply record tallies of their achievements, making it difficult to hold them accountable for missed children or areas.

5.17 In Afghanistan, microplans are being further improved in the volatile southern Region to define how much accessibility the programme has in each area and to identify individuals or groups who have access. The approach is guided by the principle that all populated areas are accessible to someone. These community-based, access-enhanced microplans allow the program to identify exactly which type of person is acceptable in each context to guide planning and to ensure that trusted faces are presented at each doorway. In Pakistan, the targeted violence against health workers in late 2012 has required more extreme modifications to microplanning. Health worker safety has become paramount and assessments of local law enforcement and security officials now form an integral part of the local microplans.

5.18 In all three endemic countries, the microplans are being expanded to ensure the integration of social mobilization activities, including details of local influencers, and to more effectively reach children outside of households. More robust, monitored plans are being developed for teams at marketplaces and major transit points, and incorporating detailed mapping of nomadic groups and their traditional routes of travel and temporary settlement areas. New technology is also being used in some areas to enhance campaign microplanning by using digital mapping to validate and refine the plans and to identify missed areas.

Frontline vaccination workers

5.19 The heart of the polio eradication programme globally is the frontline worker who ensures that polio vaccine reaches every child in their microplan. When vaccinators and supervisors with the right profiles are recruited, trained, and supported through effective supervision, even the most difficult areas achieve very high coverage. In the areas where the virus continues to circulate, one inevitably finds weaknesses in this aspect of the program. The situation is no different in the persistent poliovirus

transmission areas of Afghanistan, Nigeria, and Pakistan. In recognition of the importance of these frontline workers, all three countries raised the daily wage rates for vaccinators in 2012.

5.20 A major emphasis in each of the remaining endemic countries will be to establish vaccinator selection committees with local membership and guided by partner organization staff to find workers who are both acceptable to the local community and as accountable as possible to local authorities. Standards for team composition will be disseminated and tracked to ensure that the team has the right mix of members who are acceptable to local communities, can enter households to find all available children, and can be held accountable for their performance.

5.21 These programs will also seek to retain a higher proportion of vaccinators and to overhaul training procedures with a focus on interactive skill-based training wherein team members demonstrate their abilities before heading out to the field. Data from many countries, most recently Pakistan, show a strong correlation between caregiver satisfaction with team performance and vaccine acceptance; caregivers are more likely to refuse OPV when they are not satisfied with team performance. Maintaining trained and motivated on-the-ground staff who understand the community dynamics, speak the local language, and are socially acceptable to deliver OPV and interact with mothers is key to success. A new Interpersonal Communication skills kit is being produced and special training conducted in several high-risk areas of Nigeria and Pakistan to ensure vaccinators are able to present themselves to caregivers both courteously and professionally. In Afghanistan, a similar module was rolled out in select districts of Kandahar in the last quarter of 2012. The focus in the future will be to apply such strategies more broadly and consistently, especially through 2013-2014.

Social Mobilization and community engagement

5.23 Experience throughout the GPEI has shown that poliovirus circulation stands little chance of surviving in fully mobilized communities, even in the most difficult contexts. Many countries have also demonstrated the importance of demand-generation for OPV to create local ownership. In the areas of persistent transmission in the three remaining endemic countries, there are both significant gaps and real opportunities for generating demand for OPV. Securing the buy-in of the most marginalized and disaffected communities to accept OPV is particularly vital to complete polio eradication. Past strategies have proven successful as demonstrated by decreasing vaccine avoidance in all country programmes. Looking ahead, the GPEI's major emphasis will be to focus communication and social mobilization activities to the specific social, cultural and political context of each infected area, with less of the larger global or national flavour of the campaign. Communication activities will be tailored to specific target audiences, with greater engagement with those individuals who can credibly deliver messages to those most sceptical of the programme.

5.24 Fundamental to improved acceptance of OPV is to understand the needs of communities through appropriate social research and to match that with the capacity of the programme to deliver those needs. This research may show that communities want additional health interventions, such as deworming tablets. Such findings will be analysed and where feasible, systematically integrated into operational and financial planning. Equally, the social research may indicate basic infrastructure and

service demands, such as sanitation or schooling. The programme will work with the government and relevant partners to supplement efforts to meet these needs according to the programme's capacities.

5.25 Social mobilization networks have been scaled-up in all remaining polio-endemic countries in 2012, with early data showing that in communities where these volunteers are deployed, there are higher rates of campaign awareness, increased conversion of refusals and reduced numbers of missed children. These networks include two types of mobilizers: those who work at the household level, going door-to-door to engage and promote polio vaccination with parents and caregivers, and those who reach out to community and religious leaders to seek their support for OPV campaigns. For the household level, mobilizers are trained and supported to recognize and address the concerns of communities, provide accurate information through locally appropriate channels, and enable parents to make informed decisions. Interpersonal communications skill building is aimed at establishing trust with parents and caregivers to immunize their child with OPV every time it is offered. At the community level, local influential people such as imams, priests, village heads, school teachers, businesspeople and landowners are identified and engaged to act as key influencers at community meetings, make announcements in places of worship, or go door-to-door to encourage resistant parents and caregivers to accept OPV. Such influencers are highly effective in creating a supportive and safe environment and in building confidence in the safety and efficacy of the vaccine.

NUMBERED POINT. From a message creation perspective, social data will be utilized to develop appropriate content, deliver information through credible sources and identify channels that reach all communities. Political advocacy and mass media will continue to play an important role reinforcing local outreach. As endemic polio has now been restricted to communities with large and predominantly Muslim populations, a greater effort is underway to ensure the right mix of voices are in place to support eradication efforts. Support from international and regional level will help to ensure that advocacy plans and partnerships engage and enlist the support of such diverse and sometimes opposing groups as political parties, academics, and religious and cultural groups. Partnerships with a broad spectrum of religious and medical institutions are being rolled out and will be expanded in all polio priority areas through 2014.

Monitoring

5.26 In 2012, major gains were made in the monitoring of OPV campaign performance in the remaining endemic countries. A standard monitoring framework now covers the three phases of campaign activity – from planning to implementation to post-campaign assessment. Technological advances in data transmission over mobile networks have helped these countries to improve and the timeliness of their information flows. All three countries have established emergency operations centres at national and critical sub-national levels to review standardized information, often flowing at near real time speed, on campaign preparedness and implementation. Standards for campaign preparations have been communicated to local officials in the infected areas of all three countries. Measurements of performance in meeting those standards are now done at pre-defined intervals in advance of each campaign accompanied by criteria for deciding when an activity should be postponed due to inadequate preparation.

5.27 Once campaigns have started, the emphasis shifts to in-process monitoring. The local evening meeting becomes the critical platform for identifying gaps in implementation and taking immediate corrective action. All the endemic countries are revising the monitoring procedures to ensure that missed children are identified each day, along with the reasons that they were missed and the progress in covering them. Indicators on the daily performance are also transmitted to emergency operations centres where they are analysed and flagged for action, especially in Nigeria and Pakistan. When implementation is complete, end-process evaluations are used to gauge the overall quality and identify areas needing further work or focus during the next SIA. Market surveys and independent monitoring provide data across all campaign areas. Of particular importance, the remaining endemic countries have also adopted the new gold standard for gauging campaign quality – Lot Quality Assurance Sampling (LQAS). This methodology strikes the best balance between ease of field implementation and statistically-reliable results that can be used to track trends over time in the most sensitive areas.

5.28 For social mobilization interventions, the pre-, intra- and post-campaign monitoring is being used to ensure real-time course corrections in planning, implementation and assessment in all infected areas. To facilitate this, the GPEI has begun to refine the LQAS and independent monitoring processes to produce more consistent social data for understanding the reasons for missed children. These data guide catch-up activities and direct ‘intra-round’ communication planning to increase OPV acceptance. This is being complemented in 2013-2014 with special investigations using a standardized tool to answer specific questions such as the reasons for persistent transmission in areas of reported high coverage, the social and operational issues in areas with clusters of zero-dose Non Polio AFP cases, and areas with chronic refusal households.

5.29 Monitoring systems for communications will continue to evolve through the endgame. The PolioInfo system – now implemented in Pakistan, Afghanistan, Nigeria and India – already allows for regular monitoring of field-level activities, linked to a global data base. Standard indicators are regularly monitored and presented in a dashboard format, to measure communication performance, identify issues, develop higher impact messaging and demonstrate programme results. Media monitoring and other tactics will be scaled-up to ensure discussion in the public sphere remains supportive of the eradication effort.

Surge Support

5.30 Achieving repeated high-quality OPV campaigns in the persistent polio transmission areas requires a level of rigor and attention that is often overwhelming for the weak health system infrastructures in these areas. A consistent contributing factor for continued poliovirus circulation in persistent pockets is an outright lack of trained human resources and technical expertise – health worker positions sometimes remain vacant for years, if they even exist at all. GPEI approaches this gap in two ways: to quantify the health worker gaps and work with officials find solutions; to fill the gaps with a surge of additional human resources at the sub-district level to supplement the existing capacity until vacancies are filled. Success in India showed that this approach can successfully provide the level of field presence

and accountability required to achieve quality campaigns relatively rapidly. Before 2012, none of the three endemic countries had this kind of support. In 2012, that situation has been reversed, with WHO and UNICEF recruiting more than 5000 field-level technical and social mobilization workers on behalf of the governments to assist local eradication efforts.

5.31 The focus of 2013-2014 will be to optimize the number, distribution and skill set of this human resource surge and to track the progress in filling health worker vacancies. Particular attention will be given to further equipping and training these field-level staff so that they provide the most effective support possible to local government counterparts to interrupt polio and improve routine immunization coverage rates.

Technical Innovation

5.32 Vaccines remain the core tool of the Global Polio Eradication Initiative and a focus of technical innovation and research. The development and expanded use of bivalent OPV (bOPV) in 2009-2010 has allowed the program to maximize immunogenicity to the remaining wild poliovirus serotypes (types 1 and 3) for each contact with vulnerable children. This has resulted in record low levels of wild poliovirus type 1 and 3 circulation globally in 2012, with data suggesting that wild poliovirus type 3 may now be on the verge of eradication. The GPEI has also spearheaded the development of other vaccine products, including monovalent OPVs, and conducted key research to both reduce the costs of IPV use and to better understand its impact in developing country settings. As global polio eradication achieves various milestones, the GPEI will tailor its use of these vaccines to best fit the epidemiological context and goals.

5.33 The GPEI is also innovating the way programmes are monitored by taking advantage of advances in and geographic information systems and data transmission over mobile phone networks. In both Nigeria and Pakistan, campaign data that used to be laboriously compiled on paper and transmitted by hand or fax increasingly flows in real-time through entry into smart phones. In Nigeria, the precise location of polio cases are fixed and mapped using global positioning devices (GPS) and geographic information systems (GIS) allowing more in depth analysis of locations where polio continues to occur. Nigeria is also leading the way in an unprecedented effort to use the digital geographic tools to identify areas where children have not had the opportunity to be vaccinated and allow real time analysis of areas that have been missed or overlooked so that they can be followed-up. This is the first time that these tools have been used in this way and on this scale.

Operational tactics

5.34 As detailed in the section on 'Lessons learned', the GPEI continues to challenge and test its fundamental operational tactics to find better ways of achieving the goals. One example is the expanded use of the Short Interval Additional Dose Strategy (SIAD). This strategy exploits shorter intervals between campaigns to more rapidly boost immunity. This is particularly relevant in security compromised areas to fully exploit windows of opportunity, in outbreak situations to rapidly boost immunity, and in areas where persistent management weaknesses have left children unprotected for a long period of time. Considering the SIAD approach will be a standard strategy in each of these situations in all polio endemic and outbreak countries, as appropriate.

5.35 Other examples of operational innovations include the programme's exploration of better ways to disburse funds to frontline workers. The payment of thousands of volunteer vaccinators over vast geographical areas in settings with poor infrastructure and management accountability systems is a big challenge and a considerable risk to achieving high quality SIAs. In the remaining endemic countries, mechanisms for the direct disbursement of funds to front line workers are now in place in many areas to reduce the number of transactions between fund source and vaccinator, minimize gaps in payments and to eliminate 'ghost teams', and underage vaccinators. Discussions are now underway in Nigeria to push this further by exploring the possibility of using vaccinator mobile phones as a method of payment.

Research Priorities to Improve Campaign Impact

5.36 Research to identify and assess strategies that may further improve the impact of each campaign is another area within this activity. The current priorities for assessment are:

- Expanded Target Age Groups: experience from large outbreak response activities in 2010-11 suggests that expanding the target age group for OPV beyond 5 years of age in SIAs may accelerate the interruption of polio transmission due to a number of factors, particularly improved coverage among the very young.
- Inactivated Poliovirus Vaccine: there is increasingly strong evidence that a supplementary dose of IPV can substantially boost mucosal immunity in OPV-vaccinated populations, potentially accelerating eradication.

Although extending these approaches to the remaining endemic areas has substantial communications and logistical implications, both are being further evaluated for use in endemic reservoir areas if transmission persists beyond 2013.

The polio programme in Pakistan is collaborating with the Aga Khan University to pilot the use of IPV with OPV in 2013 as an additional tool to rapidly build an immune response in children that have not been easily reached through regular polio campaigns or routine immunization. Pakistan will investigate the operational feasibility of using IPV with OPV in campaigns in areas of the Federally Administered Tribal Areas (FATA) and Balochistan where difficult access and management issues have prevented the programme from building immunity to the levels needed to interrupt transmission. These efforts will be combined with other health promotion activities and the mobilization of paediatricians to address other health concerns of families.

ACTIVITY 4: Enhancing the safety of OPV campaign operations in insecure areas

5.41 Although the GPEI has long experience in working in insecure areas, only in late 2012 were polio vaccination workers targeted during OPV campaigns by violent, coordinated attacks that left workers injured or dead. This development establishes a new reality in some of the remaining infected areas, to which national programmes must adapt as they extend their reach to those last populations and places

where wild poliovirus remains endemic or, in the case of Somalia, where there is a persistent cVDPV. These places and populations are often characterized by a long history of neglect, receiving little or no services or external assistance. This has contributed to an environment favourable to suspicions, conspiracy theories and other issues that appear to underpin the violent reaction the programme has encountered in its work to reach some of these areas.

5.42 Addressing this new reality has required the establishment of a new overarching framework for operating in insecure areas, with tailored approaches for each priority insecure setting. The basic elements of this framework include:

(a) Adapting SIA Operations: SIA operational adjustments are being made to reduce the exposure of the programme and vaccinators to potential threats (eg. phased or low-profile campaigns, fixed-site, etc), based on district-specific risk assessments;

(b) Enhancing Safety & Security Measures: coordination between civilian, health and security services is being enhanced to improve, where necessary, the physical safety of vaccinators and facilities (eg. through provincial security coordination committees, police escorts, etc), again based on district-specific risk assessments;

(c) Improving Community Demand: particular attention is being given to improving the local community demand for access to vaccination and basic services through a combination of awareness raising activities around the disease, its consequences and its prevention, and, if appropriate, by coupling OPV with the delivery of other services/interventions;

(d) Strengthening Religious Advocacy: stronger advocacy by appropriate Islamic leaders and institutions at the local, national and international levels is being supported to ensure all Muslims are aware of their obligation to ensure the vaccination and protection of children against polio, as well as the sanctity of health workers and services; and

(e) Measures to prevent spread: increased emphasis is being given to reducing the risk of spread from such areas by continuing an intensive SIA strategy in surrounding areas and ensuring the vaccination of travellers in/out of infected areas to the degree possible. Permanent immunization teams have been established on the periphery of access-compromised areas in an effort to increase the opportunities for immunizing any children moving in and out of these areas. Such teams are also operating round-the-clock at important border crossings between Pakistan and Afghanistan, to cover travellers between the two countries, and reduce the international spread of the virus.

5.43 This overall approach, and the national level tactics in particular, will be formally reviewed and adjusted on a 6-monthly basis to review lessons learned and take corrective/new actions as needed. If the polio programme and local community are unable to address these security threats in some areas,

or unable to access sufficient children to stop transmission, a series of contingency strategies will be implemented. While some of these will operate concurrently with 2013-2014 eradication efforts as outlined above, others may take effect only at end-2014 – the target date for interrupting transmission globally – if there is continued transmission. Additional actions at that time could include a combination of: new measures to further reduce the risk of spread from any remaining infected area(s) (e.g. consideration of a standing recommendation for vaccination of travellers under the International Health Regulations); steps to further increase the impact of each immunization contact in these areas (e.g. expanded target age groups; house-to-house delivery of IPV, potentially using hand-held jet injectors); extraordinary negotiations to access children through cease-fires, Day of Tranquillity or similar measures when virus transmission is restricted to a very small area; and exceptional measures for the safety and security of vaccinators in very limited areas.

ACTIVITY 5: Preventing and Responding to Polio Outbreaks

5.37 The primary strategy for reducing the risk of polio outbreaks following WPV importations or due to the emergence of a cVDPV will be the rapid strengthening of routine immunization services, as outlined in Objective 2 of this Plan. This will be complemented by continued SIAs in areas at highest risk of importations and/or cVDPV emergence as summarized in Activity 2 above.

5.38 In addition, to further reduce the international spread of poliovirus all countries will be urged to fully implement WHO's existing recommendations for the vaccination of travellers, as outlined in chapter 6 of the WHO publication 'International Travel and Health' and reinforced by the WHO Executive Board in January 2013.¹⁴ In 2014, the Director General of WHO may convene a Review Committee, under the International Health Regulations (2005), to advise on the need for a standing recommendation on the vaccination of travellers to and from any area with persistent poliovirus transmission in 2015.

5.39 A more aggressive approach to outbreaks of both wild- and vaccine-derived polioviruses will be implemented with the goal of stopping any new poliovirus outbreak within 120 days of the index case. Building on experience from more than 100 wild and vaccine-derived poliovirus outbreaks over the last 10 years, the new response tactics will include implementing a minimum of 5 response rounds (each covering a minimum of 1 million people), expanding the target age group for the first 2 rounds (e.g. to < 15 years of age or the entire population, depending on the epidemiology), and reducing the interval between the first 3 rounds (e.g. from 4-6 weeks to 2-3 weeks). Joint national and international rapid assessments will be conducted at 3 and 6 months following the index case to assess the quality of the outbreak response and plan course corrections.

5.40 Whereas outbreak response activities have historically been driven by isolation of a poliovirus from a paralyzed child, during the eradication and endgame period environmental data will also be used more

¹⁴ International Travel and Health: <http://www.who.int/ith/chapters/en/index.html>

systematically to guide outbreak response planning and implementation. For endemic and other high risk areas, the detection of a positive environmental sample will help to guide the geographic extent as well as the duration of a response. In previously polio-free areas, the detection of a positive environmental sample will trigger both a virologic and an epidemiologic investigation to guide heightened surveillance and, if appropriate, an immunization response.

WHO IS OVERSEEING THIS WORK?

The Independent Monitoring Board

Independent oversight of polio eradication activities is provided by the Independent Monitoring Board (IMB).

6. OBJECTIVE 2: ROUTINE IMMUNIZATION STRENGTHENING AND OPV WITHDRAWAL

INTRODUCTION

6.1 High routine immunization coverage has been an important strategy for the global polio eradication program since its inception. For the polio endgame, however, high routine immunization coverage is 'essential' to optimize the management of the immediate and long-term risks of poliovirus. In addition to facilitating the interruption of wild poliovirus transmission and reducing the risk of wild poliovirus importation and spread, high routine immunization coverage is the best strategy for reducing the risk of cVDPV emergence before, during and after the withdrawal of oral poliovirus vaccines.

6.2 In addition to reducing the immediate and long-term polio risks, this imperative establishes a significant opportunity for the GPEI to effectively help strengthen routine immunization systems. Most of the world's under-vaccinated children live in countries that either remain endemic for polio or have experienced multiple poliovirus importations and outbreaks. The GPEI has acquired extensive experience in reaching the most difficult to reach children in these countries, substantial GPEI human and material resources are currently deployed in the polio endemic and high risk countries, and there is a strong interest within countries and among immunization partners, particularly GAVI, to take concerted action with GPEI to improve routine immunization in these countries. Exploiting such an apparent opportunity has to date proven quite difficult in many countries, particularly those with intensive SIA schedules.

6.3 However, a strong foundation exists for the GPEI to rapidly align with broader efforts to strengthen routine immunization systems. At a strategic level, polio eradication is a key objective under the Decade of Vaccines. At an operational level, polio eradication activities have always been part of the routine immunization programme in all countries, and polio-funded workers already contribute to routine immunization activities. This forms the basis for a more focused and strategic alignment of the GPEI with the goals of the Global Vaccine Action Plan during the period 2013-2018.

6.4 The importance of enhancing routine immunization coverage against polio is reflected in the fact that in 2012 more countries reported outbreaks caused by a circulating vaccine-derived polioviruses (cVDPV) than due to a wild poliovirus. A number of countries with persistently low immunization coverage have experienced repeated cVDPV emergences, often resulting in prolonged outbreaks.

6.5 To minimize the immediate and long term risks of polio, the essential elements of the polio endgame therefore include strengthening of routine immunization coverage and changing the polio vaccines used in both routine and supplementary immunization activities. In May 2008, in line with guidance from SAGE, the WHA endorsed the principle of synchronized OPV cessation globally.

Recognizing that wild poliovirus type 2 was eradicated in 1999 and that more than 90% of the cVDPV cases in recent years were caused by the vaccine derived type 2 strain, in 2012 SAGE further recommended the withdrawal of OPV2 as the first step towards complete withdrawal of all oral polio vaccines. In November 2012, the SAGE recommended that all countries should introduce at least 1 dose of IPV in their routine immunization programme to mitigate the risks associated with the withdrawal of OPV2.

THE GOAL

6.6 Objective 2 aims to systematically use the GPEI infrastructure to more effectively strengthen routine immunization services, particularly in a set of ‘focus countries’, thereby contributing to broader global immunization targets, facilitating the introduction and increased impact of IPV, and reducing the risks of cVDPV emergence before, during and after the withdrawal of OPV serotypes from immunization programmes globally. The key milestones on this path to this objective include the achievement of at least a 10% year-on-year increase in DPT3 coverage in the majority of worst performing districts in focus countries from 2014, the introduction of at least 1 dose of IPV in all OPV-using countries in 2015, and the withdrawal of OPV type 2 globally in 2016.

WHAT IS REQUIRED?

6.7 In order to introduce IPV and replace trivalent OPV with bivalent OPV (types 1 and 3) globally, the GPEI and immunization partners must assist the 144 countries that currently use trivalent OPV in their routine immunization programs, while giving particular attention to improving routine coverage in a number of ‘focus countries’ that harbour the greatest number of unimmunized children and where the risk of cVDPV emergence and persistence is often greatest.

WHAT WILL BE DONE?

Major Activities:

- 1. Increasing Routine Immunization Coverage**
- 2. Ensuring Appropriate IPV, bOPV and mOPV Products**
- 3. Introducing IPV**
- 4. Withdrawing OPV from Routine and Supplementary Immunization Activities**

ACTIVITY 1: Increasing Routine Immunization Coverage

6.8 Increasing routine immunization coverage will have several direct benefits for the *Polio Eradication & Endgame Strategic Plan* by minimizing the risk, rate and extent of polio outbreaks; helping to control

polio transmission if there are delays in eradication in the remaining endemic areas; reducing the emergence of VDPVs; and increasing the impact of IPV and bOPV following withdrawal of OPV2.

6.9 Geographically, the GPEI is best positioned to assist with routine immunization strengthening in those countries where it has deployed the most significant number of staff at the sub-national level as part of the intensified global eradication effort. Because persistent polio transmission has correlated most closely with weak routine immunization services, these same countries contain most of the world's under vaccinated children and most of the countries that GAVI, WHO and UNICEF have identified as priorities for targeted support based on a low national level of immunization coverage (<70%). These 'focus countries' for the GPEI's intensified attention to routine strengthening include Afghanistan, Chad, the Democratic Republic of the Congo (DRC), Ethiopia, India, Nigeria, Pakistan, Somalia, and South Sudan as well as Angola. Of these countries, several are also identified under the GAVI Fragile States policy.

6.12 Routine immunization programmes in the focus countries face challenges in a number of specific areas where the GPEI can potentially provide support, including:

- Programme management and accountability
- Human resource capacity and supervision
- Programme monitoring, vaccine-preventable disease surveillance, and data use
- Vaccine management, supply and cold chain
- Communications, health education and social mobilization
- Political support, funding, and advocacy

6.10 A coordinated approach will be developed between the GPEI, GAVI and other immunization partners to support national authorities in pursuing a revitalized and focused routine immunization strategy to increased coverage in these countries. The goal in these focus countries is to contribute to at least a 10% year-on-year improvement in DPT3 coverage rates in the worst performing high risk districts for polio. The progress will be monitored through regular program evaluations and rapid surveys to assess coverage.

6.13 The first step in the focus countries will be for the GPEI, GAVI and other immunization partners to support the respective national authorities to develop annual integrated action plans for strengthening routine immunization. Details will be elaborated and a workplan with milestones and deadlines finalized by end-2013. Within this framework, the GPEI staff activities in poor performing districts will be specifically directed towards strengthening national and local capacity in the following four areas:

- **Management**, including systematic use of accountability frameworks, enhanced data management, evidence-based planning, training and vaccine supply management,

- **Microplanning**, including population mapping, harmonization of routine immunization micro-plans with polio SIA micro-plans to enable more complete session planning, vaccine supply management, and cold chain logistics.
- **Mobilization**, including top level advocacy, engagement of local community leaders, and household level outreach. Social mobilization activities will be focused on generating demand for routine immunization, providing details on when and where routine sessions are held, mobilizing caregivers to attend routine sessions, and addressing parent and caregiver concerns regarding the safety and utility of vaccines,
- **Monitoring**, of immunization sessions, local community coverage and acceptance of vaccines, social mobilization efforts, availability of health workers, vaccine delivery and other immunization session logistics, and overall quality and impact of services. The application of real time collection and analysis will generate local data for immediate corrective action and increased accountability.

6.14 The impact of such GPEI activities on routine immunization coverage rates, when combined with political commitment and the support of local authorities, is best illustrated by the experience in the state of Bihar, India, where during the period of the most intense polio eradication activities, assessed coverage for fully immunized children increased from around 30% to nearly 70%. In the 41 most challenging, high-risk 'blocks' (sub-district unit) in which the polio programme resources were most focused, full immunization coverage rose even higher than the state average.

6.11 In Africa, the polio eradication initiative currently funds 90% of the 1000+ personnel associated with WHO Regional Offices for Africa's Immunization and Vaccine Development (IVD) effort. A full 53% of IVD staff time is already spent working on multiple diseases, while only 47% is spent on polio alone. These IVD staff are now deeply involved in activities that directly support routine immunization, performing roles and activities that range from implementation of the 'reaching every district' (RED) strategy to the provision of supportive planning and the development of GAVI applications for Immunization Systems Strengthening support.

6.15 The focus country initiatives to strengthen routine immunization systems will be supported and coordinated at the international level by the GPEI's spearheading partners (WHO, Rotary International, CDC and UNICEF) and the Bill and Melinda Gates Foundation. Of these organizations, WHO, UNICEF, CDC and the Bill and Melinda Gates Foundation all have dedicated staff supporting routine immunization strengthening at country level, while Rotary International contributes to routine immunization as a key

part of its Polio Plus Programme. Increasing collaboration on routine immunization across these organizations, as well as with GAVI, is fundamental to the Plan.

6.16 In December 2012, the GAVI Board committed to working with the GPEI on routine immunization stating that it “approved GAVI playing a complementary role to the GPEI in the polio eradication effort, specifically through routine immunization within GAVI’s strategy and mission using existing structures, processes and procedures.” The GAVI Board also “approved GAVI exploring the suitability and possible use of IFFIm as one potential financing mechanism to support this activity within GAVI’s strategy and mission using existing structures, processes and procedures.” Following this decision, the GPEI partners and GAVI initiated work to elaborate a joint work plan for priority countries that will be finalized in 2013.

6.17 To drive planning for increased GPEI support to routine immunization, the polio programme has identified key activities within each of the above-mentioned programme areas (Figure 24). These will be further consolidated in 2013. To support these activities, by end-2014 it is targeted that at least 50% of the time of polio-funded field personnel will be devoted to specific, measurable activities to help national authorities strengthen routine immunization systems and services.

Figure 24. Select activities across key Routine Immunization focus areas

Focus area	Select Activities
Management	<ul style="list-style-type: none"> • GPEI field workers: ToRs for surge staff in polio-endemic countries updated to incorporate key measurable activities to support RI strengthening. These staff will support governments to monitor fixed and outreach sessions, track vaccine supply/availability, support health worker training, develop mechanisms to identify children not immunized through RI while visiting households during supervisory visits and monitoring of SIAs (especially newborns) and drive community demand for and engagement with RI. • Performance Improvement through supportive supervision and in-service training to improve the core competencies of district and sub-district immunization managers and health workers. • Supply systems (in particular cold chain): Vaccine management data will be more regularly collected and tracked to identify supply issues (including stock outs, wastage) and rapid corrective action. Training will be rolled out where necessary to educate providers on proper handling, usage and disposal of vaccine and consumables.
Microplanning	<p>Harmonization of Routine Immunization Micro-plans with Polio Microplans: Local-level coordination on microplans will deliver greater detail on settlements and hard-to-reach populations for RI outreach services.</p> <p>New tools: The use of GIS and GPS tools to improve micro-planning</p>

	<p>and monitoring for polio in Nigeria will be expanded for use in RI programmes.</p> <ul style="list-style-type: none"> • RED Approach: The best practices from the Reaching Every District (and Community) approach will be applied to local program planning.
Mobilization	<ul style="list-style-type: none"> • Community Engagement: GPEI will support government partners/community organizations/NGOs to use existing polio channels and best practices to mobilize and engage communities for routine immunization. • Evidence-based social mobilization: Social mobilization and communications tailored to local barriers to RI, based on monitoring data obtained locally.
Monitoring	<ul style="list-style-type: none"> • Systematic monitoring: Monitoring of immunization sessions, availability of immunization staff, logistics, vaccines and cold chain and rapid assessments of local community coverage and reasons for under-vaccination. • Performance Indicators: Rationalized, standardized, and widely used by programme managers and development partners, to improve immunization programme performance. • New tools: Developed and field-tested for improving the ability to verify immunization status and confirm coverage data. • Record Quality: Identify mechanisms for increased retention and improved design of home-based and clinic immunization records • Local and global data systems: Developed with initial deployment of improved immunization information systems in focus countries. • Stronger Focus on Data Quality: Expertise shared in data quality and use, including home-based records, survey methodologies, and assisting countries with information system transitions. • VPD Surveillance: Assist with further expansion of surveillance for vaccine-preventable diseases to monitor disease control and changing epidemiology and to guide program actions.

ACTIVITY 2: Ensuring Appropriate mOPV, bOPV and IPV Products

6.18 As progress towards wild poliovirus eradication accelerated in the late 1990s, a new risk to a polio-free world became apparent. In rare cases in areas with extensive immunity gaps, vaccine-derived polioviruses (VDPVs) were able to mutate to the extent that they acquired characteristics of wild poliovirus. These VDPVs – especially type 2 – are causing circulating vaccine-derived poliovirus outbreaks (cVDPVs), which are associated with permanent paralysis, including bulbar polio, and death,

similar to WPV outbreaks. Even more rarely, VDPVs have been shown to persist for years in some individuals with primary immunodeficiency syndromes (iVDPVs).

6.19 By 2005, expert polio eradication and immunization advisory bodies concluded that addressing these risks in a comprehensive manner, and eliminating all paralytic polio disease, would ultimately require stopping all use of oral poliovirus vaccines (OPV) globally as part of the polio eradication endgame.¹⁵

6.20 Currently there are 144 countries that use trivalent OPV to vaccinate children against polio in their routine immunization programmes. The trivalent oral polio vaccine contains the poliovirus type 1, 2 and 3 serotypes and which successfully eradicated type 2 wild poliovirus by 1999, will be the first OPV to be withdrawn. At end-2012, 90% of cVDPV cases were being caused by viruses derived from the type 2 component of the oral polio vaccine. In 2012, five polio outbreaks due to circulating type 2 vaccine-derived polioviruses (cVDPV2) were detected, in Chad, DR Congo, Kenya, Nigeria, Pakistan, Afghanistan and Somalia (the outbreaks in Nigeria and Somalia represent on-going transmission for longer than 36 months). Given this, and the long-term risks of vaccine-associated paralytic poliomyelitis (VAPP) and iVDPVs, the use of specific OPV serotypes will be phased out globally from all immunization activities and programmes, beginning with withdrawal of OPV2 vaccine. This phase-out will begin with withdrawal of OPV2 vaccine by replacing all trivalent OPV with bivalent OPV (types 1 & 3) in global routine immunization programmes by mid-2016.

6.21 To safeguard against the withdrawal of the type 2 serotype, SAGE recommended in November 2012 that at least one dose of IPV should be introduced into all routine immunization programmes prior to the switch from tOPV to bOPV. This IPV dose is expected to:

- Prevent paralytic polio in individuals exposed to a cVDPV type 2 or wild poliovirus type 2;
- Improve the immunological response to mOPV2 if required to be given in response to a WPV2 or cVDPV2 outbreak after tOPV cessation;
- Reduce transmission of cVDPV2 or WPV2 should either be introduced after tOPV cessation;
- Boost immunity to wild polioviruses type 1 and 3 in vaccine recipients, which may further accelerate wild poliovirus eradication.

6.22 The introduction of IPV into all low- and low-middle-income OPV-using countries will require a combination of volume purchasing of existing IPV products, which could lead to overall reduction in price-per dose costs, and the development of alternative low-cost IPV options that can potentially be priced at < \$1.00 per dose. Two alternative, low-cost options currently under development for the near-medium term include:

- Licensing of intradermal (ID) fractional (1/5th) dose IPV; and,

¹⁵ Resolution WHA61.1: 'Poliomyelitis: mechanism for management of potential risks to eradication'

- Development of new, adjuvanted and antigen-sparing intramuscular (IM) IPV products.¹⁶

6.23 Given that countries may have a preference for either the ID or the adjuvanted IM IPV option, and that there is insufficient evidence at this time to recommend one approach over the other, both options are being pursued. At end-2012, both approaches faced regulatory and/or development challenges which could be addressed in the near-term (24-48 months) with intensive support from the international community, the development of a multi-dose policy for IPV, and rapid mapping of regulatory pathways.

6.24 Recognizing that the development of new, low-cost IPV options may not meet the optimal timeline for a 'tOPV-bOPV switch', the GPEI is working with manufacturers, GAVI and stakeholders to develop a strategy by end-2013 to allow initial introduction of IPV in low and low-middle income countries using existing products at substantially reduced prices, with a transition to more sustainable, low-cost products as they become available. GAVI will consider support for IPV as part of its Vaccine Investment Strategy by end-2013. In addition, by 2018 there should be feasible options for safely producing IPV in developing country settings (e.g. Sabin-IPV) to ensure all countries have the opportunity to produce IPV for routine immunization.¹⁷

6.25 The recent availability (since 2009), and proven efficacy of bivalent OPV against the remaining wild polioviruses type 1 and 3 serotypes is central to the OPV 2 withdrawal strategy. A sufficient and secure international supply of this product for an eventual tOPV-bOPV switch will be available by early 2015 for countries procuring WHO pre-qualified OPV. Those countries that currently rely on national OPV production will need to develop and license a bivalent OPV by end-2015. The GPEI will prioritize its work with manufacturers in such countries to ensure all countries have sufficient access to bOPV in advance of OPV2 withdrawal.

6.26 Following the tOPV-bOPV switch, bOPV will be the vaccine of choice for responding to all type 1 or type 3 wild poliovirus outbreaks and monovalent OPV2 will be the vaccine of choice for responding to any cVDPV2 outbreak or a WPV2 release from a laboratory or production facility. A stockpile of 500 million doses of mOPV2 as bulk will be available by end-2015 for this purpose. After the tOPV-bOPV switch, GPEI will make provision for rapid access to stand-alone IPV (up to 10 million doses) for countries and areas contiguous with, but outside of the area of, an outbreak to rapidly reinforce population immunity. Ideally this can be achieved through careful management of the global IPV buffer stock. The detection of an ambiguous vaccine-derived poliovirus (aVDPV) type 2 may trigger a pre-emptive IPV response in the immediate area.¹⁸

¹⁶ Resik et al Cuba study, JID, 2010 demonstrated that one fractional dose (1/5th or a full dose), after multiple OPV doses may be sufficient to establish immunity base (seroconversion and priming).

¹⁷ SAGE meeting, 10-12 April 2012: http://www.who.int/immunization/sage/previous_april2012/en/index.html

¹⁸ Ambiguous vaccine-derived polioviruses (aVDPVs) are vaccine-derived polioviruses that are either isolated from people with no known immunodeficiency, or isolated from sewage whose ultimate source is unknown.

6.27 Following bOPV cessation (target date 2019) a combination of monovalent OPVs and IPV (per above) will be used for responding to any wild or vaccine-derived poliovirus outbreak, regardless of serotype. An international stockpile of 300 million doses of mOPV1 and 300 million doses of mOPV3 will be established by end-2017 for this purpose.

ACTIVITY 3: Introducing IPV

6.28 To boost population immunity against type 2 polioviruses prior to OPV2 cessation, and to maintain a polio type 2-primed/protected population thereafter, SAGE recommended in December 2012 that all countries should introduce at least 1 dose of IPV into their routine immunization programmes. As summarized above, this will help maintain population immunity against type 2 poliovirus, improve the response to mOPV2 or an additional dose of IPV in a type 2 polio outbreak, reduce the transmission of a reintroduced type 2 poliovirus and thereby substantially reduce the consequences of a subsequent circulating poliovirus - in terms of paralytic disease - and facilitate the containment of outbreaks.¹⁹ Evidence demonstrates that this could also accelerate wild poliovirus eradication by boosting immunity to wild poliovirus 1 and 3. For countries at particular risk of cVPDV emergence, this approach may need to be complemented with additional measures such as pre-cessation tOPV campaigns to boost immunity or introduction of two routine IPV doses. Recognizing that the risks associated with eventual bOPV cessation may be similar to those associated with OPV2 cessation, it is recommended that countries plan to continue administering at least one dose of IPV in their routine immunization programmes for at least five years after bOPV cessation.

6.29 Lessons learned in the introduction of new vaccines in low and middle income countries over the past decade, (e.g. of Haemophilus influenzae type b, pneumococcal or rotavirus vaccines) will be beneficial to IPV introduction. Countries will need to perform proper planning and preparation building upon existing checklists for cold chain, logistics and vaccine management, health care worker training and supervision, waste management, injection safety and adverse events following immunization (AEFI) monitoring. GPEI partners, particularly WHO and UNICEF, in conjunction with GAVI and other immunization partners, will assist countries to prepare for the introduction of IPV. Relevant support activities will include training of health workers, communications development, cold-chain management, and development of vaccine management strategies.

6.30 Introduction of IPV in routine immunization will require intensive outreach to caregivers and providers. Communications strategies will depend on the nature of the OPV phase-out and IPV introduction and will be determined based on acceptance of routine immunization, the presence of

¹⁹ Sutter RW, Kew OM, Cochi SL, Aylward RB. Poliovirus Vaccine-Live. Plotkin SA, Orenstein WA (eds), 6th edition, in Vaccines. W.B. Saunders Company, Philadelphia, PA, 2012 (in press). Alexander LN, Seward JF, Santibanez TA, Pallansch MA, Kew OM, Prevots DR, Strebel PM, Cono J, Wharton M, Orenstein WA, Sutter RW. Vaccine policy changes and epidemiology of poliomyelitis in the United States. JAMA. 2004 Oct 13;292(14):1696-701. Estívariz CF, Molnár Z, Venczel L, Kapusinszky B, Zingesser JA, Lipskaya GY, Kew OM, Berencsi G, Csohán A. Paralytic poliomyelitis associated with Sabin monovalent and bivalent oral polio vaccines in Hungary. Am J Epidemiol. 2011 Aug 1;174(3):316-25. Epub 2011 Jun 17.

political opposition or anti-vaccine lobbies, and the operational approaches to including IPV in the schedule while OPV is still being offered. A clear rationale for OPV and IPV administration will be provided to the media, medical institutions and religious, traditional and political leaders. Public communication to caregivers will focus on the success of polio eradication, which opens the door for the provision of new vaccines such as IPV to complete the existing polio program. Advocacy among technical experts for public support and endorsement of IPV and OPV will be critical in this area.

6.31 Given the geographic scope of this vaccine shift, social research will be undertaken in all priority countries to determine acceptability of IPV and, as necessary, develop tailored messages for specific audiences. This work will help the program prepare nuanced communications that can be delivered prior to the vaccine introduction (at least six months in advance) to help prepare caregivers and providers for the change. Social mobilizer networks, trained health workers and credible community and religious leaders will be relied upon to deliver or endorse messages to caregivers and providers at the local level. If necessary, these messages will be supported through mass promotion of IPV and routine immunization in print, radio, television and new media.

ACTIVITY 4: Withdrawing OPV from Routine and Supplementary Immunization

6.32 Prior to the withdrawal of OPV2 – by replacing tOPV with bOPV in all OPV-using countries, 6 pre-requisites need to be in place:

1. Validation of the elimination of persistent cVDPV2s and confirmation of wild poliovirus type 2 eradication
2. An mOPV2 stockpile and response capacity
3. Surveillance capacity and an international notification requirement for all Sabin, Sabin-like, and cVDPV type 2 viruses
4. Sufficient bOPV products for all OPV-using countries
5. Affordable IPV option(s) for all OPV-using countries
6. Phase II bio-containment of all type 2 cVDPVs and wild polioviruses

6.33 In addition to these pre-requisites, achieving the global withdrawal of type 2 oral poliovirus vaccine (OPV) will require meeting a combination of logistical, communications, vaccine supply and programmatic challenges. Substantial logistical challenges must be addressed to synchronously switch all OPV-using countries from tOPV to bOPV, withdraw the tOPV field stocks, and safely destroy or contain residual type 2 Sabin vaccine viruses.

6.34 With these challenges in mind, four basic principles will guide the withdrawal of OPV2:

- There must be complete cessation of use of all tOPV globally by a fixed date,
- Cessation should be coordinated across all countries using tOPV,
- All remaining stocks of tOPV at the time of cessation must be collected and destroyed; and

- The process must be documented.

In practice this means that an indicative target date should be established internationally three years in advance of type 2 cessation, with a firm date established at least 12 months in advance of the switch to bOPV and cessation of tOPV use. This will enable vaccine manufacturers, suppliers, and national health authorities to plan appropriately. National plans must include:

- Logistics plans detailing the quantities of bOPV required for the replacement of tOPV, transport and storage requirements for the withdrawal of the remaining stocks of tOPV, and the designation of secure collection points during the withdrawal phase;
- Training and communication plans for health workers to ensure that they understand the reasons for and process of the switch, and that they can communicate these effectively to the communities they serve; and
- Training, logistics, and communications plans for the introduction of a dose of IPV into routine immunization schedules (see above).

Key elements of stopping tOPV use and withdrawing the remaining stocks will ideally include:

- Ensuring that the last shipments of tOPV to national level and sub-national levels are closely managed during six months, before the agreed target date for cessation
- Conducting national stocktakes of vaccine at all levels at six months and then one-two months prior to cessation and one month after cessation; and
- Designating secure collection points for tOPV, which will accept vaccine from one month prior to one month after cessation of use.

Following the transition from tOPV to bOPV, all remaining stocks of tOPV must be destroyed, or securely stored at national level, within 3 months. Documentation of the process of withdrawal of tOPV from use, and collection and destruction or remaining stocks, will be critical for National Certification Committees and the Regional and Global Certification Commissions. Understanding that this will be the first global withdrawal of an OPV serotype, it will be essential to constantly evaluate the process to validate assumptions and document best practice for eventual bOPV withdrawal.

6.35 Accompanying this logistical work will be a comprehensive communications strategy for caregivers and parents whose children will receive the new vaccine schedule, and training of the health workers who will implement it. IPV introduction has been successful in all countries that have made the switch, often with little or no public outreach regarding the change. Research on the social acceptance of IPV from Western Uttar Pradesh and Bihar India suggests that IPV will be accepted if communities are clearly informed of the reason for the transition, along with assurances of IPV safety and effectiveness. However, the reaction to IPV introduction coupled with a switch to bOPV requires more social research, especially in communities where trust in OPV or immunization in general is weak. A clear rationale for OPV and IPV administration will be provided to caregivers and the switch will be communicated as an improvement and acceleration of the existing polio program, not a move to resolve any type of vaccine

failure. Communication efforts will engage social mobilizer networks, credible community and religious leaders, and mass promotion in print, radio, television and new media.

6.36 Following global certification of eradication of all wild poliovirus serotypes, bOPV will be withdrawn from routine use globally, ensuring the elimination of all polioviruses. As with the withdrawal of tOPV, substantial logistical challenges must be addressed to synchronously stop routine bOPV use, withdraw remaining OPV field stocks and safely destroy or contain the residual Sabin strain viruses. The experience gained during the withdrawal of tOPV will be of tremendous use during this final step in the removal of all oral poliovirus vaccines.

WHO OVERSEES THIS?

SAGE

Activities under Objective 2 are overseen by the Strategic Advisory Group of Experts on immunization.

7. OBJECTIVE 3: CONTAINMENT AND CERTIFICATION

INTRODUCTION

7.1 Following interruption of wild poliovirus 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 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 wild poliovirus are:

- the absence of any wild polioviruses for a minimum of 3 years in all countries of the Region,
- the presence of certification-standard surveillance in all countries during that 3 year period, and
- the completion of Phase I bio-containment activities for all facility-based wild poliovirus stocks.²⁰

Certification at the Regional level is done by independent Regional Certification Commissions (RCC) which report in turn to the Global Certification Commission (GCC). RCCs are supported by independent National Certification Committees (NCCs), which assess, verify, and present to the RCC the required national documentation on polio-free status. 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.

THE GOAL

7.3 The goal of objective 3 is to certify the eradication and containment of all wild polioviruses by end-2018 to enhance longterm global security from poliomyelitis.

WHAT IS REQUIRED?

²⁰ See footnote 10 for the definition of certification-standard surveillance.

7.4 The global certification of wild poliovirus eradication – and verification of the elimination of vaccine-related viruses – will require ensuring highly sensitive poliovirus surveillance, and full application of relevant poliovirus bio-containment requirements, globally. Chronic gaps in surveillance sensitivity will need to be addressed in both recently infected countries and countries which have long been certified as polio-free, overcoming complacency, weak health systems, geography, insecurity and other challenges to identifying and investigating paralyzed children. International consensus will need to be established on the timelines and phasing for implementation of bio-containment 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.

WHERE ARE WE CURRENTLY?

7.5 The first Global Action Plan (GAP) for containment of wild poliovirus was developed in 1999 with the recognition that containment of wild polioviruses needed to be addressed in advance of certification of eradication. Implementation of the first Global Action Plan identified the national laboratory survey and inventory as an essential first step toward containment. These activities were started in 2000 in the Western Pacific region and subsequently expanded to other regions. Following the outbreak of cVDPV in Hispaniola (2000-01) the Global Action Plan was updated to include containment of vaccine-derived polioviruses in addition to WPV (GAP II). 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 (GAP III) outlines relevant biosafety levels and safeguards for handling wild, Sabin and Sabin-derived polioviruses following eradication and eventual OPV cessation.

7.7 Containment activities have commenced in all 6 WHO Regions. In 3 WHO Regions (Americas, Europe, and Western Pacific), all Member States have completed Phase I containment survey and inventories for wild poliovirus materials. In the 3 WHO Regions that are not yet certified (African, Eastern Mediterranean and South-East Asian), 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 wild poliovirus 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 Poliovirus Vaccine (IPV). The majority of the remaining 39 Member States to complete Phase I are located in southeast Asia and sub-Saharan Africa; the latter is thought unlikely to possess a substantial number of facilities with wild poliovirus materials

due to infrastructure challenges. Nevertheless, it is planned that these countries will complete the Phase I work in the near future.

7.8 Regional Commissions have accepted final documentation for polio-free status from 86% of member states (167 of 194). This includes all member states of the three WHO Regions which are already certified – AMR (PAHO), EUR and WPR. The majority of the remaining countries which have not yet submitted final documentation are in Africa; in the Southeast Asia Region, only India remains and in the Eastern Mediterranean, 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 Nigeria, Pakistan and Afghanistan interrupt all wild poliovirus transmission by end-2014, as targeted, the remaining two WHO Regions – Africa and the Eastern Mediterranean – could potentially be certified by end-2017, with global certification occurring as early as the following year.

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 GAP III 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 GAP III 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 reconvening of the expert ad-hoc Bio-safety Group to develop a revised timeline, followed by broad public consultation and specific consultation with vaccine manufacturers. The final step in the process of developing post eradication containment policy will be its adoption by the World Health Assembly as part of the comprehensive post eradication endgame strategy. International agreement on the timing and implementation of the plan will ideally be established by end-2014, potentially with a WHA resolution to that effect in 2015.

7.10 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. These activities have largely been completed globally with the exception of the persistent polio-infected countries and those which have suffered recurrent reinfections. Following confirmation that wild poliovirus transmission has been interrupted for one year, Appropriate legislation and regulation will need to be initiated in all countries in preparation for completion of containment of all wild polioviruses 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 full containment of all Sabin 2 polioviruses.

7.11 Countries retaining wild polioviruses for the purposes of Salk-IPV production and/or essential QA/QC, laboratory or research functions may constitute the greatest residual wild poliovirus risks. At end-2012, five countries had active Salk-IPV production sites: Belgium, Denmark, France, the Netherlands, and Sweden. The number and location of countries which retain wild polioviruses for essential QA/QC, laboratory and research functions will be finalized with completion of Phase 1 bio-containment activities globally (i.e. inventory and destruction of viruses and infectious materials). These areas will require full application of the *primary*, *secondary* and *tertiary* bio-containment safeguards outlined in GAPIII to minimize the risk of inadvertent or intentional wild poliovirus re-introduction. These safeguards are good facility design and management (primary safeguards), 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 *tertiary* safeguards while those retaining only OPV materials after cessation of routine OPV will be expected to meet *primary* and *secondary* safeguards. For wild poliovirus type 2, these safeguards will need to be in place by 2015; for wild poliovirus types 1 and 3 it is anticipated that these safeguards will need to be in place by 2018.

ACTIVITY 2: Certifying the Eradication of WPVs

7.12 It is anticipated that a 4th WHO Region – Southeast Asia – could potentially be certified polio-free in 2014, contingent on the timely submission of full documentation by all relevant National Certification Committees (NCCs) and their acceptance by the South East Asia Region (SEAR) RCC.

7.13 At its meeting in mid-2012, the Global Certification Commission (GCC) noted that prior to OPV2 cessation it will have to formally 'conclude' that type 2 wild poliovirus 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 type 2 WPV 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 6 WHO Regions.

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

7.15 For the three WHO regions that have been certified polio-free - the Americas, Europe and Western Pacific - the immediate priority will be to again achieve and maintain certification-standard performance in all areas with an AFP policy by 2015 to ensure the capacity to detect and respond to any cVDPV emergence following the planned 'tOPV-bOPV switch'.²¹ This will be achieved by continuing 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 Regions yet to be certified polio-free (as of end-2012), the priority will be to close remaining gaps in AFP surveillance by 2014 (particularly in northern Nigeria; West, Central and Horn of Africa; 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. It is anticipated that, as in the certified regions, RCCs and NCCs will play an important role in sustaining certification-standard AFP surveillance performance at the national and subnational level.

WHO OVERSEES THIS?

GCC & RCCs

The Global Commission for Certification of the eradication of poliomyelitis (GCC) oversees the overall process of certification. The Regional Certification Commissions (RCCs) provide the GCC with documentation of certification activities under their oversight.

²¹ Certification-standard performance is defined as the achievement of a non-polio AFP rate of at least 1 case of non-polio AFP / 100.000 population < 15 yrs, with adequate stool specimens collected from at least 80% of cases; specimens are defined as 'adequate' if 2 specimens are collected within 14 days of onset of paralysis, at least 24 hours apart, arriving in the laboratory in good condition; all specimens must be analyzed in a laboratory that is accredited by WHO.

8. OBJECTIVE 4: LEGACY PLANNING

INTRODUCTION

8.1 Achieving the first three objectives of the *Polio Eradication & Endgame Strategic Plan 2013-2018* will lead to the completion and closure of the GPEI. As the initiative enters its final stages, the GPEI, in collaboration with the global health community, must plan to ensure that investments made in the cause of polio eradication are built on to benefit other development goals.

THE GOAL

8.2 Objective 4 aims to ensure that the investments made to eradicate poliomyelitis contribute to future health goals, through a programme of work to systematically document and transition the learnings and assets of the Global Polio Eradication Initiative. A key milestone for this objective will be the establishment of a comprehensive polio legacy strategy by end-2015.

WHAT IS REQUIRED?

8.3 There are three principal aspects of the Polio 'legacy' work:

- mainstreaming the long-term polio immunization, surveillance, communication, response and containment functions into other on-going public health programmes in order to protect a polio-free world;
- ensuring that the knowledge generated and lessons learned during more than 20 years of polio eradication activities are shared with other health initiatives; and
- transitioning the capacities, processes and assets that the Global Polio Eradication Initiative has created to support other health priorities.

WHERE ARE WE CURRENTLY?

8.4 During 25 years of operations the GPEI has mobilized and trained millions of volunteers, social mobilizers, and health workers; reached into households untouched by other health initiatives; mapped and brought health interventions to chronically neglected communities; and, established a standardized, real-time global surveillance and response capacity. While all of these activities have been carried out primarily for the purpose of polio eradication, they have simultaneously benefited other health work, principally through the GPEI's surveillance and response capability for other vaccine preventable diseases and the delivery of basic health services by polio vaccination teams.

8.5 One major achievement stands out as a key legacy for other health programmes: over the past 25 years the GPEI has accessed the chronically unreached, marginalized and most vulnerable populations in the world. In doing so valuable lessons have been learned and the polio programme has developed the knowledge, capacities and systems to overcome the logistic, geographic, social, political, cultural, ethnic,

gender, financial and other barriers to working with the most marginalised, deprived and often security-compromised children and communities. This has provided the opportunity for polio workers to deliver a range of additional basic health services including anti-helminthics, vitamin A supplements, measles mortality reduction activities, bed-nets and routine immunization. Key elements of the GPEI that allowed it to reach chronically missed children include the programme's detailed micro-planning and mapping, tracking of mobile and migrant groups, social mobilization programmes, and systematic training and deployment of vaccination teams.

8.6 The GPEI's far-reaching access has delivered a global surveillance capacity for vaccine-preventable diseases and a response capacity for both health and humanitarian emergencies in some of the world's most demanding settings. Through its integrated AFP surveillance and laboratory capability, the GPEI receives regular and credible reporting on any instance of acute flaccid paralysis (AFP) and is able to respond appropriately. This unprecedented surveillance capability came from the need to identify, notify and investigate many tens of thousands of AFP cases worldwide every year. This has also facilitated surveillance and response for other diseases including measles, tetanus, meningitis, yellow fever and other VPDs, and assisted in the global response to both public health and humanitarian emergencies such as SARS, the Pakistan floods of 2010-11, and the South-East Asian Tsunami of 2004.

8.7 The sharing of GPEI assets and lessons with other global health initiatives is an essential element of the polio legacy. This should include the GPEI's experience in routine immunization strengthening (including modifying polio tools and innovations to benefit immunization systems), establishing best practices in data management, community engagement and mapping, and building a motivated and trained health workforce for the global public good. The polio workforce already contributes to this work and will continue to do so throughout the Endgame period. Closer linkages between measles and rubella programme activities and the GPEI have well recognized benefits for both programmes. SAGE, the IMB and donors have all recommended that countries and global immunization partners assess the potential synergies and take active steps to transition the polio infrastructure and lessons learned to support the achievement of measles and rubella elimination targets and the strengthening of routine immunization programmes.

WHAT NEEDS TO BE DONE?

MAJOR ACTIVITIES:

- 1. Mainstreaming Polio Functions**
- 2. Leveraging the Learnings**
- 3. Transitioning the Assets and Infrastructure**

ACTIVITY 1: Mainstreaming Polio Functions

8.8 Countries and organizations involved in polio eradication will need to plan to integrate activities undertaken for polio eradication into their on-going functional structures, and transition staff, as

needed. This mainstreaming of technical operations will be an essential part of securing the legacy of polio and covers a number of categories:

- Ensuring the continued integration of polio routine immunization (IPV) and communication activities into national and international routine immunization programmes;
- Fully integrating polio surveillance and response activities into national and global disease alert and response mechanisms; and
- ensuring appropriate containment of polioviruses according to agreed international and national standards, regulations and protocols in countries that maintain poliovirus stocks.

ACTIVITY 2: Leveraging the Learnings

8.9 Through its 20 plus years of operation, the GPEI has developed a set of lessons or best practices that are of potential benefit to other health programmes and priorities. By examining a number of the GPEI's areas of operation, at both the national and international levels, it should be possible to identify key lessons that may be relevant to the broader health community. This exercise will include an examination of the following indicative areas:

- strategic planning and policy development;
- partnership management and donor coordination;
- programme operations and tactics; and,
- oversight and monitoring.

This process will be undertaken by the GPEI spearheading partners in consultation with national governments and other key stakeholders and focus on GPEI's knowledge rather than its tangible assets.

ACTIVITY 3: Transitioning the Assets and Infrastructure

8.10 In order to outline the tangible assets that have been created through the polio eradication initiative, to establish the activities and contributions that polio-funded staff are conducting and making beyond polio eradication efforts, and to look at what capacities could be at risk with the eventual closure of the polio eradication programme, it is necessary to first comprehensively map the polio assets. This exercise will take place during 2013-14.

8.11 The second major element of planning for the post-polio era is the consultative process. The purpose of the consultative process is threefold. First, to tell the polio story to a broader community that understands what polio eradication is, but may not grasp the full extent of the programme's potential to benefit other health initiatives. This exercise will feed into the second purpose, which is to have broad stakeholder consultation on what the assets created through global polio eradication efforts could be used for beyond polio. This is not a proscriptive exercise but is rather intended to stimulate discussion around the potential benefits of these assets to other programmes and initiatives. The third priority in this process will be to consult with national governments on how polio assets could benefit

their health priorities (e.g. strengthening routine immunization, disease surveillance, and measles control). These consultations will take place throughout 2014. This consultative stage will examine what polio assets and learnings are able to contribute to immunization and surveillance for other vaccine-preventable diseases but will also look at whether there are potential lessons and impact for broader health systems.

8.12 The third element of the consultative process will be to examine funding and management issues and in particular whether there are potential funding sources for those GPEI assets that could be applied more widely. This includes consultation through the WHO governing bodies as the high level fora for decision-making on the GPEI. The consultative process on the wider use of the GPEI assets and infrastructure will address issues related to the management of the tangible assets, the transfer and/or integration of staff into other programmes, and the funding of human resources and/or other assets with wider applicability to vaccine-preventable diseases.

WHO OVERSEES THIS?

WHA

The initial stages of the legacy planning process will be overseen by the Governing Bodies of the World Health Organization, with decisions made for oversight and management as that plan develops.

9. RISKS, RISK MITIGATION AND CONTINGENCY PLANNING

The Polio Eradication and Endgame Strategic Plan has been designed to achieve polio eradication taking into account the specific challenges of each of the four major objectives. Unexpected factors and external risks can delay or undermine the GPEI's ability to achieve the Plan's four major objectives. Recognizing risks, identifying mitigation options and articulating contingency plans enhance the GPEI's ability to rapidly react to problems.

Six major forward-looking risks have been identified under two headings:

INPUT RISKS

1. Insufficient funding
2. Inability to recruit and retain the right people
3. Insufficient Supply of Appropriate Vaccines

IMPLEMENTATION RISKS

4. Inability to Operate in areas of insecurity
5. Decline in Political and/or social will
6. Lack of Accountability for Quality Activities

INSUFFICIENT FUNDING

Risks: All activities in this strategic plan must be funded, sufficiently in advance to allow implementation as scheduled and at a high standard. As outlined in Section 11, the GPEI projects a financial requirement of US\$ 5.5 billion for the 2013-2018 period.²² The larger the gap in financing, the more planned activities would need to be cut and the higher the risks of failure to complete eradication.

Risk Mitigation Activities: In order to secure full funding, donors must have confidence that GPEI will deliver and that the benefits of a polio-free world are worth the investment. Donor input has been incorporated into the GPEI strategy on an ongoing basis. In addition to traditional funders, innovative finance mechanisms and alternative sources of funding – including new donors – are being explored, as part of the ongoing resource mobilization effort. There is an emphasis on upfront long-term commitments in order to provide greater certainty to the GPEI on the likelihood of full funding. Over time, if funding gaps appear, new opportunities for fundraising from traditional and non-traditional donors and other sources will be explored.

Multiple options are currently being developed to ensure a robust cross-agency resource mobilization effort following the Vaccine Summit in April, 2013, to help operationalize funding commitments, and fill any funding gaps. By mid-June, 2013, it is expected that new resource mobilization structures will be in place to guide and drive the post-Vaccine Summit fundraising effort.

²² See section on Financial Resources 2013-2018

Of equal importance is the careful stewardship of raised funds, active cost management and continued transparency with donors. Continuous improvement as it relates to the GPEI's operations will be critical, particularly as vaccine and vaccination approaches evolve through 2013-2018. The GPEI will also maintain an increased level of transparency with key constituents – including donors – on the sources and uses of funds and how to manage deviations in either.

Contingencies: Without the necessary donor confidence and funding, the programme will not reach eradication in the planned timeframe and its focus and activities would necessarily be narrowed, in relation to the size of the funding gap. If extreme, this could include paring back of activities, which will occur using a pre-determined GPEI priority scheme. This mandates a list of the top five priorities that the GPEI strives most to protect: core staff, surveillance/lab net, endemic country SIAs, outbreak response and high-risk/other country SIAs. All other programme aspects would be at risk of being cut.

INABILITY TO RECRUIT AND RETAIN THE RIGHT PEOPLE

Risk: Individuals with technical expertise, management skills and those that can navigate the local, social and political dynamics are necessary for completion of eradication. Without such individuals, quality will suffer. Talent shortages have already been experienced. In addition, as the end of 2014 approaches, the projected date for WPV interruption, there is increased risk of both turnover as individuals seek alternative opportunities, assuming polio activities will be wound down, and perverse incentives for the polio workforce not to complete eradication.

Risk Mitigation Activities: First, the GPEI will systematically evaluate the consultants and the STOP resources and focus on retaining the highest performers. Second, the programme will recruit with a long term mindset, reminding current and potential staff that they have an opportunity to secure longer term employment, particularly under future Legacy arrangements. Third, the GPEI will undertake a new recruitment drive to establish a global roster for key skill sets.

Contingencies: In very limited cases, the GPEI will consider more extreme measures to get the right people in the right places. These measures will include increased compensation and/or incentives to get the most talented staff to work in challenging geographies. Similarly, international staff could be re-allocated to difficult areas. In addition, outsourcing will be considered.

INSUFFICIENT SUPPLY OF APPROPRIATE VACCINES

Risk: Due to a variety of factors that include the need to respond rapidly to changing epidemiology, periodic vaccine supply shortages have been experienced, threatening and, in some cases, causing programmatic disruptions. In 2012, unanticipated cVDPV2 outbreaks in Somalia, Kenya and Chad required unexpected (and urgent) demand for tOPV. Additionally, the de-listing of WHO prequalified

bOPV and tOPV products from two major OPV suppliers contributed to an overall OPV global shortage in 2012.

Risk Mitigation Activities: For the tOPV-bOPV switch, the GPEI will bring in new suppliers, continue to support the possible re-entry of delisted products and maintain production (avoiding shutdowns) to ensure sufficient supply. To incentivize reliable production and supply, the programme will offer longer term production contracts through 2016 and prioritize support to national manufacturers to ensure all countries have access to bOPV in advance of OPV2 withdrawal.

For the introduction of IPV, in addition to volume purchasing of existing IPV products the GPEI is pursuing the development of two low cost IPV options: adjuvanted intramuscular IPV and intradermal fractional dose IPV. . The GPEI will also work closely with regulatory authorities – utilizing tactics from sequential to parallel licensing and WHO prequalification – to ensure rapid approval. Similar to OPV supply, the GPEI will seek to incentivize production through longer term contracts.

Contingencies: Without sufficient vaccine supply, eradication will likely not meet the planned timelines. Assuming insufficient supply, vaccine delivery priorities will be based on the prevailing epidemiology. In the near-term, this would mean a focus on the endemic countries and interrupting transmission. An IPV supply shortage could be managed by subsidizing whole dose IPV until low dose becomes available.

INABILITY TO OPERATE IN AREAS OF INSECURITY

Risk:

For many years, the polio eradication programme has operated successfully in countries with challenging security environments. However, the security threat to the programme itself has always been secondary. In 2012, the landscape of the security threat altered significantly, as was forcibly demonstrated by the assassinations of polio eradication health workers in Pakistan in December 2012. In 2013-2014 in all three remaining endemic countries, complex security issues that the programme cannot control may delay expected progress in the areas of persistent transmission: in northern Nigeria, the killings of polio workers and the increased threat of kidnapping of international staff in addition to the ramifications of ongoing conflict (though the situation appears to be improving as the government has experienced success in dealing with militants, resulting in fewer and less damaging attacks); in Pakistan, the killings of polio workers and the Pakistan Taliban's vaccination ban in North and South Waziristan; in Afghanistan, increased instability due to the eventual withdrawal of coalition forces. Pending elections in Afghanistan and Pakistan, and the potential for rising tensions, may complicate already difficult situations.

Risk Mitigation Activities: At the international level the GPEI is introducing multiple strategies to attempt to ensure the safety of staff and the ability to access children. This includes investment in political and security analysis to improve understanding of evolving contexts; strengthening security

coordination and communications across the GPEI partners; strengthening capacity for political and conflict analyses; and, continued study of best practice of handling security threats in a humanitarian context. Recognizing that each situation is unique, the GPEI has identified a range of tactics to improve execution quality. Of primary importance is gaining community acceptance. Creating new alliances and partnerships with Muslim and Islamic financial, social and development-oriented institutions will promote greater public confidence in areas where polio is making its last stand. The GPEI is deepening its engagement with the Organization of Islamic Cooperation and other Islamic institutions to increase public support, access and demand for polio vaccination.

For the three remaining endemic countries and Somalia, the GPEI has established a Strategic Framework for Polio Eradication under Complex Security Threats. This outlines the security threats in each country and identifies key strategies to mitigate these threats and maintain continuity of programme operations. Host government capacity and strength of response are the most important factors in risk mitigation, supported by local threat assessment, security planning, coordination and strategic deployment of security assets. Within the Strategic Framework, a key element is the development of security access operations plans with the overarching principle to **'Stay and Deliver'** – maintaining polio eradication programme criticality at a high level across the UN, ensuring safety and security mechanisms go beyond hardware and a bunker approach, and instituting strong local capacity for threat assessment, conflict analyses and negotiations with all parties. The programme will also seek to maximize use of local versus international staff. This will be complemented by structures and practices that promote transparency and accountability and these staff should have expertise in conflict, political mapping and associate skills.

Strengthening security capacity – including an emphasis on training polio managers on security management, accountability and engagement strategies – will help prepare staff to handle issues as they arise. The engagement model going forward will focus on enhanced coordination and information sharing, including engagement with UN Department of Safety and Security (UNDSS), UN security, resident coordinators, UN Country Teams and local government security forces.

Security analysis will also be disaggregated to a more local level to identify and engage nontraditional partners and decision makers, and to allow for effective identification of issues and development of area-specific strategies. This approach has been used in limited ways in Afghanistan and has offered valuable insight into the nature, timing and duration of conflict and calm.

Finally, the GPEI is exploring the viability and potential of packaged health services delivery or 'pluses'. Fatigue associated with campaigns and distrust for the program may be overcome if a larger set of health services are offered that deal with other acute needs (i.e. clean water).

Contingencies: A series of contingencies may be utilized in regions where insecurity cannot be managed and access to children is restricted despite the best efforts of national governments and the international community. Following the WHO Executive Board deliberations and guidance of January 2013, an IHR committee would be convened to advise the Director-General, WHO, on additional

measures that should be implemented to reduce the risk of international spread, that might include recommendations on vaccination of travellers in and out of inaccessible areas and, if necessary, travel restriction into those areas. Eradication efforts would rely heavily on vaccination points in and out of inaccessible areas, with an effort to increase vaccination coverage of surrounding areas. Civil-military structures would be revisited to see how they may be helpful and the GPEI would consider substantially increasing incentives for periods of calm, and invest in advocacy and mediation for corridors of peace for vaccination. In addition, the polio infrastructure would be used to support rapid scale-up of routine immunization services in specific areas with the addition of IPV, and during windows of opportunity, an expanded age range of children (up to 15 years) would be vaccinated.

WAVERING POLITICAL AND SOCIETAL SUPPORT FOR ERADICATION

Risk: Three different issues related to political and societal commitment may threaten the success of eradication efforts. The first is the loss of momentum often sustained during periods of political change, including elections and governmental transitions. Second, there is the risk of sub-national level political entities resisting national government commitment to eradication, and complicating cooperation. Third, there is a risk of reduced or limited interest of communities in polio eradication activities. The reasons for this vary according to the local context (fatigue, problems with polio staff, with health staff, misunderstanding, lack of information, religious and or local practices, marginalized or vulnerable groups, mobile and nomadic population groups).

Risk Mitigation Activities: Structures and mechanisms have been, and will continue to be, established in each of the endemic countries to ensure that strong support for eradication efforts at a national level are continued and that there is similar commitment at state and district levels, as outlined in the country-specific sections of Objective 1. It is imperative to ensure that eradication efforts are institutionalized and not intertwined with individual political actors. It may also be necessary, in certain circumstances, for the GPEI partners to assume increased responsibility for national programmes and bring in additional, experienced outside talent until federal-level transition is complete. Support from bi- and multilateral organizations will be sought to help influence these types of situations. To counter community and health worker disinterest, appropriate strategies will be developed to promote local ownership and leadership in order to bring onboard communities to the goals of eradication, through addressing specific needs and requests.

Contingencies: If eradication efforts are impeded due to political resistance, and advocacy from national, regional and international leadership does not translate into timely action, the GPEI may be left with little choice but to postpone activities and allow the situation to improve before recommencing operations.

INABILITY TO ENSURE ACCOUNTABILITY

Risk: Accountability against established programmatic targets and outcomes – at all levels (global, national, regional, district, organization, individual levels) – is critical to reaching key eradication milestones. While detailed plans on reaching these targets and outcomes exist at national levels, there is no legal framework in place to hold country partners accountable. An inability to impose meaningful consequences for missing or failing to achieve targets poses threats to full execution of the plan.

Risk Mitigation Activities: This strategic plan details critical targets and indicators by Objective, with specific ownership assigned against each. This will promote greater transparency and accountability as the GPEI will clearly understand, at any point in time, whether and how much progress has been made and who is responsible. Furthermore, the GPEI is continuing in its efforts to make the governance structure more effective – for example, raising issues to the United Nations General Assembly (UNGA) and consistently keeping polio on the WHA agenda; stressing global level accountability and discussing international health regulations for non-compliance. The World Health Assembly governs the scope and direction of the GPEI at a global level. At a management level, the GPEI has refined its structures to ensure greater accountability with management groups reporting to a Polio Oversight Board. At a national level, polio programme managers report directly to Presidential/Prime Ministerial Task Forces.²³ The IMB provides a vital independent oversight function and will be sustained and used as a mechanism to shine light on risk-bearing issues.

Contingencies: If plans are not followed and targets and outcomes are missed, it may be necessary to escalate issues to international bodies. In addition, though challenging to orchestrate in a manner that is not counter-productive, the GPEI may consider forms of punitive consequences as a last resort.

²³ More detailed information on governance and management structures is available in Section 11.

10. ENABLING FUNCTIONS

10.1 Successful execution of the 2013-2018 Polio Eradication and Endgame Strategic Plan will require collaboration across the GPEI partners, national governments, donors and other relevant organizations and institutions. Whilst national governments will be primarily responsible for successful execution of the Plan at the local level, the GPEI and its partners will lead on a set of enabling functions to facilitate successful execution of country operations. These functions include:

- Strategic Planning and Priority Setting
- Resource Mobilization and Advocacy
- Financial Resources and Management
- Vaccine Security and Supply
- Research and Policy Development

STRATEGIC PLANNING AND PRIORITY SETTING

10.2 The GPEI spearheading partners (WHO, Rotary International, CDC, and UNICEF) and the Bill & Melinda Gates Foundation are responsible for the provision of overall technical direction and strategic planning for the management and coordination of the Global Polio Eradication Initiative. This includes the development of strategic plans for the GPEI and delivery of accompanying budgets. Global strategic plans are developed by national governments in conjunction with the partner and donor community to ensure that national and stakeholder priorities are reflected. Once finalized, the spearheading partners and BMGF work to ensure that all components of the strategic plans are implemented. This includes oversight of technical support for strategy implementation and a leading role in monitoring and evaluating all aspects of the plans.

10.3 Technical assistance is deployed to fill capacity gaps when relevant skills are unavailable within a national health system, to build capacity, and to facilitate international information exchange. This technical assistance ensures sufficient human resource capacity for immunization campaign planning (including micro-planning, logistics, forecasting and supply management) and maintaining the AFP surveillance network.

10.4 The GPEI has historically been required to change agreed plans and cancel immunization campaigns due to unpredictable funding. In the event that sufficient funds are not available to fully support the GPEI budget in 2013 and 2014 when the focus is upon achieving the interruption of types 1 and 3 wild poliovirus, available resources will be allocated according to the following priorities:

Priority 1	Core staff (12 months of funding)
Priority 2	Surveillance/Laboratory Network (6 months)
Priority 3	Endemic Country SIAs (6 months)
Priority 4	Outbreak Response (3 months)

From 2015 onwards, resource allocation priorities will be updated to reflect a greater emphasis on Objectives 2 and 3, in particular product development and preparation for IPV introduction.

RESOURCE MOBILIZATION AND ADVOCACY

10.8 The GPEI spearheading partners and the Bill & Melinda Gates Foundation have developed a strategy to obtain long-term, predictable funding for the 2013-2018 period. This will ensure that lack of funding is not a barrier to implementation of the 2013-2018 Polio Eradication and Endgame Strategic Plan and thus to polio eradication. The integrated resource mobilization, advocacy and communications strategy aims for:

- 1) traditional donors to maintain or increase their commitments;
- 2) new and non-traditional donors to be activated;
- 3) polio-affected countries to increase their domestic financial contributions; and,
- 4) innovative financing mechanisms be identified and exploited.

10.9 Sustainable financing will require renewed commitments from governments and development partners as well as the recruitment of additional country support. The participation of civil society organizations is critical, as is the importance of individual and private sector giving, such as that provided by Rotary International. Significant financial support comes from some polio-affected countries, which should be further strengthened. National governments should continue to play a lead role in identifying resource needs and sources of self-financing and coordinating with immunization partners to track the effective, efficient use of resources.

Resource mobilization is increasingly coupled with advocacy and communication activities to ensure donors have confidence that GPEI will deliver and that the benefits of a polio-free world are worth achieving. A key element is ensuring ongoing confidence from partners, countries, donors, influencers and the engaged public, so each player remains supportive of GPEI and committed to the long-term strategy. GPEI is working with a broader set of advocacy partners, e.g. Global Poverty Project, with the capability to reach younger audiences and new markets. Additionally, the partnership has invested in reaching a wider set of influential people – former politicians, technical and scientific leaders, well-known business leaders, academics and others - to inform them about the immediate window of opportunity to eradicate polio and employ both their voices and their networks in support of the program.

10.10 To support the strategic plan, coordinated advocacy efforts will be developed and implemented, targeting the polio-endemic countries, high-risk countries, and polio-free areas. The advocacy efforts will address three areas:

- Ensuring sustained high-level commitment of National Governments of polio-endemic countries and high-risk countries, to provide oversight and accountability for the full implementation of their national emergency action plans and to allocation of domestic financing;
- Ensuring consistent commitment and ownership by sub-national governments (provincial/state and lower levels as relevant) to closely evaluate the planning, implementation and monitoring of polio eradication activities and to take immediate and appropriate actions to address local challenges;
- Securing the support of the global community including donor governments, multilateral organizations, private sector organizations, civil society partners, the media and relevant religious institutions to advocate with polio-affected governments and communities. This includes the engagement of multilateral fora such as the African Union, the Organization of Islamic Cooperation (OIC), the Commonwealth, the United Nations General Assembly, ECOWAS, the BRICs, and the Gulf Cooperation Council to encourage polio-affected and high-risk countries to effectively implement their national plans, and when needed, to provide confidence to communities to allay their concerns about polio vaccinations.

10.11 Leading Islamic scholars and Muslim technical experts, under the aegis of Al Azhar University, have formed an Islamic Advisory Group to leverage the historically strong role played by Islamic leaders in global eradication. This group will periodically assess the remaining and emerging socio-religious and political challenges to polio eradication in the remaining polio-affected parts of the Islamic world and propose solutions. Members will advocate within their constituencies and provide guidance on the social and religious responsibilities to protect children from vaccine-preventable disease and to eradicate polio. The work of this group will inform the efforts of relevant actors such as the Organization of Islamic Cooperation, the Gulf Cooperation Council, the Islamic Development Bank, other senior Islamic religious scholars and GPEI partner agencies and stakeholders.

NUMBERED POINT. Significant advocacy will also be necessary to engage the 144 WHO member states to ensure the coordinated switch from tOPV to bOPV in their routine immunization programmes, to effectively implement the post-eradication elements of the Plan and to support the polio legacy planning process at national, regional and global level to ensure outcomes that are supported by the WHA.

FINANCIAL RESOURCES AND MANAGEMENT

10.14 The financial requirement for the activities contained in the 2013-2018 Polio Eradication and Endgame Strategic Plan is projected to be US\$5.5 billion. This figure does not include Government of India funding at approximately US\$1.23 billion, nor any other national or in-kind contributions (see

FRR). This projection takes into account various scenarios, and has been projected in consultation with relevant global, regional and country stakeholders.²⁴

An inter-agency resource mobilization strategy is being implemented with rigorous weekly follow-up, to help mobilize funding commitments for 2013-18 ahead of the Vaccine Summit in April 2013. This strategy will be reviewed and revised after the Vaccine Summit to ensure continued coordination of advocacy and resource mobilization activities.

The US\$5.5 billion cost model includes the following key assumptions:

- Interruption of residual wild poliovirus transmission by end-2014;
- Complementary OPV campaigns to boost type 2 immunity before the tOPV-bOPV switch and additional coverage as needed between 2014-2015, declining post-interruption;
- Introduction of at least one dose of IPV in routine immunization prior to the tOPV-bOPV switch;
- Human resource surge capacity to support eradication efforts in remaining polio-endemic and high-risk countries;
- Maintaining outbreak response capacity through 2018;
- Maintaining 2013 levels of technical assistance, social mobilization, global laboratory requirements, and research and product development through 2018;
- Maintaining environmental surveillance through 2018; and
- Stockpile Projections for 2014 and 2016 are based upon existing contracts.

The key budget drivers are:

- The number of OPV campaigns;
- Vaccine costs;
- Technical assistance to countries;
- Surveillance and Laboratory costs;
- Outbreak Response capacity & stockpiles; and
- IPV use in Routine Immunization

The main cost components are:

- Immunization Activities (OPV Campaigns and IPV in Routine Immunization): 44%
- Surveillance and Laboratory Activities, Response Capacity, Containment and Certification: 16%
- Technical Assistance: 19%
- Core Functions (including Surge Capacity, R&D, On-going Quality Improvement) and other Indirect Costs: 21%

²⁴ An adjusted year of interruption of transmission would increase/decrease costs accordingly; however some flexibility is built into this budget.

10.15 During the eradication and endgame period, OPV campaign activity will remain high through 2015 and then gradually decline. Technical assistance and surveillance costs will remain relatively stable. Some costs, such as those for innovation and campaign quality improvement, will decrease following interruption of transmission. Other costs, such as the use of standalone IPV in routine immunization, will continue well after interruption of wild poliovirus globally.

The financial requirements for the period will be presented in an accompanying Financial Resource Requirements (FRR) document with corresponding costs and underlying assumptions per major budget category. The FRR will be reviewed and updated quarterly and the proportion of requirements under key budget categories adjusted as progress against key milestones is evaluated.

10.16 Though costs have not been modelled beyond 2018, reduced levels of continued funding will be needed beyond polio eradication certification in 2018, including limited OPV campaigns and technical assistance continuing into 2020 as bOPV is withdrawn globally. Additionally, the GPEI expects certain costs associated with containment, surveillance and lab costs to continue for up to five years post-certification.

10.17 The GPEI has continually evaluated costs throughout implementation of polio eradication activities and sought opportunities to ensure good stewardship of available resources. The GPEI partners are in the midst of a project (VfM) to evaluate the key drivers of costs and performance and identify areas where the GPEI can use funds most effectively. This will help identify how the GPEI can shift resources from lower to higher impact and deliver higher value activities. To date, in addition to cost shifting opportunities, the VfM exercise has identified areas where the GPEI can improve risk mitigation measures, improve forward planning, develop cost-sharing opportunities with other initiatives and expand the use of best practices to achieve greater value for money..

10.18 The findings to date fall into two categories:

- A set of near-term priority actions that could shift funding to higher impact and higher value activities over the next 12 months. Near-term priorities include more effective training and tighter management of vaccine use. Medium-term priorities are related to the scale of operations and could be implemented in 2-3 years. The long-term priorities hinge on further planning and discussions with GPEI and its partners; and,
- Areas with existing high value for money on which the program can capitalize and expand best practice: for example, innovative and tailored approaches to reaching inaccessible population segments and employing new technology such as GPS to improve operational effectiveness. The partnership is now conducting a final consultation phase, before outlining implementation steps for discussion and conclusion.

VACCINE SECURITY AND SUPPLY

10.12 Sufficient supply of OPV (bOPV and tOPV) to meet the global requirements for SIAs and routine needs of countries is a key programmatic priority. It is imperative that the programme has the capacity to respond to changing demand requirements due to epidemiological shifts in the virus, outbreaks in any one type and increased target populations while also being able to meet global demand requirements for routine immunization. UNICEF, as the GPEI programme procurement partner, has long-term arrangements with multiple suppliers in place to meet the projected demand, and will endeavour to maintain a continuous buffer of 70 million doses of OPV in order to meet outbreak response and other unplanned vaccine requirements.

10.13 OPV demand projection is based on the annual SIA calendar and estimated routine immunization requirements, for UNICEF-procuring and non-UNICEF procuring countries. Long-term supply arrangements are in place in line with the projected SIA and routine demand for UNICEF-procuring countries in support of the implementation of the 2013-2018 Polio Eradication and Endgame Strategic Plan. Supply is monitored continuously, with monthly and quarterly reviews to ensure supply by type meets planned SIA activities and is sufficient to meet routine needs. To support activities under Objective 2 - OPV2 withdrawal, ensuring a switch from tOPV to bOPV, and providing one dose of IPV - supply requirements will be carefully planned in advance, including ensuring sufficient bOPV and IPV to support the tOPV-bOPV switch. Concurrently, global vaccine supply will be taken into consideration to ensure non-UNICEF procuring countries are able to access sufficient OPV supply for the tOPV-bOPV switch.

RESEARCH AND POLICY DEVELOPMENT

10.5 An intensified research agenda has underpinned many of the approaches outlined in the 2013-2018 Polio Eradication and Endgame Strategic Plan, and will be critical in its implementation. Strategically guided by the Polio Research Committee (PRC) and SAGE, the core elements of the research work are designed to accelerate eradication of remaining WPV transmission and to ensure the necessary strategies and products are in place to manage the long-term poliovirus risks associated with the Polio Endgame.

10.6 To facilitate the tOPV-bOPV switch (and help prepare for the eventual cessation of all OPVs in routine immunization), the research agenda will help drive the risk management strategies through implementation of the necessary prerequisites for the switch (validation of persistent cVDPV2 elimination and WPV2 eradication; stockpile of mOPV2 and response capacity; surveillance and international notification of Sabin, Sabin-like and cVDPV2; availability of licensed bOPV in all OPV-using countries; affordable IPV options for all OPV-using countries; and, containment phase II for cVDPV2 and WPV2 and phase I for Sabin type 2). The work to ensure the availability of affordable IPV options includes the realization of low-cost and easy-to-administer IPV options (i.e. new intradermal, fractional dose and adjuvanted IPV formulations, Sabin IPV formulations and new delivery technologies, eg needle-free injections).

10.7 Ongoing and new research projects are evaluating innovative methods to improve operations - particularly to help address persistent SIA coverage and surveillance gaps. A specifically established cross-partner Inter-Agency Innovation Working Group is coordinating work to ensure innovative solutions help address identified systemic challenges. Examples of this include: assessing technologies such as GIS to more adequately identify missed areas or population groups during SIAs; evaluating community perceptions to communications strategies; examining the role of older age groups in outbreak settings; assessing the use of cellular phone technology for data transmission in LQAS and to help prompt active AFP surveillance; and, expanding the role of environmental sampling.

11. GOVERNANCE, MONITORING, OVERSIGHT AND MANAGEMENT

GOVERNANCE

As the primary WHO decision-making body, the **World Health Assembly (WHA)**, comprised of all 194 WHO Member States, provides the highest level of governance of the GPEI. The WHA adopts the resolutions that determine the scope and direction for the GPEI globally and secures the commitment of all Member States to support the full implementation of the GPEI Strategic Plan. The **Regional Committees of WHO (RCs)** allow for more detailed discussion by Member States, adopt resolutions on polio eradication and its impact at a Regional level, and provide input to the **WHO Executive Board (EB)** deliberations, that then inform the discussions at the annual WHA meeting.

ADVISORY and MONITORING

A set of advisory, monitoring and technical groups inform the decision-making of the WHO governing bodies and provide oversight of the management bodies.

The **Independent Monitoring Board (IMB)**, an independent body appointed by the WHO Director General after soliciting nominations from GPEI core partners (i.e., WHO, Rotary International, US CDC, UNICEF, and the Bill & Melinda Gates Foundation), will provide programmatic oversight of GPEI, in particular the implementation of Objective 1 of the Plan. The IMB meets on a four to six-monthly basis to independently evaluate progress on the basis of polio epidemiology, poliovirus virology, standard performance indicators and other programme data. Additionally, the IMB provides assessments of the risks to the programme and informs the Polio Oversight Board. The IMB is comprised of global experts from a variety of fields relevant to the work of the GPEI. The IMB will continue in its functions through to the end of 2015. The GPEI responds to the IMB's recommendations and guidance in managing eradication efforts.²⁵

The **Strategic Advisory Group of Experts on immunization (SAGE)**, supported by the **SAGE Polio Working Group**, provides technical oversight for all GPEI global policy decisions on immunization. The SAGE will be the advisory body providing oversight on the implementation of Objective 2 of the Plan. The SAGE provides guidance to the WHA and informs the Polio Oversight Board. **Regional and National Technical Advisory Groups (TAGs)** are comprised of experts in related fields of polio eradication, and regularly convene to review a region or country's polio epidemiology and make recommendations for appropriate strategies to more rapidly achieve eradication.

The Global Commission for Certification of the Eradication of Poliomyelitis (GCC), an independent body appointed by the WHO Director General, oversees the process for certifying the world as polio-free and will provide oversight on the implementation of Objective 3 of the Plan. **Regional Certification**

²⁵ Reports of the IMB are available at:

<http://www.polioeradication.org/Aboutus/Governance/IndependentMonitoringBoard/Reports.aspx>

Commissions (RCC), independent bodies appointed by WHO Regional Directors, will certify their Regions as polio-free once wild poliovirus transmission appears to have been interrupted in a Region (i.e., 36 months after the last circulating wild poliovirus is detected), and provide the GCC with essential documentation of polio eradication. **National Certification Committees** report to their respective RCC.

OVERSIGHT

National authorities

11.1 National governments are both the owners and beneficiaries of the GPEI. Polio-affected countries should undertake the full range of activities detailed in their country plans and summarized in this plan and take primary responsibility for the achievement of the first three Major Objectives of the 2013-2018 Polio Eradication and Endgame Strategic Plan. Achievement of country milestones requires polio-affected countries to ensure accountability at national, sub-national and district level and, with GPEI partners, to plan, implement and monitor the activities to reach every child with polio vaccine. Concurrently, national governments in the three WHO Regions certified as polio-free, and polio-free member states in the three remaining polio-endemic Regions, have a critical role to play in maintaining high population immunity and sensitive surveillance for AFP. National authorities are also responsible for fully implementing internationally agreed processes to manage the long-term risks following WPV eradication, including applying bio-containment requirements and mainstreaming polio functions as part of the Legacy work.

The **Polio Oversight Board (POB)**, comprised of the heads of agencies of core GPEI partners, provides close oversight of the GPEI and programme management, and ensures high-level accountability across the GPEI partnership. The POB receives and reviews inputs from the various advisory and monitoring bodies (IMB, SAGE, GCC), and operational information from the **Polio Steering Committee (PSC)**. The **POB's** directives are implemented by the PSC through the various programme management bodies. The POB meets quarterly. The POB's deliberations are also informed by the Global Polio Partners Group.

The **Global Polio Partners Group (PPG)** serves as the stakeholder voice for the GPEI in the development and implementation of eradication strategic plans and fosters greater engagement among polio-affected countries, donors and other partners to ensure GPEI has the necessary political commitment and financial resources to reach the goal of polio eradication. The PPG meetings are held at the Ambassadorial/senior-officials level and results are reported to the Polio Oversight Board.

EXECUTIVE MANAGEMENT

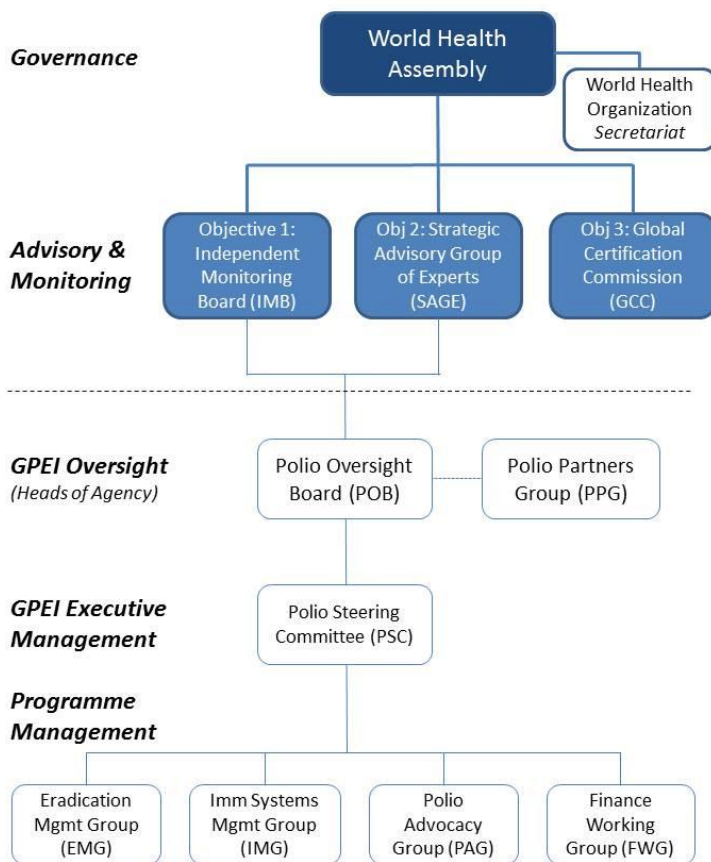
GPEI PARTNERS

11.2 The GPEI Spearheading Partners and the Bill & Melinda Gates Foundation take primary responsibility for management of activities described under the Enabling Functions section (Section 10). This includes responsibility for providing technical support to countries in the implementation of their

polio eradication efforts and the staffing surge to support national efforts. As part of the legacy, WHO and UNICEF will take responsibility for mainstreaming technical functions within existing and/or new or revised structures. The GPEI will coordinate the consultative aspect of the Legacy process.

The **Polio Steering Committee (PSC)** comprised of senior-level officials from the GPEI partner agencies serves as the overall GPEI Executive Management body that closely reviews and monitors the various technical, financial, and advocacy functions of the global programme, provides direction and input to the work of the various management bodies, and also implements the directives of the POB. The PSC will drive the implementation of the Objectives of the Plan and also provide necessary input to the Advisory and Monitoring bodies. The PSC’s policy and strategy decisions are implemented through the GPEI Management Groups described below.

Figure 25. GPEI Governance and Oversight



PROGRAMME MANAGEMENT

Four Management Groups, reporting to the PSC, have overall responsibility for implementing the Strategic Plan, working with WHO and UNICEF Regional Offices, national governments, other stakeholders, and country-level partners:

The Polio Eradication Management Group (EMG) has responsibility for overall management of the activities under Objective 1 needed to achieve eradication in the endemic countries and those at highest risk of importation, attaining high-quality SIAs and surveillance while managing security risks. The work of the IMB, the SAGE, the GCC and RCCs, and the Regional and National TAGs, informs and supports the work of the EMG.

The Immunization Systems Management Group (IMG) has responsibility for overall management of the activities under Objective 2 to strengthen routine immunization and introduce IPV and bOPV. The work of the IMB, the SAGE, the GCC and RCCs, and the Regional and National TAGs, informs and supports the work of the IMG. The IMG also works closely with the GPLN, and the PRC.

The Polio Advocacy Group (PAG) has responsibility for developing and implementing a cross-agency resource mobilization strategy to ensure that the required financing is available to fully implement the Plan. The PAG also works closely with and receives inputs from the communications staff of partner agencies, and the finance/ resource management staff through the Polio Finance Working Group.

The **Polio Finance Working Group (FWG)** is responsible for closely tracking the short-term and long-term financing needs of the programme, developing consistent and accurate financial information for strategic decision-making, and establishing processes to support predictability of financing.

Additional groups reporting to the three Management Groups will be formed as needed to support key areas of responsibility and enabling functions. Management structures within the GPEI will be outlined in detail on the GPEI website at www.polioeradication.org. These structures will be reviewed and modified regularly to reflect the changing needs of the initiative. In addition, the website will provide terms of reference of GPEI management and functional support groups.

13. MONITORING

MONITORING FRAMEWORK

The GPEI has developed a high-level Monitoring Framework to assess progress against the major milestones and targets laid out in the 2013-2018 Polio Eradication and Endgame Strategic Plan. Given the duration of the Plan, the Monitoring Framework is not intended to be a full Monitoring and Evaluation plan but instead to provide an overview of progress against the plan's major objectives. As detailed work plans are developed for each of the objectives, detailed M&E plans will also be developed. National plans should be referred to for details of national responsibilities, targets and progress

indicators. The GPEI will provide detailed reporting on progress against key indicators to its oversight and governance bodies at agreed intervals to inform their work.