

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

Global Polio Eradication Initiative

WORKING DRAFT: 23 JANUARY 2013

TABLE OF CONTENTS

ACRONYMS

EXECUTIVE SUMMARY

1. STATEMENT OF INTENT

2. BACKGROUND

3. OVERVIEW

- What's New
- The Major Objectives
- Milestones

4. CONTEXT

- Where we are today
- Lessons Learned
- New Evidence for Interruption of WPV Transmission by end-2014
- The Case for Completing Eradication
- The Opportunity

5. OBJECTIVE 1: POLIOVIRUS DETECTION & INTERRUPTION

- Strengthening Global Surveillance
- Enhancing Campaigns to Interrupt Transmission
- Response to Outbreaks of VDPVs and WPV Importations

6. OBJECTIVE 2: ROUTINE IMMUNIZATION STRENGTHENING & OPV WITHDRAWAL

- Increasing Routine Coverage
- Development of IPV, bOPV and mOPV
- IPV Introduction
- OPV2 Withdrawal
- Full OPV Withdrawal

7. OBJECTIVE 3: CONTAINMENT AND CERTIFICATION

- Containment
- Certification

8. OBJECTIVE 4: LEGACY PLANNING

- Mainstreaming Polio Functions
- Managing the transition of Assets and Infrastructure

9. ENABLING FUNCTIONS

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

10. ROLES AND RESPONSIBILITIES

11. FINANCIAL RESOURCES 2013-2018

12. RISKS, MITIGATIONS AND CONTINGENCY PLANNING

13. GOVERNANCE AND OVERSIGHT

14. MONITORING

ANNEX A: ADDITIONAL SUPPORTING MATERIAL

ANNEX B: MONITORING FRAMEWORK

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 | WHO Executive Board |
| FATA | Federal Administered Tribal Areas |
| FRR | Financial Resource Requirements |
| GAPIII | Third edition of the Global Action Plan to minimize post eradication poliovirus facility-associated risk |
| 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 |
| PESC | Polio Emergency 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 polio |
| VDPV | Vaccine-derived poliovirus |
| VPD | Vaccine-preventable disease |
| WHA | World Health Assembly |
| WHO | World Health Organization |
| WPV | Wild poliovirus |

EXECUTIVE SUMMARY (*UNDER DEVELOPMENT*)

DRAFT

1. STATEMENT OF INTENT

The goal of the 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.

DRAFT

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 Eradication and Endgame Strategic Plan, developed in consultation with national health authorities, scientific experts, global health initiatives, donor partners 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 GPEI infrastructure as the programme comes to completion. In November 2012, the Strategic Advisory Group of Experts on Immunization (SAGE) reviewed the plan and endorsed these major components.

2.2 The 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 and trend in 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 2013 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 outcomes, based on the evolving epidemiology of polio and the priorities for managing the vaccine-related and post-eradication risks, and the needs of the Polio Legacy work. With full implementation of this Plan, polio will be the first disease of humans to be eradicated from the face of the earth in the twenty-first century.

2.4 This document is intended to be used by individuals and organizations involved in polio eradication efforts. Potential users of the document are likely to include:

- National Polio programme managers and staff
- Representatives of the core partners supporting the Global Polio Eradication Initiative
- Personnel from other partners supporting polio eradication efforts
- WHO and UNICEF country and regional focal points for polio eradication efforts
- Members of Interagency Coordinating Committees
- Polio eradication oversight bodies
- Polio eradication technical advisory bodies

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

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

³ Resolution WHA65.17 'Global vaccine action plan'

3. OVERVIEW

WHAT'S NEW ABOUT THIS STRATEGIC PLAN

3.1 As part of the broader health agenda, the Polio Eradication and Endgame Strategic plan brings together for the first time a comprehensive approach to completing polio eradication. There are several major elements that are new in this plan versus previous strategic plans:

- Addresses all polio disease (wild and vaccine-related)
- Places an urgent emphasis on routine immunization
- Introduces new IPV options for managing long-term poliovirus risks
- Includes 'Plan B' for interrupting transmission, should there be a delay in endemic countries
- Outlines a timeline to complete eradication

3.2 Previous plans focused primarily on interrupting wild poliovirus transmission. This plan incorporates innovative tactics, strategies and tools that will enable the programme to not only interrupt transmission but also address the risks of all polioviruses. Importantly, the programme's experience – and success – in India have demonstrated that these methods can, and will, be successful in even the most challenging geographies. With unprecedented levels of political commitment and accountability, improvements in vaccination campaign quality, scale-up of support to endemic countries and evidence of progress in the remaining endemic countries, the GPEI is confident that it can interrupt transmission by end-2014 and complete eradication.

3.3 In this strategic plan, the importance and urgency of strengthening routine immunization is outlined. Strengthened routine immunization will contribute to the successful introduction of new vaccines to manage poliovirus risks such as affordable IPV and bivalent OPV, and accelerate efforts to drive high and sustained population immunity to poliovirus.

3.4 Objective 1 of this strategic plan is to interrupt transmission in the remaining endemic countries. This plan outlines the tactics that will be used to both detect and interrupt poliovirus transmission. Running concurrently, intensified efforts to strengthen routine immunization using polio-funded staff, assets and tools, provide a Plan B should emergency campaign efforts fail to achieve the goal of interrupting transmission. Boosting population immunity, introducing IPV and removing OPV from immunization will provide a contingency for any failings in the remaining endemic countries.

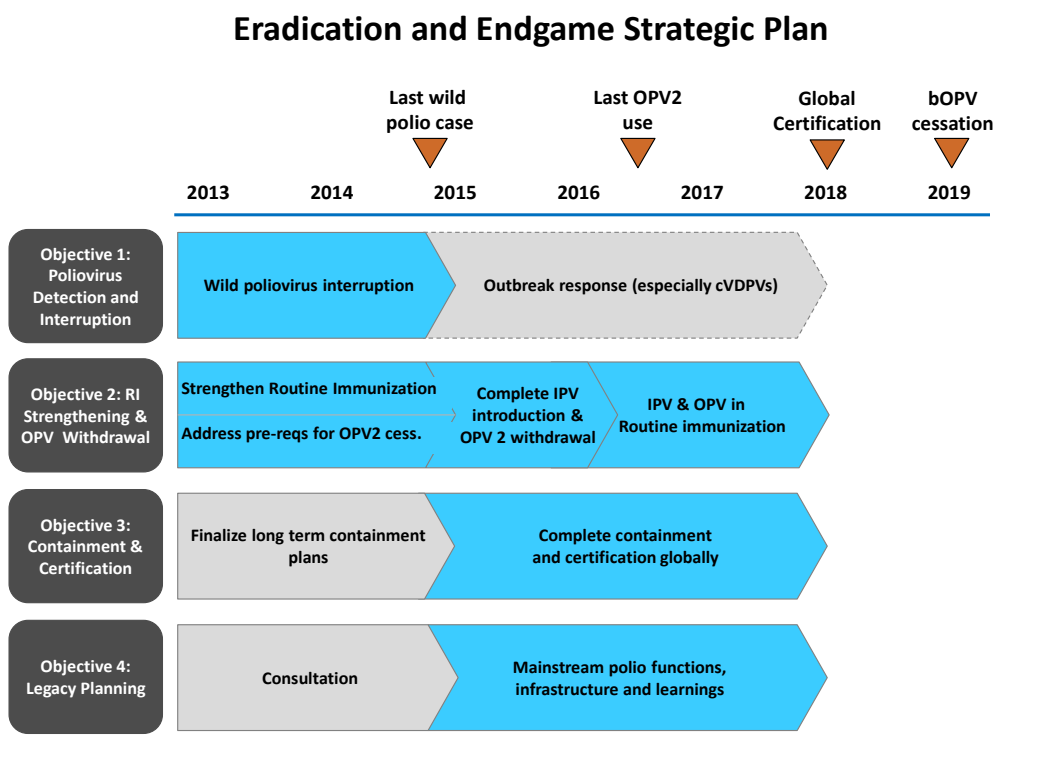
THE MAJOR OBJECTIVES

There are four major objectives to the 2013-2018 Polio Eradication and Endgame Strategic Plan:

- 1. Poliovirus Detection and Interruption:** Through the effective implementation of national emergency plans, the goal is to detect and interrupt wild poliovirus transmission in the remaining endemic countries by the end of 2014. While interruption cannot be guaranteed by an exact date, and various factors could intervene, GPEI will meet this objective by raising population immunity to levels high enough to interrupt transmission in currently infected areas - as well as achieve those immunity levels in areas prone to outbreaks and re-importation - and by rapidly containing outbreaks in endemic and re-infected countries, as well as other countries to which virus is exported from endemic or re-infected countries.
- 2. Routine Immunization Strengthening and OPV Withdrawal:** To manage vaccine-derived poliovirus risks, it is recommended that all Oral Polio Vaccine be removed from vaccination campaigns and routine immunization. The first stage in this is the withdrawal of OPV 2. To do this entails the strengthening of routine immunization systems, meeting several pre-requisites to enable the necessary tOPV-bOPV switch and the introduction of affordable IPV globally.
- 3. Containment and Certification:** As a small number of essential facilities will retain poliovirus stocks, planning for safe handling and biocontainment of facility-based poliovirus is critical to manage risks related to re-introduction of poliovirus into the population. This will require international consensus on updated biocontainment requirements and national application of those requirements. Following interruption of wild poliovirus transmission, the necessary processes for certifying the global eradication of wild poliovirus will begin, under the oversight of the Global Certification Commission.
- 4. Legacy Planning:** As the polio programme approaches key eradication milestones, successful legacy planning will include the mainstreaming and transfer of essential polio functions, assets and infrastructure to benefit other development goals and global health priorities. This will require detailed consultation, and planning and implementation processes to ensure the investments made in polio eradication provide public health dividends for years to come.

As illustrated in Figure 4, the four major objectives of the Eradication and Endgame Strategic Plan are not sequential but will run in parallel. Whilst activities to interrupt transmission are ongoing, significant planning is required for the remaining objectives, and some activities are intended to run over the course of this plan. For example: routine immunization strengthening.

Figure 4. Overview of Eradication and Endgame Strategic Plan⁴



MILESTONES AND TIMING

Although interruption cannot be guaranteed by an exact date, given the various challenges and factors that may intervene, the GPEI expects to achieve key programmatic milestones according to the following timeline:

Figure 5. Key milestones

| DATE | MILESTONE |
|---------------|----------------------------|
| End-2014 | Last wild poliovirus case |
| During 2015/6 | Withdrawal of OPV2 vaccine |
| End-2018 | Global WPV Certification |
| During 2019 | bOPV Cessation |

⁴ Some activities (e.g. surveillance and laboratory costs) will continue beyond 2019.

In addition to the four major Objectives, this plan outlines key enabling functions, the budget requirements and the roles and responsibilities of national authorities and partners to the plan's success.

DRAFT

4. CONTEXT

WHERE WE ARE TODAY

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 Global Polio Eradication Initiative (GPEI), spearheaded by national governments, WHO, Rotary International, the US Centers for Disease Control and Prevention (CDC) and UNICEF.

4.2 At that time, more than 125 countries were endemic with the disease 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%, 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 was reaching 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 eradication, but also the potential for success as shown by India, in May 2012 the WHA declared the completion of polio eradication a *programmatic emergency for global public health* and called for a marked increase in the intensity of eradication activities in the poorest performing regions.⁶

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; and 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 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.

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

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

4.6 As a direct result of emergency actions taken by GPEI partners and national governments 2012 witnessed the lowest number of new cases in fewer districts of fewer countries than at any previous time. Globally, 222 cases were reported in 2012, a 66% decline compared with 2011. Angola successfully stopped transmission of its re-established poliovirus (last case: July 2011), and the Democratic Republic of the Congo (DR Congo) was on track to do the same (last case: December 2011). Five countries reported cases in 2012 compared with 16 in 2011. In three of these countries, Chad, Pakistan and Afghanistan, case numbers declined by 95%, 65% and 42% relative to 2011, respectively. In Nigeria, however, case numbers increased by 140% compared with the same period in 2011, despite the strong evidence of improving programme performance in the historically worst-performing areas.

4.7 Furthermore, viruses from these endemic areas, particularly Nigeria, 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.

Figure 6. 2011 versus 2012 highlights

| 2011 | 2012 |
|--|--|
| Last case in India | Angola and DRC have not reported cases since July 2011 and December 2011, respectively |
| Cases increased >2-fold in 3 endemic countries | Cases have declined significantly in both Afghanistan and Pakistan |
| 3 countries with re-established transmission | 3 countries with re-established transmission: possible interruption |
| 11 outbreaks in 9 countries | 1 outbreak |
| 16 countries and 650 cases | 5 countries, 222 cases (down 66% over 2011) |

ACKNOWLEDGING THE PAST – LESSONS LEARNED

4.8 Since the launch of the Global Polio Eradication Initiative, three major targets have been set out: interrupt transmission in 2000, eradication in 2005 and, most recently interruption of transmission by end-2012. This 2012 target has, like earlier targets, been missed, with three polio endemic countries remaining at the beginning of 2013.

4.9 At the point of launching this six year strategic plan, the GPEI acknowledges it has been in seemingly similar positions in the past: an 'almost there' moment in polio eradication, marked by a major programmatic milestone recently missed, and in the position of soliciting additional funding from a donor community that has heard the eradication story before.

As part of developing this Plan, the GPEI embarked on a critical review of the programme to assess:

- How the programme arrived to its current state and how lessons from past successes and failures can inform future strategy
- The current state of eradication efforts within the remaining endemics, including an analysis of coverage trends, to project the programme's trajectory for interrupting transmission
- The public health and financial benefits of completing eradication, taking into account new resources required through 2018

4.10 The combination of these evaluations has provided the GPEI with a better understanding of why past milestones were missed, how close we are to achieving our goals in the remaining endemics and how critical this effort continues to be.

One Size Did Not Fit All

4.10 The GPEI missed its first interruption target date of 2000. This was, in no small part, due to the late launch of campaigns in key geographies, particularly those plagued by high case rates and transmission. At that time eradication was expected to occur on average 2.7 years after the launch of National Immunization Days (NIDs). The launch of these campaign activities as late as 2000 in geographies such as the Democratic Republic of Congo and Sierra Leone meant that a 2000 interruption of transmission goal was both poorly planned for and impossible to achieve. The GPEI, equipped with a better understanding of the critical importance of campaigns in interrupting transmission, doubled the number of SIAs conducted in the period 2000 to 2005. This was supported by a tenfold increase in technical support staff and ran in conjunction with house-to-house vaccination. By 2005, six endemics remained – down from more than 20 in 2000.

Technological Innovation cannot overcome Gaps in Management and Community Engagement

4.11 Though only six remaining endemic countries globally marked an improvement, the target of eradication by 2005 had not been achieved. The GPEI attempted to avoid a 'more-of-the-same' strategy. However, the mindset remained that of essentially intensifying existing approaches without true innovation, or refinement to the specific country context. This complicated the situation in India and Egypt because unlike other areas where the issue was reaching children, both countries had high levels of vaccination coverage but were not successfully seroconverting children sufficiently to interrupt transmission.

4.12 In 2005, mOPV1 and mOPV3 were introduced as a means to address this issue. Egypt stopped transmission within 6 months of the introduction of mOPV1. India, on the other hand, introduced mOPV1 and mOPV3 in 2006 and – over the course of the next 3 years – had major issues with type 1 and 3 outbreaks. In India, technical solutions alone were not sufficient. By 2010, four endemic countries still remained and the GPEI recognized three critical learnings:

- All countries do not have similar speed of virus interruption once OPV campaigns are introduced
- Programme performance data is often not accurate
- Technical solutions cannot compensate for basic management and accountability issues

A Combination of Effective Technological, Managerial and Social Innovation Can Succeed in the Most Challenging Settings

4.13 With four endemic countries remaining in 2010, the GPEI had to develop a more effective way to reach missed children in order to drive immunity levels above the interruption threshold. It was necessary to consider who these children were and how they could be reached. Furthermore, the GPEI had to consider how to monitor the success of these efforts and how to optimize protection if and when children were reached. This represented a marked 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 utilization of a set of critical tactics and tools including, but not limited to: 'underserved' strategy, SIADs, seroprevalence, surveys and modeling, universal finger-marking, migrant and transit strategies, independent monitoring, LQAS and the use of bOPV.

4.15 Armed with an improved understanding of at risk populations and better tactics for reaching and protecting these children, India became polio-free in 2012. Translating these approaches to the remaining endemics and enhancing accountability against programme targets to substantially enhance the quality of vaccination campaigns forms a core component of the programme's strategy in the Eradication and Endgame Plan.

- India was able to interrupt transmission because of its ability to comprehensively apply a set of tactics and tools to reach children
 - o Microplanning
 - o Operations innovation
 - o Monitoring & accountability
 - o Technical innovations
 - o Social mobilization
 - o Surge support

NEW EVIDENCE THAT TRANSMISSION CAN BE INTERRUPTED BY END-2014

4.16 Lessons learned from the India experience have informed emergency activities within the three remaining endemic countries. Intensifying these approaches forms a key component of the GPEI's activities to interrupt transmission (outlined in detail under Objective 1), but a more fundamental question is whether the programme can achieve interruption of wild poliovirus. Though the exact date of interruption cannot be guaranteed, as various factors may always intervene, new evidence of progress in eradication in the remaining endemic countries shows that the eradication effort turned a corner in 2012 and is now on a trajectory to interrupt transmission by the end of 2014.

Evidence of progress

4.17 One of the critical obstacles to interrupting WPV transmission is driving up vaccination coverage in order to reach the immunity levels needed to interrupt transmission. Accessing certain 'at-risk' populations – particularly those children that have persistently been missed – has been a key challenge.

4.18 2012 saw major progress in SIA quality and accessing of missed children. Endemic countries showed measurable improvements in the quality of immunization campaigns, leading to more children being vaccinated.

4.19 As seen in Figure 7, Pakistan has progressed from 78% of high risk districts at the 90% coverage target in January 2012 to 91% in October of 2012. Nigeria has also seen substantial levels of improvement at the 80% coverage target. As seen in Figure 8, Afghanistan (not currently using LQAS) saw a dramatic reduction in the number of inaccessible children in the key southern districts.

Figure 7: LQAS-based measures of improvement in SIA quality for select Pakistan districts⁷ and Nigeria LGAs in 2012⁸

⁷ GPEI presentation to SAGE, *Accelerating Emergency Polio Eradication Activities* (November 2012). Please note, data based on past LQAS methodology, which has been updated per new global guidelines.

⁸ Nigeria Immunization Plus Days, November 2012. Nigeria using latest LQAS methodology.

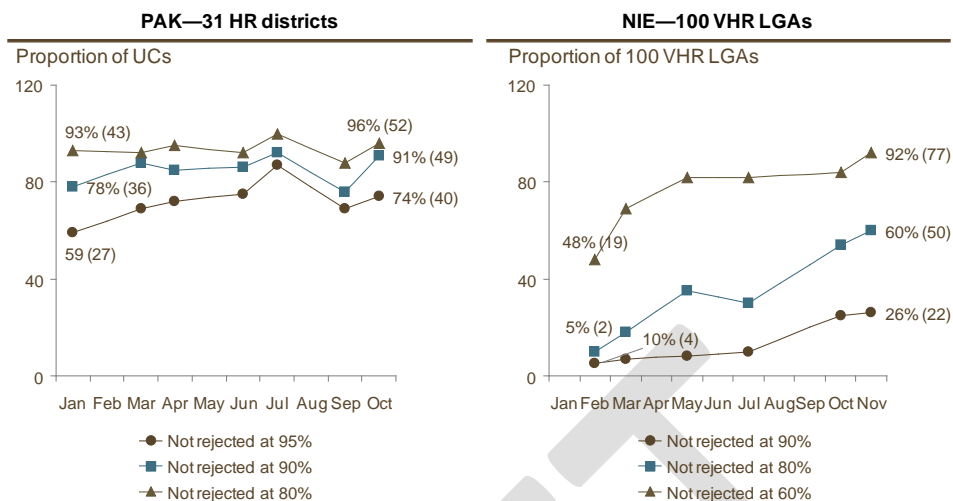
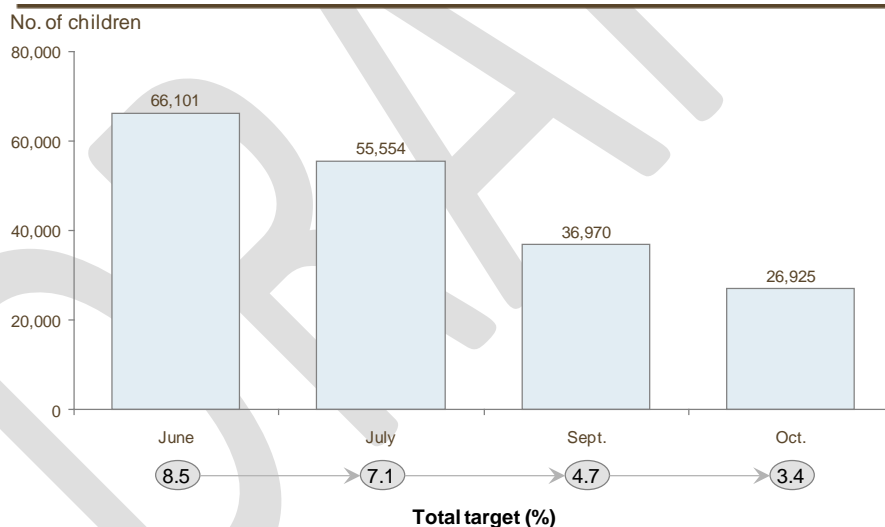


Figure 8: Reduction of inaccessible children in key Afghanistan districts.⁹

Inaccessible children in 13 High Risk Districts in Southern Afghanistan during last four SIAs (Jun–Oct, 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 transmission in Nigeria and Afghanistan is 80% immunity, and in Pakistan 90% immunity. Based on an analysis of the number of doses of OPV received, it is estimated that the proportions of children immune are beginning to approach these benchmarks, as seen in Figure 9.

⁹ GPEI presentation to SAGE, *Accelerating Emergency Polio Eradication Activities* (November 2012).

Figure 9: Type 1 Immunity changes over time for 2 key areas of Pakistan, and number of type 1 WPV cases in the province¹⁰

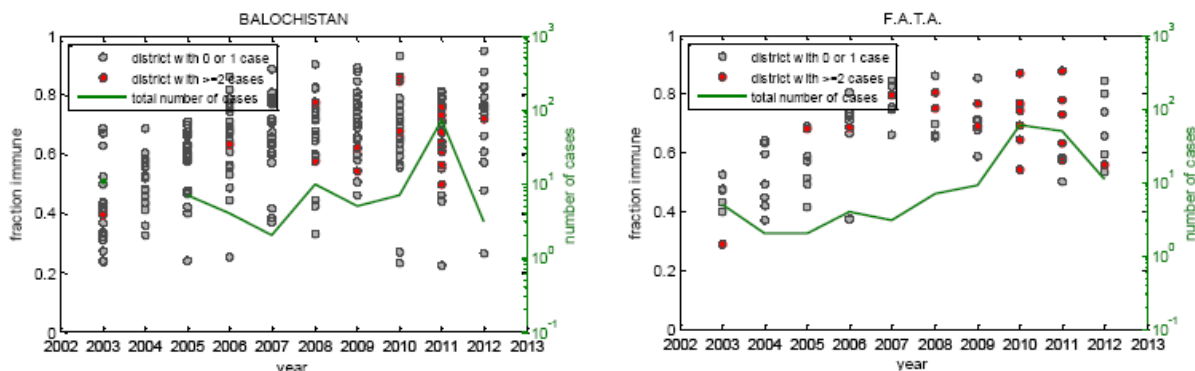
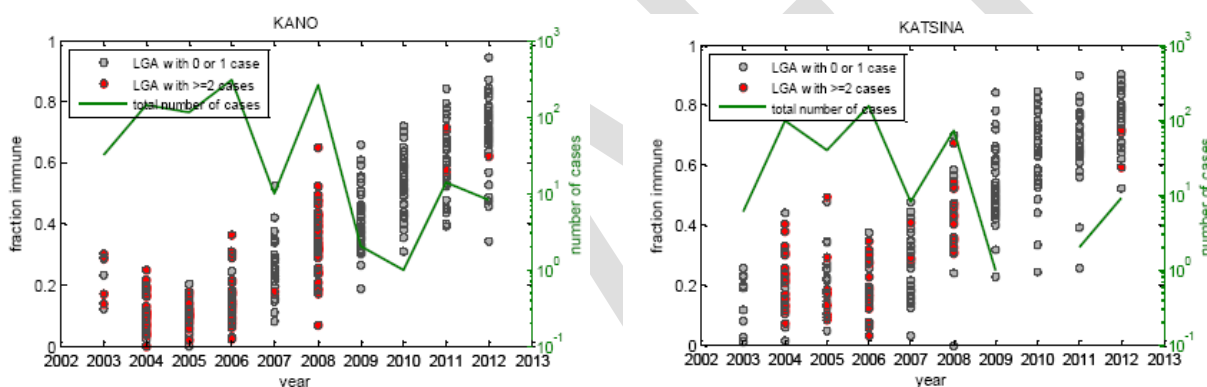


Figure 10: Nigeria NC Region – Type 1 immunity changes, as well as number of type 1 WPV cases in the state¹¹



4.21 Another encouraging trend is the decreasing diversity and geographic reach of poliovirus. 2012 saw a dramatic decrease in WPV genetic clusters (Figure 11). In addition, the epidemiology points to increasingly focused transmission of virus. That is, transmission is highly concentrated among limited geographic areas, or reservoirs. This also holds true for Afghanistan and Pakistan (Figure 12).

¹⁰ Global Good analysis, September 2012. Note: In a column of each year, there is a dot for each district in the state: red for 2+ cases and gray for 1 or 0 cases in that year. The height of each dot indicates estimated immunity based on NP-AFP (left y-axis). The total annual incidence of WPV1 cases in the state is shown by the green trace (right y-axis). Any breaks in the green trace are years of zero cases.

¹¹ Global Good analysis, September 2012. Note: In a column of each year, there is a dot for each district in the state: red for 2+ cases and gray for 1 or 0 cases in that year. The height of each dot indicates estimated immunity based on NP-AFP (left y-axis). The total annual incidence of WPV1 cases in the state is shown by the green trace (right y-axis). Any breaks in the green trace are years of zero cases.

Figure 11: Decline in WPV clusters (Pakistan)¹²

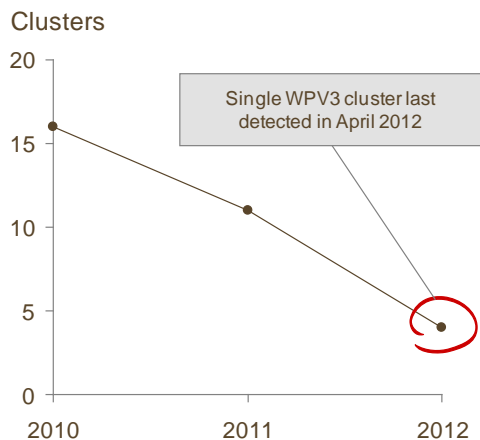
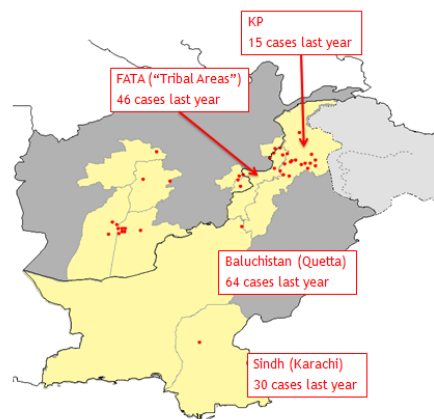
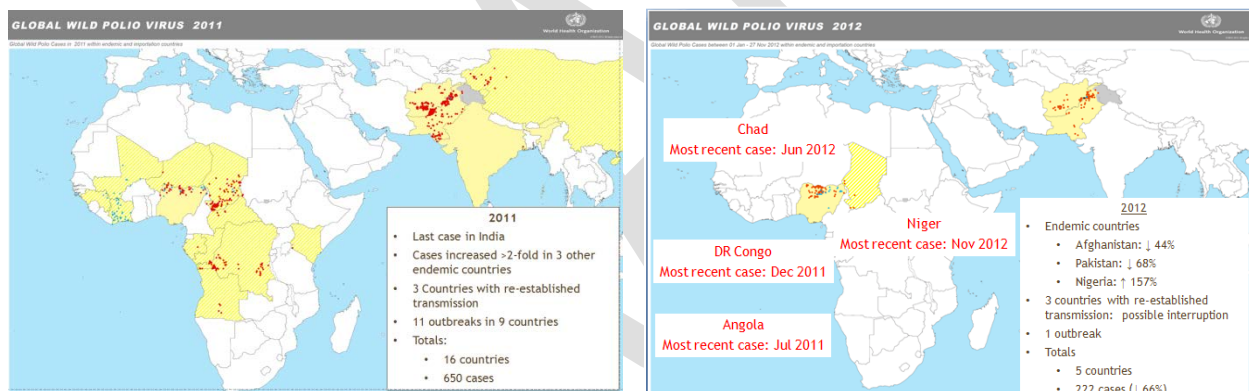


Figure 12: Distribution of cases, Pakistan 2012¹³



Overall, 2012 saw the fewest cases of poliovirus in the fewest number of countries on record.

Figure 13: Global polio cases, 2011 vs. 2012¹⁴



Other measures of access, coverage and population immunity all suggest a similar upward trajectory for the programme in the endemics.

¹² WHO NEAP Pakistan presentation, December 2012.

¹³ CDC PPG Presentation, December 2012.

¹⁴ CDC PPG Presentation, December 2012.

THE CASE FOR COMPLETING POLIO ERADICATION

4.22 The case for completing the eradication of polio is compelling. The direct, indirect and intangible benefits of reaching eradication continue to far outweigh the costs and alternative approaches. In addition, despite the difficulty of guaranteeing a specific date of interruption, given the potential for various external factors to interfere, significant progress in the three remaining endemic countries strongly suggests WPV transmission can be interrupted by the end of 2014.

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 – it could be expected that case rates would leap to as many as 200,000 cases annually in low-income countries, a rate comparable to the situation in 1998.¹⁵ 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 Taken from an economic perspective, completing polio eradication also provides significant benefit. In total, the financial requirements for the Eradication and Endgame Plan, separate from the vital national contributions of polio-afflicted countries are projected to be US\$ 5.5 billion covering the period 2013-2018. This does not include the Government of India, which will largely fund its own polio programme, at approximately US\$ 1.23 billion over the six year period. Taking into consideration the financial resources that have already been invested to this point, as well as countries which contribute hundreds of millions annually, the projected requirement is substantial.

4.25 However, a 2010 analysis of the long-term impact of the GPEI estimates that achieving eradication will generate net benefits of US\$ 40-50 billion over the next two decades.¹⁶ This same study also finds that GPEI efforts disproportionately benefit low income countries, with 85% of 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 been conducted and similarly find the health and economic gains far exceed the financial costs of polio eradication efforts.¹⁷

Indirect and Intangible Benefits of Eradication Efforts

¹⁵ Tebbens, Thompson, *Eradication versus control for poliomyelitis: an economic analysis* (The Lancet, April 2007).

¹⁶ Tebbens, Pallansch, Cochi, et al, *Economic analysis of the Global Polio Eradication Initiative* (Vaccine, Oct. 2010).

¹⁷ Thompson, Tebbens, *Eradication versus control for poliomyelitis: an economic analysis* (Lancet, 200). Musgrove, *Is polio eradication in the Americas economically justified?* (Bulletin of the Pan American Health

4.26 The impact of the GPEI's efforts extends beyond polio, benefiting other global and country health priorities. Support to measles campaigns and distribution of vitamin A supplements are just two areas that have benefitted greatly from polio eradication staff and infrastructure and delivered clear public health dividends. Conservative estimates peg the value of GPEI coordination with other health initiatives at US\$ 17-90 billion in benefits associated with mortality reduction,¹⁸ and vitamin A supplements are estimated to have averted between 1.1 (conservative) and 5.4 (maximum) million childhood deaths to date.¹⁹ Looking ahead, a well-organized and supported 'Legacy' plan that builds on relevant aspects of the polio network's infrastructure would drive gains across other health priorities. Health infrastructure, such as strengthened routine immunization systems and the Global Polio Laboratory Network (GPLN), can provide a strong platform for addressing other vaccine preventable diseases and support country health systems advancement.

4.27 There is also the significant and incalculable impact the programme has and will continue to deliver as the world moves towards eradication. The size and scope of the programme has required collaboration and cooperation across countries and between the public and private sectors. New relationships, communication channels and instruments have been developed in the process that will benefit global health at large. Vulnerable populations, including those in insecure areas, have been reached as never before. Achieving eradication will drive further momentum behind similarly ambitious programmes (e.g. measles) and demonstrate the impact that coordinated and concentrated action can achieve.

THE OPPORTUNITY

The GPEI has developed a comprehensive Polio Eradication and Endgame Strategic Plan to address all aspects of polio eradication and exploit the unique opportunity to stop all polio disease once and for all. The plan builds on new tactics and new evidence of progress in interrupting wild poliovirus transmission and the development of new tools and new strategies in managing the risks of vaccine-derived poliovirus. With this comprehensive plan, the GPEI believes the prospect of success in completing polio eradication has never been more likely or more favourable.

¹⁸ 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).

¹⁹ 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: INTERRUPT WPV TRANSMISSION

OVERVIEW

| Activities | Sub-Activities | Primary Targets |
|---------------------------------------|--|---|
| Strengthen surveillance | Implement corrective measures to improve sensitivity of AFP surveillance | 100% of countries in non-certified regions achieving 2/100,000 AFP detection rate in under 15 population by end-2013 |
| | Scale up environmental surveillance | Environmental surveillance sites in 5-7 cities in each endemic country by end-2015 |
| Establish, maintain high-quality SIAs | Focus on Microplanning, Monitoring, Social Mobilization, Utilization of the Surge, Technical Innovations and Operation Tactics to improve effectiveness and quality of campaigns | Conduct 6-8/year in Northern Nigeria, Pakistan and Afghanistan |
| | | Conduct 2-4/year in W. Africa, Chad By end-2013, establish >80% LQAS-confirmed coverage in all high risk areas of Nigeria and Afghanistan; >90% in Pakistan |
| Improve outbreak response | Improve existing response methods by leveraging new response tactics and rapid assessments | Stop outbreak within 120 days after first index case |
| | | 100% of countries employing outbreak response after first index case |

Note: Reflects primary Objective Targets – comprehensive monitoring framework with complete list of operational targets to be found in Annex B.

INTRODUCTION

5.1 The aim is to be able to detect and interrupt all polio viruses globally, including the interruption of wild poliovirus transmission in the remaining endemic countries – Afghanistan, Nigeria and Pakistan - by the end of 2014.

WHAT IS REQUIRED TO INTERRUPT TRANSMISSION?

5.2 Interruption of wild poliovirus transmission requires the raising of population immunity in the three remaining endemic countries, in re-infected countries, and in areas prone to outbreaks and re-importations, to sufficiently high levels to interrupt transmission. This is done by vaccinating children with polio vaccines, through routine immunization and vaccination campaigns (supplementary immunization activities). This is particularly important in specific areas of the remaining endemic countries where low immunity levels have allowed continued virus transmission and reintroduction. It is

considered essential to reach >80% coverage in all high risk LGAs/districts of northern Nigeria and southern Afghanistan and >90% coverage in all high risk districts in Pakistan.

WHAT WILL BE DONE?

MAJOR ACTIVITIES:

- 1. Strengthen Surveillance**
- 2. SIAs**
- 3. Outbreak Response**

ACTIVITY 1: Strengthen Surveillance to Detect Virus Circulation

5.3 Major surveillance gaps persist in key geographies, particularly in Africa, leaving the programme vulnerable to undetected virus circulation. The primary focus will be on strengthening AFP surveillance to ensure comprehensive detection of symptomatic poliovirus transmission, prioritizing endemic, re-established and high risk countries. In addition, during this time period environmental surveillance will be scaled up as a critical complement to AFP surveillance in detecting the presence of asymptomatic polio in the environment. This will serve to ensure more robust identification of outbreaks in high risk areas and provide additional validation of transmission interruption.

Acute Flaccid Paralysis Surveillance

In Polio Endemic Countries and Countries with recurrent outbreaks and re-importations

5.4 The detection and investigation of AFP cases remains the core strategy for detecting both wild and vaccine-derived polioviruses, validating the absence of circulating VDPVs and guiding the GPEI SIA strategy. For the three regions not certified polio-free at end-2012, the priority will be to close remaining gaps in AFP surveillance sensitivity. Based on the global epidemiology of polio at mid-2012, the areas of greatest risk 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, 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 Particular attention will be given to ensuring documented active (at least monthly) AFP surveillance at all major reporting sites, including tracking AFP sensitivity in marginalized and at-risk populations through the categorization of all detected AFP and targeted analyses. In addition, the programme is working to institutionalize systems for modifying surveillance networks through tracking of health care providers visited by AFP cases and updating reporting networks. This will also include, for example, determining health care providers for Pashtun, migrant and nomadic groups and incorporating them into the surveillance reporting and informant networks. 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 and instituting appropriate management and accountability structures, in-depth analysis of surveillance data, and use of technology. There will also be a focus on expanding networks of community informants to supplement these more official channels and, potentially, establishment of rewards for polio-confirmed AFP cases. Finally, where orphan viruses are detected, an investigation will be conducted and surveillance procedures will be reviewed, as appropriate.

5.6 In areas with extraordinary challenges, in addition to the above, special activities will be put in place, including targeted AFP community searches, 6-monthly active case searches and case searches during vaccination campaigns. Regional and national plans will elaborate specific activities and budgets and there will be more systematic regional risk assessments and response.

5.7 In countries at risk of poliovirus importation, sensitive AFP surveillance is also of critical importance. In these geographies, there will be systematic analysis of surveillance sensitivity with corrective activities determined and implemented, as necessary. In addition, like the endemics, there will be 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. Furthermore, there will be a focus on increasing networks of community informers.

5.8 Given the planned switch under Objective 2 to bOPV and the introduction of IPV, AFP surveillance must be sustained at interruption levels to ensure detection of any reemergence of wild poliovirus, particularly in previously endemic and high risk areas.

In Polio-Free Countries

5.9 In polio-free countries, the detection and investigation of Acute Flaccid Paralysis (AFP) cases remains the core strategy for detecting any introduction of wild poliovirus or development of circulating vaccine-derived polioviruses, and to validate the absence of all circulating poliovirus. 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 special attention. For the three regions that are certified polio-free - the Americas, Europe and Western Pacific - the priority will be to sustain strengthened AFP surveillance. A similar priority will operate for those countries that have been polio-free for several years in regions that have not yet been certified. High quality AFP surveillance will not only contribute to regional and global certification, but will ensure the capacity to detect and respond to any cVDPV emergence following the tOPV-bOPV switch.²⁰ This will be achieved through heightened

²⁰ 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.

political commitment to the goals of the endgame, through allocation of additional resources where needed – including for laboratory capacity - and through WHO Regional Offices support to countries in revitalizing AFP surveillance. Oversight of surveillance quality will be provided by Regional Certification Commissions.

Optimize environmental surveillance

5.10 The systematic sampling of sewage for polioviruses will be geographically expanded to 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 will not only include sites in Nigeria, Afghanistan and high-risk areas/routes for importation but also select areas where vaccine switches must be monitored based on a particular risk of a VDPV emergence, or which have a national tOPV production facility. Consequently, sampling sites in an additional 15-20 cities will be added globally, prior to the tOPV-bOPV switch in 2015.

Special Surveillance

5.11 AFP and environmental surveillance will be complemented by special surveillance studies with four specific objectives. First, there will be expanded use of serologic surveys 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 inadequate AFP cases, will be used to more rapidly rule out ongoing 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: Supplementary Immunization Activities (SIAs)

5.12 In the remaining endemic countries, the key to interrupting transmission is to overcome the remaining barriers to reaching vulnerable children with OPV. This is done principally through Supplementary Immunization Activities which build on routine immunization programmes to establish very high population immunity in order to interrupt both poliovirus transmission and outbreaks following importations.

5.13 In the remaining endemic areas, an intensive schedule of supplementary immunization activities will be implemented to interrupt any residual wild poliovirus transmission, to maintain high population immunity in areas at highest risk of importation and/or persistent circulation, and to reduce the risk of VDPV emergence prior to OPV cessation. Figures 14 and 15 below illustrate the rigorous, geography-

specific schedules to support SIA planning. In areas where 2 or more countries have historically shared a common poliovirus reservoir or route of international spread, these activities will be internationally synchronized with special cross-border coordination and activities to optimize coverage in border areas.

Figure 14. SIA Guidelines, by Country

| Country Status | Country | Annual SIA Rounds |
|----------------------------------|--|--------------------------|
| Endemic | Northern Nigeria, Pakistan, Southern Afghanistan | 6-8 |
| Recurrent Importation | West Africa, Chad, Sudan, South Sudan | 2-4 |
| Recurrent cVDPV Emergence | Northern India, Somalia, Kenya, Ethiopia, eastern DR Congo | 2-4 |

Figure 15. SIAs Planned for 2013-2014 and 2016-2018



Effective SIA implementation by national governments, with the support of partner organizations, requires excellent campaign management across the following areas.

- Microplanning
- Monitoring
- Social Mobilization
- Surge
- Technical Innovation
- Operational tactics

The following sub-sections elaborate in greater detail the actions being taken in Afghanistan, Nigeria and Pakistan.

DRAFT

5.1 AFGHANISTAN

“Afghanistan will do all it can to fight polio in Afghanistan and also in other countries that polio is still present.”

Afghanistan President Hamid Karzai, High Level Polio Event, UN General Assembly, New York, September 27, 2012

5.1.1 Afghanistan has successfully interrupted indigenous wild poliovirus transmission in all but one region of the country – the southern region. In this region, the provinces of Kandahar and Helmand in particular have been responsible for maintaining continued endemic wild poliovirus transmission, repeatedly re-infecting other provinces of the country, and transmitting wild poliovirus across international borders to neighbouring Pakistan. Achievement of a polio free Afghanistan depends on these provinces, and the others of the southern region, successfully overcoming the barriers to implementing the strategies that have yielded success in other parts of the country while maintaining overall quality of activities and rapidly responding to polio cases outside of this endemic zone. The recent establishment of the highest level government commitment to achieving polio eradication by President Hamid Karzai along with a well-established track record for problem solving, innovation, and close coordination among partners and government mean that the key ingredients for success are present to rapidly achieve the as-yet elusive goal of a polio free Afghanistan.

Epidemiology

5.1.2 All of the cases in Afghanistan since 2010 have been due to wild poliovirus type 1. The last case of polio due to wild poliovirus type 3 was reported in April 2010. The last case of polio due to wild poliovirus type 2 was in 1997, though cases of polio due to emergence of type 2 circulating vaccine derived poliovirus (cVDPV type 2) have occurred since, with the most recent cases reported in December 2012.

5.1.3 Over 70% of all polio cases in the country since 2010 have been reported in just 2 out of 34 provinces, representing less than 10% of the total population – Kandahar and Helmand. This trend continues in 2012 with these 2 provinces reporting 22 of 35 cases (63%). The remaining 13 cases in 2012 to date were reported from 6 other provinces: Kunar (4); Khost (3); Paktya (2); Uruzgan (2); Ghor (1); and Farah (1). Analysis of wild poliovirus genetic data by the regional polio reference laboratory in Islamabad shows a continuing reduction in genetic diversity, indicating elimination of circulating strains, and confirms the southern endemic zone as the main source of continued wild poliovirus transmission in the country with only sporadic cases due to cross border transmission from Pakistan.

5.1.4 Polio continues to paralyze primarily young children in Afghanistan: 70% of the cases are in children under 2 years of age meaning a lifetime of disability and increased risk of early death for these children. Polio is occurring in these children because they are heavily under-immunized compared to the general population – over 65% of the cases in 2012 had received less than 3 doses of OPV and

approximately 35% had never received OPV (zero dose). This indicates a failure of the programme to reach these children with both routine immunization services and multiple supplementary immunization campaigns. Understanding the reasons these children and communities are missed is the key to overcoming the remaining barriers to achieving a polio free Afghanistan.

Reasons for continued poliovirus transmission

5.1.5 The southern region, particularly Kandahar and Helmand provinces, are the only remaining reservoirs for endemic poliovirus transmission in Afghanistan. These 2 provinces frequently feature in global headlines due to intense conflict and insecurity and many have questioned whether it is even possible to reach enough children to interrupt polio transmission in such a volatile context. Without doubt this setting significantly complicates implementation of the programme's strategies. However, careful analysis shows that children in areas of even the most intense conflict and insecurity can be reached. In fact, programme data shows that most children are NOT missed due to conflict and insecurity but instead due to continued weaknesses in delivering OPV to communities in areas that are relatively accessible. An analysis conducted by the Government of Afghanistan, with support from its partners (WHO & UNICEF), showed that 80% of children identified by vaccinators as missed during a campaign were from areas of the southern region without severe conflict and insecurity. Furthermore, the analysis shows that these children were missed either due to the team not showing up (30%), the child being absent when the team showed up (50%), the child being reported by caregivers as sick or asleep and consequently not wanting the child immunized at the time of the team visit (15%), or the caregivers simply refusing to have the child immunized (5%). The remaining 20% of overall missed children were located in areas where access to households with OPV was compromised due to insecurity and conflict. In these areas, the children were missed primarily due to either reluctance of field workers to conduct the activity due to a perception of insecurity or lack of agreement for the activity by anti-government elements (AGE) in some areas. The programme meticulously tracks the reasons for missed children and this information is used to inform the development of the strategies that will be implemented over 2013-14 to overcome the remaining challenges and achieve success in Afghanistan.

What's new – strategies for success in Afghanistan

5.1.6 The strategies in Afghanistan are designed to ensure greater reach to missed children during each SIA and in routine immunization, particularly in the endemic southern Region, in the context of high level oversight and accountability and with the support of an expanded and better trained field workforce. The guiding document for these strategies is the *National Emergency Action Plan* that was developed by the Government of Afghanistan with the support of its partners and officially launched by His Excellency the President.

Reaching chronically missed children in SIAs and routine immunization

- **Improved SIA microplanning:** the local microplan is the blueprint - detailing the people, places, timings, and logistics - for ensuring all children are reached with OPV. The Afghanistan programme

will augment existing microplans to improve operations. First, given the fluid security and conflict situation in the polio priority areas, all microplans will include detailed analysis of the access situation of each area. Direct or third party negotiations will be pursued in the most insecure areas with the aim of continuing to find conditions agreeable for activities to proceed – whether this means flexibility in the timing of campaigns, the type of vaccinators involved, or the means of vaccine delivery - fixed post or limited house to house. When activities can proceed in areas that have not had OPV for some time, the programme will seek to deliver multiple doses at short intervals (SIADs) and offer a broad range of health interventions during the window of opportunity. In all areas, additional mobile teams will be added to increase the opportunity to immunize children outside of the household – on the street, at playgrounds, or in the market. Finally, the procedure for recording missed children and re-visiting households with missed children during or shortly after the campaign will be revised and closely tracked in order to provide maximum opportunities to reach every child.

- **Better selected, trained, monitored, and supported frontline workers:** Much of the credit for interrupting poliovirus transmission around the world goes to the frontline workers who ensure that polio vaccine reaches every child. When the right profile of vaccinators and supervisors are recruited, trained, and supported through effective supervision, the virus stands little chance of survival. In the areas where the virus continues to circulate, one inevitably finds weaknesses in this aspect of the programme. The situation is no different in the southern endemic zone of Afghanistan. One of the primary strategies will be to establish proper vaccinator selection committees with local membership and guided by partner organization staff to find workers that are both acceptable to the local community and as accountable as possible to local authorities, whoever they may be. In the specific context of Afghanistan, local customs restrict easy entry into the household. The programme will therefore seek to create vaccinator teams that facilitate entry. Where possible, each team will have females. In areas where this is difficult, other options will be explored – recruiting females accompanied by male family members, recruiting local birth attendants, etc. Efforts will also be made to provide each team with attractive health incentives – items that would benefit newborns and other children and motivate caregivers to ensure all children are brought forward – even those sleeping, playing in the street, sick, or newborn. Finally, training of frontline workers will be revised – it will be more practical and hands on and include a component of inter-personal communications (IPC) skill building to equip teams for success at the household.
- **Mobilized communities:** Community engagement is a core strategy for success. In priority districts of Afghanistan, a full time community mobilization network will be developed. This will entail recruitment of 2 types of mobilizers – those that can work at the household level and those who can reach out to community leaders. At the household level, mobilizers will dialogue with caregivers about immunization and other health interventions and encourage immunization of their children during routine and campaign activities. At the community level, religious, health, and other local leaders will be identified and engaged to seek their support of the programme. Both mobilizers will work with their local contacts to identify important social gatherings where vaccine can be

distributed as well. All of these activities will be supported by an overarching media campaign and messages on radio and other media outlets.

- **Monitoring and supervision leading to corrective action:** Monitoring and supervision play a key role in a successful polio campaign. Lessons learned from India showed that monitoring is most effective when corrective actions can be taken as soon as they are identified. The Afghanistan programme will revise their monitoring procedures so that findings are available for daily evening meetings where actions required will be identified for follow-up. The programme will also introduce LQAS as the gold standard for assessing campaign performance and use this data to track trends in the quality.
- **Responding to polio outbreaks in areas outside of the endemic transmission zone:** Protecting the gains in areas that have succeeded in interrupting endemic poliovirus transmission is key. In order to achieve this, all of these areas will conduct at least 4 supplementary immunization campaigns per year to boost immunity over and above that achieved via routine immunization. Furthermore, the national level will establish an outbreak response team who will be responsible to visit any province outside the southern endemic zone that reports a polio case to engage with the provincial governor and provide technical support for conducting an immunization outbreak response. Any case reported outside of the southern endemic zone will be covered by at least 3 large-scale, short-interval, outbreak response immunization activities within 2 weeks of case notification.
- **Other Innovations:** The programme in Afghanistan has an established track record for finding innovative solutions to seemingly intractable problems. One such solution that will be expanded is the use of *permanent polio teams (PPTs)*. In areas of insecurity, vaccinators are hired on a permanent basis and requested to visit households in a continual cycle of activity – outside the timing of campaigns. The PPTs are local trusted people and they are supported by regular re-supply of vaccine and supervision. There will also be enhanced efforts to immunize travelers at major transit points and border crossings. This will include SOPs for district to district cross border coordination and standardized exchange of information. Immunization teams will continue continuous operation on both sides of the Pakistan / Afghanistan boundary at all major border crossings

Ensuring effective oversight and accountability

5.1.7 Accountability for activities and delivery of results is the driving force for implementing the key national strategies. Accountability in Afghanistan will involve the frontline field workers, the international partners supporting the activity, and district/ provincial government officials ultimately tracked at the highest level, the Office of the President. An accountability framework has been developed with clearly identified TORs of each polio manager at provincial and district level along with reporting lines, process of performance appraisals against clear deliverables and follow up action based on the appraisal results that will be used to gauge progress and take appropriate action.

5.1.8 To ensure full engagement of the entire government structure, H.E the President of Afghanistan has assigned a Focal Person on Polio Eradication to provide liaison between the office of H.E the Minister of Public Health and H.E the president, engagement and accountability of the provincial and priority district governors and support and monitor assistance provided by other Ministries and International Partners. Provincial governors, particularly the Governors of Kandahar, Helmand, Uruzgan, Kunar and Farah will lead to ensure high quality implementation of vaccination campaigns through engagement of district governors and members of Shura. Provincial governors will regularly submit monthly reports on each vaccination round to the office of President and Ministry of Public Health reinforced through direct quarterly meetings with H.E the President

5.1.9 Polio control rooms will be established in all high priority districts and provinces and at the National level. The overall purpose of the Polio Control Rooms is to be connected through mobile phone and link districts with provinces and provinces with national level in order to make real time monitoring of the campaign possible and provide guidance to the field in order to improve the quality of SIAs.

Surge support and enhanced technical assistance

5.1.10 The Government of Afghanistan's partners in polio eradication will provide support for all of these activities by expanding the field based staff in priority areas. UNICEF will expand the Immunization Communication Network to cover at least 90% of the low performing and priority districts through both full time and campaign specific social mobilizers. WHO will work with the Government of Afghanistan to hire additional district polio officers in all low performing districts. Together, both partners will conduct a series of technical and managerial trainings of District EPI management teams (DEMTs) and other relevant staff to improve capacity. The goal will be to have an expanded and well trained workforce to identify and correct problems in reaching all children within the 1st quarter of 2013.

5.2. PAKISTAN

Introduction

5.2.1 In its October 2011 report, the Independent Monitoring Board (IMB) assessed the polio eradication programme in Pakistan as ‘Deeply Dysfunctional’ and had projected that Pakistan would most likely be the last country on earth to become polio-free. In comparison, in its June 2012 report the IMB stated that ‘with revitalized energy and support of the highest political leadership the Programme has lifted its game considerably, and needs to continue to do so.’ Indeed, in 2012, the polio eradication programme in Pakistan made substantive and fundamental changes to its strategic and operational approaches. Most crucial was the transformation in the level, intensity and structure of government oversight, programme operations management, and performance accountability. These steps, coupled with intensified partnership support, bolstered by an emergency human resource surge have led to an impressive reversal in the direction of a programme that was spiraling downward as it faced a series of escalating polio outbreaks during 2008 to 2011. The substantive progress in 2012 has created the momentum and the opportunity for the programme to make a final push against poliovirus in the low poliovirus transmission season (January to June) of 2013. Based on the progress and the lessons learned in 2012, the programme has identified and refocused its strategic priorities and updated the National Emergency Action Plan – 2013, calling it the ‘Last Low Season’ for polio in Pakistan.

5.2.3 The recent episodes of violence against health workers, including polio vaccinators, in late December 2012, and escalating social disruption in advance of national elections expected in the spring of 2013 undoubtedly pose formidable challenges to the programme in Pakistan. While the strategic priorities and the roadmap to interruption of poliovirus transmission are clear, the programme is taking steps to maintain continuity of operations through this period of political turmoil to minimize any loss in the ground that it gained in 2012.

Background

5.2.4 Before Pakistan launched its polio eradication programme in 1994, an estimated 20,000 cases of paralytic polio occurred each year. With progressive intensification of SIAs, the programme achieved significant control of polio during the years 2004 to 2007 when less than 100 cases of polio were reported annually, and with only 27 cases in 2005. The coverage and quality of these immunization activities were insufficient, however, to interrupt transmission of wild poliovirus. A contributing factor to continued transmission of polio was a weak routine immunization programme with coverage levels that were highly variable between provinces and across districts within each province.

Polio in Pakistan

5.2.5 Although polio was widely endemic in Pakistan by 1999 clear persistent poliovirus transmission zones had become apparent from where periodic outbreaks of polio originated and spread to other parts of the country. These transmission zones included Peshawar and surrounding districts of central

Khyber-Pakhtunkhwa (KP) province and adjoining areas of FATA, southern KP, Quetta and adjoining districts in Balochistan province, northern Sind province and southern Punjab province. Karachi, although repeatedly infected by migrants and mobile populations, was not a persistently endemic polio reservoir until more recently.

5.2.6 Pakistan and Afghanistan make up a single epidemiologic block for polio and thus have continued to experience substantial cross-border transmission of polioviruses, principally across the southern border in Balochistan and the northern border in FATA. Successful interruption of poliovirus transmission therefore requires synchronous progress in both countries.

The Recent Polio Outbreak Years – 2008-11

5.2.7 By 2008, Pakistan programme began to lose the high level of control it had had on polio, as reflected by an outbreak that affected all provinces in 2008. There is clear evidence that there was a concomitant and progressive decline in the vaccination of children that was at its lowest point during 2009-10. This decline was particularly pronounced among children in FATA and Baluchistan. This reduction in population immunity explains the intensity and characteristics of the polio outbreaks that commenced in 2008 and peaked in 2011. The most notable features of these outbreaks were that

- 1) they were largely driven by intense transmission in FATA-adjointing KP and Baluchistan;
- 2) more than 70% of the cases were from families that identified Pashtu as their first language (an estimated 15% of the population of Pakistan is Pashtun); and,
- 3) the transmission also affected Pashtun populations from these polio reservoirs that have settled in and around Karachi and other major cities of Pakistan.

Reasons for Programmatic Decline during 2008-11

5.2.8 A combination of factors led to the significant deterioration of the polio eradication efforts in Pakistan from 2008-11. The major factors include the following:

- Erosion in the national ownership of the programme
- Gaps in programme management, transparency and performance accountability
- Poor campaign preparation with inappropriate vaccination team selection, including use of child vaccinators
- Inadequate follow up of missed children and corrective actions
- Inaccessibility in parts of FATA, especially Khyber Agency that accounted for a disproportionate number of polio cases during this period
- Gaps in social mobilization, especially the inability to engage high risk populations, and in particular the underserved Pashtun populations.
- Unreliable monitoring and misreporting of quality and coverage of campaigns

Programme Transformation - 2012

5.2.9 Transformative changes have been made as the polio eradication programme has been reconstructed during late 2011 and 2012. The major transformative initiatives include:

- Declaration of polio eradication as a national emergency by the President of the Republic, constitution of the National Task Force on Polio Eradication chaired by the Prime Minister with members including provincial chief ministers and chief secretaries, and appointment of a cabinet level leader as Prime Minister’s Focal Person on Polio to head the newly created Polio Cell in the Prime Minister’s secretariat. This was complemented by creation of a Polio Control Room in each province.
- Development of the Augmented National Emergency Action Plan (a-NEAP) for 2012. Based on a number of lessons learned in India and elsewhere, the major changes and new approaches in the a-NEAP included:
 - Assigning responsibility for planning and implementing polio vaccination campaigns to the District Commissioner, who is the chief executive officer in each district.
 - Assigning responsibility of micro-planning and vaccination team and supervisor selection to the Union Council Medical Officer, instead of the paramedical zonal coordinators, many of whom were chronically under performing and misappropriating resources.
 - Establishment of District Polio Control Rooms for campaign preparedness, monitoring and corrective action and formation of District and Union Council Polio Eradication Committees to ensure cross-sectorial coordination.
 - Establishment of clear indicators of campaign preparedness with creation of a ‘campaign dashboard’ with deferral of campaigns in union councils that did not meet preparedness criteria.
 - Wider application of LQAS as an objective measure of campaign quality, coupled with efforts to improve quality of independent monitoring.
 - Enforcement of performance accountability using objective and standard criteria through the framework that included district and provincial control rooms, the Prime Minister’s Polio Monitoring Cell, and the National Task Force on Polio Eradication.
 - Initiation of a direct disbursement mechanism (DDM) for direct provision of funds to vaccinators, ensuring appropriate selection and timely reimbursement of vaccinators.
- Tactical and operational innovations in a-NEAP 2012 included the following:
 - A more refined high risk approach that clearly defined the key polio reservoirs, the high risk districts and within them the worst performing and high risk union councils.
 - A human resource surge deployed by WHO and UNICEF (total of >1350) in high risk districts and union councils.
 - Aggressive implementation of Short Interval Additional Dose rounds (SIADs) to rapidly raise population immunity in high risk areas.
 - Strategies to improve access in FATA, particularly establishing civil-military cooperation.

- Strategic provision of additional health interventions (PolioPlus) in special sub-populations and insecure areas.
- Special strategies to engage female community members as vaccinators in high threat areas.
- An expanded 'Transit Strategy' to vaccinate children on the move, with a particular focus on Pashtun populations.

Impact of a-NEAP implementation in 2012

5.2.10 Implementation of the a-NEAP has led to very impressive progress during 2012. Several lines of evidence substantiate programmatic progress and commensurate impact on polio. The evidence relates to different aspects of the programme, but is remarkably consistent and thus gives confidence in the authenticity of the progress.

- Of the three major polio reservoirs in Pakistan, transmission continued only in the FATA-KP reservoir in 2012. During the recent outbreak years, three areas of Pakistan served as the main polio reservoirs, namely FATA and adjoining KP province, selected towns of Karachi and three districts of Baluchistan that make up the 'Quetta Block'. All polio cases during recent years either occurred in these reservoirs or were caused by spread of polio from these areas.
- The number of polio cases declined by more than three-fold in 2012 (58 cases) compared with 2011 (198 cases). Substantial geographic restriction in poliovirus circulation occurred, polio cases were reported from 28 districts in 2012 compared with 60 districts in 2011.
- There have been additional important and encouraging epidemiologic changes in polio during 2012 which when taken together, signal significant progress towards eradication of polio:
 - No wild poliovirus type 3 has been detected in environmental surveillance in Pakistan for two years and the most recent type 3 polio case occurred in April 2012.
 - There was substantial reduction in genetic diversity of type 1 wild poliovirus. Only 4 of the 11 genetic clusters isolated in 2011 were detected in 2012.
 - In all provinces of Pakistan, except KP, the number of cases declined during the high poliovirus transmission season in 2012 compared with 2011.

5.2.11 Vastly improved vaccination of children through better quality campaigns achieving higher coverage is the main factor that underpins the progress observed in 2012. Lot Quality Assurance Sampling (LQAS), the most objective measure to directly estimate the quality of polio campaigns, demonstrated impressive improvements in vaccination campaigns. There has been a steep and consistent trend in improvement of campaign coverage as assessed by LQAS. Compared with only 18% of LQAS lots accepted at 95% vaccination coverage during the January 2011 polio campaigns, 78% of lots were accepted at 95% coverage during the October 2012 campaign round. Even in KP province which experienced an outbreak in 2012, the LQAS trends have shown improvements, from 35% lots accepted at 95% in May 2011 to 90% in October 2012. Consistent with these data, compared with 2011, the proportion of 'zero OPV dose' children has declined in all areas of Pakistan, except FATA in 2012.

The implementation of a-NEAP and the impressive progress in 2012 has created strong momentum and has positioned the programme in Pakistan to make a concerted and perhaps the final push to stop polio during the current low transmission season of 2013.

Lessons learned in 2012 and remaining challenges

5.2.12 Important lessons were learned, valuable insights gained and significant challenges were encountered during implementation of the a-NEAP in 2012. These challenges and insights mainly relate to remaining gaps in local programme management and accountability, access to certain populations - both geographically and socially, and rapid decline in routine immunization coverage.

With guidance of the National Task Force and increasing effectiveness of the Prime Minister's Monitoring Cell, provincial support and oversight improved considerably, as did the engagement of District Commissioners and formation of district and union council polio eradication committees. Important gaps remained, however, in full operationalization of the provincial and district Polio Control Rooms and optimal functioning of the Union Council Polio Eradication Committees.

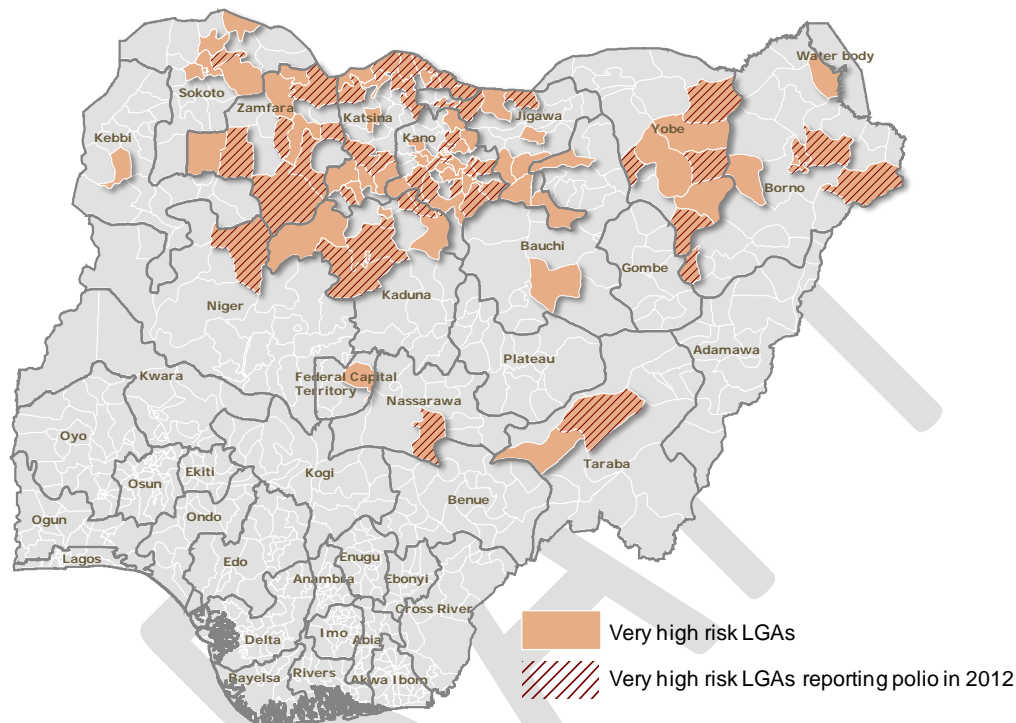
- Gaps/variability in management and accountability
- FATA: Inaccessibility and Ban, access in Khyber
- Pashtun underserved
- Social mobilization and Operations
- Insecurity and the Gadaap model
- Rapid decline in immunization coverage

Way Forward in 2013 – the 'Last Low Season' (TO BE ADDED)

Updated NEAP and low season priorities

5.3. NIGERIA

Figure 16. 107 Local Government Areas in Nigeria identified as very high risk (VHR) for sustaining wild poliovirus transmission and outbreaks. Risk algorithm developed by CDC, WHO and Global Good combining historical patterns of virus transmission with vulnerability based on immunity gaps.



“I wish to reaffirm Nigeria’s steadfast commitment to eradicate polio. We believe we must do it and we are progressing.”

– Nigeria President Goodluck Jonathan, High Level Polio Event, UNGA, New York, September 27, 2012

5.3.1 Nigeria remains the only country in Africa yet to interrupt indigenous transmission of wild poliovirus. However, in the last four years, it has made remarkable progress in shifting the course of the disease from a recurrent cycle of large-scale, national outbreaks to more focal transmission in well-defined reservoirs in northern States. This positions the country to intensify and direct its resources to find and immunize unprotected children, while sustaining the gains made since 2008 in improving overall population immunity.

Epidemiology and challenges

5.3.2. Nigeria reported circulation of all three poliovirus serotypes in 2012: WPV types 1 and 3, as well as cVDPV type 2. Historic progress was achieved between 2009 and 2010 in restricting what was previously widespread national transmission to persistent transmission in localized sanctuaries in northern Nigeria, with a reduction in annual reported wild type cases from 388 to just 21. Despite notable increases in the total number of wild type cases reported since then – from 62 in 2011 to double that number in 2012, transmission is now mostly focused in key reservoirs across northern Nigeria. In 2012, 97% of polio cases were located in just 100 of 9,555 wards in the country.

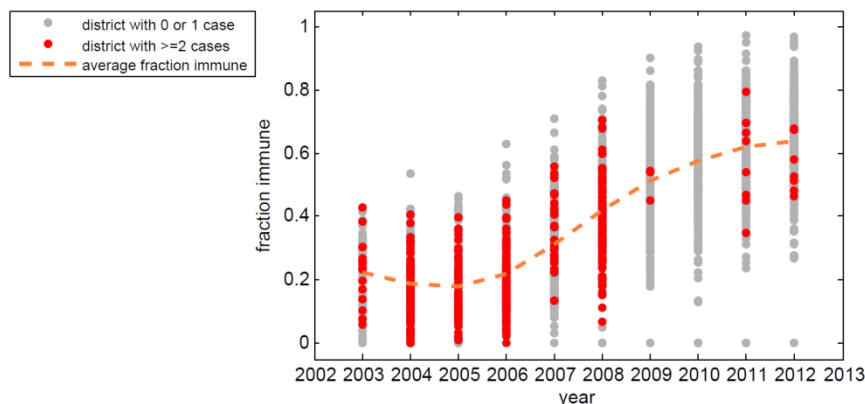
5.3.3 Additionally, from the beginning of 2011 through November 2012, the genetic diversity decreased for both WPV1 and WPV3 despite the increase in the number of cases. As reported by the CDC, the number of co-circulating clusters reporting cases of WPV1 fell from 8 in 2011 to 4 in the second half of 2012; for WPV3, 4 clusters were reduced to only 1. The decreases in genetic diversity likely correlate with the reductions in geographic spread: both types appear to be once again restricted to northern Nigeria.

5.3.4 Kano state, in particular, plays a key role as a transmission hub for all serotypes and has reported more cases cumulatively than any other state since 2010. The northern states of Katsina, Kaduna, Borno, Sokoto, Jigawa, and Zamfara have also been identified as localized sanctuaries for continued transmission over the last three years. Wild poliovirus spread from these key reservoirs to four previously polio-free states in late 2012, underscoring the need to address transmission in these key reservoirs to preserve gains achieved over the last five years.

5.3.5 Despite these challenges, Nigeria is making progress. A Global Good analysis of the OPV status of children investigated for paralysis indicates that immunity levels needed to stop transmission are improving across the highest risk northern states. In 2008 when Nigeria had its last large outbreak (798 cases), population immunity was approximately 42%. By the end of 2012, the fraction of the population immune to polio had climbed to 64%. The improvement in immunity is accompanied by the sharp decline in reported polio cases, as demonstrated in the accompanying graph.

Figure 17. Improving immunity levels, northern Nigeria, 2002-2012

Average immunity estimated from OPV doses received status of non-polio AFP cases, children 9 mos-15 years

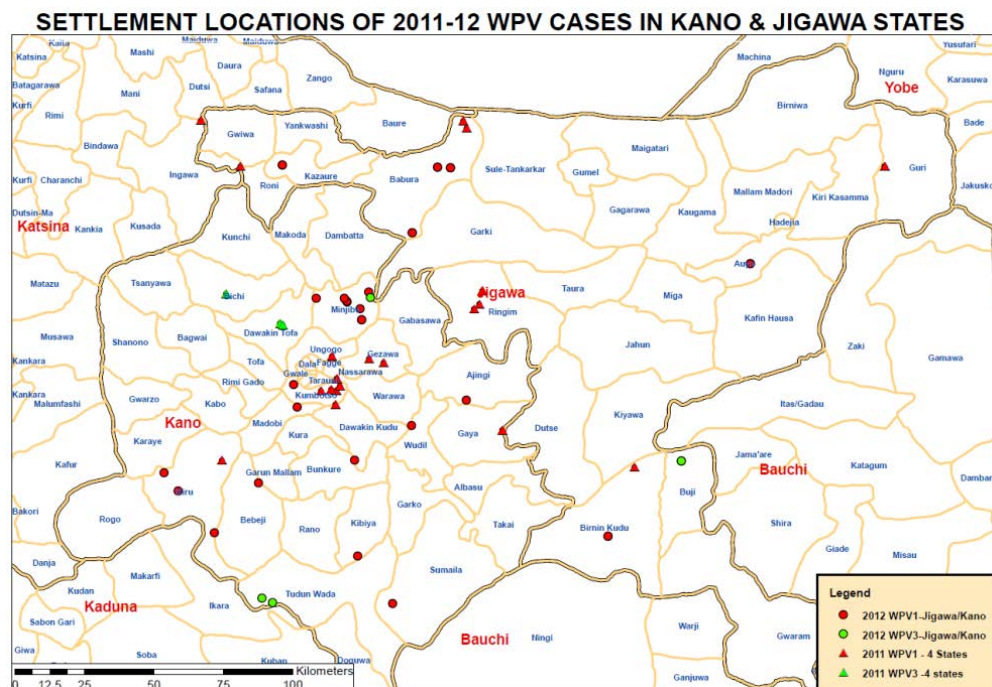


5.3.6 Also, Lot Quality Assurance Sampling (LQAs), which is now being used extensively in the programme as a measure of the quality of immunization campaigns, is showing improvement. In May 2012, only 35% of LGAs measured with LQAs were accepted at >80% coverage. By December 2012, nearly double (69%) the number of LGAs were accepted at >80%.

5.3.7 Children with polio in Nigeria are almost all from poor families, live in rural, hard-to-reach settlements in border areas between districts, are not visited by vaccinator teams or whose parents refuse the vaccine. These border areas are also often in close proximity to major travel routes for nomadic herdsmen, whose children are chronically missed by the programme. Geographic Information System (GIS) maps of northern Nigeria developed for the polio programme show that 80% of polio cases in 2012 were located in the border areas between district and states. These border areas are also often in close proximity to major travel routes for nomadic herdsmen, whose children are chronically missed by the programme. New tools, such as this, are helping the Nigeria programme to pinpoint its greatest challenges.

Figure 18. Distribution of polio cases in Kano and Jigawa states, 2011-12

Accurate spatial distribution using GIS maps indicate that 80% of polio cases in 2012 happened on state and LGA borders



5.3.8 In built-up rural villages and urban areas, the performance of vaccinator teams is the key determinant of whether or not a child is immunized. Independent monitoring data suggests that the biggest cause of missed children – nearly 40% - is due to teams not seeking out all children (as of October 2012). Families who refuse to accept the vaccine are also a barrier to immunization.

5.3.9 According to the same data, 18% of missed children were due to refusals. ‘Refusals’ tend to be clustered, particularly in urban areas of Katsina, Kaduna, Sokoto and Kano, where communities are influenced by clerics who claim the vaccine will create sterility or make people sick. As well, communities refuse vaccination because they say it is not their priority, or because of demands for other services. In Borno and Yobe states, insecurity remains a significant obstacle.

What’s new?

5.3.10 In Nigeria, the programme aims to achieve an SIA coverage target of 80% coverage across high risk areas by the end of 2013 while maintaining other areas polio-free. The focus is to (1) improve the quality of the immunization activities in rural settlements and urban areas; (2) reach children missed previously by the programme; and, (3) fast track the response to the spread of virus in areas of the country that have been polio free.

5.3.11 There are several reinforcing thrusts in the Nigeria program that are driving change. First, there is an unprecedented level of **political commitment** to polio eradication that is driving accountability and coordination at all levels. Second, there is a strong recognition of the need to improve the **quality of each polio campaign** so that fewer children are missed. Third, a new culture of **innovation** is allowing the Nigeria programme to adapt global best practices. Fourth, Nigeria is making a significant effort to

revitalize its **routine immunization** programme, including leveraging the massive polio effort in ways that help overcome some of the systemic and operational hurdles that are keep vaccines from reaching children. Each of these was present to some degree in the Nigeria program. However, what is different is the scale at which these inputs to the programme are now operating; the intensity of management and oversight by the federal and state governments; and, the rigorous use of independently collected and managed data to validate performance in reaching children.

Political commitment

5.3.12 Nigeria's political commitment to polio eradication is unprecedented. President Goodluck Jonathan leads the national effort through a Presidential Task Force, and reviews progress quarterly. The Minister of State for Health chairs the Task Force, which includes federal legislators, state health commissioners, traditional leaders and GPEI partners. The Task Force has commissioned Emergency Operations Centers in Abuja (established), Kano (established) and four other states to drive operational planning, monitoring and feedback. This is providing greater opportunity for programme coordination, monitoring and accountability.

5.3.13 A new 'dashboard' is being used by the Emergency Operations Centers (EOC) to assess the readiness of the programme to implement each of its supplementary immunization campaigns. With a three-week countdown, States and Local Government Areas need to report against a number of indicators to assess their preparedness: funds released; planning meetings held; ward team selection committee meetings taking place, microplans verified, social mobilization initiated, trainings conducted and logistics in place. The dashboard data is being used by the Task Force to hold State, LGA and the immunization staff accountable for the quality of the work. Poor quality is resulting in campaigns being suspended, and administrative sanctions against government and partner staff.

5.3.14 The Task Force also tracks the political oversight being provided by State Executive Governors and LGA Chairmen through the *Abuja Commitments*, a declaration signed by the Executive Governors in 2009. The *Abuja Commitments* require political leadership in the state to oversee polio and immunization activities, to ensure the release of state funds, and to involve the state's traditional leaders in planning and implementing the programme.

5.3.15 President Goodluck Jonathan personally intervenes when those commitments are not being met. Pre and intra-campaign advocacy field visits to the highest risk states and LGAs by Task Force members also provides feedback and motivational support to political leaders and technical teams at the operational level.

5.3.16 The Bill & Melinda Gates Foundation instituted an Immunization Challenge in 2012 to reward those states which performed best in achieving key polio and routine immunization targets. In 2013, the Challenge will focus on rewarding those states that interrupt wild poliovirus transmission. Winning states receive a grant award for a public health priority identified by the state's Executive Governor.

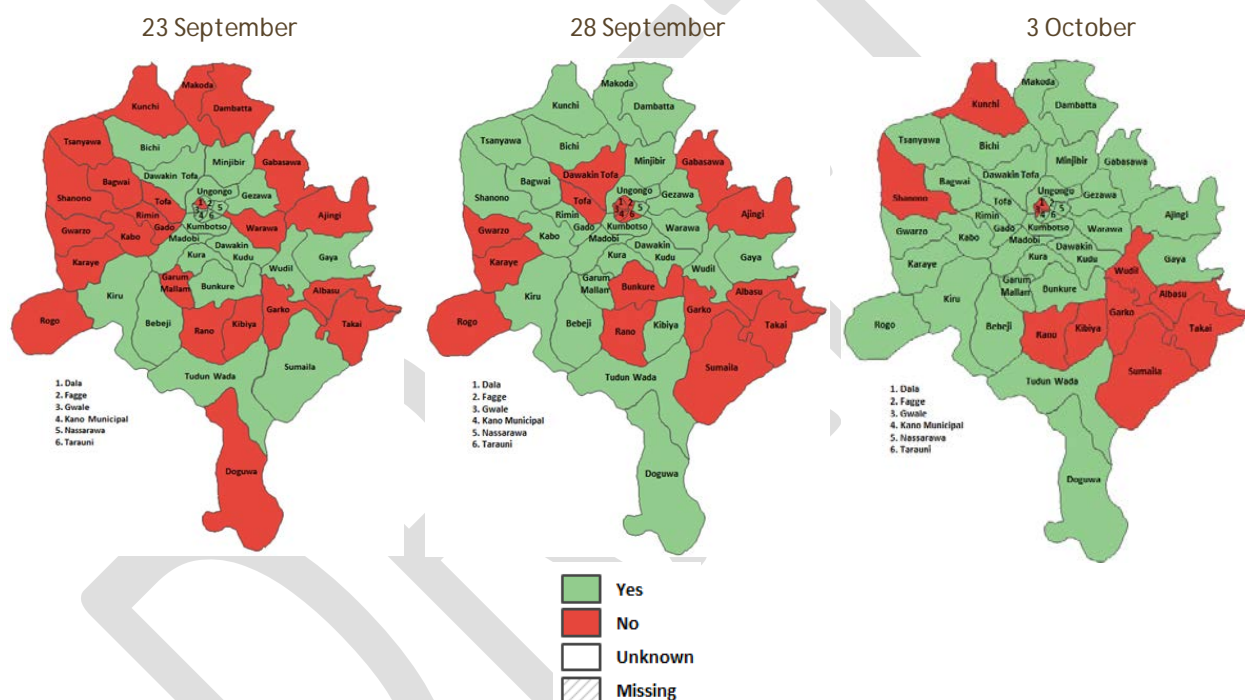
Improving SIA quality and reaching all children

- **Team structure and selection** – Nigeria will continue to maximize the restructuring of vaccinator teams implemented in 2012 to ensure adequate supervision and oversight is maintained. Vaccination teams have been restructured from 6-person to 4-person teams, including a community leader. This improves the mobility of teams and makes supervision and validation of work more effective. Concurrent monitoring has been used to monitor team performance and ensure real time corrective action. Rigorous implementation of agreed-upon guidelines for selecting, training and monitoring vaccinators. For example, traditional leaders through Ward Selection Committees are taking increased responsibility for proper selection of vaccinators and recorders. As such, there has been an increase in female vaccinators and recorders in local areas and Ward-level daily meetings have been instituted to increase team oversight and drive local accountability. The EOCs will work with states to test and implement strategies for improving team motivation and performance management, including vaccinator recognition/incentive programmes.
- **Improved SIA microplanning** – Campaign microplans have been updated by the LGA teams through an intensive engagement supported by WHO at the local level. For example, in Nigeria this resulted in the identification of more than 3,000 additional settlements in mid-2012 that were missed in previous planning exercises. Nigeria is also using some of the tactics pioneered in the successful polio programme in India. Staff from that programme are providing regular input to the work in Nigeria, including a revision of the tools used for microplans. Nigeria also shifted to a house-based approach to its microplans so that teams are assigned specific households, instead of the general instruction to immunize within a village or urban neighborhood.
- **Social mobilization** – a Volunteer Community Mobilizer (VCM) Network was launched by UNICEF in early 2012, which has been expanded to 73% of target high-risk areas, with additional scale-up in 2013. This increases sensitization of mothers in highest risk settlements to the importance of polio eradication and routine immunization. In 2013, partnerships with religious groups and specific leaders such as the Tsangaya (Koranic) School Strategy, traditional leaders, polio survivors and FOMWAN will be expanded at the community level. This will be supplemented by an extensive visibility and mass media strategy, with entertainment-education at its centre. UNICEF will introduce and evaluate a new Interpersonal Communication skills kit to improve vaccinators' ability to engage effectively with community members, with special trainings to be initiated in 2013. It will also collect social data to understand reasons behind missed children (particularly children absent from the home) and develop strategies to address these barriers.
- **Surge support and technical assistance** – WHO will maintain support for the 2,500-strong human resource surge initiated in 2012 through 2018, with ongoing efforts to improve staff management and accountability processes. UNICEF has expanded its communications capacity in LGAs in the high risk states. 1827 Volunteer community mobilizers have been deployed to the highest risk settlements, with further expansion in 2013. CDC will support greater data analysis capacity within the NPHCDA and through its nSTOP programme. The Nigeria programme will continue its technical

exchange with India, including periodic deployment of Indian Surveillance Medical Officers to high risk areas of Nigeria.

- **Monitoring data & local accountability** – In Nigeria campaign dashboards are being utilized to more effectively prepare and track campaign implementation and the government has begun to delay campaigns deemed ‘not ready’ to implement immunization activities. This is helping to drive local accountability for SIA quality using campaign dashboards showing critical LGA-level campaign preparedness and implementation indicators.

Figure 19. Progress in verified, quality microplans against proscribed indicators at the Ward level in Kano in the three-week lead up to the October 2012 polio campaign



Innovations

- **Focused interventions to reach previously missed children** – Special vaccination campaigns will be scaled up targeting wards to accelerate containment of wild poliovirus transmission in localized areas, including borders, nomadic routes and hard to reach scattered settlements. These activities will be conducted periodically as stand-alone, in-between round activities and embedded within scheduled SIA rounds. Nigeria will also use the Short Interval Additional Dose strategy to rapidly build immunity in communities that have not been reached before, including security-compromised areas. Where access is a problem because of insecurity, the programme will also test the use of permanent polio teams who can take responsibility for ensuring a pre-identified population is immunized over a specified period of time, rather than being bound by the campaign schedule. The engagement of local stakeholders such as FOMWAN will be scaled up further to help overcome

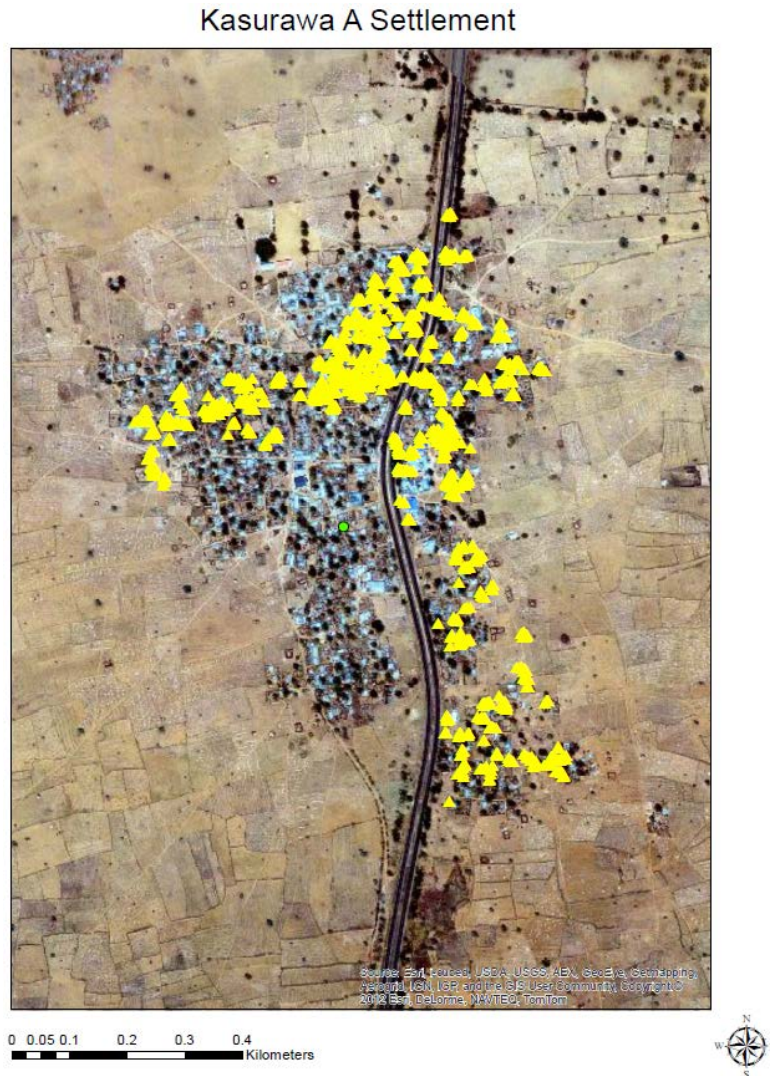
issues of mistrust and suspicion at the local level, especially where there is tension resulting from conflict and insecurity.

- **GIS mapping and GPS tracking** - Nigeria is making more extensive use of GIS mapping than any other country in the global polio programme. These maps are helping to improve settlement identification, resource allocation and microplanning. This also incorporates mapping and engagement of nomadic populations: a pilot took place in July 2012 in 10 LGAs in 7 states, with scale-up in August 2012 to 41 LGAs in 10 states. This found more than 8000 additional settlements not already included in micro-plans. 15% of these settlements had never been visited by a vaccination team. Now all these are in the micro-plan. The programme will continue intensive engagement with traditional rulers to identify and track immunity status of children at settlement level. The programme will also scale up the use of GPS tracking to capture real-time movement of vaccination teams to determine missed areas and improve supervision.

DRAFT

Figure 20. GPS tracking of vaccinators, November 2012

Kasurawa A village, Sokoto state. Each yellow dot represents one track collected every two minutes. Density of dots is converted into an algorithm to approximate the percentage of geographic area visited by the team. In this graph, more than 50% of the village was not visited.



- **Enhancing surveillance** – To further enhance the sensitivity of the surveillance system, additional informants have been recruited, with further scale-up in 2013. Environmental surveillance sampling sites were established in Kano and Sokoto. The location of sampling sites in Kano will be reviewed to optimize the potential of detecting circulating viruses. At the end of 2012, Lagos was added as a new site, with possible expansion to Maiduguri when the security situation permits.

Innovations to Improve SIA efficacy

5.14 In addition to the aforementioned country level activities, a combination of outstanding scientific and operational research items may further improve the efficacy of campaigns in the future.

- First, is the potential utility of expanding the age groups targeted during OPV SIAs, based on success realized with this tactic in Pakistan, to all endemic areas. Recent data from polio outbreak response activities 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.
- Second, 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 endemic areas has substantial communications and logistical implications, both can be evaluated for use in endemic reservoir areas where transmission persists into late 2013.

ACTIVITY 3: Outbreak Response

5.15 A more aggressive approach to outbreaks of both wild- and vaccine-derived polioviruses will be implemented in endemic countries and in countries with recurrent outbreaks, with a goal of stopping any poliovirus within 120 days of an 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 (i.e. to < 15 years of age or the entire population, depending on the epidemiology), and reducing the interval between the first 3 rounds (i.e. from 4-6 to 2-3 weeks). Joint national and international rapid assessments will be conducted at 3 and 6 months following the index case to assess quality of outbreak response and plan any course corrections. Together, this represents a marked step-up in the response to polio outbreaks.

5.16 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 to guide outbreak response planning and implementation.

- **For endemic and other high risk areas**, the detection of a positive environmental sample will 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 or an immunization response.

- **In Polio free Countries** systematic and regular risk analysis drives the work. Those countries with high levels of susceptible children and at risk of poliovirus importation (link with polio infected country) will need to continue regular SIAs to maintain baseline immunity, and synergize adding OPV to campaigns being conducted for other antigens / purposes. Rapid implementation of international outbreak response protocols to all WPV importations and cVDPV emergences is also required.

WHO IS OVERSEEING THIS WORK?

The Independent Monitoring Board

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

DRAFT

6. OBJECTIVE 2: ROUTINE IMMUNIZATION STRENGTHENING AND OPV WITHDRAWAL

| Activities | Sub-Activities | Primary Targets |
|--|--|---|
| Increase Routine Immunization coverage | Leverage detailed plans focused on <i>Management, Microplanning, Mobilization and Monitoring</i> | <p>>50% of the time of polio-funded field personnel by end-2014 will be devoted to specific, measurable activities to help national authorities strengthen routine immunization systems and services</p> <p>In focus countries, achieve a 10% improvement in coverage rates in the highest risk districts on a year-on-year basis, achieving 70-80% DPT3 coverage.</p> |
| Develop IPV, bOPV and mOPV | Secure stockpile of mOPV and response capacity | Determined supply secured and available by end-2015 |
| | Facilitate global access to bOPV for RI programmes | Determined supply secured and available |
| | Secure affordable IPV globally available | IPV available at <\$1/dose by end-2015 |
| Introduce affordable IPV | Introduce IPV through routine immunization | 100% of OPV countries have introduced at least 1 dose of IPV into routine immunization schedule by end-2015 |
| Withdraw OPV2 | Eliminate persistent cVDPV2 | All outbreaks eliminated within 12 months of OPV2 withdrawal |
| | Improve surveillance and ensure notification in place of Sabin, Sabin-like and cVDPV2 | 100% of countries in non-certified regions achieving 2/100,000 AFP detection rate in under 15 population by end-2013 |
| | Ensure type-2 containment processes under-way | Complete Phase 2 (WPV-2) and Phase 1 (Sabin-2) |
| Full OPV Withdrawal | Strengthen Routine Immunization to improve IPV coverage | Adequate IPV coverage achieved |

Note: Reflects primary Objective Targets – comprehensive monitoring framework with complete list of operational targets to be found in Annex B.

INTRODUCTION

6.1 As progress towards wild poliovirus eradication accelerated in the late 1990s, new risks to a polio-free world became apparent. Vaccine-derived polioviruses (VDPVs) were – rarely – found to be able to regain the ability to both circulate and paralyze, causing polio outbreaks due to circulating VDPVs (cVDPVs) and – even more rarely – VDPVs were shown to persist for years in some individuals with primary immunodeficiency syndromes (i.e. as ‘iVDPVs’). It has since been confirmed that cVDPVs can become biologically equivalent to wild polioviruses, causing severe paralysis, bulbar polio, and death, and can circulate indefinitely in areas with immunity gaps.

6.2 By 2005, expert polio eradication and immunization advisory bodies had 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. In May 2008, in line with guidance from SAGE, the WHA endorsed the principle of synchronized OPV cessation globally, requesting acceleration of the programme of work on post-eradication risk management, including, when appropriate, establishing a timeline for the eventual cessation of the use of OPV in routine immunization programmes.²¹ The importance of withdrawing the type 2 component of OPV as soon as possible from routine immunization programmes globally was reinforced by the detection in 2012 of five polio outbreaks due to circulating type 2 vaccine-derived polioviruses (cVDPV2) in Chad, DR Congo, Kenya, Nigeria, Pakistan, Afghanistan and Somalia (two of these outbreaks, in Nigeria and Somalia, represent ongoing transmission for greater than 36 months).

6.3 Currently there are 130 countries that use OPV to vaccinate children against polio. In these countries children are immunized against polio using a trivalent oral polio vaccine that contains types 1, 2 and 3 polio serotypes. Through the use of this vaccine, type 2 wild poliovirus has been eliminated globally for over 10 years (last case isolated in 1999). With progress in eradication, as of end-2012 90% of cVDPV cases are currently caused by viruses derived from type 2 polio vaccine. Given this, and the long-term risks of vaccine-associated paralytic poliomyelitis (VAPP), iVDPVs and cVDPVs, the use of specific OPV serotypes will be phased out globally from all immunization activities and programmes, beginning with withdrawal of OPV2 vaccine. This serotype will be eliminated by replacing all trivalent OPV with bivalent OPV (types 1 & 3) with a target date of late-2015 (at latest 2016) for a global cessation of all tOPV use.

6.4 In addition, to boost immunity in advance of the cessation of tOPV, it is recommended that at least one dose of IPV, should be introduced into routine immunization programmes. The introduction of IPV is expected to yield the following benefits:

- The prevention of paralytic polio in individuals successfully vaccinated with IPV who get exposed to a cVDPV type 2, Sabin type 2 (VAPP) or wild poliovirus type 2;
- Improved immunological response in individuals previously vaccinated with IPV when receiving mOPV2 vaccination given in response to a WPV2 or cVDPV2 outbreak that occurs after OPV2 cessation;

²¹ Resolution WHA61.1: ‘Poliomyelitis: mechanism for management of potential risks to eradication’

- Reduced transmission of cVDPV2 or WPV2 should they be introduced (i.e. there is evidence to suggest that IPV reduces the titer of fecal virus excretion and duration of shedding and is equivalent to OPV in decreasing oropharyngeal shedding);
- Boosting of immunity to wild polioviruses type 1 and 3 in vaccine recipients, which may further accelerate wild poliovirus eradication.

WHAT WILL BE DONE?

MAJOR ACTIVITIES:

- 1. Increase Routine Immunization Coverage**
- 2. Development of IPV, bOPV and mOPV**
- 3. Introduction of Affordable IPV**
- 4. Withdrawal of OPV 2**
- 5. Full OPV Withdrawal**

ACTIVITY 1: Increasing Routine Immunization Coverage

Introduction

6.5 Polio and routine immunization activities do not exist in complete isolation from each other. At a strategic level, polio eradication is a key objective under the Decade of Vaccines and this Polio Strategic Plan has been developed to align with the goals of the Global Vaccine Action Plan. In almost all countries of the world, the polio eradication activities are part of the routine immunization programme which in itself is part of the public health system. If this plan is successful, in time polio vaccination campaigns will no longer be needed. Nevertheless, to prevent further spread of wild and vaccine-derived poliovirus and to maintain a polio free world in the future, the delivery of polio vaccine as part of routine immunization is paramount.

6.6 There are clear linkages and complementarities at an operational level, in terms of infrastructure, assets, and staff functions. It is well known that polio-funded workers already contribute to immunization as part of their routine activities, and this will continue. Nevertheless, it is incumbent upon the GPEI to join more closely with immunization activities in order to achieve the goal of polio eradication and contribute more broadly to global public health. Therefore routine immunization strengthening has a front and central role within the Polio Eradication and Endgame Strategic Plan.

Why strengthen routine immunization as part of the Polio Eradication and Endgame Strategic Plan?

6.7 Although it has been shown in certain contexts that it is possible to eradicate poliovirus predominantly through vaccination campaigns, there are several reasons why strengthening routine

immunization is vital to the Eradication and Endgame Strategic Plan, and why the GPEI partner organizations will increase engagement with immunization partners through the 2013-2018 period.

- **To drive and maintain population immunity**
 - Of direct benefit to eradication efforts in the remaining endemic countries
 - Maintaining polio-free status in non-endemic countries
 - Of direct benefit to managing outbreaks
- **To provide a sustainable platform for vaccine delivery**
 - Essential to the introduction of IPV, bOPV and withdrawal of OPV 2
- **To leave a long-lasting benefit of polio eradication**
 - To maximize the broader benefits of polio assets and infrastructure

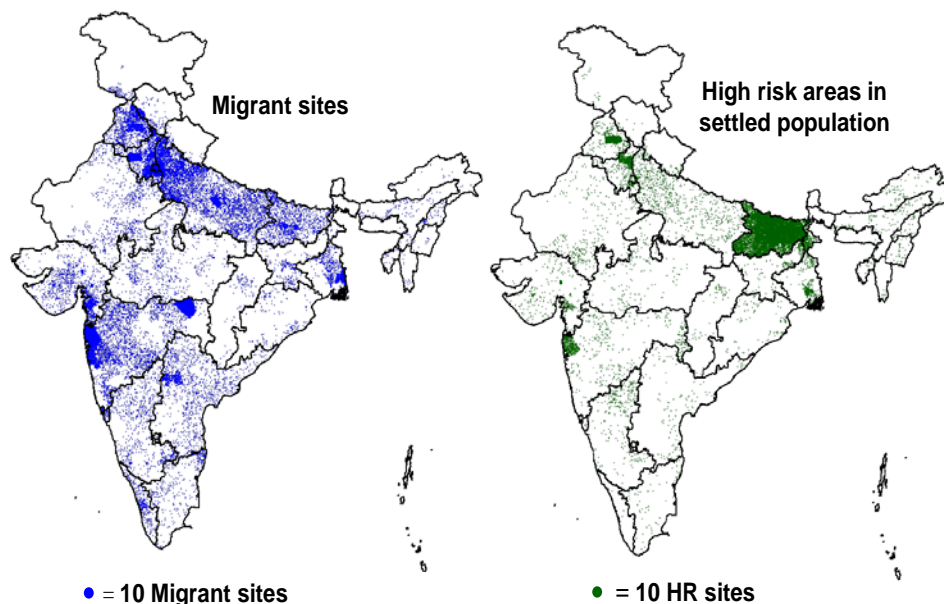
6.8 While the GPEI has a clear focus on polio eradication, this Plan recognizes that strengthening routine immunization will contribute to its success. There are complementarities between Polio and Routine Immunization support to strengthening routine immunization programmes (vaccine supply, demand creation, delivery, partnerships) but these need to be more clearly articulated, further intensified in those countries and districts at greatest risk of sustaining WPV transmission and with agreed accountabilities on improving routine immunization coverage and system strengthening. There is a significant and deliberate overlap with routine immunization programmes in most polio-affected countries. Within the context of the Strategic Plan this is intentional.

India and Africa present examples of GPEI and immunization partners efforts to support routine immunization, as well as how far the initiative has to go to make an impact on RI coverage.

6.9 After interrupting WPV transmission in 2011, the Government of India/WHO National Polio Surveillance Project has reoriented its significant staffing structure to assume greater responsibilities towards routine immunization. It is focused in five areas, linking both grassroots activities with:

1. Support **tracking of settlements/areas** identified by the polio programme as at high risk of being missed by regular RI delivery (migrant and migratory populations, brick kilns, urban slums, etc)
2. Guide setting up of dedicated **state and district task forces** for routine immunization
3. Support intensified, focused **RI training** of medical officers, health workers, ASHAs and Anganwadi workers
4. Realign **monitoring strategy** to generate evidence for action to improve RI coverage
5. Integrate **Universal Immunization Programme reviews with AFP surveillance reviews**

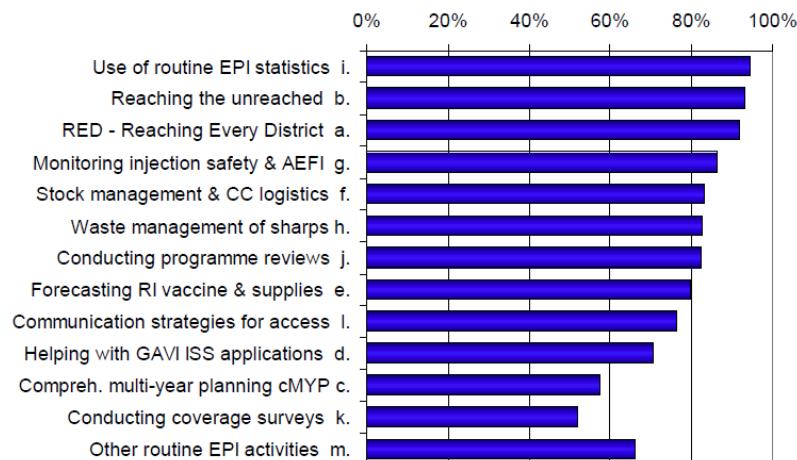
Figure 21. Tracking settlements in India at high risk of missed children for normal RI delivery



6.10 The figure above shows the distribution of high risk settlements/areas tracked by the polio programme to both promote RI planning and delivery, as well as monitoring of sessions. Specific interventions include the orienting of local health staff to include these high risk areas in the RI microplans, updating these areas on a regular basis, and monitoring by polio field workers. The other key activities in India build from that basis. There are clear benchmarks for training of health workers by polio staff. GPEI will also help facilitate the establishment of state and sub-state level task forces to focus on routine immunization. And the key deliverable will be intense monitoring of field activities to identify gaps and to generate timely, reliable, systematic data in RI for policy decision making by the government

6.11 In Africa, the polio eradication initiative funds 90% of the 1000+ personnel associated with AFRO's Immunization and Vaccine Development (IVD) effort. A full 53% of IVD staff time is spent working on multiple diseases, including polio, or explicitly working on non-polio work – while 47% is spent on polio alone. IVD staff spends a significant portion of their time directly supporting routine immunization strengthening. The overwhelming majority are now deeply involved in strengthening routine immunization, performing roles and activities ranging from vaccine delivery aimed at reaching every child to supportive planning and communication strategies.

Figure 22. IVD, WHO AFRO staff's involvement in strengthening routine immunization



Addressing poor Routine Immunization coverage

6.12 According to WHO-UNICEF coverage estimates (WUENIC) for DTP1 and DTP3 in 2010, there were about 14 million unvaccinated children and nearly 8 million under-vaccinated in the world, mostly in low income countries, giving a total of about 22 million who did not complete the primary immunization series. These figures hide immense uncertainty, however and true coverage may be lower. WUENIC in some of the largest countries (India, Indonesia, Nigeria and DRC) are based on surveys due to poor quality of administrative reports.

6.13 In the last decade, vaccination records were available for only a minority of children in DHS and MICS surveys in these countries, thus survey results reflected the caretakers' verbal reports of vaccination, of unknown accuracy. Given the size of the India and Nigeria birth cohort, the uncertainty in these countries affects not only national estimates but also regional and global estimates of numbers of unvaccinated children, which is in turn used to estimate burden of disease averted and remaining. In 2011, seven countries – three of which are the remaining polio endemic countries – were estimated to have about two-thirds of all children who did not receive DTP3. At these levels, interruption will be more difficult.

Increasing collaboration

National Authorities, GPEI Partner Organizations and GAVI

6.14 At the country level, national authorities are responsible for development of immunization plans and for routine immunization systems. The GPEI, partner organizations and GAVI can play a supplementary and catalytic role in strengthening systems and driving greater routine immunization coverage. With funding support from the GAVI Alliance, partners will increasingly provide technical assistance for the formulation of these plans, describing concrete steps, including the definition of high priority districts and resource requirements to accelerate the strengthening of routine vaccination.. These plans will also put a special focus on the development of district micro-plans for all high risk

districts and define the engagement of partner staff in supportive supervision and follow-up of activities. Collaborative planning around the deployment of personnel and infrastructure for routine immunization will become a stronger and deliberate area of focus between partners and countries. In addition, tracking and monitoring of coverage and troubleshooting obstacles should become part of the country engagement model for GPEI and partners.

6.15 At the global level, the GPEI is led by the 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 in countries - Rotary International contributes to routine immunization as a key part of its Polio Plus Programme. Increasing collaboration across these organizations as well as with the GAVI Alliance is of fundamental importance to the Polio Eradication and Endgame Strategic plan.

6.16 The GAVI Fragile States policy identifies several countries where the GPEI has extensive experience and a significant staff presence. Activities that will benefit both the goals of polio and routine immunization strengthening include i) joint planning and monitoring; ii) cold-chain infrastructure and vaccine supply management and iii) data management. Beyond contributing to the strengthening of routine immunization programmes, a closer collaboration in these fields will also contribute to strengthening of the broader Health System.

6.17 On the funding side, GAVI already provides significant financial support in the remaining polio endemic countries, and to India. In addition, polio eradication represents a potential IFFIm opportunity in the following areas:

- Fund IPV (both development and introduction)
- Fund Routine Immunization strengthening

6.18 Outlining its commitment to working with the GPEI, at its Meeting in December 2012 the GAVI Board “approved GAVI playing a complementary role to the Global Polio Eradication Initiative (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 will work together to elaborate a joint workplan in priority countries. Details will be elaborated and a workplan with milestones/deadlines finalized later in 2013.

Specific Actions

6.19 There are two main elements to Polio's contribution to routine immunization strengthening:

1. Globally, utilizing polio staff presence, advocacy capability, tools and expertise to boost routine immunization coverage levels, and to support the introduction of IPV, and bOPV and the withdrawal of OPV2.
2. In specific geographies, utilizing polio staffing and infrastructure to support routine immunization activities, including session planning and implementation, outreaches, supervision, training, use of data to redirect the programme when needed and ultimately raise population immunity levels in order to interrupt poliovirus.

6.20 In collaboration with immunization partners, the GPEI will invest in routine immunization strengthening to drive polio population immunity and provide a long-term, sustainable platform for vaccine delivery. At a local level, human resource capacity will be enhanced and dedicated to routine immunization activities as a percentage of polio staff time. This will apply to all countries with a polio staff presence (over 60 countries). Particular attention will be given to those GVAP activities which build on the training and experience of GPEI staff such as improving session and outreach planning and implementation, identifying and reaching unreached populations, strengthening monitoring and surveillance systems, strengthening infrastructure and logistics, building advocacy capacity, creating incentives and engaging individuals and communities.

6.21 In coordination with the respective national authorities, the partner organizations within the GPEI will work to support the development and implementation of national immunization plans. GPEI staff capabilities and experience will be specifically directed towards:

- **Management**, including the use of accountability frameworks, data management, training and vaccine supply management
- **Microplanning**, including population mapping, session planning, vaccine supply management, cold chain logistics
- **Mobilization**, including top level advocacy and household level outreach. Social mobilization activities will be focused on generating demand for routine immunization and addressing caregiver and provider concerns regarding the shift to bOPV and IPV.
- **Monitoring**, of mobilization efforts, vaccine delivery and other consumables, session execution and quality and overall impact

To drive this planning forward, GPEI has identified some key activities in each of those areas. These will be further consolidated in 2013, with clear targets established by the end of Q1, 2013, and a reporting mechanism established by mid-year 2013.

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 are being updated to incorporate key activities to support RI strengthening. These staff will monitor fixed and outreach sessions, monitor vaccine supply and vaccine availability, support health worker training, develop mechanisms to identify children not immunized through RI while visiting households during SIAs (especially newborns) and, finally, drive greater community engagement. Ultimately, by end-2014, >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. • Strengthened Internal Capacity – demonstrated by all UNICEF health staff and all WHO immunization country focal points who will have fulfilled learning requirements on immunization essentials as part of their annual performance reviews. • Performance Improvement – researched the use and limits of training materials and methodologies for RI workers • Core RI Competencies for District Managers – identified • Knowledge Hub - established by UNICEF and WHO and with buy-in from global actors and countries that performs the following functions in support of RI: 1) data and information aggregation; 2) agenda setting; 3) stakeholder coordination; and 4) coordination of technical assistance. |
| Microplanning | <ul style="list-style-type: none"> • New tools – developed and field-tested for improving our ability to verify immunization status and confirm coverage data – immune assays, biometric identifiers, and new coverage survey methodologies. The use of GIS and GPS tools to improve microplanning and monitoring for polio in Nigeria will be expanded for use in routine immunization programmes. • Supply systems (in particular cold chain) will require expansion to accommodate IPV vaccine volumes where they are currently constrained. Vaccine management data will be more regularly collected and tracked to identify supply issues (including stock outs, wastage) and direct corrective action. Finally, training will be rolled out where necessary to educate providers on proper handling, usage and disposal of vaccine and consumables. |
| Mobilization | <ul style="list-style-type: none"> • Community Engagement – identified how GPEI and government partners/community organizations/NGOs can best help district |

| | |
|------------|---|
| | <p>managers and front line health workers engage communities</p> <ul style="list-style-type: none"> • Surge Capacity – new, target-based focus on leveraging incremental resources for specific routine immunization activities |
| Monitoring | <ul style="list-style-type: none"> • Indicators – rationalized, standardized, adopted, and used by programme managers and donors, including GAVI, to improve immunization programme performance • Record Quality – 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 4 countries; established peer- learning network to diffuse technologies and practices in 8-10 additional countries • Stronger Focus on Data Quality – taken by WHO in certain areas of data quality and use, such as home-based records, survey methodologies, and assisting countries with information system transitions |

To support all of the above activities, by end-2014, >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.

Priority Countries

6.22 In conjunction with GAVI, WHO and UNICEF have identified a number of priority countries for support based on a low national level of immunization coverage (<70%). These countries include a number in which the GPEI has deployed significant staff presence: Afghanistan, Chad, DRC, Ethiopia, India, Nigeria, Pakistan, Somalia, and South Sudan. A joint programme of work will be developed with the aim of pursuing a revitalized and focused routine immunization strategy to increase coverage in Nigeria, Pakistan, Afghanistan, Chad, DRC, Angola, Sudan and India. The GPEI and all immunization partners should contribute to the development and implementation of this plan. The goal in these focus countries, in collaboration with immunization partners, is to contribute to at least a 10% improvement in coverage rates in the highest risk districts on a year-on-year basis, achieving 70-80% DPT3 coverage.

Polio Endemic Country Specifics – Plan B

6.23 Given the urgency of interrupting poliovirus transmission in the three remaining endemic countries it is worth highlighting activities to strengthen routine immunization in 2013 that have already been planned in Afghanistan, Nigeria and Pakistan. There is a rationale to this that extends beyond the criticality of strengthening routine immunization in order to introduce IPV and withdraw OPV as part of the polio endgame, which is that by strengthening routine immunization in the remaining endemic

countries, population immunity will be raised. Should it eventuate that poliovirus is not interrupted in any or all of the remaining endemic countries through vaccination campaigns then it will be essential to have boosted immunity through routine immunization in order to interrupt transmission, notwithstanding the additional health benefits brought by immunization.

Afghanistan

6.24 In conjunction with immunization partners the GPEI will help support national government efforts to intensify routine immunization efforts across the country. Quarterly EPI meetings will be conducted with NGOs to review performance progress, monthly meetings for priority areas including the Southern Region. Clearer linkages will be made between polio and routine immunization. AFP surveillance data and active polio surveillance visits will be used to help monitor routine immunization efforts. And polio staff and systems will be leveraged to communicate routine immunization services to local populations to generate awareness and demand.

Nigeria

6.25 There is an urgent need to strengthen routine immunization in Nigeria, and the polio programme has a role to play. The GPEI partners (both Polio and EPI) will work with other development partners, including USAID, DFID, JICA, the European Union, Bill & Melinda Gates Foundation, Clinton Health Access Initiative amongst others to support the federal government in the development of a national immunization and accountability framework. This will include active participation in the working groups of the Inter-Agency Coordinating Committee (ICC) to strengthen vaccine supply and management, monitoring and evaluation, training and social mobilization.

6.26 WHO, in particular, will continue to leverage its nationwide network of surveillance officers to generate evidence on vaccine availability, routine immunization programme implementation and disease surveillance. CDC will focus on strengthening the capacity of the national government for data management and analysis. During 2013, WHO, UNICEF and CDC will support 8 states to implement accelerated immunization outreach activities to address persistent transmission of cVDPVs.

6.27 Additionally, WHO and UNICEF will collaborate with Kano state, the Dangote Foundation and the Bill & Melinda Gates Foundation in a three-year effort to revitalize routine immunization from 2013. The focus will be on improved tracking of vaccine supplies, support for data management, training and monitoring of immunization sessions, and intensification of social mobilization activities to increase demands for immunization services.

Pakistan

6.28 In conjunction with immunization partners, the GPEI will work closely to expand routine immunization reach, including within Pashtun populations. Establishing fixed site immunization posts will be enabled through a series of actions, including: mapping of locations with poor routine immunization coverage suitable for fixed site delivery; planning for cold chain logistics to meet supply

needs; development of communication plans customized to high risk populations and to address misconceptions of the programme; and clearly defined responsibilities for polio staff supporting routine immunization services.

ACTIVITY 2: Development of IPV, bOPV and mOPV

6.29 The introduction of IPV into low and middle income countries will require a combination of volume purchasing of existing IPV products and the realization of low-cost IPV options that have been identified in clinical and pre-clinical studies and have the potential to achieve a market price of <US\$1.00/dose. Two approaches will be pursued to achieve the development of low-cost/dose IPV options in the near-term: licensing of intradermal (ID) fractional (1/5th) dose IPV and development of new, adjuvanted intramuscular (IM) IPV products.²²

6.30 As countries may have different preferences with respect to the ID versus the adjuvanted IM option, and there is insufficient evidence at this time to recommend one of these approaches over the other as a supplementary dose at the time of OPV2 cessation, both options are being pursued. At end-2012, both approaches faced substantial regulatory and/or development challenges which could potentially 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.

6.31 Recognizing that the development of these 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 by mid-2013 a strategy that would allow initial introduction in low and low-middle income countries using existing IPV products at substantially reduced prices, with a subsequent transition to more sustainable, low-cost products as they became available. By 2017 there should be feasible options for safely producing IPV in developing countries settings (e.g. Sabin-IPV) to ensure that all countries have the opportunity to produce IPV for their routine childhood immunization.²³

6.32 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. While a sufficient and secure international supply of this product will, by end-2013, be available for an eventual tOPV-bOPV switch globally, all countries relying on a national producer of trivalent OPV will need to switch to a producer that has developed and licensed a bivalent OPV. 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 will be available through the buffer stock strategy. After the tOPV-bOPV switch, monovalent OPV2 will be the vaccine of choice for responding to any cVDPV2 outbreak or a WPV2 release from a laboratory or

²² 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).

²³ SAGE meeting, 10-12 April 2012: http://www.who.int/immunization/sage/previous_april2012/en/index.html

production facility; the detection of an ambiguous vaccine-derived poliovirus (aVDPV) may trigger a pre-emptive IPV response in the immediate area.²⁴

6.33 Based on programmatic needs, a stockpile of over 500 million doses of mOPV2 as bulk, will be available by 2015 for this purpose. After the tOPV-bOPV switch, provision will be made 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.

6.34 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 regardless of serotype (i.e. the same strategy for type 2 viruses will apply to all viruses). A stockpile of 300 million doses of mOPV1 and 300 million doses of mOPV3 will be established by 2018 for this purpose. To reduce the risks associated with hoarding or stockpiling of tOPV following the tOPV-bOPV switch, in that period the vaccine of choice for a type 2 cVDPV would generally be mOPV2.

ACTIVITY 3: Affordable IPV Introduction

Introduction of at least one dose of IPV

6.35 To boost population immunity against polioviruses prior to or at the time of OPV2 cessation, and to maintain a polio-primed population thereafter, all countries are recommended to introduce at least 1 dose of IPV into their routine immunization programmes prior to or at the time of OPV2 cessation. 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.²⁵ Evidence also suggests it will accelerate wild poliovirus eradication by boosting immunity to wild poliovirus 1 and 3. For countries at particular risk of cVDPV emergence, this approach may need to be complemented with additional measures (e.g. pre-cessation tOPV campaigns to boost immunity; 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 at least one dose of IPV for at

²⁴ 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.

²⁵ Sutter RW, Kew OM, Cochi SL. 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.

least five years after bOPV cessation. As this will continue till at least 2024, this will need to be managed and funded through routine immunization programmes. IPV may also have a role to play in helping to interrupt transmission in endemic countries, when administered alongside OPV.

6.36 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, rotavirus or HPV vaccines will be beneficial to IPV introduction. Countries will need to perform proper planning and preparation using existing checklists for cold chain, logistics and vaccine management, health care worker training and supervision, waste management and injection safety and adverse events following immunization (AEFI) monitoring. The GPEI, in conjunction with GAVI and other immunization partners, will assist countries in preparation 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.

6.37 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 political opposition or anti-vaccine lobbies, and the operational approaches to including IPV in the schedule while OPV is still being offered. It will be important to provide a clear rationale for OPV and IPV administration to the media, medical institutions and religious, traditional and political leaders. However, 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 as an improvement and acceleration of the existing polio program, not a move to resolve any type of vaccine failure. Advocacy among technical experts for public support and endorsement of IPV and OPV will be critical in this area.

6.38 Given the geographic scope of the vaccine shift, social research will be undertaken in all priority countries, particularly in the high risk communities, in order to determine acceptability of IPV and, as necessary, develop tailored messages for specific audiences. The work will help the program prepare nuanced communication that can be delivered prior to the vaccine introduction (at least 6 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.

6.39 The polio programme in Pakistan is collaborating with the Aga Khan University to pilot the use of inactivated polio vaccine (IPV) with OPV in 2013 as an additional tool to rapidly build an immune response in children that have not been easily accessed through regular polio campaigns or routine immunization. Evidence from Indian studies suggests that two doses of IPV given to a child already exposed to OPV essentially closes the immunity gap against all three polio serotypes. Pakistan will investigate the operational feasibility of using IPV with OPV in campaigns in the select areas of Federally Administered Tribal Areas (FATA) and Balochistan where access and management issues have prevented the program from building immunity levels need to interrupt transmission. These efforts will

be combined with other health promotion activities and the mobilization of pediatricians to address other health concerns of families.

ACTIVITY 4: Withdrawal of OPV 2

6.40 There are several pre-requisites that need to be met in order to withdraw OPV2 and therefore switch from use of tOPV to bOPV. These are:

- **Validation of persistent cVDPV2 elimination and wild poliovirus type 2 eradication** (persistent cVDPV2 stopped / new cVDPV2 stopped within 6 months)
- **Stockpile of mOPV2 and response capacity** - to respond to possible post-switch cVDPV2 outbreaks
- **Surveillance and international notification of Sabin, Sabin-like, and cVDPV type 2 viruses**
- **Licensed bOPV available in all OPV-using countries**
- **Affordable IPV option(s) available for all OPV-using countries**
- **Containment phase II for cVDPV2 and wild poliovirus type 2 and phase I for Sabin type 2** [phase I: inventory & safe handling; phase II: regulatory framework, BSL3/polio, repository or destruction]; (implementation, verification, validation), meeting in mid-2013 (policy: timing and phasing), endorsement by WHA in 2014].

6.41 In addition to meeting the 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, withdrawing the tOPV field stocks, and safely destroying or containing residual vaccine virus.

6.42 There are four basic principles to the withdrawal of OPV2:

- There must be complete cessation of use of tOPV
- Cessation must be coordinated across all countries using tOPV
- All remaining stocks of tOPV at the time of cessation must be collected or destroyed
- The process must be documented

In practice this means that an agreed target date must be established internationally for the switch to bOPV and cessation of tOPV use, approximately 12 months in advance of cessation to enable vaccine manufacturers, suppliers, and national health authorities to make the necessary plans for the switch. National plans must include:

- Logistics plans detailing quantities of bOPV required for the replacement of tOPV, transport and storage requirements for the withdrawal of 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 this effectively to the communities they serve
- Training, logistics, and communications plans for the introduction of a dose of IPV into routine immunization schedules (see above).

Key elements for stopping tOPV use and withdrawing remaining stocks include:

- The last shipments of tOPV to national level should be at least 6 months, and within country at least 3 months, before the agreed target date for cessation
- National stocktakes of vaccine at all levels one month prior to cessation and one month after cessation
- Designation of secure collection points for tOPV, accepting 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.

6.43 Accompanying this logistical work will be communications strategies for caregivers and parents whose children will receive the new vaccine schedule, and training of the health workers who must implement it. IPV introduction has been successful in all countries that have made the switch, with little or no public outreach regarding the change. Research on the social acceptance of IPV from Western Uttar Pradesh and Bihar India suggests IPV would be accepted if communities were 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 has been eroded.

6.44 In general, it will be important to provide a clear rationale for OPV and IPV administration to caregivers and communicate the shift more broadly as an improvement and acceleration of the existing polio program, not a move to resolve any type of vaccine failure. From a communication dissemination point of view, social mobilizer networks, credible community and religious leaders, and mass promotion in print, radio, television and new media will be key.

ACTIVITY 5: Total OPV Cessation

6.45 Following global certification the total global cessation of OPV will be required. This activity is the final step in assuring the total eradication of all polioviruses (including vaccine-related) and management of associated risks. To complete the cessation of all OPV will requires the withdrawal of all remaining bOPV, full implementation of introduction of IPV into the routine immunization schedules of

all countries, an assured supply of affordable IPV, and adequate IPV coverage to maintain population immunity.

WHO OVERSEES THIS?

SAGE

The Strategic Advisory Group of Experts on Immunization

DRAFT

7. OBJECTIVE 3: CONTAINMENT AND CERTIFICATION

Overview

| Activities | Sub-Activities | Primary Targets |
|--|---|---|
| Containment (Management of facility-based poliovirus risks) | Update GAP III | Finalize international guidelines by end-2014 |
| | Finalize laboratory survey and inventory activities in all polio-free countries | Implement phase 2 activities by end-2015 |
| | Prepare for containment activities globally | Complete bio-containment by 2019 |
| | | Ensure safeguards in place for wild poliovirus type 2 by end-2015 |
| | | Ensure safeguards in place for wild poliovirus types 1 & 3 by end-2018 |
| Certification | Re-constitute Global Certification Commission (GCC) | Ensure global, regional certification mechanisms in place by end-2013 |
| | Focus on surveillance – specifically, cVDPV emergence in polio-free countries and closing of gaps in regions not yet polio-free | For regions not certified polio-free, close surveillance gaps by end-2014 |
| | | For polio-free regions, complete and sustain certification-standard performance by end-2015 |
| | | Complete across regions by end-2018 |

Note: Reflects primary Objective Targets – comprehensive monitoring framework with complete list of operational targets to be found in Annex B.

INTRODUCTION

7.1 Following interruption of WPV transmission, safe handling and containment of WPV infectious and potential infectious materials in laboratory and vaccine production facilities is crucial to minimize the risk of reintroducing the virus into the population. A reintroduction of WPV from a poliovirus facility would risk the potential serious consequences of reestablishing poliomyelitis. Although many countries will maintain high population coverage with IPV, other countries may have sub-optimal coverage or have discontinued national polio immunization activities.

7.2 A reintroduction of an OPV/Sabin strain from a poliovirus facility would risk unrecognized virus transmission, reversion to cVDPV, and again the potential serious consequences of reestablishing poliomyelitis. Most poliovirus facility-associated risks can be eliminated through destruction of WPV and OPV/Sabin infectious and potential infectious materials. However, poliovirus facilities will be necessary in a number of countries to continue essential international functions, including IPV production, OPV

stockpiles, vaccine quality assurance, diagnostic reagent production, virus reference functions, and crucial research. Minimizing the number of essential facilities worldwide reduces the magnitude of risk, facilitates national and international oversight, and ensures global containment standards can be met.

7.3 The primary requirements for certifying a WHO region as free of wild poliovirus are (a) the absence of any wild polioviruses for a minimum of 3 years in all countries of the Region, (b) the presence of certification-standard surveillance in all countries, and (c) the completion of Phase I bio-containment activities for all facility-based wild poliovirus stocks.²⁶ Certification at the Regional level is done by Regional Certification Commissions (RCC) which report in turn to the Global Certification Commission (GCC). If Nigeria, Pakistan and Afghanistan interrupt all wild poliovirus transmission by end-2014, as planned, 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 IS REQUIRED?

7.4 The global certification of wild poliovirus eradication – and verification of the elimination of type 2 vaccine-related viruses – will require ensuring highly sensitive poliovirus surveillance, and full application of relevant poliovirus biocontainment requirements, across the entire world. Chronic gaps in surveillance sensitivity will need to be addressed in recently infected countries as well as those 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 biocontainment requirements for the safe handling of residual polioviruses (e.g. for vaccine production, research, diagnostics); the necessary inventorying, destruction and containment activities will then need to be implemented and verified in all countries. As importantly, 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. This Plan summarizes the certification process and major criteria, and explains the approach that will be taken to achieve the necessary surveillance sensitivity globally and implement containment.

WHERE ARE WE CURRENTLY (SITUATION ANALYSIS)?

7.5 The first Global Action Plan (GAP) for containment of wild poliovirus was developed in 1999 with the recognition that containment of WPV needed to be addressed in advance of achievement 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 poliovirus in addition to WPV (GAP II). As this was happening, implementation of

²⁶ See footnote 10 for the definition of certification-standard surveillance.

national survey and inventory activities was completed in all countries of the Western Pacific, European and Americas regions (by 2008).

7.6 Renewed discussions on OPV cessation, as integral to the success of polio eradication, prompted the development of a third addition to 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 155 Member States have completed Phase I containment survey and inventories for wild poliovirus materials. In the 3 polio endemic WHO Regions, 40 Member States have completed Phase I containment activities. In total, 155 of 194 (80%) 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 6 facilities for producing Salk WPV 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.

WHAT WILL BE DONE?

MAJOR ACTIVITIES:

- 1. Containment**
- 2. Manage Polio-virus associated Risks**
- 3. Certification**

ACTIVITY 1: Containment

7.8 Key updates to GAP III are 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 the 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 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 2014.

7.9 The first stage of biocontainment 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 Phase II containment activities will 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.

ACTIVITY 2: Manage facility-based poliovirus risks

7.10 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 mid-2012, five countries have 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 biocontainment activities globally (i.e. inventory and destruction of viruses and infectious materials). These areas will require full application of the *primary, secondary and tertiary* biocontainment safeguards to minimize the risk of inadvertent or intentional wild poliovirus re-introduction. 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 3: Certification

7.11 For the GCC, the first step will be to reconstitute the GCC and in doing so optimize its membership to meet the evolving demands and timelines of the new 'polio endgame'. This will include bringing in membership with additional expertise in such areas as biosafety / bio-containment, surveillance and virology. The GCC suggests that the full Commission should be appointed by mid-2013. The secretariat should be in a position to support at least annual meetings (and potentially more frequent meetings) during the 2014 to 2018 period.. At its meeting in August 2012, the GCC indicated that it could in mid-to-late 2013 consider evidence that type 2 wild poliovirus has been eradicated, based on its absence for more than 10 years and regional surveillance sensitivity. The consideration of this evidence would be the first stage of a process to 'conclude' that type 2 wild poliovirus has been eradicated, a critical step in the process of OPV2 cessation. It is anticipated that a 4th WHO Region – Southeast Asia – could potentially be certified polio-free by mid-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.

7.12 For the three regions that are certified polio-free - the Americas, Europe and Western Pacific - the priority will be to achieve 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 tOPV-bOPV switch.²⁷ This will be achieved through heightened political commitment to the global goals of the endgame, through allocation of additional resources where needed – including for laboratory capacity - and through WHO Regional Offices support to countries in revitalizing AFP surveillance.

7.13 For the three regions not certified polio-free at end-2012, the priority will be to close remaining gaps in AFP surveillance sensitivity (particularly in northern Nigeria; West, Central and Horn of Africa; Pakistan; and, Afghanistan) by 2014 in advance of a global tOPV-bOPV switch and then to sustain certification-standard performance at the national and subnational level through regional and global certification. Particular attention will be given to ensuring documented active (at least monthly) AFP surveillance at all major reporting sites, expanding networks of community informants and, potentially, establishing rewards for polio-confirmed AFP cases.

WHO OVERSEES THIS?

GCC

The Global Commission for Certification of the eradication of poliomyelitis (GCC) oversees the process of certification.

²⁷ 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

Overview

| Activities | Sub-Activities | Primary Targets |
|---|--|---|
| Manage the transition of assets and infrastructure | Sustain and increase efforts to mainstream polio functions into long term infrastructure | Finalize inventory agreement by Q2 2013 |
| | Map programme assets | Complete broad stakeholder consultations by Q1 2014 |
| | Conduct broad consultations | Initiate successful transition by 2014-15 |
| | Secure global consensus on legacy elements | Secure WHA ratification & budget to ensure global consensus in May 2014 |

Note: Reflects primary Objective Targets – comprehensive monitoring framework with complete list of operational targets to be found in Annex B.

INTRODUCTION/EXPLANATION OF OBJECTIVE

8.1 Achieving the first three objectives of the Polio Eradication and Endgame Strategic plan will lead to eventual closure of the Global Polio Eradication Initiative. As the initiative begins to enter its final stages the global health community, as well as the GPEI, should plan for a future beyond polio eradication. This is to ensure not only a world safe from polio but also that investments made in the cause of polio eradication are built on to benefit other development goals and that investments made do not go to waste.

WHAT IS REQUIRED?

8.2 There are two principal requirements of the Polio ‘legacy’ work:

- First, to mainstream the long-term polio immunization, surveillance, communication, response and containment functions in order to protect a polio-free world.
- Second, to ensure the knowledge, capacities, processes and assets that the programme has created are utilized for other health priorities.

8.3 During more than 20 years of operations the GPEI has mobilized and trained millions of volunteers, social mobilizers, and health workers; reached into households untouched by other initiatives; mapped and brought health interventions to communities previously unreached; and, established a standardized, real-time global surveillance and response capacity. All these activities have been done

for the cause of polio eradication. However, in doing so the GPEI has also been able to benefit other health work, principally through its surveillance and response capability for other VPDs and the delivery of basic health services by its vaccination teams. After more than 20 years of implementation, one major achievement stands out. The GPEI has reached and learned lessons in accessing the chronically unreached, marginalized and most vulnerable populations in the world. This in turn has led to two major dividends – the delivery of health services, and a global surveillance and response capacity for both health and humanitarian emergencies.

Accessing the most vulnerable

8.4 The polio programme has been able to develop sustained access to the most marginalized children and communities, reaching the most inaccessible 20 percent of all children. The polio programme has developed the knowledge, capacities and systems to overcome the logistic, geographic, social, political, cultural, ethnic, gender, financial and other barriers/bottlenecks to working with the most marginalised, deprived and security compromised children and vulnerable populations in the world. Elements that allowed the GPEI to do this include social mobilization programmes, the training and deployment of vaccination teams, micro-planning, and mapping that more recently has made use of innovations such as GPS/GIS. This has enabled the polio workforce to provide other basic health services including anti-helminthics, vitamin A supplements, measles mortality reduction activities, delivery of bed-nets amongst other basic health services.

Integrated Disease Surveillance and Response (IDSR)

8.5 Polio eradication efforts have led to the creation of a global surveillance and response capability for VPDs. Through the creation of 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 humanitarian emergencies such as SARS and the South-East Asian Tsunami of 2004.

Contribution to other Health Work

8.6 The sustained sharing of assets and learnings with other global health initiatives is an essential element of the polio legacy. This would include strengthening routine immunization (including modifying polio tools and innovations to benefit immunization), best practice 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 through the Endgame. Closer linkages between measles and rubella programme activities and the GPEI has well recognized benefits for both programmes. SAGE, the IMB and donors have all recommended countries and global immunization partners assess the potential synergies and take active steps, where

appropriate, to transition the polio infrastructure and lessons learnt to support achievement of measles and rubella elimination targets and strengthening of routine immunization programmes. Through the process outlined below, planning will take place for transfer of assets and best practice to the broader global health community.

WHAT NEEDS TO BE DONE?

MAJOR ACTIVITIES:

- 1. Mainstream long-term Polio functions**
- 2. Manage the Transition of Polio Assets and Infrastructure**

ACTIVITY 1: Mainstream long-term Polio functions

8.7 Organizations involved in polio eradication will need to plan to integrate activities undertaken for polio eradication into separate and ongoing functional structures and transition staff, as needed. This mainstreaming of technical operations under polio will be an essential part of the legacy of polio. This mainstreaming covers a number of categories.

- Ensure continued integration of polio immunization and communication activities into national and international routine immunization programmes.
- Fully integrate polio surveillance and response activities into national and global mechanisms under the International Health Regulations (IHR 2005).
- For countries intending to maintain poliovirus stocks, ensure appropriate containment of polioviruses according to agreed international and national standards, regulations and protocols.

ACTIVITY 2: Manage the Transition of Polio Assets and Infrastructure

8.8 The first step in the process is to map the polio assets. This exercise will take place in the first half of 2013. This is intended to outline what has been created through polio eradication - both tangible and intangible assets - establish what activities and contributions polio-funded staff are making beyond the polio programme, and to look at what capacities could be at risk with the intended eventual closure of the polio eradication programme. This exercise will examine the following four indicative areas: policy and strategy; partners and donors; operations and tactics; and, oversight and monitoring, and will be undertaken by the GPEI spearheading partners in consultation with national governments and other key stakeholders (see Item 4 in Annex A for more details).

8.9 The second major element of planning for the post-polio era is the consultative process. The purpose of this 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, 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 meant to be a prescriptive exercise but is instead intended to stimulate discussion around the potential benefits of these assets to other programmes and initiatives. A priority in this process will be to get input from 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 2013. This consultative stage will examine whether polio assets and learnings are able to contribute to strengthening of health systems, benefits to immunization and fighting other vaccine-preventable diseases.

8.10 The third element of the consultative process will be to examine funding issues and potential sources of funding for the assets of the GPEI that could be used more widely than polio. This includes the WHO governing bodies process as the high level forum for making decisions on priorities, though this does not preclude other decision-making, agreements and related activities at any stage during the process. The consultative process on wider use of polio assets will address the issue of how to manage tangible assets and any transfer of staffing to other programmes and funding to continue assets with wider applicability to other vaccine-preventable diseases. The staff that were recruited as part of the ‘Surge’ capacity to support efforts to interrupt wild poliovirus transmission in the remaining endemic countries are not included within this planning process.

Table 5. Legacy Planning Process

| ACTIVITY | PURPOSE | TIMEFRAME |
|----------------------------------|--|---------------------|
| Map Assets | To have a full picture of the polio infrastructure | January– April 2013 |
| Stakeholder Consultations | To understand risks/benefits of the polio infrastructure | Throughout 2013 |
| WHO Regional Committees | WHO Member State input | Q3-Q4 2013 |
| WHO Executive Board | Review proposals | January 2014 |
| World Health Assembly | Decisions on Legacy | May 2014 |

WHO OVERSEES THIS?

WHA

For relevant elements, the Legacy planning work will be overseen by the WHA.

DRAFT

9. ENABLING FUNCTIONS

9.1 Successful execution of this comprehensive, long-term 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, with relevant partner support, the GPEI and its partners will lead on a set of enabling functions that will facilitate successful execution of country operations. These functions include:

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

RESEARCH AND POLICY DEVELOPMENT

9.2 An intensified research agenda has underpinned many of the approaches outlined in the 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.

9.3 To facilitate the eventual switch from tOPV to bOPV in routine immunization programmes (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 of such a 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 IPV options (i.e. new intradermal, fractional dose and adjuvanted IPV formulations, and Sabin IPV formulations).

9.4 Ongoing and new research projects are evaluating innovative ways to improve operations, particularly to help address persistent SIA coverage gaps 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 to improved operations. Examples of this include: assessing technologies such as GIS to more adequately identify missed areas or population groups during SIAs; evaluating community perceptions to target 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.

STRATEGIC PLANNING AND PRIORITY SETTING

9.5 The GPEI Spearheading partners (WHO, Rotary International, CDC, and UNICEF) and the Bill and 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 overall strategic plans for the GPEI and accompanying budgets. Global strategic plans are developed in conjunction with the broader partner and donor community, as well as national governments, to ensure that national and stakeholder priorities are reflected in the finalization of plans. Once finalized, the spearheading partners and BMGF work to ensure that all components of the strategic plans are well-implemented. This includes oversight of technical support for strategy implementation and a key role in monitoring and evaluating all aspects.

9.6 Technical assistance is deployed to fill capacity gaps when relevant skills are not available 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. This technical assistance also supports the surveillance network, which provides reporting on AFP incidence from every district in the world on a weekly basis.

9.7 The GPEI has historically been required at times to change plans and cancel immunization campaigns due to lack of funding and unpredictable funding. In the event sufficient funds are not available to fully support the GPEI budget in a given year, available resources are allocated according to the following priority order:

| | |
|------------|--|
| 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) |
| Priority 5 | SIAs: High-Risk/Other Countries |

RESOURCE MOBILIZATION AND ADVOCACY

ACTIVITY: Resource Mobilization

9.8 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 help to ensure that lack of funding is not a barrier to implementation of the 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 mechanisms be identified and exploited.

9.9 Sustainable financing will require renewed commitments from governments and development partners as well as additional countries joining as development partners. The participation of civil society organizations is critical as is the importance of individual and private sector giving, such as Rotary International. Significant financial support comes from endemic countries and national governments should continue to play a lead role in the identification and quantification of resource needs, identifying sources of self-financing, coordinating with immunization partners and tracking the effective and efficient use of these resources. A key element is ensuring ongoing buy-in from partners, countries, donors, influencers and the engaged public, so each player remains supportive of GPEI and committed to the long-term strategy.

ACTIVITY: Advocacy

9.10 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 four areas: 1) 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 allocate domestic financing; 2) 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 the activities and to take immediate and appropriate actions to address local challenges; 3) Obtaining sustained support from the global community through 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, the Gulf Cooperation Council to encourage polio-affected and high-risk countries to effectively implement their national plans, and to provide confidence to communities to allay their concerns; 4) Securing the support of key stakeholders 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. The relative strengths of the GPEI partners, including the Bill & Melinda Gates Foundation and key stakeholders in the Polio Partners Group, will be fully exploited to support the development and implementation of the above mentioned advocacy efforts.

9.11 To address specific concerns expressed in Islamic countries and leverage the historically strong role played by Islamic leaders in global eradication, a new approach is being developed to establish an Islamic Advisory Council on polio eradication that would include key leaders from the OIC, the GCC, the Islamic Development Bank, senior Islamic religious scholars and GPEI partner agencies and stakeholders. The Regional Director of WHO EMRO will play a leadership role in the development of this Council. Significant advocacy will also be necessary to engage around 130 WHO member states to ensure a

coordinated switch from tOPV to bOPV in their routine immunization programmes, and also to effectively implement the post-eradication elements of the strategic plan. An advocacy plan will also need to be developed to support the polio legacy planning process at national, regional and global level discussions to ensure outcomes that are supported by the WHA.

VACCINE SECURITY AND SUPPLY

ACTIVITY: Ensure a Reliable Supply of OPV

9.12 A key programme priority will be to ensure availability of sufficient global supply of OPV (bOPV and tOPV) to meet the global requirements for both SIAs and routine needs of countries. In addition, an important element to the programme is the ability to respond to changing demand requirements due to epidemiological shifts in the virus, outbreaks in any one type, increased target populations, while also being able to meet global routine demand requirements. UNICEF, the main procurement partner on behalf of the programme, has in place long-term arrangements with multiple suppliers 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 demand requirements.

10. ROLES AND RESPONSIBILITIES

NATIONAL AUTHORITIES

10.1 National governments are both the owners and beneficiaries of the GPEI. Polio-affected countries undertake the full range of activities detailed in their country plans and summarized in this GPEI Strategic Plan. Achievement of country milestones requires polio-affected countries to ensure accountability at national, subnational and district level, and with other GPEI partners, to plan, implement and monitor the activities to reach every child with polio vaccine. At the same time, national governments in the three WHO regions already certified as polio-free, and polio-free member states in the three remaining endemic Regions, have a critical role to play in maintaining high population immunity and sensitive surveillance for AFP and to fully implement internationally-agreed processes to manage the long-term risks after WPV eradication. National authorities are also responsible for fully implementing internationally-agreed processes to manage the long-term risks following WPV eradication. This includes applying required biocontainment requirements and mainstreaming polio functions as part of the Legacy work.

GPEI PARTNERS

10.2 The GPEI Spearheading Partners and the Bill and Melinda Gates Foundation take primary responsibility for management of activities described under the Enabling Functions section (Section 9). This includes responsibility for providing technical support to countries in the implementation of their polio eradication efforts. This includes the 'Surge' of staffing, as detailed above. As part of the Polio Endgame, WHO and UNICEF will take responsibility for mainstreaming technical functions within existing and/or new or revised structures. The GPEI will manage the consultative aspect of the Legacy process.

11. FINANCIAL RESOURCES 2013-2018

PROJECTED FINANCIAL REQUIREMENTS

11.1 The cost of the eradication and endgame period (2013-2018) is projected to be approximately US\$ 5.5 billion. This figure does not include Government of India funding of its own program, at approximately US\$ 1.23 billion, nor does it include national and in-kind contributions. This projection reflects substantial work under various scenarios in consultation with the relevant global, regional and country stakeholders. The proportion across key budget categories will be adjusted as progress against key milestones is evaluated. An adjusted year of interruption of transmission would increase/decrease costs accordingly.

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 tOPV to bOPV switch and allow for additional coverage as needed between 2014 and 2015, then declining post-interruption;
- IPV used in routine immunization at 1 dose/year starting at 50% uptake in 2014; then 100% from 2015-2018
- Surge capacity in endemic and high-risk countries to interrupt transmission
- Maintaining technical assistance staff at 2013 levels through 2018
- Maintaining Global Lab costs at 2013 levels
- Maintaining research and product development at \$10M/year
- Maintaining environmental surveillance at \$5M/year
- Ongoing quality improvement, surge capacity, endgame risk management, OPV cessation, additional innovations and program adjustments costs of US\$ 416.6M between 2013 and 2018
- Outbreak response of US\$ 66M in 2013 and then held constant at US\$ 75M through 2018
- Social Mobilization is held constant at 2013 levels through 2018 (\$66M annually)
- Stockpile Projections for 2014 (\$24.6m) based upon existing contract

The key budget drivers are:

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

11.2 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 throughout the period. 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. 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 information will be reviewed and updated every 4 months. Though the costs have not been modeled beyond 2018, some modest funding will be needed past the point of certification in 2018 – including for limited OPV campaigns and technical assistance continuing into 2020. Additionally, the GPEI expects certain costs, such as certification and containment, AFP surveillance, environmental surveillance, and lab costs, to continue for 5-7 years post certification.

DRAFT

GPEI – POLIO ERADICATION AND ENDGAME STRATEGIC PLAN
WORKING DRAFT OF 23 JANUARY 2013

Table 6: Budget breakdown by Category and Year

| | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | Total 2013 - 2018 |
|---|-------------------------|-------------------------|-------------------------|-------------------------|-----------------------|-----------------------|-------------------------|
| Planned OPV Campaigns | \$ 406,843,333 | \$ 406,843,333 | \$ 301,647,134 | \$ 268,739,428 | \$ 203,399,246 | \$ 203,399,246 | \$ 1,790,871,721 |
| Complementary OPV Campaigns | \$ 38,704,340 | \$ 58,736,913 | \$ 69,040,917 | \$ 39,312,472 | \$ 9,389,839 | \$ - | \$ 215,184,481 |
| IPV in Routine Immunization | \$ - | \$ 31,698,026 | \$ 63,396,052 | \$ 63,396,052 | \$ 57,810,210 | \$ 57,810,210 | \$ 274,110,550 |
| HIGH POPULATION IMMUNITY | \$ 445,547,673 | \$ 497,278,272 | \$ 434,084,103 | \$ 371,447,952 | \$ 270,599,295 | \$ 261,209,456 | \$ 2,280,166,751 |
| Surveillance and Laboratory | \$ 74,796,243 | \$ 74,796,243 | \$ 74,796,243 | \$ 74,796,243 | \$ 74,796,243 | \$ 74,796,243 | \$ 448,777,457 |
| Environmental Surveillance | \$ - | \$ 5,000,000 | \$ 5,000,000 | \$ 5,000,000 | \$ 5,000,000 | \$ 5,000,000 | \$ 25,000,000 |
| Emergency Response | \$ 66,000,000 | \$ 75,000,000 | \$ 75,000,000 | \$ 75,000,000 | \$ 75,000,000 | \$ 75,000,000 | \$ 441,000,000 |
| Stockpiles for Emergency Response | \$ - | \$ 12,300,000 | \$ - | \$ 12,300,000 | \$ - | \$ - | \$ 24,600,000 |
| SURVEILLANCE AND RESPONSE CAPACITY | \$ 140,796,243 | \$ 167,096,243 | \$ 154,796,243 | \$ 167,096,243 | \$ 154,796,243 | \$ 154,796,243 | \$ 939,377,457 |
| Surveillance and Lab enhancement for certification | \$ - | \$ 3,739,812 | \$ 3,739,812 | \$ 3,739,812 | \$ 3,739,812 | \$ 3,739,812 | \$ 18,699,061 |
| Containment and Certification | \$ 5,000,000 | \$ 10,000,000 | \$ 10,000,000 | \$ 10,000,000 | \$ 10,000,000 | \$ 10,000,000 | \$ 55,000,000 |
| POLOVIRUS CONTAINMENT | \$ 5,000,000 | \$ 13,739,812 | \$ 13,739,812 | \$ 13,739,812 | \$ 13,739,812 | \$ 13,739,812 | \$ 73,699,061 |
| Ongoing quality improvement, surge capacity, endgame risk mgmt, OPV cessation, add'l innovations & progr. adjustments | \$ 83,229,305 | \$ 83,597,000 | \$ 99,813,695 | \$ 83,320,000 | \$ 33,320,000 | \$ 33,320,000 | \$ 416,600,000 |
| Technical Assistance | \$ 161,740,917 | \$ 161,740,917 | \$ 169,965,782 | \$ 164,878,895 | \$ 185,417,426 | \$ 186,091,285 | \$ 1,029,835,222 |
| Community Engagement and Social Mobilization | \$ 65,837,022 | \$ 65,837,022 | \$ 65,837,022 | \$ 65,837,022 | \$ 65,837,022 | \$ 65,837,022 | \$ 395,022,131 |
| Research and Product Development | \$ 10,000,000 | \$ 10,000,000 | \$ 10,000,000 | \$ 10,000,000 | \$ 10,000,000 | \$ 10,000,000 | \$ 60,000,000 |
| CORE FUNCTIONS AND INFRASTRUCTURE | \$ 320,807,244 | \$ 321,174,939 | \$ 345,616,499 | \$ 324,035,917 | \$ 294,574,448 | \$ 295,248,307 | \$ 1,901,457,353 |
| Subtotal Direct Costs | \$ 912,151,160 | \$ 999,289,266 | \$ 948,236,656 | \$ 876,319,924 | \$ 733,709,798 | \$ 724,993,818 | \$ 5,194,700,621 |
| Indirect costs | \$ 60,402,650 | \$ 66,172,935 | \$ 62,792,231 | \$ 58,029,905 | \$ 48,586,263 | \$ 48,009,091 | \$ 343,993,075 |
| ANNUAL TOTAL excl. GOI | \$ 972,553,809 | \$ 1,065,462,201 | \$ 1,011,028,888 | \$ 934,349,829 | \$ 782,296,060 | \$ 773,002,908 | \$ 5,538,693,697 |
| India (GOI) Planned OPV Campaigns | \$ 206,999,372 | \$ 206,999,372 | \$ 174,358,881 | \$ 180,336,900 | \$ 192,292,938 | \$ 192,292,938 | \$ 1,153,280,401 |
| India (GOI) IPV in RI | \$ - | \$ 8,347,552 | \$ 16,695,105 | \$ 16,695,105 | \$ 16,695,105 | \$ 16,695,105 | \$ 75,127,970 |
| ANNUAL TOTAL w/GOI | \$ 1,179,553,181 | \$ 1,280,809,125 | \$ 1,202,082,874 | \$ 1,131,381,834 | \$ 991,284,103 | \$ 981,990,951 | \$ 6,767,102,068 |

FINANCIAL MANAGEMENT AND EFFECTIVENESS (VALUE FOR MONEY)

11.3 The GPEI has continually evaluated costs throughout implementation and sought opportunities to ensure good stewardship of available resources. Currently, the GPEI partners are considering other ways to optimize costs and ensure maximum value for money through a project to evaluate the key drivers of costs and performance across the global GPEI program (GPEI Value for Money project) and identify areas where the GPEI can use funds most effectively. The Value for Money exercise is designed to help identify how the program can shift resources from lower impact to higher impact and higher value activities to benefit eradication efforts as a whole. In addition to cost shifting opportunities, the VfM exercise has identified areas where the GPEI could improve risk mitigation measures, improve forward planning, develop cost-sharing opportunities with other initiatives, and expand the use of best practices to achieve greater VfM.

11.4 The findings so far fall into several categories. First, a set of near-term priority actions that could shift funding from lower to higher impact and higher value activities over the next 12 months. The near term priorities include more effective training and tighter management of vaccine use. The medium term priorities are related to the scale of operations and could be implemented in 1-2 years. The long term priorities hinge on further planning and discussions with GPEI and its partners. Secondly, areas where there is already good Value for Money and the program could 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.

12. RISKS, MITIGATIONS 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 (Sections 5-8). Nevertheless, exogenous factors and risks associated with the strategic choices made within the plan may delay or degrade the GPEI's ability to achieve these objectives. Recognizing risks, identifying mitigation options and articulating contingency plans enhance the GPEI's ability to rapidly react to roadblocks.

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

INPUTS

1. Insufficient funding
2. Inability to recruit and retain the right people
3. Vaccine supply

IMPLEMENTATION

4. Operating in areas of insecurity
5. Political and social will
6. Accountability

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.²⁸ 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.

Mitigation options: 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 non-traditional donors and sources will be explored.

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.

²⁸ See section on Financial Resources 2013-2018

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.

Mitigation options: 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.

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 may 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-licensing of two tOPV manufacturers contributed to an overall tOPV global shortage.

Mitigation options: For the tOPV-bOPV switch, the GPEI will bring in new suppliers (and re-qualify previous suppliers) and maintain production (avoiding shutdowns) to ensure sufficient supply. Finally, to incentivize production, the programme will offer longer term production contracts through 2016 to incentivize reliable supply.

For the introduction of IPV, the GPEI will seek to fast track adjuvanted IPV development With clinical trials currently underway. The GPEI will also work closely with regulatory authorities – utilizing tactics from sequential to parallel licensing – to ensure rapid approval. Similar to bOPV 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: As was forcibly demonstrated by the assassinations of health workers in Pakistan in December 2012, security and access issues remain a significant, on-going risk to polio eradication efforts. Dynamic political situations in polio-affected regions have required the programme to manage complex security issues. Conflict in Northern Nigeria has escalated, though the situation appears to be improving as the government has experienced success in dealing with militants, resulting in fewer and less damaging attacks. The Taliban's vaccination ban in North and South Waziristan and the eventual withdrawal of coalition forces from Afghanistan have created uncertainty around eradication efforts. Pending elections in Afghanistan and Pakistan, and the potential for rising tensions, may complicate already difficult situations.

Mitigation options: Across the three endemic countries, the GPEI has established two near-term action items to improve vaccine delivery. The first is a security access operations plan with a 'Stay and Deliver' plan for each reservoir. Secondly, the programme will deepen its engagement and support from the Organization of Islamic Cooperation (OIC), the Islamic Development Bank and other Islamic institutions in terms of financial, technical and communication assistance both to improve the overall strategic approach, and to inspire greater confidence in Muslim communities and constituencies in the remaining polio-endemic countries. 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. Partnership models that allow for acceptance of efforts from all necessary stakeholders are under consideration. The programme will also seek to maximize use of local versus international staff as experience with indigenous staff suggests that they generally have greater freedom to operate and a better understanding of local complexities, though this needs to be complemented by structures and practices that promote transparency and accountability. These staff should have expertise in conflict, political mapping and associate skills. Communication strategies will be tailored to the local context. Social mobilization led by UNICEF will directly support this area. Finally, the GPEI will explore 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).

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 must 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.

Contingencies: A series of contingencies may be utilized in regions where insecurity cannot be managed and access is restricted despite best efforts of national governments and the international community. Eradication efforts would rely heavily on vaccination points in and out of conflict 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. If all else fails, it may be necessary to have a cooling off or waiting period before resuming access negotiations.

WAVERING POLITICAL AND SOCIAL 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).

Mitigation options: 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 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

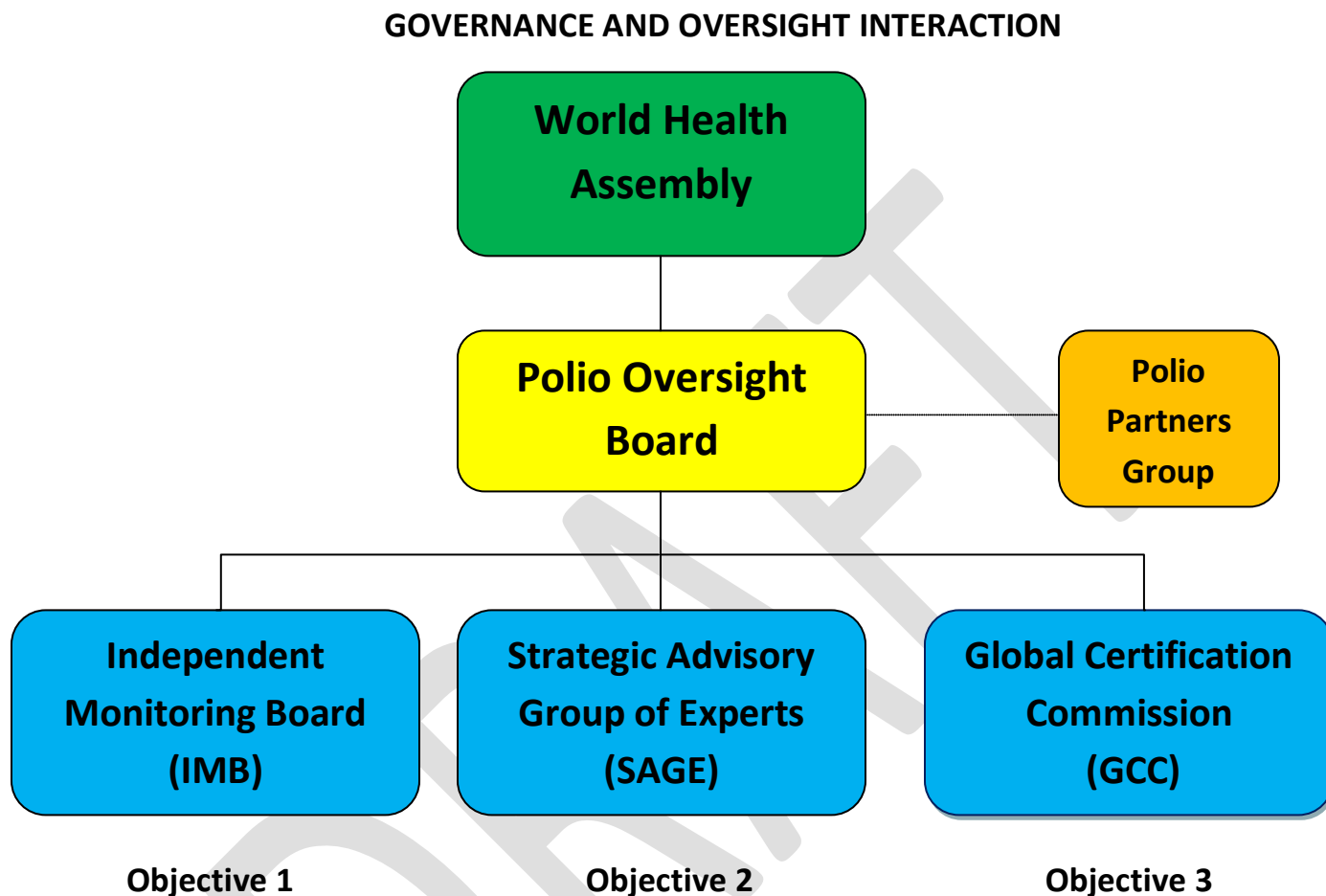
Risk: Accountability against established programmatic targets and outcomes – at all levels (global, national, regional, district, organization, individual levels) – is critical to reaching key eradication milestones. While detailed plans on reaching these targets and outcomes exist at national levels, 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.

Mitigation options: This strategic plan details critical targets and indicators by Objective, with specific ownership assigned against each. This should promote greater transparency 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 UNGA and consistently keeping polio on the WHA agenda; stressing global level accountability and discussing international health regulations for non-compliance. The IMB will also 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.

13. GOVERNANCE AND OVERSIGHT

Figure 25. GPEI governance model – Key Relationships



World Health Assembly (WHA). The WHA issues the resolutions that determine the scope and direction for the GPEI. The WHA is attended by all WHO Member States. The Regional Committees of WHO allow for more detailed discussion by regional member states and provide input to the WHO Executive Board which provides the WHA with specific agenda items, including polio resolutions.

The Polio Oversight Board, comprised of the heads of agencies of WHO, Rotary International, CDC, UNICEF and the Bill & Melinda Gates Foundation, meets quarterly to provide operational oversight and ensure high-level accountability across the GPEI partnership. Reports of the Polio Oversight Board are made public on the GPEI website.²⁹

²⁹ <http://www.polioeradication.org/>

The Global Polio Partners Group (PPG) is a multi-stakeholder body with senior representatives of the Polio Emergency Steering Committee agencies (WHO, Rotary International, CDC, UNICEF and the Bill & Melinda Gates Foundation), donors/prospective donors, polio-affected countries and key non-governmental organizations/foundations working in polio eradication. The group provides input and guidance on strategy and implementation, ensures stakeholder voices are heard by the GPEI at the level of the Polio Oversight Board and undertakes both advocacy and diplomatic activities to mobilize resources for the polio programme. It is expected that the PPG will continue its role throughout the Eradication and Endgame period.

The Independent Monitoring Board (IMB) provides oversight of polio eradication activities. The IMB meets on a four to six-monthly basis to independently evaluate progress towards the GPEI's objectives on the basis of polio epidemiology, poliovirus virology, standard performance indicators and other programme data. Additionally, the IMB provides assessments of the risks posed by existing funding gaps. The IMB is comprised of global experts from a variety of fields relevant to the work of the GPEI, and was established at the request of the Executive Board (EB) and the WHA. 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.³⁰

The Global Commission for Certification of the eradication of poliomyelitis (GCC) oversees the process for certifying the world as polio-free. Regional Certification Commissions (RCC) will provide the GCC with essential documentation to certify their Regions as polio-free once wild poliovirus transmission appears to have been interrupted in a Region (i.e. 12 months after the last circulating wild poliovirus is detected). National certification committees report to their respective RCC.

The Strategic Advisory Group of Experts on immunization (SAGE) provides crucial technical guidance on immunization, ensuring a sound basis for policy decision making. SAGE is supported in its work on polio by the SAGE Polio Working Group and the Polio Research Committee. Regional and national Technical Advisory Groups (TAGs) comprise experts in related fields of polio eradication, and regularly convene to review a region or country's polio epidemiology and put forward appropriate strategies to more rapidly achieve eradication. In the African Region the Task Force on Immunization (TFI) provides independent technical guidance in identifying cost-effective strategies aimed at ensuring the delivery of quality immunization services in the Region.

³⁰ Reports of the IMB are available at:
<http://www.polioeradication.org/Aboutus/Governance/IndependentMonitoringBoard/Reports.aspx>

14. MONITORING

MONITORING FRAMEWORK (under development)

The GPEI has developed a Monitoring Framework to assess progress, inform course-correction and to hold the GPEI accountable to its eradication targets. This framework outlines at a high level the outcomes needed to reach the four objectives of the plan, but also outlines each of the major activities, their targets and how they will be measured. Please see Annex B for the full framework.

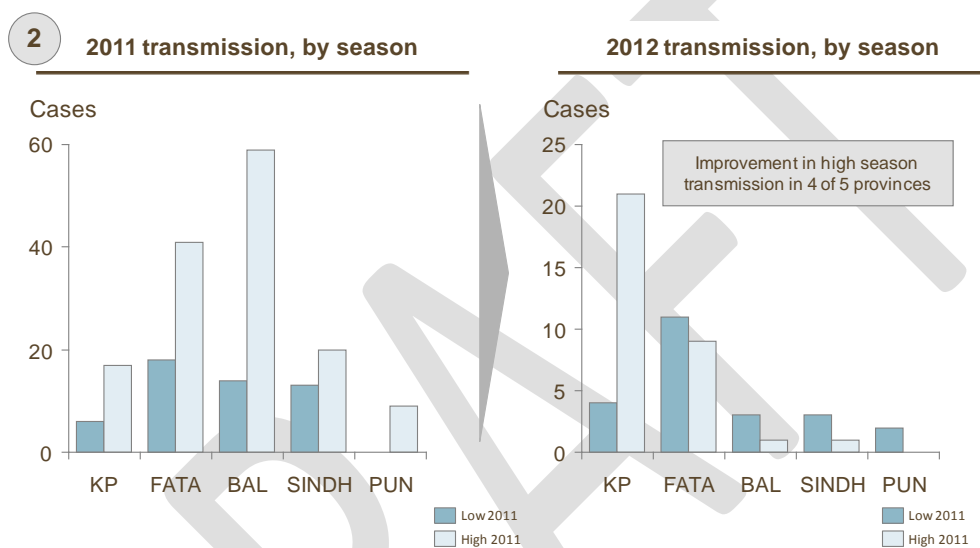
DRAFT

ANNEX A - ADDITIONAL SUPPORTING MATERIAL

Item 1: Supplementary evidence of progress

Across the three remaining endemic countries, the two most important quantitative measures of success have never been more favorable – (1) Case rates and (2) SIA coverage. In addition to previously discussed evidence, there is significant data to show additional progress across the three endemic countries

Declining aggregate case rates in Pakistan have also meant a decline in high season transmission.³¹

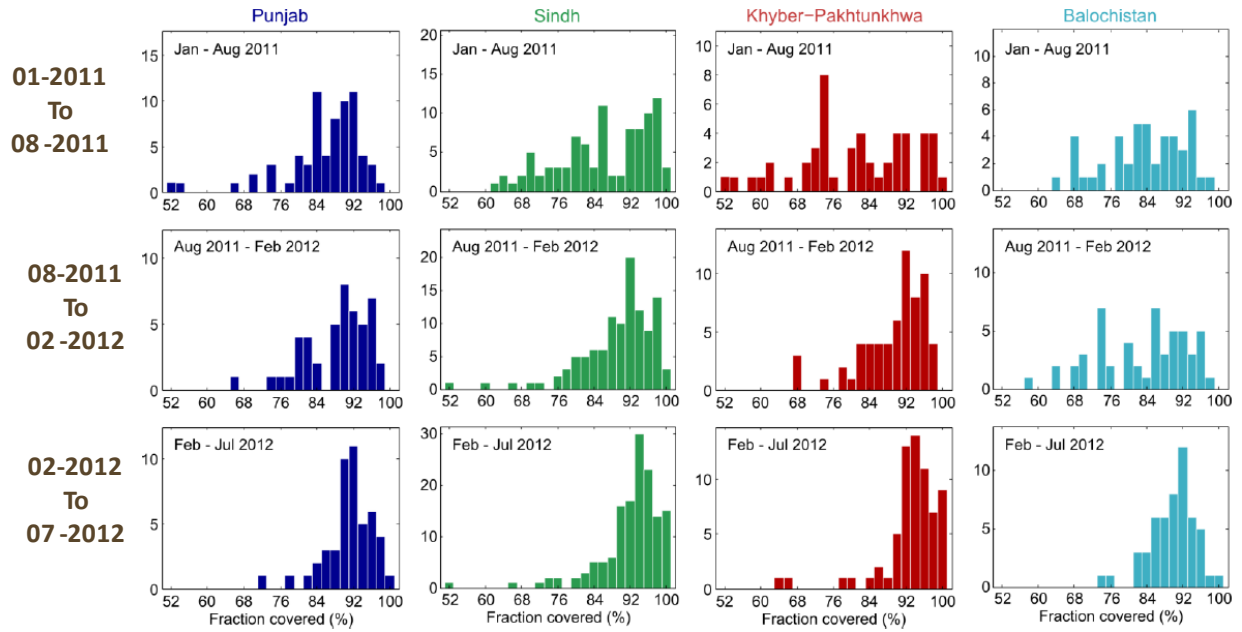


Improvement in LQAS-coverage rates is validated by the same positive trajectory at the sub-national level. Across four key regions in Pakistan, this improvement trend is demonstrated across three periods – ranging from January 2011 to July 2012³²:

³¹ WHO NEAP Pakistan presentation, December 2012.

³² CDC PPG Presentation, December 2012

GPEI – POLIO ERADICATION AND ENDGAME STRATEGIC PLAN
WORKING DRAFT OF 23 JANUARY 2013



DRAFT

ITEM 2: New Diagnostics

Laboratory testing requirements have the potential to evolve significantly with the phase-out of all routine OPV use. The increased use of environmental surveillance, together with the tOPV-bOPV switch, presents an opportunity to introduce new diagnostic techniques and algorithms into the Global Polio Laboratory Network (GPLN). New diagnostic techniques for environmental surveillance will focus on two areas: a) improved methods for field concentration of sewage specimens to allow sampling in more remote locations while reducing the logistic challenges of specimen transport to the laboratory; and b) simpler and more rapid detection of poliovirus in sewage concentrates through improved extraction and purification procedures to make specimens testable directly by molecular methods. Proof of concept studies are expected to develop two approaches before the end of 2013, with pilot testing and field evaluation to take place through 2014. Either or both approaches can be introduced into new locations or replace current procedures in existing locations to provide more and quicker environmental surveillance data in more locations.

Additional laboratory method changes will be implemented at the time of the tOPV-bOPV switch and again at the time of complete OPV cessation. The current challenges of finding wild polioviruses and cVDPVs amongst a background of OPV will be removed and alternative assays could be developed with a focus on more rapid detection and characterization of polioviruses, including possible direct detection without cell culture. The core technology to achieve this is expected to be worked out by 2014 and can be applied to all specimen types. These changes may also allow for increased flexibility in where assays are performed and increase options for supporting polio surveillance long-term. A rapid immunity assessment tool, under development, will help more easily and accurately measure population immunity. The assays would be based on existing platforms that are already available for other antibody testing, but will focus on two seroprevalence questions: a) measure polio antibodies directly from small volumes of sera without the need of a laboratory; and b) measuring polio antibodies from alternative specimen types such as oral fluids or dried blood spots. Since the technology already exists, the only key activity will be validation of the assay against gold standard neutralization tests and adaptation of the assays to the known platforms. The validation, including collection of seronegative sera, will be completed in 2013, while the platform evaluations will begin in 2013 and field evaluation could occur in 2014.

ITEM 3: MANAGING VACCINE-DERIVED POLIOVIRUS RISKS

The greatest risk will be due to *circulating vaccine-derived polioviruses (cVDPVs)* prior to, at the time of, and immediately following the tOPV-bOPV switch. While all OPV-using countries are potentially at risk of cVDPVs, especially those with low-moderate coverage, the risk appears to be geographically concentrated in certain areas with recurrent cVDPV emergence. As of mid-2012, these areas included northern Nigeria, southern Afghanistan, south-central Somalia and bordering areas of Ethiopia, eastern DR Congo, southern Madagascar, Yemen, and, possibly, western Uttar Pradesh, India. These areas will require particularly intensive efforts to boost routine immunization coverage prior to the tOPV-bOPV switch and to enhance AFP and surveillance activities to detect and respond rapidly to any newly emergent cVDPVs. Additional strategies will be considered to reduce the risk of a cVDPV emergence at the time of a tOPV-bOPV switch in such areas, including the conducting of a tOPV mass campaign immediately prior to the switch and adding a two dose routine IPV schedule for at least a transition period. It is assumed that any cVDPVs that emerge at the time of OPV cessation can be rapidly interrupted using monovalent OPV (mOPV) campaigns and, if necessary, ring vaccination with IPV.³³ It is further assumed that any such time-limited mOPV responses would at most very rarely, if ever, give rise to new cVDPVs, particularly in the period immediately following OPV cessation. The experience to date with OPV response campaigns in low coverage areas supports this assumption.

Vaccine-related polioviruses that have not genetically evolved to where they have become VDPVs because they differ from the corresponding OPV strain by >1% of nucleotide positions by genetic sequencing, can still rarely cause sporadic cases of vaccine associated paralytic polio (VAPP). A WHO evaluation estimated that the global burden of VAPP is between 250-500 cases per year.³⁴ The risk of VAPP is directly related to susceptibility to the type-specific poliovirus causing the VAPP; thus, already immune individuals are not at risk. VAPP cases may occur in either immunologically normal or immunodeficient individuals who are either recipients of OPV or contacts of OPV recipients. VAPP cases are manifest as single, sporadic cases and do not cause polio outbreaks. Cessation of OPV use will eliminate all risk of VAPP cases permanently.

Although less well characterized, the risk of *chronic iVDPVs* (i.e. with persistence of VDPV shedding for >36 months) appears to be concentrated primarily in industrialized countries where treatment is more often available for individuals with primary B-cell immunodeficiency syndromes (i.e., having defects in antibody production). These iVDPVs could theoretically reintroduce poliovirus into the wider population. However, since OPV was introduced in the 1960s none of the 30 recorded cases of prolonged iVDPV excretion (i.e. > 6 months) have been shown to cause secondary cases. All 4 of the chronic iVDPVs that have been detected as of mid-2012 occurred in high-income countries with high polio immunity and hygiene levels. As of mid-2012, only 2 chronic iVDPVs were either known or suspected to be continuing to shed virus – one each in the United Kingdom and the United States. A three-pronged strategy is being developed to manage this risk. First, enhanced identification and

³³ Defined as the vaccination of all susceptible individuals in a prescribed area around an outbreak

³⁴ <http://www.polioeradication.org/Research/PolioPipeline/No8Summer2011.aspx>

systematic screening of individuals with primary B-cell immunodeficiency syndromes will be used to identify potential iVDPVs. Secondly, immediate contacts will be recommended full vaccination to reduce the risk of infection and spread. Thirdly, the development and testing of polio antiviral compounds is being accelerated to identify a minimum of 2 compounds with the capacity to clear iVDPVs. As of mid-2012, one such compound was in Phase 1 trials and 3 additional compounds were under assessment.

DRAFT

Item 4: Polio asset mapping (indicative areas)

POLICY AND STRATEGY PROCESSES (examples)

- Multi-year strategic plans and planning processes
- Technical advisory bodies and policy processes (national, regional & global)
- National, State, and sub-national task forces to guide and implement strategy

PARTNER AND DONOR PROCESSES (examples)

- The GPEI architecture – managing a global public-private partnership
- Interagency Coordinating Committees (ICCs)
- Financial Resource Requirements (FRRs) & cashflow management

OPERATIONAL AND TACTICAL PROCESSES (examples)

- Social Mobilization and advocacy
- Global surveillance and response capacity
- Mapping Communities
- Evidence-based decision making
- Accountability frameworks
- Outreach
- Surveys – M&E
- Data management
- Vaccination Teams – recruitment, training, monitoring, payment
- Pre-campaign and in-process monitoring of activities
- Building a trained and motivated health workforce

OVERSIGHT AND INDEPENDENT MONITORING PROCESSES (examples)

- Performance indicators
- Global and Regional Certification Commissions (GCC/RCCs)
- Independent Monitoring Board (IMB)

ANNEX B – MONITORING FRAMEWORK (separate document under development)

DRAFT

DRAFT