

**POLIO ERADICATION ENDGAME
(2013-2018)**

STRATEGIC PLAN & LEGACY PLANNING

Global Polio Eradication Initiative

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1. PURPOSE

On 26 May 2012 the World Health Assembly (WHA) declared the completion of poliovirus eradication to be a programmatic emergency for global public health and called for the development of a comprehensive polio endgame strategy.¹ In response, the Global Polio Eradication Initiative (GPEI) has developed this Endgame Strategic Plan in consultation with national health authorities, scientific experts, global health initiatives, donor partners and other stakeholders. This Plan 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. Particular attention has been given to aligning this Plan with the goals, objectives and major activities of the Global Vaccine Action Plan (GVAP).²

This Endgame Strategic Plan outlines at a high level the necessary activities to complete the polio eradication initiative over the period 2013-2018. The timeline 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. The Plan runs parallel to the GPEI Emergency Action Plan 2012-2013 which outlines specific activities to complete wild poliovirus eradication in specific geographies.³ Beyond 2013 this Plan will be complemented by new bi-annual operational plans that 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. 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.

This document also frames the process for planning the polio 'Legacy', building on the polio programme's achievements and experience, to sustain a polio-free world after programme closure and to ensure that the assets, learnings, capacities and workforces developed in the fight against polio are applied to other major public health challenges.

2. STATEMENT OF INTENT

The goal of this 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.

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

² Resolution WHA65.17 'Global vaccine action plan'

³ EAP available at:

<http://www.polioeradication.org/resourcelibrary/strategyandwork/emergencyactionplan.aspx>

3. CONTEXT

In January 2012, a fourth WHO Region (South East Asia) became polio-free 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, Pakistan, and Nigeria. Given the increasing evidence from recent outbreaks of the terrible consequences of failure, 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*.⁴ In all three remaining polio-endemic countries, national emergency action plans were established to reach every child with the polio vaccine; and in each country oversight bodies were established that answer directly to their heads of state to scrutinize implementation and ensure accountability for the quality of key activities. The core GPEI partners restructured their polio programmes 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. By mid-2012 thousands of additional polio workers were applying new tactics, including lessons from India, to reach every child in the remaining infected areas; by end-2012 independent analyses were concluding that these course-corrections were improving OPV campaign coverage such that the worst-performing infected areas were now on track to stop transmission by end-2014⁵.

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

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. By 2005, expert polio eradication and immunization advisory bodies concluded that addressing these risks in a comprehensive manner,

⁴ Notably outbreaks in adults in DR Congo 2010-2011 caused by type 1 wild poliovirus

⁵ Global Good analyses – Nigeria & Pakistan 2012.

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 WHO's Scientific Advisory Group of Experts on immunization (SAGE), the WHA endorsed the principle of synchronized OPV cessation globally, requesting acceleration of the programme of work on post-eradication risk management, including if and when appropriate, establishing a timeline for the eventual cessation of the use of OPV in routine immunization programmes.⁶

Throughout the GPEI, commentators and stakeholders have highlighted that key achievements of this public-private partnership could and should be built on for the broader global good. The GPEI has faced extraordinary challenges - technical, programmatic, financial, geopolitical - but has developed capacities to meet those challenges and has learned lessons that can be applied to other global health initiatives. After more than 20 years of implementation, the principal achievement that stands out is the capacity to reach the "fifth child" (i.e. the 20 percent of all children globally who are not reached with other health services, even routine immunization). This achievement has translated into an expanded global surveillance and response capacity and the ability to deliver basic services to the most marginalized and vulnerable populations in the world. These capacities have wider utility beyond the polio programme. A central element of the polio 'legacy' must be to garner the programme's potential to contribute to improving routine immunization coverage and the delivery of other health interventions, , and to conduct surveillance and response activities for other important diseases. With sufficient funding and support, other global health programmes can benefit from the experience, lessons learned, and assets of the polio programme for the greater global public good.

⁶ Resolution WHA61.1: 'Poliomyelitis: mechanism for management of potential risks to eradication'

4. ENDGAME STRATEGIC PLAN – MILESTONES & MAJOR CHALLENGES

The ultimate milestone of the endgame strategic plan is global certification of wild poliovirus eradication by end-2018. Achieving this milestone, and the overall goal of this Plan, requires interrupting wild poliovirus transmission by end-2014 and stopping all routine immunization with type 2 oral polio vaccine in a globally synchronized manner at some point during the period 2015-2016 (Table 1). There are major challenges to achieving each of these milestones.

Table 1: Key Dates

DATE	MILESTONE
End-2014	Interruption of residual wild poliovirus transmission
During 2015/6	Synchronized switch of trivalent OPV with bivalent OPV globally
End-2018	Global Certification
During 2019	bOPV Cessation

Most immediately, and significantly, three of the four polio-infected countries at end-2012 – Afghanistan, Pakistan, and Nigeria – have never interrupted the transmission of indigenous wild polioviruses. 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 no such international spread has occurred in 2012 as of end-October, importations will remain a significant and constant threat until all wild poliovirus is interrupted globally. At end-2012, independent analyses of the impact of the GPEI Emergency Action Plan 2012-2013 concluded that the combination of innovations being applied in the remaining endemic areas to improve programme oversight and accountability, field operations, and community demand was translating into improved OPV campaign coverage trends such that all of these countries were on track to achieve the population immunity thresholds needed to stop transmission by end-2014. This plan summarizes the national and international actions detailed in the GPEI Emergency Action Plan to sustain this progress while addressing emerging threats, including in the areas of security, suspension of vaccination, and political change.

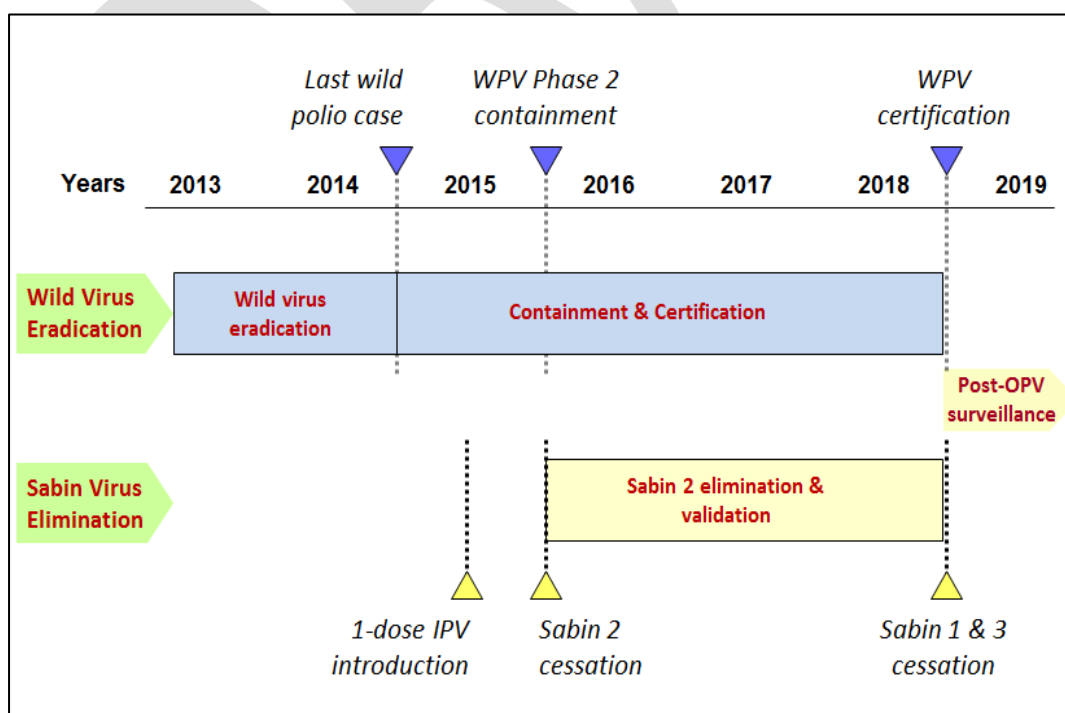
Achieving the globally synchronized cessation of routine immunization with type 2 oral poliovirus vaccine (OPV) faces a combination of logistical, communications, vaccine supply and programmatic challenges across a much greater geographic area given that over 125 countries were using trivalent OPV as of end-2012. The recent availability (2009), and proven efficacy of bivalent OPV against the remaining wild polioviruses type 1 and 3 serotypes is central to the new endgame 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 national tOPV production will need to develop and license a bivalent product. More complicated will be ensuring the availability of sufficient supplies of inactivated poliovirus vaccine (IPV) – at an affordable price – to allow all countries to introduce at least 1 dose of this product into their routine immunization programmes in advance of the tOPV-bOPV switch. As daunting are the logistical challenges of synchronously switching all OPV-using countries from tOPV to bOPV, withdrawing the tOPV field stocks, and safely destroying or containing residual vaccine virus. Accompanying this logistical work will be a

significant communications effort for the parents whose children will receive the new vaccine schedule, and training of the health workers who must implement it. This Plan outlines the strategic approach to OPV2 cessation and the activities required to address the associated challenges. Operational plans for each of these aspects will be updated and refined as the programme of work on post-OPV risk management is implemented.

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 confirmed on the final 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.

Figure 1 illustrates the timelines and key dates for each of the two main work streams – completion of wild poliovirus eradication and elimination of Sabin polioviruses – needed to achieve the goal of the Polio Endgame Strategic Plan.

Figure 1: The Endgame Milestones



5. OUTCOMES AND MAJOR ACTIVITIES

OUTCOMES

The Polio Endgame Strategic Plan is designed to produce four major outcomes to complete the eradication and containment of all polioviruses:

1. Population immunity in infected and high risk areas above the thresholds needed to interrupt circulating polioviruses and prevent re-establishment of imported or emergent viruses.
2. Global poliovirus surveillance and response capacity to rapidly detect and interrupt any emergent poliovirus.
3. Sabin 2 polioviruses removed from routine immunization programmes in all OPV-using countries.
4. Appropriate biocontainment globally of all wild polioviruses, vaccine-related polioviruses and Sabin strain type 2 poliovirus.

Table 2 summarizes the relationship between these outcomes and the major activities outlined in sections 5.1-5.5 of the Plan.

Table 2: Outcomes and Major Activities

Outcome	Major Activities
High population immunity	<ul style="list-style-type: none"> - routine immunization systems strengthening - national & subnational immunization days - IPV introduction - community engagement & social mobilization
Surveillance & response capacity	<ul style="list-style-type: none"> - outbreak response & mop-ups - stockpiles for emergency response - acute flaccid paralysis surveillance - environmental surveillance - new diagnostics & special studies
Sabin 2 poliovirus removal	<ul style="list-style-type: none"> - OPV cessation (type 2)
Poliovirus containment	<ul style="list-style-type: none"> - biocontainment of residual polioviruses - certification of eradication & containment

MAJOR ACTIVITIES

5.1 ROUTINE IMMUNIZATION

Routine Immunization Systems Strengthening

Strengthening routine immunization systems to achieve the Global Vaccine Action Plan (GVAP) coverage targets is fundamental to the polio endgame. Improvements in routine immunization coverage against poliovirus are essential to minimize the risk of cVDPV emergence following OPV cessation and to optimize the impact of IPV. Given the inherent weaknesses of health systems in many OPV-using countries GVAP envisages the strengthening of both fixed site delivery of routine vaccination programmes and sustainable outreach activities.

The GPEI will seek to contribute to specific GVAP objectives through a two-pronged approach that is coordinated with global health partners, particularly the Global Alliance for Vaccines & Immunization (GAVI), and exploits the GPEI infrastructure and processes to assist national authorities and the broader immunization community to improve coverage.

First, in all countries with a polio staff presence (over 60 countries), there will be an increased emphasis on using these staff and related GPEI capacities and experience to contribute directly to the GVAP objectives and activities related to strengthening immunization systems (GVAP objective 4) and ensuring individuals and communities understand and demand vaccines (GVAP objective 2). Particular attention will be given to those GVAP activities which build on the training and experience of GPEI staff such as strengthening monitoring and surveillance systems, improving the capacity of managers and frontline workers, strengthening infrastructure and logistics, building advocacy capacity, creating incentives, and engaging individuals and communities.

Secondly, in those geographies where the GPEI has deployed and maintained a strong human resource infrastructure which extends down to the subnational level (i.e. recently endemic and re-established transmission areas), the GPEI emphasis will also extend to include key activities under the GVAP objective of extending the benefits of immunization equitably to all people. In these contexts the GPEI experience, staff and capacities will be applied to the development and implementation of existing and/or new approaches to tackle inequities in immunization coverage. This will include using GPEI staffing, microplanning, experience in reaching marginalized groups, and effective monitoring to drive up DTP3/Penta 3 coverage.

TARGET: By 2016, >50% of the time of polio-funded field personnel will be devoted to specific, measurable GVAP activities to help national authorities strengthen routine immunization systems and services.

TARGET: By end-2018, DTP3/Penta3 coverage should be a minimum of 70% in the worst-performing Local Government Areas (LGAs), districts or agencies of the northern states of Nigeria and India, Pakistan, southern provinces of Afghanistan, Angola, Chad, eastern DR Congo, Somalia and south Sudan.

OPV Cessation

Due to the long-term risks of vaccine-associated paralytic poliomyelitis (VAPP), iVDPVs and cVDPVs, the use of specific oral polio vaccine (OPV) serotypes will be phased out globally from all routine immunization programmes in a synchronized manner. Given that type 2 wild poliovirus has been eliminated globally for over 10 years, and that the greatest burden of VDPV-associated disease is due to the Sabin type 2 virus, OPV2 cessation is a central, prominent and near-term goal of the polio endgame. 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 globally-synchronized cessation of all tOPV use.

The most critical pre-requisites for a tOPV-bOPV switch are that any persistent cVDPV2 outbreaks (e.g. Nigeria, Somalia at mid-2012) have been stopped and that there is proven capacity to detect and stop any new outbreaks. All countries should have the capacity to detect and interrupt cVDPV outbreaks within 6 months of an index case. An additional pre-requisite will be the availability of an adequate supply of the appropriate vaccines to allow for a globally-coordinated tOPV/bOPV switch, including availability of sufficient bOPV and 'affordable' IPV options (see below). Additional pre-requisites include international consensus on stopping the use and delivery of tOPV formulations globally, and the availability of stockpiles of mOPV2 to respond to possible post-switch cVDPV2 outbreaks. Cessation of bivalent OPV is targeted for 2019 (i.e. as soon as feasible, following global certification).

TARGET: By end-2016, 100% of tOPV-using countries have replaced tOPV with bOPV for routine immunization.

TARGET: By end-2019, 100% of countries have stopped all bOPV use.

IPV introduction

To boost population immunity against polioviruses prior to a tOPV-bOPV switch, 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, thereby substantially reducing the consequences of a subsequent circulating poliovirus - in terms of paralytic disease - and facilitating the containment of outbreaks. For countries at particular risk of cVPDV 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). Recognising 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 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, given the need to mainstream operations. IPV may also have a role to play in helping to interrupt transmission in endemic countries, when administered alongside OPV (see SIA section 5.2 below).

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 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.⁷ 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. 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.⁸

TARGET: By end-2015, at least 1 IPV product available for < US\$1/dose; at least 2 such products available by end-2016.

TARGET: By end-2015, 100% of OPV-using countries have introduced > 1 dose of IPV into the routine immunization schedule.

5.2 SUPPLEMENTARY IMMUNIZATION ACTIVITIES (SIAs)

Supplementary immunization activities (SIAs) build on routine immunization programmes to establish very high population immunity in order to interrupt both endemic polio transmission and outbreaks following importations. In polio-free areas SIAs can also help to maintain population immunity at sufficient levels to prevent the circulation of a poliovirus following an importation. This section outlines the fundamental elements of the SIA strategy for the polio endgame.

⁷ 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).

⁸ SAGE meeting, 10-12 April 2012: http://www.who.int/immunization/sage/previous_april2012/en/index.html

National & Subnational Immunization Days (NIDs & SNIDs)

An intensive schedule of supplementary immunization activities will be conducted 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. Geographically the most intensive schedule of NIDs and SNIDs will be conducted in endemic areas (i.e. 6-8 rounds per year in northern Nigeria, Pakistan, southern Afghanistan), areas of recurrent importations from these endemic areas (i.e. 2-4 rounds per year in parts of West Africa, Chad, Sudan and South Sudan), and areas of recurrent cVDPV emergence (e.g. 2-4 rounds per year in northern India, Somalia, eastern Ethiopia, eastern DR Congo, and Yemen). 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.

The GPEI will continue to intensify its risk analysis and modeling on an ongoing basis to help refine the SIA calendar to achieve and sustain immunity levels needed to interrupt transmission and remain polio-free. For endemic areas, the intensity of SIAs will be scaled-back only after at least 18 months following the last confirmed detection of a circulating wild poliovirus (i.e. after 2 high seasons without wild poliovirus detection); for re-infected areas, the intensity of SIAs will be scaled-back only after at least 12 months following the last confirmed detection of circulating wild poliovirus. Following the tOPV-bOPV switch (see section 6.1), a baseline schedule of 2 SIAs per year will be continued in the areas of highest risk of types 1 and 3 VDPV emergence until the time of bOPV cessation.

As OPV campaigns are the core strategy for boosting population immunity above the threshold for stopping polio transmission in endemic areas, it is essential that a sufficiently high quality of campaigns is achieved and maintained in the endemic countries. This requires professional campaign management; clear accountabilities; appropriate and tailored tactics for insecure and conflict affected areas; and, the utilization of proven innovations and best practice in campaign planning and implementation to ensure that campaigns reach every last child. The combination of tactics introduced under the GPEI Emergency Action Plan 2012-13 will be sustained and expanded as needed to address persistent gaps in SIA coverage, including the deployment of the technical assistance surge through partner agencies, review and refinement of microplanning in the highest risk areas, greater scrutiny of vaccinator selection and training and retention rates, reworking of vaccination team supervision strategies, introduction of direct payment mechanisms for vaccinators and supervisors, and enhanced community mobilization. Annex 1 summarizes the major actions being employed in each of the remaining endemic countries, under the GPEI Emergency Action Plan 2012-13, to improve SIA performance and accountability to achieve the population immunity levels needed to stop transmission. These actions are categorized across six thematic areas:

- Leadership to ensure a whole of government/society approach,
- Oversight to guarantee accountability for programme and partner performance
- Microplanning for missed children
- Institutionalizing best practice for vaccination team performance
- Social mobilization to enhance community demand

- Surge of technical support to assist for worst-performing areas

Pre-, intra- and post-campaign monitoring will be used to ensure real-time course corrections in SIA planning, implementation and assessment. Standardized dashboards will be systematically applied in all polio-endemic areas to assess SIA preparedness at district level, with immediate deferment and urgent surge support to areas failing to meet the defined standard. Building on the best practices of India, intra-campaign monitoring will be utilized to ensure more effective end-of-day review meetings and targeting of remedial or catch-up activities in priority areas. Lot Quality Assurance Sampling (LQAS) and independent monitoring will be used to assess campaign coverage in all accessible areas and guide catch-up activities.

A combination of scientific and operational research will inform decisions on the potential utility of expanding the age groups targeted during OPV SIAs in endemic areas as well as the types of polio vaccines administered. Recent data from polio outbreak response activities suggests that expanding the target age group for OPV beyond 60 months of age in SIAs may accelerate the interruption of polio transmission due to a number of factors, particularly improved coverage among the very young. Similarly, 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.

TARGET: by end-2013, LQAS confirmed coverage of > 80% in all very high risk LGAs/districts of northern Nigeria and southern Afghanistan.

TARGET: by end-2013, LQAS confirmed coverage of > 90% in all very high risk LGAs/districts of Pakistan.

Outbreak Response & Mop-Ups

A more aggressive approach to outbreaks of both wild and vaccine-derived polioviruses will be implemented 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.

Whereas outbreak response activities have historically been driven by isolation of a poliovirus from a paralyzed child, during the endgame period environmental data will also be used to guide outbreak response planning and implementation. For known infected 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.

The vaccine of choice for outbreak response will depend on the nature of the virus (wild vs. VDPV), and the phase of the eradication programme (i.e. prior to or following the tOPV-bOPV switch). Prior to the tOPV-bOPV switch the vaccine of choice for a wild poliovirus outbreak (i.e. type 1 or 3) will be bOPV; the vaccine of choice for a cVDPV will be bOPV for type 1 or 3 cVDPVs and tOPV for type 2 cVDPVs. 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.

TARGET: By mid-2013, 100% of polio outbreaks stopped within 120 days of an index case.

Stockpiles for Emergency Response

Prior to the tOPV-bOPV switch, OPV will be the vaccine of choice to respond to all wild and VDPV outbreaks (see above). During this period, global OPV supply will be managed to ensure a sufficient buffer stock (i.e. a minimum of 50 million bOPV doses) is maintained for this purpose. 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 production facility; the detection of an ambiguous vaccine-derived poliovirus (aVDPV) may trigger a pre-emptive IPV response in the immediate area.⁹

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. 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.

5.3 COMMUNITY ENGAGEMENT & SOCIAL MOBILIZATION

Securing the buy-in of the most marginalized and disaffected communities to campaigns is vital to complete polio eradication. Persistent pockets of vaccination refusals can potentially derail the

⁹ 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.

global eradication effort. The closer the programme moves to eradication the more critical it is to be able to access socially disaffected groups. In addition, the new polio endgame brings new communication challenges requiring the development of new strategies to address IPV introduction and OPV cessation.

Reaching the most marginalized children requires understanding and overcoming local social, cultural, political and religious barriers. Rapid social research will be used to help build understanding of why the programme continues to miss children, with findings quickly operationalized to better inform the response. In May 2012 a new tool was developed to investigate areas with evidence of chronically missed children. Already the data generated is guiding the targeting of locally-specific interventions. Quarterly reporting against a set of global communication indicators, with social data now collected right down to settlement level in the highest risk areas is helping drive more systematic evidence-based planning and implementation of a mix of communication and social mobilization interventions.

Public advocacy

Mobilizing decision makers and administrative structures involves a range of activities at various levels to ensure that polio eradication is fully on the political and administrative agenda. This involves persuading influential people and organizations to advocate and organize support. As polio has now been largely restricted to three countries with large and predominant Muslim populations a greater effort is underway to ensure the right mix of international and locally respected Islamic voices support polio efforts.

Health professionals, including private practitioners and medical associations, must be fully aligned with programme to publicly reinforce the call for vaccination and allay any fears and concerns. For example, the Nigerian Medical Association members have been sensitized on the importance of reporting suspected polio and involved in OPV campaigns to accompany teams to high risk areas and visit houses or settlements that have been historically resistant to polio immunization.

In all endemic and polio priority countries, plans will include the holding of local government meetings, official memos and press briefings to demonstrate public commitment; systematic use of mass media to raise visibility of polio activities through news coverage, talk shows, soap operas, celebrity spokespersons, discussion and other entertainment education programmes; and regular meetings and question and answer sessions among government representatives, local and community organizations and leadership to discuss campaign plans and allay fears.

Community engagement and mobilization

Community mobilization through involvement, engagement and participation is critical to build support for polio campaigns at local levels, and to help mitigate the consequences of any crisis that may arise from rumours and misinformation. Local community leaders (political, social and religious, influential people) will be mobilized to play an active role in planning, organizing and promoting campaigns, and engaging community members to discuss and personalize the risks associated with polio and actions that can be taken to protect the community. Community mobilization will be

organized by local government and partners (including UNICEF, Rotary and local NGOs) through: community group meetings; traditional and new media, such as a town criers, film showings and theatre groups; grassroots organizations; schoolchildren; religious institutions; and traditional healers.

Social Mobilization networks

Based on the highly successful 9000 strong social mobilization network model in India (SMNet), dedicated networks are now being scaled up in the highest risk areas for polio transmission in Afghanistan, Nigeria and Pakistan with thousands of volunteers recruited in 2012. These local men and women are empowered to address local concerns about polio and routine immunization to ensure communities have the right information, delivered through locally appropriate channels, to enable parents to make the right decisions to protect their children. This is already having an effect, as evidenced by higher rates of awareness of campaigns, increased conversion of refusals and reduced numbers of missed children in polio reservoirs in Pakistan, Afghanistan and Nigeria. Social research consistently cites social mobilizers and community health workers to be among the most credible, trustworthy sources of information.

Promotion and advertising

Leading up to and during campaigns promotional materials and advertising remind communities that polio is still a problem and that they should vaccinate their children. Appropriate promotional materials, such as leaflets, pamphlets, banners, flags, and radio and television spots will be used strategically, as has been used in India to achieve awareness levels as high as 98%. To build awareness in Pakistan a national media strategy featuring Shahid Afridi, one of Pakistan's most famous cricketers, was launched in 2012. The private sector in the endemic countries will continue to be engaged to provide support.

Point of service promotion

Wherever polio or routine vaccination is provided at a fixed service point it will be promoted with visible promotional signs and symbols to emphasize the availability and accessibility of support and advice and to visibly reinforce the value of the intervention. When OPV doses are provided house-to-house, this visibility will be provided through promotional signs and symbols on vaccination team clothing, caps, bags or even vaccine carriers. In Nigeria, to ensure vaccinators are able to present themselves to caregivers both courteously and professionally a new Inter-Personal Communication skills kit was produced and special training conducted in several high risk states in 2012.

5.4 SURVEILLANCE

Sensitive surveillance systems are essential to polio eradication. They enable the identification of any residual viruses and are a crucial basis for certification of eradication. This section outlines the steps that will be taken to further build and maintain a comprehensive polio surveillance system for eradication.

Acute Flaccid Paralysis Surveillance

The detection and investigation of Acute Flaccid Paralysis (AFP) cases remains the core strategy for detecting both wild and vaccine-derived polioviruses, to guide SIA strategy, to facilitate certification and to validate the absence of circulating VDPVs. There will be three major priorities during the endgame period. For the three regions that are certified polio-free - the Americas, Europe and Western Pacific - the priority will be to revitalize AFP surveillance 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.¹⁰ This will be achieved through heightened 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.

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.

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. In areas with extraordinary challenges, in addition to the above, special activities will be put in place, to include 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.

TARGET: By end-2014, 100% of countries in certified Regions achieving and sustaining certification-standard surveillance.

TARGET: By end-2013, 100% of countries in non- certified Regions achieving AFP detection rates of 2 cases per 100,000 population <15 years, at province/state level.

Environmental Sampling

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

¹⁰ 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.

recurrently re-infected areas, and to document the elimination of Sabin viruses following the tOPV-bOPV switch and eventual bOPV cessation. Additional endemic sampling sites in Nigeria and Afghanistan, as well as new sites in highest-risk areas/routes for importation would be in place by mid-2014. Based on the number of countries/areas at particular risk of a VDPV emergence, or which have a national tOPV production facility, this will be complemented by an additional 15-20 cities with sampling sites globally, prior to the tOPV-bOPV switch in 2015.

TARGET: By end-2015, environmental sampling sites established in an additional 15-20 cities globally to help monitor OPV2 cessation and the elimination of type 2 vaccine-related polioviruses.

Special Surveillance

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 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.

TARGET: By end-2013, seroprevalence surveys underway in all areas of residual wild poliovirus transmission.

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). Incremental introduction of new diagnostic techniques for environmental surveillance will take place through 2014. Additional 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. 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.

5.5 CONTAINMENT & CERTIFICATION PROCESSES

Appropriate biocontainment of polioviruses is a fundamental step towards global certification and minimizing the long-term risks associated with poliovirus stocks. This section outlines the biocontainment requirements and the process for global certification.

Biocontainment of Residual Polioviruses

Following global interruption of wild and vaccine-derived polioviruses and cessation of OPV use, facility-based polioviruses will represent the only remaining source for reintroduction to human populations.¹¹ These risks can be eliminated in most areas through the destruction of wild poliovirus and OPV/Sabin infectious and potentially infectious materials, as the majority of countries will have no need for live viruses in the post-eradication era. However, a small number of poliovirus facilities (10-20) will be necessary to ensure continued essential international functions, including IPV production, OPV stockpile maintenance, vaccine quality assurance, diagnostic reagent production, virus reference functions, and crucial research.

Dates for the destruction of poliovirus materials and implementation of safeguards will differ for wild and Sabin polioviruses and be linked to global WPV interruption, the tOPV-bOPV switch, and global OPV cessation. 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 persistent polio-infected countries. By the time that wild poliovirus transmission has been interrupted for one year – interruption targeted for end-2014 - Phase II containment activities will have been initiated in all countries in preparation for containment of all wild polioviruses by mid-2016. Sabin type 2 polioviruses will be controlled at the time of the tOPV-bOPV switch. At the time of global OPV cessation all remaining Sabin polioviruses will be contained.

The development and finalization of the Global Action Plan for the Laboratory Containment of Wild Polioviruses (GAP III) will be used to establish international consensus on the timeframe and mechanisms for ensuring that the containment requirements for laboratory stocks of wild poliovirus and VDPVs are appropriate to the risks. A finalized GAP III will also address the need to establish consensus on the relevant biosafety levels for handling Sabin and Sabin-derived polioviruses during the OPV cessation phase. International agreement on long-term containment standards for all polioviruses (i.e. Sabin as well as wild poliovirus strains) will need to be established by 2014.

TARGET: by end-2014, international agreement on long-term containment of polioviruses and post-eradication use of OPV.

TARGET: by end-2015 phase 2 biocontainment activities implemented for wild polioviruses.

Certification of Wild Poliovirus Eradication & Containment

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.¹² Certification at the Regional level is done by Regional Certification Commissions (RCC) which report in turn to the Global Certification Commission (GCC). At its meeting in August 2012, the GCC indicated that it could in 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 formal 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 – can 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. If Nigeria, Pakistan and Afghanistan interrupt all wild poliovirus transmission by end-2014, 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.

A number of programmatic challenges and policy issues will need to be addressed for global certification of wild poliovirus eradication and validation of the elimination of all vaccine-related viruses, including: the revitalization of certification-standard surveillance in the three Regions which have already been certified (i.e. the Americas, the Western Pacific and Europe); verification of bio-containment of all wild and, eventually, Sabin polioviruses; and, establishment of formal criteria for verifying the absence of circulating vaccine-derived polioviruses (cVDPVs) globally.

TARGET: by end-2013, reconstitution of global and all regional certification mechanisms.

TARGET: by end-2014, full documentation submitted to the South East Asia Regional Certification Commission.

¹² See footnote 10 for the definition of certification-standard surveillance.

6. GEOGRAPHIC DISTRIBUTION OF POLIOVIRUS RISKS

The poliovirus risks that must be addressed during the endgame are not geographically homogeneous but instead are concentrated in certain areas, depending on whether they pertain to wild or vaccine-derived polioviruses. These risks constitute both national and international hazards and will require additional, sometimes tailored, measures to mitigate them.

6.1 WILD POLIOVIRUSES

In 2013-2018, wild poliovirus risks will be concentrated in a combination of developing and industrialized countries. Initially, the greatest risk will be in *areas with ongoing or recent wild poliovirus transmission*. Based on the global epidemiology of polio at mid-2012, these 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 as detailed in the GPEI Emergency Action Plan 2012-2013 and summarized in Annex 1 and section 5 of this Plan.

As the endgame period progresses, 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 the Phase 1 biocontainment activities globally. 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.

6.2 VACCINE-DERIVED POLIOVIRUSES

In 2013-2018, VDPV risks will also be concentrated in a combination of developing and industrialized countries. 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 generating 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.¹³ 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. 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 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.

¹³ Defined as the vaccination of all susceptible individuals in a prescribed area around an outbreak

7. MAJOR RISKS TO THE ENDGAME

The immediate risk to the endgame strategic plan is failure to interrupt wild poliovirus transmission. As indicated by the recent interruption of wild poliovirus in India, the strategies to interrupt transmission outlined in this plan will work if fully implemented to a sufficiently high standard. The risks to interrupting transmission are chiefly operational and financial. This section examines these risks under four principal headings and outlines approaches to mitigate these risks.

Operational

- Inadequate management of large-scale eradication operations
- Failure to reach the last children in reservoir areas due to:
 - Geographic barriers to access
 - Insecurity

Without adequate management of eradication operations, no matter the funding, the Endgame will not achieve its goals. Clear management plans, including accountabilities must continue to be strengthened in all infected countries, and managers must be held accountable for meeting the targets enshrined within these plans. The risks are too high to allow poor management to derail eradication efforts. Annex A outlines how each of the remaining endemic countries has structured its polio programme management and operations to interrupt transmission of wild poliovirus.

The GPEI has gained invaluable experience from eradicating polio in conflict-affected and insecure areas. Common principles exist, particularly that people living in conflict-affected areas are highly motivated to improve their children's futures and can be readily engaged in the delivery of basic health services. Major humanitarian actors can also provide valuable assistance in negotiating access. A range of tactics has been developed and employed to access children and boost immunity more rapidly in insecure areas. Whilst not underestimating the challenges posed by insecurity and conflict, with appropriate investment of resources and attention, and the introduction of tailored strategies, conflict and insecurity should not pose an insurmountable barrier to achieving eradication.

Financial

- Insufficient pledges against the US\$ 5.5 billion budget
- Insufficient cash flow

All activities outlined in this strategic plan must be fully funded, sufficiently in advance to allow implementation as scheduled and at a high standard. The GPEI projects a financial requirement of US\$ 5.5 billion for the 2013-2018 Endgame period.¹⁴ The larger the gap in financing, the more planned activities would need to be cut and the higher the consequent risks of failure to complete eradication. In the worst-case scenario, insufficient financing would result in unmet eradication targets, polio would re-establish itself in previously polio-free countries and the virus would take a stronger hold in the endemic countries. The GPEI is developing a resource mobilization strategy for the endgame period (see Section 9.2 below). The GPEI will work closely with donors to ensure predictable cash flow to enable planned activities to go ahead as scheduled.

¹⁴ See section 8 'Financial Resources 2013-2018

Political

- Inability to establish and/or sustain political support in worst-performing districts/communities
- Inability to sustain national and state/provincial commitments and oversight in key geographies due to political change and competing priorities.

Political alignment with the goals of polio eradication at all levels is an essential enabling factor to the success of the Endgame. The political commitment at the national and sub-national levels in the remaining endemic and reinfected countries must be sustained and deepened. This commitment is essential to mobilize the local resources, access and accountability needed to improve the programme's reach to all children and sustain efforts beyond the interruption of wild poliovirus transmission. Structures and mechanisms have been established in each of the endemic countries to ensure that the strong political support for the polio programme at a national level is continued down to the state and district levels. For each of the endemic countries, this is outlined in Annex, along with accountabilities. The potential impact of political change cannot be fully mitigated; however, the development and sustained implementation of polio advocacy campaigns in key geographies can help to address this risk.

Societal

- Development of substantial resistance to, or boycott of, polio campaigns in key geographies
- Persistent suspension of polio campaigns (e.g. in parts of Pakistan and Somalia)

Alignment with the goals of the polio programme at the sub-national level is an essential element in ensuring communities buy-in to the vaccination campaigns. Appropriate community leaders need to be engaged. These are often traditional or religious or tribal leaders. Working to ensure alignment is a priority, as outlined in section 6.3.

The worrying suspension of campaigns in parts of Pakistan and Somalia threatens to create new vulnerable areas. Political leadership and commitment to negotiate is needed to overcome these bans.

8. FINANCIAL RESOURCES 2013-2018

8.1 INDICATIVE BUDGET

The financial requirements for the 'Endgame' are projected to be US\$ 5.5 billion for the period 2013-2018, taking into account the Endgame Milestones outlined in Section 4.¹⁵ This reflects substantial work under various scenarios and is the consensus position of the core GPEI partners, 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. Adjusting the estimated year of interruption will increase/decrease costs accordingly.

The key budget drivers are:

- The cost of OPV campaigns
- Technical assistance to countries
- Surveillance and Laboratory costs
- Outbreak Response capacity & stockpiles
- IPV introduction
- Containment & Certification costs
- Surge Capacity
- Research and Product Development
- Programme Support Costs

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.

Please see Annex B for a table outlining the projected costs per budget category. – **TO BE ADDED**

8.2 RESOURCE MOBILIZATION

The financial needs of the endgame strategic plan will be met by implementing a resource mobilization, communications and advocacy strategy aligned with the endgame strategic plan and jointly developed by GPEI partners with the guidance of the relevant executive groups in the GPEI architecture, particularly the Polio Partners Group and the Polio Emergency Steering Committee. The resource mobilization strategy that is under development will aim to ensure that traditional donors maintain or increase their commitments, that new and non-traditional donors are courted and activated, that polio-affected countries increase their domestic financial contributions and that innovative mechanisms for funding are identified and exploited. A specific task force is being formed to drive this strategy.

Sustainable financing will require renewed commitments from governments and development partners as well as additional countries joining as development partners. The participation of in-

¹⁵ This does not include the nationally funded elements of the polio eradication campaigns in India.

country civil society organizations is also critical. National governments should play a lead role through their Ministries of Health in coordinating with immunization partners, through national Interagency Coordinating Committees (ICCs), the identification and quantification of resource needs and in tracking the effective and efficient use of these resources.

TARGET: By May 2013, secure pledges to fully fund US\$ 5.5 billion 2013-2018 period.

8.3 FINANCIAL MANAGEMENT AND EFFECTIVENESS

The GPEI has continually evaluated costs throughout implementation and sought opportunities to ensure good stewardship of available resources. In recent years, reviewing the costs associated with SIAs in countries such as Chad and DR Congo led to substantial reductions in operational costs. Currently, the GPEI partners are considering other ways to optimize costs and ensure maximum value for money including a project supported by external consultants to evaluate the key drivers of costs and performance across the global GPEI program (GPEI Value for Money project). The primary goal of this project is to identify areas where results can be delivered more cost-effectively, ideally by cost shifting within the current budget. An important secondary goal of the project is to promote greater transparency on major GPEI cost categories. A report detailing partnership findings and next steps will be available by November 2012.

9. PLANNING FOR THE POLIO LEGACY

INTRODUCTION

During more than 20 years of operations the GPEI has mobilized and trained millions of volunteers 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. As the programme enters its final stages there is a need for the global health community to plan for a future beyond polio eradication. This is to ensure not only a World safe from polio but also to ensure that investments made in the cause of polio are fully exploited. These are two principal goals of the Legacy work:

- First, to mainstream the longterm polio immunization, surveillance, 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 initiatives.

This section maps out how this will be accomplished through first outlining the work needed to mainstream the major elements of the GPEI's activities; detailing the GPEI's major achievements and the contribution of the polio workforce to other health activities; and, outlining a process and timeframe for consultation, planning and shaping the post-polio era.

9.1 MAINSTREAMING LONG-TERM POLIO FUNCTIONS

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 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.

9.2 ACCOMPLISHMENTS

This section highlights specific GPEI achievements that could have benefit and applicability to other global health initiatives.

After more than 20 years of implementation, one major achievement stands out. The GPEI has reached and regularly accessed the chronically unreached, marginalized and most vulnerable populations in the world. This in turn has led to two major dividends – the delivery of basic health services, and a truly global surveillance and response capacity for both health and humanitarian emergencies.

Resolving serious problems of access

The polio programme has gone further than any other programme in being able to develop sustained access to the most marginalized children and communities: the ‘fifth child’ (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 the success of social mobilization programmes, the training and deployment of vaccination teams, improved micro-planning, mapping that made use of innovations such as GPS/GSI. This capability 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)

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

The sharing of assets and learnings with other global health initiatives is an essential element of the polio legacy. This could include strengthening routine immunization (including modifying polio tools and innovations to benefit RI), 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 contribute to this work and will continue to do so through the Endgame. Through the process outlined below, planning will take place for transfer of assets and best practice to the broader global health community.

9.3 PLANNING FOR THE POST-POLIO ERA

The first step in the process is to map the polio assets. This exercise will take place through the end of 2012 and into the first quarter 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 areas and will be undertaken by the GPEI spearheading partners in consultation with national governments and other key stakeholders:

1. POLICY AND STRATEGY PROCESSES (examples)

- Multi-year strategic plans and planning processes
- Technical advisory bodies and policy processes (national, regional & global)

2. PARTNER AND DONOR PROCESSES (examples)

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

3. OPERATIONAL AND TACTICAL PROCESSES (examples)

- Social Mobilization
- Global surveillance and response capacity
- Mapping Communities
- Data management
- Vaccination Teams
- Building a trained and motivated health workforce

4. OVERSIGHT AND MONITORING PROCESSES (examples)

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

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. measles campaigns). 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. 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. The spearheading partners within the GPEI will lead this process, according to the timeline laid out below. This includes the WHO governing bodies process as the high level forum for making decisions on priorities.

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 2104

The final major element of planning for the post-polio era is a responsible and well-managed ramp-down of polio eradication efforts. This process will include addressing the issues surrounding the long-term future of the polio workforce. 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.

10. GOVERNANCE AND OVERSIGHT

Global Governance

The World Health Assembly issues the resolutions that determine the scope and direction for the Global Polio Eradication Initiative. The Polio Oversight Board, comprised of the heads of agencies of WHO, UNICEF, Rotary International, the US CDC and the Bill & Melinda Gates Foundation, meets quarterly to provide operational oversight and ensure high-level accountability across the GPEI partnership.

The Global Polio Partners Group is a multi-stakeholder body with representatives from donor and technical agencies, foundations, NGOs, polio-affected countries and the spearheading partners. 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 Endgame. As the focus of the GPEI evolves over the endgame period, as necessary, oversight arrangements will evolve to reflect changing realities.

National Governance

In Nigeria and Pakistan, the 2 most endemic countries at mid-2012, a Presidential and Prime-Ministerial oversight body were established, respectively, to ensure full implementation of the national emergency action plans, close oversight of LGA and district SIA performance, introduction of course-corrections as needed, and appropriate accountability for the quality and coverage of eradication activities. These bodies will be sustained for at least 12 months after the last wild poliovirus cases in each country.

Global & Regional Certification Commissions

Once wild poliovirus transmission appears to have been interrupted in a Region (i.e. 12 months after the last circulating wild poliovirus is detected), the work of the relevant Regional Certification Commission will intensify. The work of the Global Certification Commission (GCC) will intensify 12 months after the last wild poliovirus is detected globally.

Global Oversight and Technical Advisory Bodies

Independent oversight of eradication activities is provided by the Independent Monitoring Board (IMB). The GPEI responds to the IMB's recommendations and guidance in managing eradication efforts. 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 by the SAGE Polio Working Group.

The SAGE will continue its polio advisory role throughout the endgame period. The IMB will continue to evaluate progress towards the goal of the interruption of transmission.

Regional and National Advisory Bodies

Technical Advisory Groups (TAGs). Regional or national 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.

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11. ROLES AND RESPONSIBILITIES

11.1 Roles of GPEI Partners

National governments:

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 will require polio-affected countries to hold 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. The remaining endemic countries Afghanistan, Nigeria and Pakistan are the focus of surge efforts under the Emergency Action Plan.

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 governments play a critical financing role in the eradication initiative. Of note, the proportion of the GPEI budget that is funded by domestic resources of polio-affected countries has increased from less than 10% in 2003-2005 to more than 30% in 2007-2009. This increase is driven largely by India, but also by Nigeria, Pakistan and Bangladesh. Other major in-kind contributions from polio-affected countries - such as the time of volunteers, health workers and others in SIA planning and implementation - have an estimated dollar value similar to that of international financial contributions.

Coordination amongst GPEI partners

The GPEI partners have created new structures and processes for international support, coordination and interagency leadership under the Emergency Action Plan. This includes the leadership role of the Polio Emergency Steering Committee (PESC) which oversees a number of groups designed to assist countries in their eradication efforts, drive operational innovations and mobilize resources. Whilst these structures will continue under the EAP, the GPEI is working to include coordination with other global health initiatives. This will be particularly important as the legacy planning takes place. The GPEI will develop structures to facilitate broader cross-agency cooperation. The GPEI is also developing an accountability framework to ensure that responsibilities and appropriate accountabilities for the spearheading partners are clearly defined during the endgame period.

Donor partners:

Since the 1988 WHA resolution to eradicate polio, funding commitments to the GPEI have totalled US\$9 billion. In addition to contributions by national governments to their own polio eradication

efforts, 45 public and private donors have given more than US\$1 million, with 19 of these having given US\$25 million or more.

Donors to the GPEI include a wide range of donor governments, private foundations (eg Rotary International, the Bill and Melinda Gates Foundation, the UN Foundation), multilateral organizations, development banks, non-governmental organizations and, corporate partners. Donor engagement in polio-affected countries, to ensure optimal planning, implementation, monitoring and financing of country activities, will be a necessary complement to their engagement at the global level. In addition to financing, donor partners play an important advocacy role, both with polio-affected countries and donor peers. Some donor governments also provide access to technical expertise from within their national institutions, including through participation in global, regional and country-level technical advisory groups.

ANNEX A – COUNTRY UPDATES

This annex outlines how each of the remaining endemic countries has made improvements to its polio programme under six thematic areas since the launch of the Emergency Action Plan in 2012, in order to accelerate the interruption of transmission of wild poliovirus. For further information on each of the endemic countries please refer to national plans and the Emergency Action Plan.

NIGERIA (to be completed)

Leadership for a whole of government/ society approach

- **State and Provincial Task Forces** – Following a directive from the Presidential Task Force earlier this year, State Task Forces will be Chaired by the Deputy Governor. Local Government Area Task Forces have been established and should be chaired by the LGA Chairmen or Deputy. It is expected that the LGA Chairmen or a senior representative chair the evening review meetings during IPDs – The involvement of state and LGA leadership and over- sight is tracked through the Abuja Commitments and reported publically each quarter.
- **Traditional Leader Engagement** – Much has been done to engage and mobilize the revered traditional leadership to support polio eradication in Nigeria. His Eminence the Sultan of Sokoto has called publically for traditional leaders to support the programme and Emirs, District Heads, Village Heads and Ward Heads are actively involved. These leaders sensitize communities to upcoming rounds, are responsible for suitable selection of locally appropriate vaccinators, and resolve non-compliance and reporting if areas in their control are poorly covered.

Oversight of Programme and Partner Performance

- **President Task/Prime Ministerial Task Forces and other monitoring mechanisms** – Presidential Task Force on Immunization meeting regularly. Chaired by Minister of Health for State Dr. Pate who is responsible for reporting to the President.
- **Dashboard** – A new innovation operational in September. Tracks a number of pre-implementation indicators at the LGA and State level. Provides clear evidence to the programme of areas that are not ready for implementation, allowing local or state authorities to provide additional support or postpone implementation in certain areas. The dashboard now also tracks in-process indicators daily to the state and national operations room allowing much closer tracking of how campaigns are proceeding.
- **LQAS monitoring** – Has been scaled up considerably since its introduction in late 2009 and in the last IPD conducted in July 124 LGAs were evaluated using this methodology. The LQAS has proven very effective in Nigeria and has helped identify gaps in Independent Monitoring and identify more accurately good or poor performing areas.

Microplanning for Missed Children

- **House-by-house approach** – Based on learnings from the Indian polio programme, Nigeria has moved from a focus on children and settlement to household. This promotes a bottom-up approach with involvement of local health staff and traditional leadership. Walk through

of finished plans and verification strengthened. This results in a rationalized workload, greater accountability of teams, and easier supervision.

- **Nomad/Migrant** – Considerable work is underway to better map nomadic populations and engage with local leaders to ensure these populations are covered during IPDs and by routine services. A Recent pilot in July conducted in 41 LGAs in states with large nomadic populations and most at risk of polio infection found more than 8000 additional settlements not included on July micro-plan. 15% of these settlements had never been visited by a vaccination team. The study also found evidence of recent missed transmission with nine AFP cases with onset of paralysis in the last six months found not reported. Plans to scale up to other LGAs with large nomadic populations in coming months.
- **Improved Mapping** – GIS project underway in four states: Kano, Jigawa, Sokoto and Zamfara. Ward and LGA level maps completed with plans to scale up in November to remaining polio infected states.

Vaccination Teams to Institute Best Practice

- **Optimizing Recruitment, Training, IPC Skills, Retention** – Ward Selection Committees led by local traditional leaders established to ensure that locally acceptable vaccinators and supervisors are selected. Focus on retaining vaccinators, recorders and team supervisors to ensure over time capacity is built and teams are able to build trust with community. New coordinated training package for all new surge staff being developed with a focus on adult learning techniques and strong IPC skills.
- **Direct Disbursement Mechanisms** – Long-established. Nigeria is a leader in this regard. Little problems with payment of vaccinators
- **Restructuring Vaccination Teams** – Restructuring of vaccination teams and re-alignment to feasible daily targets was the first step in improving team performance.
- **Supervision** – Surge support Group Supervisor as well as field volunteers. Too early to demonstrate impact but managing this surge is one of the key priorities of the Nigerian programme.
- **Special Vaccination Teams (cross border, migrant/nomadic, transit)** – Newly reinvigorated emphasis on cross border coordination with teams who cover border areas expected to coordinate coverage and meet in the field to ensure settlements or households are not missed. Transit teams strengthened with better micro-plans that allow for greater supervision. Teams expected to cover markets, busy transit or bus stops, hospitals, large medical centres and water points. Evening teams being used at busiest points where children can be found: evening markets, hospitals and evening koranic schools.
- **Permanent Polio Teams in High Threat Settings** – Under discussion. Nigerian programme looking to rapidly learn from Afghanistan experience and deploy in areas where security threats are greatest or where access is hindered from terrorist activities.

Social Mobilization for Community Demand

- Intensifying Community Engagement
 - Intensified Ward Communication Strategy
 - Volunteer Community Mobilizer network/Other Partnerships

- Engagement of traditional/Religious leaders
- Sustaining high level commitment
- Increasing awareness & demand for immunization
- Building capacity at State/LGA level
- Measuring what we do
- Significant scale up of community engagement approaches
 - Launch of Tsangaya 'koranic' school project
 - Integrated Ward Communication Strategy & Volunteer Community Mobilizer Network
 - Focused & increased engagement of traditional/Religious Leaders
- Expanded Human Resource capacity
 - Volunteer Community Mobilizers
 - LGA/state communication consultants
- Training & capacity development
- Abuja commitments with more focus on LGA

Surge for worst-performing areas

- Delivery of surge (>3900 staff) focused on most under-performing LGAs
- Short-term support of Surveillance Medical Officers from the India programme

PAKISTAN (to be completed)

Leadership for a whole of government/ society approach

- Key national cross-sectoral leads reporting to PM
- Head of state has appointed single focal person
- Single focal person per province

Oversight of Programme and Partner Performance

- Prime Minister's Cell for Polio Eradication established and maintained through change of PM.
- Domestic contributions: 3-year financing from the Islamic Development Bank (US\$ 227 million)
- District Commissioners and UC Medical Officers now held responsible for overall implementation as outlined in Augmented National Emergency Action Plan launched.
- Accountability and management training for nation and provincial staff and frontline workers.
- Regular use of LQAS to complement other campaign monitoring techniques and cross-check against epidemiology.
- Real time reporting of preparedness indicators (300+ staff in districts and UCs).

Microplanning for Missed Children

- working with UN country team to ensure vaccination in camps for internally displaced and refugees, vaccination at transit points, etc.
- Access: working across sectors – military, political, administration, civil society - to help reach children in areas of insecurity.
- Regular cross-border planning and activities with Afghanistan.

- Expansion of age group and increased use of SIADs in newly-accessible areas or displaced and high-risk population groups in sanctuary areas.

Vaccination Teams to Institutionalize Best Practice

- Direct payment mechanism: to motivate frontline workers as well as ensure transparency and accountability. Requires use of ID cards, thus ensuring workers are minimum age.
- Joint SOPs on operational and comms workers

Social Mobilization for Community Demand

- Deployment of CommNet
- Consultation of national experts on FATA access issues and creative solutions

Surge for worst-performing areas

- Delivery of surge in technical assistance (>900): Union Council level polio workers and social mobilization network. Surge prioritized to clearly identified, worst-performing districts and UCs.
- Government appointed medical officers in high-risk UCs

AFGHANISTAN (to be completed)

Leadership for a whole of government/ society approach

- Inter-ministerial task force established.
- Head of state has appointed single focal person.

Oversight of Programme and Partner Performance

- Presidential action: signed Emergency Action Plan.
- District EPI Management Teams trained and active in the 13 high-risk districts
- Increased technical support to high-risk districts, including full-time District Polio Managers.
- Focus on management training to overcome administrative and managerial obstacles.

Microplanning for Missed Children

- Delivery of increased technical assistance (34)
- Improved access in Southern Region: through negotiation with parties in conflict and community leaders, special fixed site vax teams, religious leaders' support.
- Regular cross-border planning and activities with Pakistan.

Vaccination Teams to Institutionalize Best Practice

- Permanent polio teams in 8 of 13 high-risk districts.

Social Mobilization for Community Demand

- New communication strategy rolled out in September: 'Polio eradication is MY responsibility' theme, based on the role of different parts of society in eradication.