

Objective 2: Immunization systems strengthening and OPV withdrawal

IMMUNIZATION SYSTEMS STRENGTHENING & OPV WITHDRAWAL		
Main Objectives	Outcome Indicators	Major Activities
Strengthen immunization services in “focus countries”, introduce IPV and withdraw OPV2 globally	<p>OPV type 2 withdrawn globally by end-2016</p> <p>At least 10% annual increase in DTP3 coverage achieved in 80% of high-risk districts of all focus countries from 2014 to 2018</p>	<p>1. Increasing immunization coverage</p> <p>2. Ensuring appropriate IPV, bOPV and mOPV products</p> <p>3. Introducing IPV</p>
Monitored by the SAGE		

6.1 INTRODUCTION

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

High immunization coverage is essential to achieving the goals of the polio endgame. In this Plan, the GPEI commits to working with immunization partners to strengthen immunization systems.

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

A strong foundation exists for the GPEI to rapidly align with broader efforts to strengthen immunization systems.

6.3 A strong foundation exists for the GPEI to rapidly align with broader efforts to strengthen immunization systems. At a strategic level, polio eradication is a key objective under the GVAP, the framework approved by the World Health Assembly in May 2012 for achieving the Decade of Vaccines vision by delivering universal access to immunization.¹⁹ At an operational level, at least some activities supporting eradication have been part of immunization programmes in all countries, and polio-funded workers already contribute to broader immunization activities, albeit at widely varying levels across countries. This forms the basis for the GPEI's more focused and strategic alignment

¹⁹ Information on the Decade of Vaccines collaboration is available at http://www.who.int/immunization/newsroom/press/decade_of_vaccines_commitment_every_woman_child_october_2012/en/index.html.

with the goals of the GVAP and the GAVI Alliance during the 2013-2018 period. Polio eradication and immunization managers will work together to realize programmatic synergies in support of national plans and strategies.

6.4 The importance of enhancing immunization coverage against polio is reflected in the fact that in 2012 more countries reported outbreaks caused by a cVDPV than a WPV. A number of countries with persistently low immunization coverage have experienced repeated cVDPV emergencies, often resulting in prolonged outbreaks.

6.5 To minimize the immediate and long-term risks of polio, the essential elements of the polio endgame therefore include strengthening immunization coverage and changing the polio vaccines used in both routine and supplementary immunization activities. In May 2008, in line with guidance from the SAGE, the World Health Assembly endorsed the principle of synchronized OPV cessation globally. Recognizing that WPV2 was eradicated in 1999 and that more than 90% of the cVDPV cases in recent years were caused by the vaccine-derived type 2 strain, in 2012 the SAGE further recommended the withdrawal of OPV2 as the first step towards complete withdrawal of all oral polio vaccines. In November 2012, the SAGE recommended that all countries introduce at least one dose of IPV in their routine immunization programme to mitigate the risks associated with the withdrawal of OPV2.

The GPEI will systematically use its infrastructure to more effectively strengthen immunization systems.

6.2 THE GOAL

6.6 Objective 2 aims to systematically use the GPEI infrastructure to more effectively strengthen immunization services, particularly in a set of “focus countries”, thereby contributing to broader global immunization targets, facilitating the introduction and increased impact of IPV, and reducing the risks of cVDPV emergence before, during and after the withdrawal of OPV serotypes from

immunization programmes globally. The key milestones on this objective’s path include the achievement of at least a 10% year-on-year increase in diphtheria–tetanus–pertussis vaccine third dose (DTP3) coverage in the majority of worst-performing districts in focus countries from 2014, the introduction of at least one dose of IPV in all OPV-using countries in 2015 and the withdrawal of OPV2 globally in 2016.

6.3 WHAT IS REQUIRED?

6.7 To introduce IPV and replace tOPV with bOPV (types 1 and 3) globally, the GPEI and immunization partners will assist the 145 countries that currently use tOPV in their immunization programmes, while giving particular attention to improving immunization coverage in a number of focus countries that harbour the greatest number of unimmunized children and where the risk of cVDPV emergence and persistence is often greatest. In focus countries, it is likely to require polio-funded and other immunization staff to work together to find new ways of collaborating and define how to join forces most efficiently in support of national plans.

6.4 WHAT WILL BE DONE?

Major activities

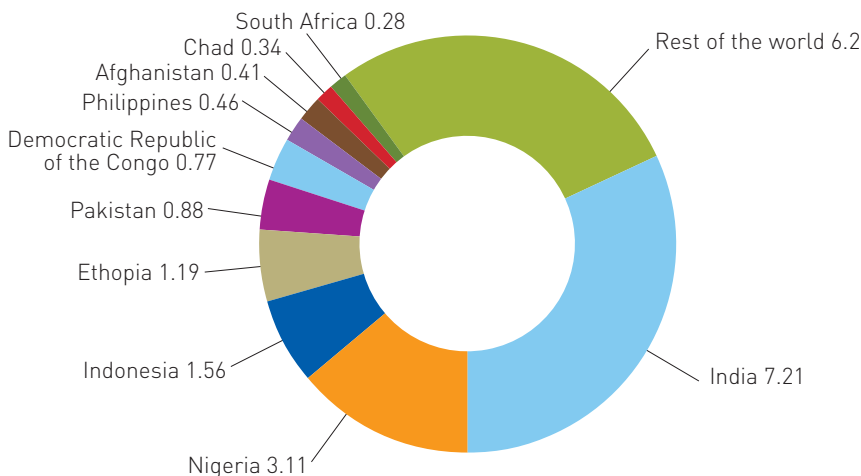
1. Increasing immunization coverage
2. Ensuring appropriate IPV, bOPV and mOPV products
3. Introducing IPV
4. Withdrawing OPV from routine and supplementary immunization activities

Activity 1: Increasing immunization coverage

6.8 Increasing immunization coverage will have several direct benefits for polio eradication efforts, including minimizing the risk, rate and extent of polio outbreaks; helping to control polio transmission if there are delays in eradication in the remaining endemic areas; reducing the emergence of VDPVs; and, increasing the impact of IPV and bOPV following withdrawal of OPV2.

6.9 Geographically, the GPEI is best positioned to assist with immunization systems strengthening in those countries where it has deployed the most significant number of staff at the subnational level, as part of the intensified global eradication effort. Because persistent polio transmission has correlated closely with weak immunization services, these same countries contain most of the world's under-vaccinated children (Figure 14). The majority of these countries have already been identified as priorities for targeted support based on a low national level of immunization coverage (DTP3<70%) by GAVI, WHO and UNICEF. These focus countries for the GPEI's intensified attention to immunization systems strengthening include Afghanistan, Chad, the Democratic Republic of the Congo, Ethiopia, India, Nigeria, Pakistan, Somalia and South Sudan as well as Angola. Of these countries, all but Ethiopia, India and Angola are also identified under GAVI's policy for fragile states that allows for support more closely tailored to a country's situation.

Figure 14: 22.4 million under-immunized or unimmunized children worldwide in 2011



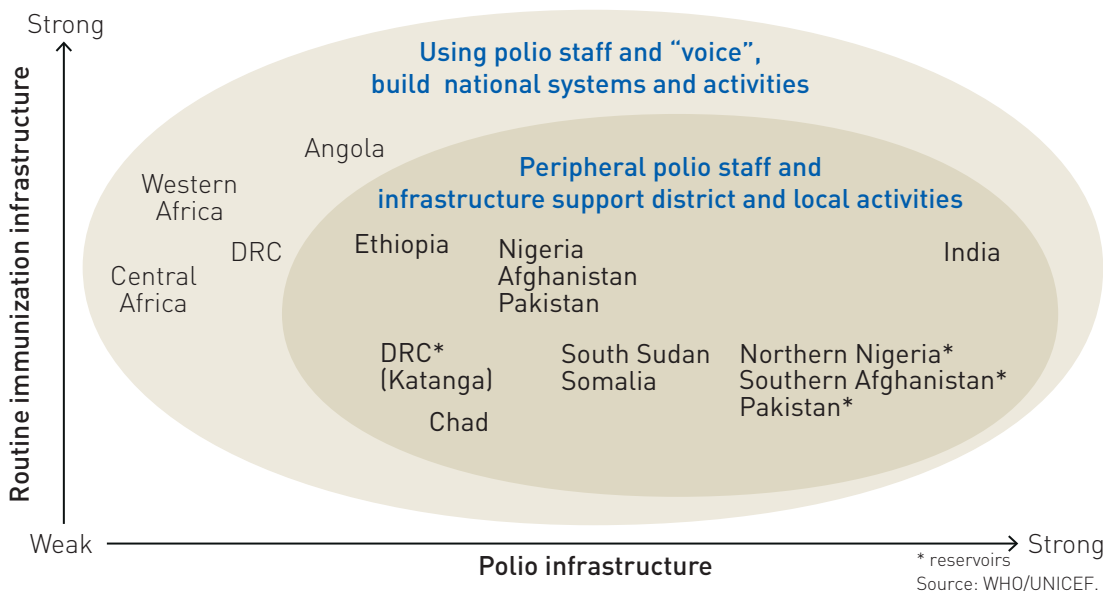
Sources: WHO/UNICEF coverage estimates 2011 revision, 25 July 2012; Immunization Vaccines and Biologicals (IVB); World Health Organization, 194 WHO Member States.

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

- programme management and accountability
- human resource capacity and supervision
- programme monitoring, vaccine-preventable disease surveillance and data use
- vaccine management, supply and cold chain
- communications, health education and social mobilization
- political support, funding and advocacy.

6.11 A coordinated approach will be developed between the GPEI, GAVI Alliance and other immunization partners to support national authorities in pursuing revitalized and focused immunization strategies to increase coverage in these countries (Figure 15). The goal in these focus countries is to contribute to at least a 10% year-on-year improvement in DTP3 coverage rates in the worst-performing high-risk districts for polio from 2014. The progress will be monitored through regular programme evaluations and rapid surveys to assess coverage.

Figure 15: Countries with weak routine immunization systems and strong GPEI presence



GPEI staff will focus on immunization strengthening across four activity areas:

- Management
- Microplanning
- Mobilization
- Monitoring

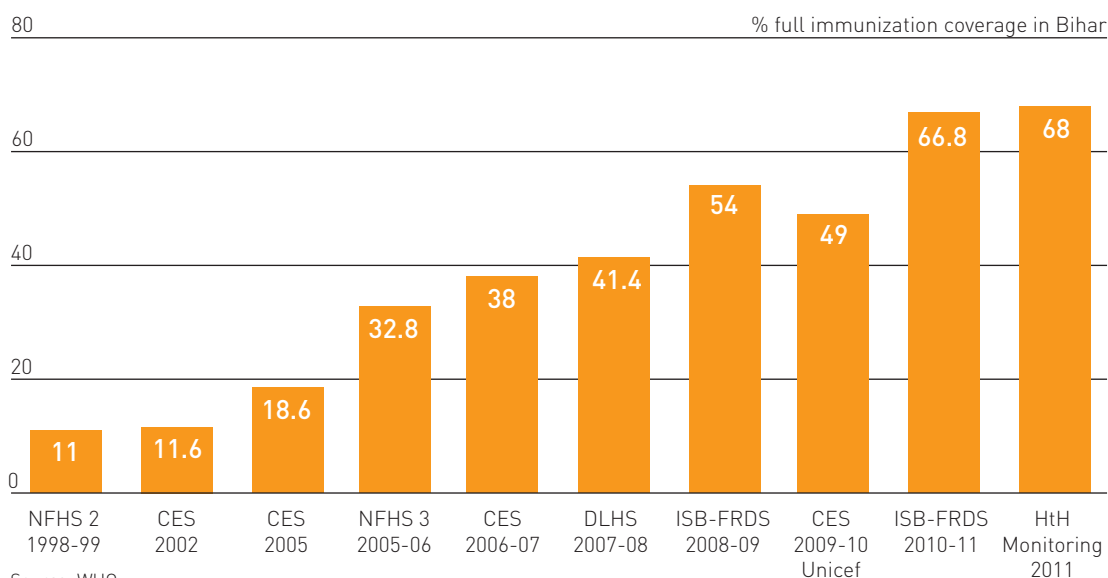
6.12 The first step in the focus countries will be for the GPEI, GAVI and other immunization partners to support the respective national authorities to develop annual integrated action plans for strengthening immunization services. Details will be elaborated and a workplan with milestones and deadlines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

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

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

6.13 The impact of such GPEI activities on immunization coverage rates, when combined with political commitment and the support of local authorities, is best illustrated by the experience in the state of Bihar, India (Figure 16), where during the period of the most intense polio eradication activities, assessed coverage for fully immunized children increased from around 30% to nearly 70%. In the 41 most challenging, high-risk blocks (subdistrict unit) in which the polio programme resources were most focused, full immunization coverage rose even higher than the state average.

Figure 16: Immunization coverage in Bihar, India, 1998-2011



Source: WHO.

NFHS: National Family Health Survey

CES: Coverage Evaluation Survey

DLHS: District Level Household and Facility Survey

ISB-FRDS: Immunization Survey-Bihar, Formative Research and Development Service

HtH Monitoring: House to House Monitoring

6.14 In Africa, the GPEI currently funds 90% of the over 1000 personnel associated with WHO regional offices for Africa's Immunization and Vaccine Development (IVD) effort. A full 53% of IVD staff time is already spent working on multiple diseases, while only 47% is spent on polio alone. Many of these IVD staff are now deeply involved in activities that directly support immunization systems, performing roles and activities that range from implementing the Reaching Every District (RED) strategy to providing supportive planning and contributing to the development of GAVI applications for health systems strengthening support.

6.15 GPEI contributions to the focus country initiatives to strengthen immunization systems will be supported and coordinated at the international level by the GPEI's spearheading partners (WHO, Rotary International, CDC and UNICEF) and the BMGF. Of these organizations, WHO, UNICEF, CDC and the BMGF all have dedicated staff supporting immunization systems strengthening at the country level, while Rotary International contributes to immunization as a key part of its PolioPlus Programme. The GAVI Secretariat will assist coordination with Alliance members, also reinforcing GPEI and GAVI support behind a unified effort at the country level. Increasing collaboration on immunization across these organizations, as well as with GAVI, is fundamental to the Plan.

In December 2012, the GAVI Alliance Board committed to working with the GPEI on immunization systems strengthening.

6.16 In December 2012, the GAVI Alliance Board committed to working with the GPEI on immunization systems strengthening, stating that it "approved GAVI playing a complementary role to the GPEI in the polio eradication effort, specifically through routine immunization within GAVI's strategy and mission using existing structures, processes and procedures". The GAVI Board also "approved GAVI exploring the suitability and possible use of IFFIm [Innovative Financing Facility for Immunization] as one potential financing mechanism, to support this activity within GAVI's strategy and mission using existing structures, processes and procedures"²⁰. Following this decision, GPEI partners and GAVI initiated work to strengthen complementary approaches in their support for focus countries. This support will be reflected in national workplans that will be finalized in 2013.

6.17 To drive planning for increased GPEI support to immunization systems strengthening, the polio programme has identified key activities within each of the above-mentioned programme areas (Table 6) for further consolidated in 2013. To support these activities, the target is that by the end of 2014, at least 50% of polio-funded field personnel's time will be devoted to specific, measurable activities to help national authorities strengthen immunization systems and services.

²⁰ See GAVI Alliance Board Meeting 4-5 December 2012 Final Minutes. Available at <http://www.gavialliance.org/library/minutes/searchtext/board%20decisions/>.

Table 6: Select activities across key immunization focus areas

Management
<ul style="list-style-type: none"> • GPEI field workers: Updating of terms of reference for staff in polio-endemic countries to incorporate key measurable activities to support routine immunization strengthening; staff will support governments to monitor fixed and outreach immunization sessions, track vaccine supply/availability, support health-worker training, develop mechanisms to identify children not immunized through routine immunization while in households during supervisory visits and monitoring SIAs (especially newborns), and drive community demand for and engagement with routine immunization • Performance improvement through supportive supervision and in-service training: Improvement of the core competencies of district and subdistrict immunization managers and health workers • Supply systems (in particular cold chain): More regularly collected and tracked vaccine management data to identify supply issues (including stock-outs, wastage) and rapid corrective action; training rolled out where necessary to educate providers on proper handling, usage and disposal of vaccines and consumables
Microplanning
<ul style="list-style-type: none"> • Harmonization of routine immunization microplans with polio microplans: Local-level coordination on microplans to deliver greater detail on hard-to-reach populations and settlements for routine immunization outreach services • New tools: Expansion of the use of GIS and GPS tools to improve microplanning and monitoring for polio in Nigeria for use in routine immunization programmes • RED approach: Application of the best practices from the Reaching Every District (and Community) approach to local programme planning
Mobilization
<ul style="list-style-type: none"> • Community engagement: GPEI support of government partners/community organizations/ non-governmental organizations (NGOs) to use existing polio channels and best practices to mobilize and engage communities for immunization • Evidence-based social mobilization: Social mobilization and communications tailored to local barriers to routine immunization, based on monitoring data obtained locally
Monitoring
<ul style="list-style-type: none"> • Systematic monitoring: Monitoring of immunization sessions, availability of immunization staff, logistics, vaccines and cold chain and rapid assessments of local community coverage and reasons for under-vaccination • Performance indicators: Rationalized, standardized and widely used by programme managers and development partners, to improve immunization programme performance • New tools: Developed and field-tested for improving the ability to verify immunization status and confirm coverage data • Record quality: Identification of mechanisms for increased retention and improved design of home-based and clinic immunization records • Local and global data systems: Developed with initial deployment of improved immunization information systems in focus countries • Stronger focus on data quality: Expertise shared in data quality and use, including home-based records, survey methodologies, and assisting countries with information system transitions • VPD surveillance: Assistance with further expansion of surveillance for vaccine-preventable diseases to monitor disease control and changing epidemiology and to guide programme actions

Activity 2: Ensuring appropriate IPV, bOPV and mOPV products

6.18 As progress towards WPV eradication accelerated in the late 1990s, a new risk to a polio-free world became apparent. In rare cases in areas with extensive immunity gaps, VDPVs were able to mutate to the extent that they acquired characteristics of WPV. These VDPVs – especially type 2 – are causing cVDPV outbreaks, which are associated with permanent paralysis, including bulbar polio, and death, similar to WPV outbreaks. More rarely, VDPVs have been shown to persist for years in some individuals with primary immunodeficiency syndromes.

Addressing the risks of vaccine-derived polioviruses requires stopping all use of oral poliovirus vaccines (OPV) globally through a switch from tOPV to bOPV.

6.19 By 2005, expert polio eradication and immunization advisory bodies concluded that addressing these risks in a comprehensive manner and eliminating all paralytic polio disease would ultimately require stopping all use of OPV globally as part of the polio eradication endgame.²¹

6.20 Currently 145 countries use tOPV to vaccinate children against polio in their routine immunization programmes. The tOPV contains the poliovirus type 1, 2 and 3 serotypes. The use of this vaccine led to the successful eradication of WPV2 in 1999. At the end of 2012, 90% of cVDPV cases were being caused by viruses derived from the type 2 component of the OPV. In 2012, five polio outbreaks due to cVDPV type 2 were detected, in Afghanistan, Chad, the Democratic Republic of the Congo, Kenya, Nigeria, Pakistan and Somalia (the outbreaks in Nigeria and Somalia represent ongoing transmission for longer than 36 months). Given this and the long-term risks of VAPP and iVDPVs, the use of specific OPV serotypes will be phased out globally from all immunization activities and programmes, beginning with the withdrawal of OPV2 and the replacement of all tOPV with bOPV (types 1 and 3) in global routine immunization programmes by mid-2016.

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

- prevent paralytic polio in individuals exposed to a cVDPV type 2 or WPV2;
- improve the immunological response to mOPV type 2 if required to be given in response to a WPV2 or cVDPV2 outbreak after tOPV cessation;
- reduce transmission of cVDPV type 2 or WPV2 should either be introduced after tOPV cessation;
- boost immunity to WPV1 and WPV3 in vaccine recipients, which may further accelerate WPV eradication.

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

²¹ Resolution WHA61.1, “Polio myelitis: mechanism for management of potential risks to eradication”.



WHO/Bachir Chaibou

Polio eradication expertise and capacity will contribute to stronger immunization systems through support specific areas such as management of programmes and vaccine supply.

- the licensing of intradermal fractional (one fifth) dose IPV;
- the development of new, adjuvanted and antigen-sparing intramuscular IPV products.²²

6.23 Given that countries may have a preference for either the intradermal or the adjuvanted intramuscular IPV option and that insufficient evidence exists at this time to recommend one approach over the other, both options are being pursued. At the start of 2013, both options faced regulatory and/or development challenges. It may be possible to address these challenges in the near term (24 to 48 months) through active engagement with manufacturers and national regulatory authorities; with intensive support from the international community; through the development of a multi-dose policy for IPV; and with rapid mapping of regulatory pathways.

6.24 Recognizing that the development of new, low-cost IPV options may not meet the timeline for a “tOPV-bOPV switch”, the GPEI is working with manufacturers and other stakeholders to develop a strategy by the end of 2013 to allow the introduction of IPV in low- and low-middle-income countries using existing products at substantially reduced prices, with a transition to lower-cost products as they become available. The GAVI Alliance will consider supporting IPV in eligible countries as part of its Vaccine Investment Strategy by the end of 2013. In addition, by 2018 options should be available to safely produce IPV in developing-country settings (e.g. Sabin-IPV) to ensure all countries have the opportunity to produce IPV for their immunization programmes.²³

²² Resik S et al. in the Cuba study, *Journal of Infectious Diseases*, 2010, demonstrated that one fractional dose (one fifth or a full dose) after multiple OPV doses may be sufficient to establish immunity base (seroconversion and priming). See Resik S et al. Randomized controlled clinical trial of fractional doses of inactivated poliovirus vaccine administered intradermally by needle-free device in Cuba. *Journal of Infectious Diseases*, 2010, 201 (9):1344-1352.

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



WHO/Thomas Moran

As countries prepare for IPV introduction, they will need to put a particular focus on training frontline health workers.

6.25 The recent availability (since 2009) and proven efficacy of bOPV against the remaining WPV1 and WPV3 serotypes are central to the OPV2 withdrawal strategy. A sufficient and secure international supply of this product for an eventual tOPV-bOPV switch will be available by early 2015 for countries procuring WHO prequalified OPV. Those countries that currently rely on national OPV production will need to develop and license a bOPV by the end of 2015. The GPEI will prioritize its work with manufacturers in these countries to ensure that all have sufficient access to bOPV in advance of OPV2 withdrawal.

6.26 Following the tOPV-bOPV switch, bOPV will be the vaccine of choice for responding to all WPV1 or WPV3 outbreaks and mOPV type 2 will be the vaccine of choice for responding to any cVDPV type 2 outbreak or a WPV2 release from a laboratory or production facility. A stockpile of 500 million doses of mOPV type 2 as bulk will be available by the end of 2015 for this purpose. After the tOPV-bOPV switch, the GPEI will ensure rapid access to stand-alone IPV (up to 10 million doses) for countries and areas contiguous with, but outside the area of, an outbreak to rapidly reinforce population immunity. Ideally, this can be achieved through the careful management of the global IPV buffer stock. The detection of an ambiguous vaccine-derived poliovirus (aVDPV) type 2 may trigger a pre-emptive IPV response in the immediate area.²⁴

6.27 Following bOPV cessation (by the target date of 2019), a combination of mOPVs and IPV will be used to respond to any WPV or VDPV outbreak, regardless of serotype. An international stockpile of 300 million doses of both mOPV type 1 and mOPV type 3 will be established by the end of 2017 for this purpose.

²⁴ aVDPVs are vaccine-derived polioviruses that are either isolated from people with no known immunodeficiency, or isolated from sewage whose ultimate source is unknown.

All countries should introduce at least one dose of IPV into their routine immunization schedules.

Activity 3: Introducing IPV

6.28 To boost population immunity against type 2 polioviruses prior to OPV2 cessation and to maintain a polio type 2-primed/protected population thereafter, the SAGE recommended in November 2012 that all countries introduce at least one dose of IPV into their routine immunization programmes. As summarized above, this will help maintain population immunity against type 2 polioviruses, improve the response to mOPV type 2 or an additional dose of IPV in a type 2 polio outbreak, reduce the transmission of a reintroduced type 2 poliovirus and thereby substantially reduce the consequences of a subsequent circulating poliovirus – in terms of paralytic disease – and facilitate the containment of outbreaks.²⁵ Evidence demonstrates that this could also accelerate WPV eradication by boosting immunity to WPV1 and WPV3. For countries at particular risk of cVDPV emergence, this approach may need to be complemented with additional measures, such as pre-cessation tOPV campaigns to boost immunity or the introduction of two routine IPV doses. Recognizing that the risks associated with eventual bOPV cessation may be similar to those associated with OPV2 cessation, it is recommended that countries plan to continue administering at least one dose of IPV in their immunization programmes for at least five years after bOPV cessation.

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

6.30 The introduction of IPV in routine immunization will require intensive outreach to caregivers and providers. Communications strategies will depend on the nature of the OPV phase-out and IPV introduction and will be determined based on the acceptance of immunization, the presence of political opposition or anti-vaccine lobbies, and the operational approaches to including IPV in the schedule while OPV is still being offered. A clear rationale for OPV and IPV administration will be provided to the media, medical institutions and religious, traditional and political leaders. Public communication to caregivers will focus on the success of polio eradication, which opens the door for the provision of new vaccines such as IPV to complete the existing polio programme. Advocacy among technical experts for public support and endorsement of IPV and OPV will be critical in this area.

The GPEI partners, particularly WHO and UNICEF, in conjunction with the GAVI Alliance and other immunization partners, will help countries prepare for the introduction of IPV.

²⁵ Sutter RW, Kew OM, Cochi SL, Aylward RB. Poliovirus Vaccine–Live. In: Plotkin SA, Orenstein WA, eds. *Vaccines*, 6th ed. Philadelphia, PA, W.B. Saunders Company, 2012 (in press); Alexander LN et al. Vaccine policy changes and epidemiology of poliomyelitis in the United States. *Journal of the American Medical Association*, 2004, 292 (14):1696-1701; Estivariz CF et al. Paralytic poliomyelitis associated with Sabin monovalent and bivalent oral polio vaccines in Hungary. *American Journal of Epidemiology*, 2011, 174 (3):316-325. Epub 2011 Jun 17.

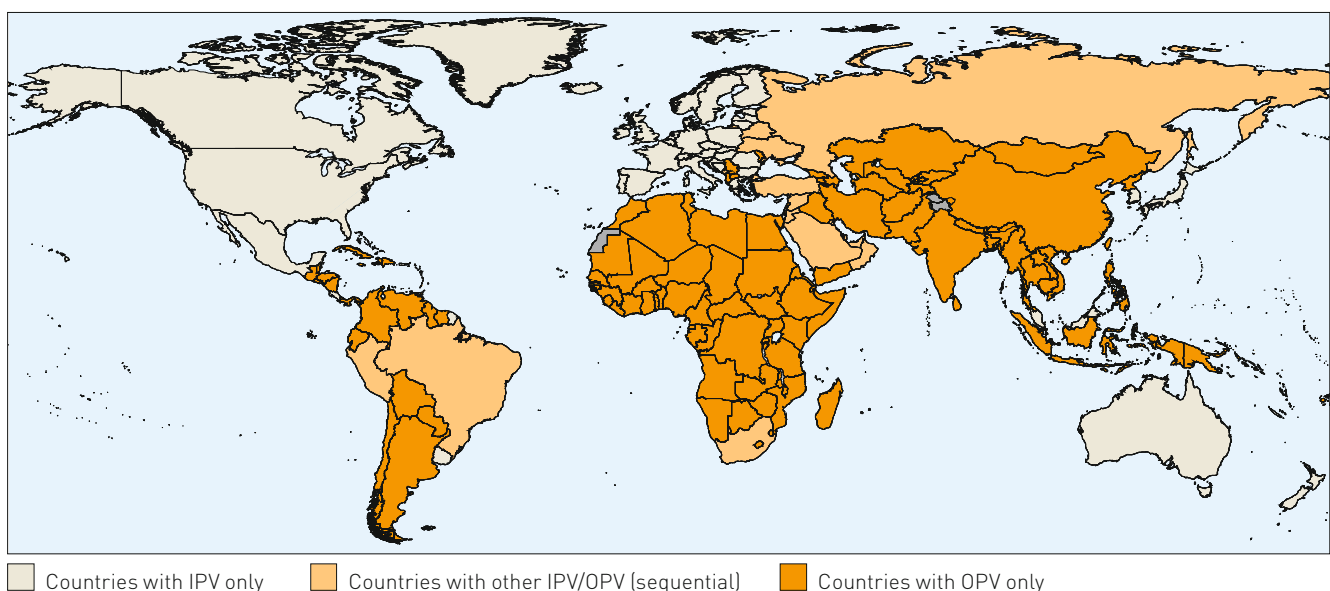
6.31 Given the geographic scope of this vaccine shift, social research will be undertaken in all priority countries to determine acceptability of IPV and, as necessary, develop tailored messages for specific audiences. This work will inform the preparation of nuanced communications that can be delivered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

Activity 4: Withdrawing OPV from routine and supplementary immunization activities

6.32 Prior to the withdrawal of OPV2 – by replacing tOPV with bOPV in all OPV-using countries, six prerequisites must be in place:

1. validation of the elimination of persistent cVDPV type 2 and confirmation of WPV2 eradication;
2. an mOPV type 2 stockpile and response capacity;
3. surveillance capacity and an international notification requirement for all Sabin, Sabin-like and cVDPV type 2 viruses;
4. sufficient bOPV products for all OPV-using countries;
5. affordable IPV option(s) for all OPV-using countries;
6. phase II biocontainment of all cVDPVs type 2 and WPVs.

Figure 17: Countries using oral polio vaccine, April 2013



6.33 In addition to these prerequisites, achieving the global withdrawal of OPV2 will require meeting a combination of logistical, communications, vaccine-supply and programmatic challenges. Substantial logistical challenges must be addressed to synchronously switch all 145 OPV-using countries (Figure 17) from tOPV to bOPV, withdraw the tOPV field stocks, and safely destroy or contain residual type 2 Sabin vaccine viruses.

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

- the complete cessation of use of all tOPV globally must occur by a fixed date;
- cessation should be coordinated across all countries using tOPV;
- all remaining stocks of tOPV at the time of cessation must be collected and destroyed;
- the process must be documented.

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

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

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

- ensuring that the last shipments of tOPV to the national and subnational levels are closely managed during six months, before the agreed target date for cessation;
- conducting national stocktakes of vaccine at all levels six months as well as one to two months prior to cessation and one month after cessation;
- designating secure collection points for tOPV, which will accept vaccine from one month prior to one month after cessation of use.

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

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A comprehensive communications strategy for caregivers and patients will accompany the introduction of IPV and withdrawal of OPV2.

6.35 A comprehensive communications strategy for caregivers and parents whose children will receive the new vaccine schedule and training of the health workers who will implement it will accompany this logistical work. IPV introduction has been successful in all countries that have made the switch, often with little or no public outreach regarding the change. Research on the social acceptance of

IPV from western Uttar Pradesh and Bihar, India suggests that IPV will be accepted if communities are clearly informed of the reason for the transition and receive assurances of IPV safety and effectiveness. However, the reaction to IPV introduction coupled with a switch to bOPV requires more social research, especially in communities where trust in OPV or immunization is generally weak. A clear rationale for OPV and IPV administration will be provided to caregivers, and the switch will be communicated as an improvement and acceleration of the existing polio programme and not as a move to resolve any type of vaccine failure. Communications efforts will engage social mobilizer networks, credible community and religious leaders, and mass promotion in print, radio, television and new media.

Following the global certification of total WPV serotype eradication, bOPV will be withdrawn from routine use worldwide, ensuring the elimination of all polioviruses.

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

6.5 WHO OVERSEES THIS WORK?

The Strategic Advisory Group of Experts on Immunization

6.37 Activities under Objective 2 are overseen by the Strategic Advisory Group of Experts on Immunization (SAGE).