

P O L I O

**ENVIRONMENTAL
SURVEILLANCE
EXPANSION PLAN**

Global Expansion Plan under
the Endgame Strategy 2013-2018

April 2015



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Design by Paprika (Annecy, France)

Printed by the WHO Document Production Services, Geneva, Switzerland

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ACRONYMS

AFP	Acute flaccid paralysis
bOPV	Bivalent oral polio vaccine
cVDPV	Circulating vaccine-derived poliovirus
cVDPV2	Circulating vaccine-derived poliovirus type 2
DTP3	Diphtheria–tetanus–pertussis vaccine third dose
ES	Environmental surveillance
GPEI	Global Polio Eradication Initiative
GPLN	Global Poliovirus Laboratory Network
IPV	Inactivated polio vaccine
NPL	National polio laboratory
OPV	Oral poliovirus vaccine
OPV2	Oral polio vaccine type 2
tOPV	Trivalent oral poliovirus vaccine
VDPV	Vaccine-derived poliovirus
VDPV2	Vaccine-derived poliovirus type 2
WPV	Wild poliovirus

CONTENTS

Acronyms	IV
1. Overview	1
1.1 Introduction	1
1.2 Scope of this document.....	1
1.3 Relationship to the Polio Eradication & Endgame Strategic Plan's objectives and timelines	2
1.4 Current Status of ES	2
2. Priorities for expansion	4
2.1 Detection of WPV and cVDPV emergence from 2014 to 2016	4
2.1.1 Country selection.....	4
2.1.2 Area selection within a country	5
2.1.3 Endemic and reinfected countries.....	5
2.1.3.1 Expansion in 2014	5
2.1.3.2 Expansion in 2015/2016.....	5
2.1.3.3 Deliverables and timelines in 2015/2016	6
2.1.4 Polio-free regions.....	7
2.1.5 Contingency planning for high-priority countries, districts or population groups	7
2.2 Expansion of ES to monitor the effectiveness of containment from 2016 to 2018.....	8
3. Further considerations.....	9
3.1 Site selection for ES	9
3.2 Increasing ES effectiveness within the GPEI.....	9
3.3 Key partners and their roles	10
3.4 Building laboratory capacity to support the expansion of ES for polioviruses	10
3.4.1 Importation and high-risk countries.....	10
3.4.2 Poliovirus repository laboratories and manufacturers' production sites.....	10
3.5 Resource needs	11
3.6 Legacy.....	11
ANNEX A. ES for polioviruses – status in early 2014 and future expansion.....	12
ANNEX B. Containment safeguards.....	13

1. OVERVIEW

1.1 Introduction

Environmental surveillance (ES) for programmatically relevant polioviruses has been used for many years to supplement acute flaccid paralysis (AFP) surveillance. ES has played a key role in documenting the elimination of wild poliovirus (WPV) in Egypt and India, and in detecting WPV or vaccine-derived polioviruses (VDPVs) in several polio-free countries, such as Brazil, China, Egypt, Estonia, Finland, Israel and Mexico.

The *Polio Eradication & Endgame Strategic Plan 2013-2018* (the Plan),¹ developed by the Global Polio Eradication Initiative (GPEI) in response to a directive of the World Health Assembly and in consultation with national health authorities, global health initiatives, scientific experts, donors and other stakeholders, is a comprehensive, long-term strategy that addresses what is needed to deliver a polio-free world by 2018. The Plan has four objectives:

1. detect and interrupt all poliovirus transmission – stopping all WPV transmission by the end of 2014 and new outbreaks of circulating vaccine-derived poliovirus (cVDPV) within 120 days of confirmation of the first case;
2. strengthen immunization systems and withdraw oral poliovirus vaccine (OPV) – beginning with the withdrawal of the type 2 component of trivalent oral poliovirus vaccine (tOPV);
3. contain poliovirus and certify interruption of transmission – certifying polio eradication in all regions of the world and ensuring that all poliovirus stocks are safely contained by 2018;
4. plan polio's legacy – ensuring a permanently polio-free world and that the investment in polio eradication provides public-health dividends for years to come.

The Plan calls for ES enhancement and expansion to help identify any residual transmission in endemic areas and to provide early indications of new importations or emergence of VDPV. Expansion will consist of establishing additional sites in high-risk areas along routes of WPV importation and in selected areas where low immunization coverage places populations at particular risk of a VDPV emergence. ES will assist in documenting the elimination of Sabin viruses following the withdrawal of oral polio vaccine type 2 (OPV2) from tOPV, and the eventual cessation of all live poliovirus vaccine use.

Consequently, environmental sampling sites in at least 15-20 additional cities and locations will be added globally, prior to the planned withdrawal of OPV2, which is expected to occur at the earliest in 2016. With global eradication approaching, data from systematic ES is anticipated to provide important supportive documentation for certifying polio's eradication.

1.2 Scope of this document

While ES for polioviruses has been implemented in many countries for a variety of reasons, this document is intended to plan the expansion needed to support polio eradication and long-term global risk management. Specifically, the purpose of expansion is to:

help identify any residual transmission in endemic and reinfected areas;

provide early indication of new poliovirus importation;

ensure early detection of any new emergence of VDPV, and document the elimination of Sabin viruses following the withdrawal of OPV2 and eventual cessation of all OPV.

The strategy outlined in this document supplements the *Guidelines on Environmental Surveillance for Detection of Polioviruses*.²

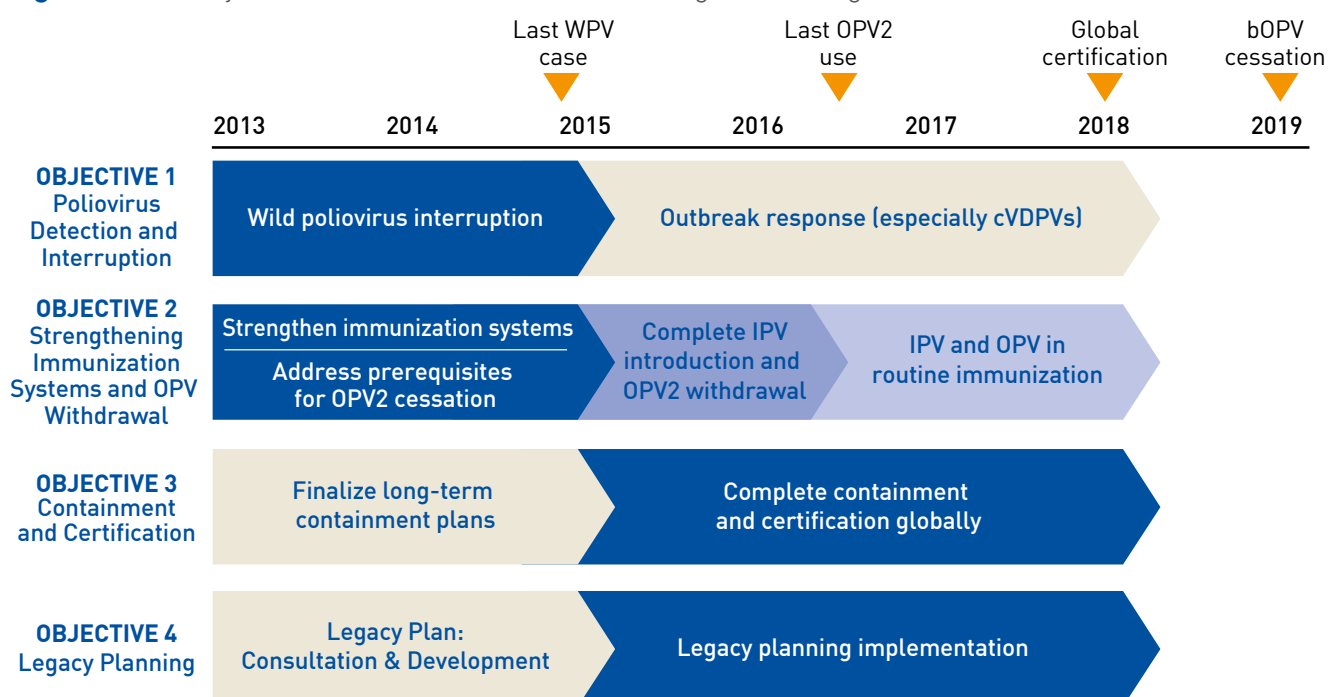
¹ The *Polio Eradication & Endgame Strategic Plan 2013-2018* (WHO/POLIO/13.02). Available at <http://www.polioeradication.org/resourceLibrary/strategyandwork.aspx>.

² Available at <http://www.polioeradication.org/ResourceLibrary/GPLNpublications.aspx>.

1.3 Relationship to the Polio Eradication & Endgame Strategic Plan's objectives and timelines

The timelines for the four objectives of the Plan are represented in Figure 1:

Figure 1: Four objectives of the Polio Eradication & Endgame Strategic Plan



ES supports objectives 1, 2 and 3:

- Objective 1: ES will supplement AFP surveillance in the early detection of any circulating poliovirus and in monitoring progress towards interruption of WPV or VDPV transmission in polio-affected countries.
- Objective 2: ES will be important in the early detection of emerging VDPV2 following the withdrawal of OPV2, planned for 2016. It will also play a critical role in providing documentation on the elimination of Sabin-like viruses following the phased withdrawal of OPV2 and OPV types 1 and 3.
- Objective 3: ES will provide supportive documentation to certify polio's eradication, and will monitor the effectiveness of poliovirus type 2 containment in accredited facilities after withdrawal of OPV2.

The Plan targeted the establishment of 10 new environmental sampling sites by 2014 in countries at risk of cVDPV and WPV outbreaks, and another 10 sites in 2015 in countries with national OPV facilities. Consequently, some expansion of ES in endemic and other polio-affected countries occurred in 2013/2014.

1.4 Current Status of ES

ES for poliovirus is already implemented in many locations. The currently active sites, as known by WHO headquarters, are indicated in Table 1, and an illustrative map summarizing ES status compared to future expansion is given in Annex A.

Table 1: Known locations of ES for poliovirus, as of March 2015

WHO region, and country/territory	No. of sites	Description of location
African Region		
Kenya	5	Nairobi
Nigeria	32	Katsina, Kebbi, Kano, Sokoto, Lagos, Kaduna, Borno, FCT/Abuja, Jigawa, Yobe
Region of the Americas		
Brazil	1	Sao Paulo
Eastern Mediterranean Region		
Afghanistan	11	Kandahar, Helmand, Nangarhar, Kabul
Egypt	21	Nationwide
Pakistan	32	Punjab (Multan, Lahore, Faisalabad, Rawalpindi); Sindh (Karachi, Sukkur, Hyderabad, Jacobabad); Khyber Pakhtunkhwa (Peshawar); Balochistan (Quetta, Kabdulah); Islamabad
West Bank and Gaza Strip	18	
European Region		
Israel	18	Nationwide
Azerbaijan, Baltic States, Belarus, Croatia, Finland, Georgia, Italy, Kazakhstan, Kyrgyzstan, Netherlands, Republic of Moldova, Russian Federation, Turkey, Ukraine	n/a	Various
South-East Asia Region		
India	6 states	Maharashtra (Mumbai); Delhi; Bihar (Patna); West Bengal (Kolkata); Punjab (Mohali, Amritsar, Patiala and Sangrur); Gujarat (Ahmedabad)
Indonesia	1	Yogyakarta
Western Pacific Region		
Australia	3	New South Wales
China	10	10 provinces
Japan	5	Nationwide
Malaysia	3	3 states

2. PRIORITIES FOR EXPANSION

2.1 Detection of WPV and cVDPV emergence from 2014 to 2016

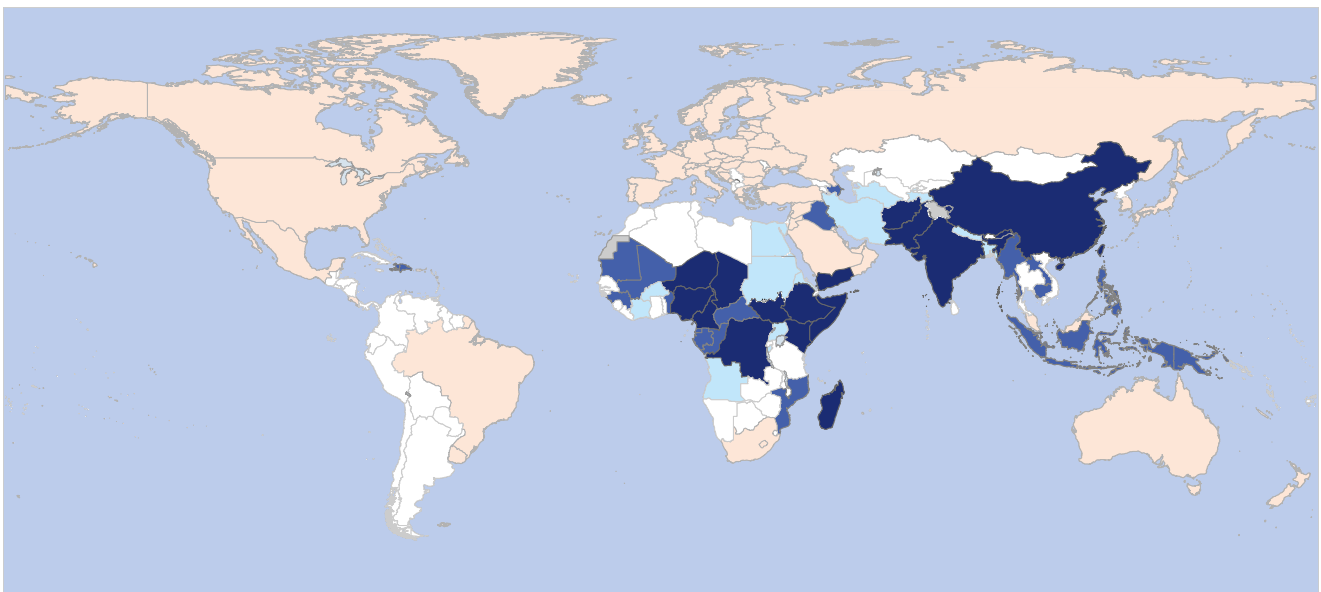
This section describes the immediate priorities for expansion: to monitor both the effectiveness of eradicating WPVs and the emergence and circulation of VDPVs prior to OPV2 withdrawal. Section 2.2 describes further expansion required to monitor the effectiveness of poliovirus containment in essential poliovirus laboratories and vaccine-manufacturing facilities.

2.1.1 Country selection

Consistent with the timeline of the Plan, the priorities for expanding ES are as follows:

- endemic countries;
- countries currently infected by poliovirus;
- countries at high risk of importing poliovirus because of geographical proximity to infected areas or past history of repeated poliovirus importation;
- areas at risk for emergence and circulation of VDPVs (Figure 2).

Figure 2: Country tiers based on risk of emergence and circulation of VDPVs



		# of countries
Tier 1	WPV endemic countries OR countries that have reported a cVDPV2 since 2000	15
Tier 2	Countries who have reported a cVDPV1/cVDPV3 since 2000 OR large/medium sized countries with DTP3 coverage <80% in 2009, 2010, 2011 as per WUNIC	20
Tier 3	Large/medium countries adjacent to Tier 1 countries that reported WPV since 2003 OR countries that have experienced a WPV Importation since 2011	13
Tier 4	All other OPV only using countries	78

2.1.2 Area selection within a country

The criteria for selection of areas or districts within these countries are as follows:

- locations affected by ongoing or recent insecurity;
- locations with extensive population movement to and from poliovirus reservoir or endemic areas – for example, the population from conflict-affected areas in Pakistan;
- locations with a large, so-called floating or underserved population (migrants, nomads, refugees, informal settlements, undocumented guest workers);
- locations hosting mass gatherings of people for commercial, religious or other occasions, especially where women and infants are included;
- locations with suboptimal levels of routine and supplementary vaccine coverage, including known or suspected population immunity gaps such as adults and specific age cohorts that missed vaccination, and groups refusing vaccination on religious, philosophical or other grounds;
- conflict-affected areas where the quality of AFP surveillance is suboptimal and the risk of undetected poliovirus transmission is high.

2.1.3 Endemic and reinfected countries

Applying the criteria from section 2.1.2, countries selected for ES expansion in 2014/2015 are in the two remaining endemic regions: Africa and the Eastern Mediterranean.

2.1.3.1 Expansion in 2014

In 2014, the following activities were undertaken to expand ES:

African Region

Five WHO-accredited poliovirus laboratories were assessed as suitable to carry out testing of environmental samples in the African Region. These laboratories are located in Nigeria, Senegal, Cameroon, South Africa and Kenya, and will support

expanded ES across Africa. Initial assessment and site selection has been completed in Cameroon, which is a high priority because of recurrent poliovirus importations and circulating vaccine-derived poliovirus type 2 (cVDPV2). Nigeria started additional sites in 2014 in high-risk states (Kebbi, Katsina, Jigawa and Yobe).

Elsewhere in the region, Niger is adjacent to poliovirus reservoirs in northern Nigeria and has experienced recurrent poliovirus importations. An initial assessment and site selection have been completed. In Angola, as a regional priority, ES was established in Luanda, with samples concentrated in the national polio laboratory (NPL) and shipped to South Africa for further testing.

Eastern Mediterranean Region

The WHO-accredited poliovirus laboratory in Pakistan has been carrying out testing of environmental samples since 2009. The Kenyan lab will support expanded ES in Somalia, and capacity-building will be undertaken in the Sudanese and Jordanian NPLs. New sites began reporting ES results in both Afghanistan (Helmand, Nangarhar and Kabul provinces) and Pakistan (Jacobabad and Kabdulah).

2.1.3.2 Expansion in 2015/2016

The following countries in the two endemic regions will undertake activities to expand ES in 2015 and the first quarter of 2016:

African Region

- Chad: has a history of multiple emergences and persistent cVDPV2.
- Congo: may be considered as a regional priority.
- Democratic Republic of the Congo: has recurrent WPV importation and a history of emergence and persistent cVDPV2.
- Eastern Mali (Gao) and Burkina Faso: have recurrent WPV importation, as the two countries are on the land routes along which WPV has historically spread to West Africa.

- Madagascar: has recurrent emergences of VDPV, including type 2.

Eastern Mediterranean Region

- Pakistan: may include further expansion into some of the following provinces or districts not currently implementing ES:
 - Federally Administered Tribal Areas: Khyber, Bajour, North and South Waziristan
 - Khyber Pakhtunkhwa: Dera Ismail Khan, Bannu, Mardan
 - Punjab: Rahim Yar Khan, Dera Ghazi Khan
 - Balochistan: Pishin.
- Iraq (Baghdad): is affected by the Middle East polio outbreak and high risk of undetected transmission.
- Yemen: has a history of importation and emergence of cVDPV.
- Somalia (Mogadishu): has recurrent WPV importation and a history of persistent cVDPV2.
- Syria: may be considered if feasible.

2.1.3.3 Deliverables and timelines in 2015/2016

For site selection:

- consult with countries selected for ES expansion (Quarters 1 and 2 [Q1–Q2] 2015) – polio laboratory coordinators and surveillance officers from regional offices supported by WHO headquarters' polio department;
- assess potential sites and develop country or regional implementation plans (Q2–Q3 2015) – polio lab coordinators and surveillance officers from regional offices supported by WHO headquarters' polio department;
- select additional sites (Q2–Q4 2015) – polio lab coordinators and surveillance officers from regional offices supported by WHO headquarters' polio department.

For site establishment:

- conduct training activities to orient sample collectors, surveillance officers and sample-processing laboratory staff (complete by Q4 2015).

With the start of expanded ES (Q2 2015–Q1 2016):

- report, monitor, evaluate and troubleshoot.

Milestones in ES expansion for 11 countries in the 2015/2016 period are covered in Table 2.

Table 2: Milestones in ES expansion in 2015/2016

Country	Assessment	Site selection	Training	Start of ES
Cameroon	done	Q1	Q2	Q2
Niger	done	Q1	Q2	Q2
Chad	Q1	Q2	Q2	Q3
Democratic Republic of the Congo	Q2	Q3	Q3	Q4
Mali	Q3	Q4	Q4	Q1 (2016)
Burkina Faso	Q3	Q4	Q4	Q1 (2016)
Madagascar	Q3	Q3	Q3	Q4
Somalia	Q2	Q3	Q4	Q1 (2016)
Iraq	Q2	Q3	Q3	Q4
Yemen	Q3	Q3	Q4	Q1 (2016)
Syria	Q3	Q3	Q4	Q1 (2016)
Pakistan	done	ongoing	ongoing	ongoing

2.1.4 Polio-free regions

Additional sites will be selected in 2015/2016 to optimize ES in the non-endemic regions and ensure that results of extant ES are systematically reported to WHO. Outside the endemic regions, only China and India are among Tier 1 countries at risk of cVDPV2 (Figure 2). China and India already have ES in selected locations. Any further expansion within the two countries will be guided by evolving epidemiological risks and the monitoring of any breach of facility containment of polioviruses.

Based on regional priorities, further expansion of ES might need to be considered in non-endemic regions before OPV2 withdrawal, but should be limited to those at highest risk of cVDPV emergence (e.g. Tier 2 countries in Figure 2; China and India are the only Tier 1 countries in non-endemic regions).

2.1.5 Contingency planning for high-priority countries, districts or population groups

The risk status of any location or population can and will change with time, according to epidemiological and programmatic developments. Countries may also finalize their plans for essential facilities that will hold polioviruses, and select locations for new poliovirus vaccine production sites. Based on the evolving risks, high-priority sites and population groups will be identified for the establishment of ES.

The criteria for selecting countries that may require future ES expansion are:

- newly infected countries, provinces or districts;
- locations with recent or recurrent importation, re-establishment of transmission or history of so-called silent transmission despite apparently adequate surveillance indicators;
- areas at risk due to proximity to newly infected locations;
- areas around newly designated essential laboratories or polio vaccine production facilities.

2.2 Expansion of ES to monitor the effectiveness of containment from 2016 to 2018

ES will be an important tool to detect the release of any poliovirus resulting from a breach in containment in facilities holding these viruses. Thus, ES will be a key part of any strategy to monitor the effectiveness of containment in facilities that will retain polioviruses after eradication of WPVs and cessation of OPV use.

Under the Endgame Strategy, containment of poliovirus types 1 and 3 is planned for 2018, while containment of poliovirus type 2 will be needed in 2016 to coincide with OPV2 withdrawal. Further ES expansion is therefore needed in 2016 to detect any breach of containment of poliovirus type 2 from essential facilities including laboratories and vaccine manufacturers, and to monitor the effectiveness of Sabin 2 withdrawal. In this second expansion stage, ES will be extended globally, with priority in countries holding type 2 viruses. Sites will be chosen according to their proximity to vaccine manufacturers and essential poliovirus laboratories. As the final locations and number of such sites are not currently known, this second stage cannot be planned yet in specific detail.

Consultation with regions and GPEI partners on the expansion plan, in relation to countries with WPV repositories and national OPV and inactivated polio vaccine (IPV) manufacturing facilities, will commence in 2015. ES sites will be determined in an updated expansion plan at that time, depending on the location of the relevant facilities.

After 2018, all wild and Sabin poliovirus types are expected to be contained when polio's global eradication is certified and use of all OPV types is stopped. ES will need to be implemented in all six regions to monitor the effectiveness of OPV2 withdrawal in 2016, followed by cessation of all OPV in 2019.

Biorisk management at designated essential facilities is achieved by implementing international standards for *primary safeguards* of facility containment, *secondary safeguards* of an immunized population and *tertiary safeguards* of facility location, and by assuring through *national and international accreditation* that the required safeguards are met (Annex B).

ES can be used to monitor for any breach of these safeguards, particularly the effectiveness of effluent treatment and waste disposal.

3. FURTHER CONSIDERATIONS

3.1 Site selection for ES

Country programmes should consider certain factors, in consultation with WHO, to identify specific sites for establishing or discontinuing ES for polioviruses. These factors are described in the revised WHO *Guidelines on Environmental Surveillance for Detection of Polioviruses*.³

In summary, a major factor limiting the wider application of ES is the lack of sewer networks in some of the highest-priority areas. This poses a significant challenge for authorities attempting to identify representative sampling sites. Local sanitary engineering experts must be consulted in most circumstances to assess the feasibility of collecting samples representative of the target population.

Key considerations for the selection of sampling sites include:

- Sufficient households must be equipped with water closets connected to a converging sewer network, allowing for collection of downstream samples that represent a large number of the people living in the catchment area.
- There must be no contamination with industrial waste that may contain compounds detrimental to poliovirus stability or be toxic to cell cultures and/or interfere with poliovirus replication.
- In the absence of a sewer network, representative sampling from open canals or water channels may be possible but should only be attempted if major flow routes of waste water containing human faecal material are well known.
- Sampling sites chosen for regular monitoring should represent selected high-risk populations (preferably of 100 000–300 000 people).
- Consideration should be given to the relative ease or convenience of physically collecting appropriate samples from the site, for initial processing of

the samples and transporting them rapidly to the laboratory.

- Under appropriate epidemiological circumstances, sampling sites near, for example, orphanages, schools, slum areas, migrant camps, and hospitals with significant infectious disease wards may be considered.

3.2 Increasing ES effectiveness within the GPEI

As experience grows in the use of ES for programmatically detecting polioviruses, the relative merits and constraints of different technical methods and approaches are being evaluated. WHO is coordinating this evaluation through the Global Poliovirus Laboratory Network (GPLN). Additional input is being sought from other technical agencies and experts regarding proposed changes in ES that can be further tested and validated. Work will include:

- supporting countries to draft and finalize national ES operational strategies that are embedded in national surveillance plans;
- evaluating alternative sample collection and concentration methods;
- improving timeliness and efficiency in detecting polioviruses in sewage samples;
- developing laboratory and field-training curricula to ease and speed ES implementation in new areas;
- evaluating and optimizing ES for monitoring the effectiveness of poliovirus containment in facilities;
- developing standardized indicators to monitor and track the effectiveness of ES.

³ Available at <http://www.polioeradication.org/Dataandmonitoring/Surveillance/GlobalPolioLaboratoryNetwork.aspx>.

3.3 Key partners and their roles

Further development and use of systematic ES, particularly as the strategy moves towards collection of evidence to certify polio eradication, will require the active participation of additional partners and stakeholders:

The GPLN will seek to collaborate with organizations and laboratories that may already be operating in high-risk areas and may be able to assist in field and lab activities.

Health and environmental agencies, at the national and local levels, will be involved in planning sample collections and identifying local partners.

National health authorities will be encouraged to integrate environmental sampling into existing national disease surveillance and/or control programmes.

Funding agencies will be approached as necessary to support ES expansion.

3.4 Building laboratory capacity to support the expansion of ES for polioviruses

Endemic and importation countries will be supported by laboratories that can provide timely and accurate results. While the three remaining endemic countries are covered by two laboratories upgraded to perform ES of poliovirus (the regional reference laboratory for Pakistan and Afghanistan in Islamabad, and the Ibadan NPL in Nigeria), building additional capacity is required to support the expansion of ES in importation or high-risk countries, and poliovirus repository laboratories and manufacturers' production sites.

3.4.1 Importation and high-risk countries

Capacity will be built in additional laboratories to support current and future high-risk countries that are or will be included in the regional expansion plan, depending on current and unanticipated epidemiological developments.

Global workshops will be organized in 2015 to provide standardized ES training for key laboratories from selected regions. Subsequent regional training will be organized by the end of 2015 to fit all regional needs.

- In the African Region, in addition to Ibadan NPL, four laboratories (in Cameroon, Kenya, Senegal and South Africa) are targeted to support central, eastern, western and southern African countries, respectively. Training was completed in Q1 2015.
- In the Eastern Mediterranean Region, the Sudan and Syria NPL will be supported to build sewage-concentration capacity by Q2 2015; Iran and Iraq NPL staff will be trained for concentration, viral isolation and intratypic differentiation of poliovirus by the end of 2015.

3.4.2 Poliovirus repository laboratories and manufacturers' production sites

These laboratories and production sites will be targeted to provide evidence of non-release of wild and/or Sabin viruses during the Plan's post-eradication and post-OPV phases. In 2015, ad hoc training on WHO recommended methodologies for poliovirus surveillance in the environment will be provided as needed.

3.5 Resource needs

As an essential polio endgame strategy, ES expansion will be financed by the GPEI with support from donors, partners and host governments. The estimated cost of ES from 2015 to 2018 is US\$ 14.2 million.

Year	2015	2016	2017	2018	Total
Planned cost (in US\$)	4 300 000	3 300 000	3 300 000	3 300 000	14 200 000

The following assumptions were used for the estimate:

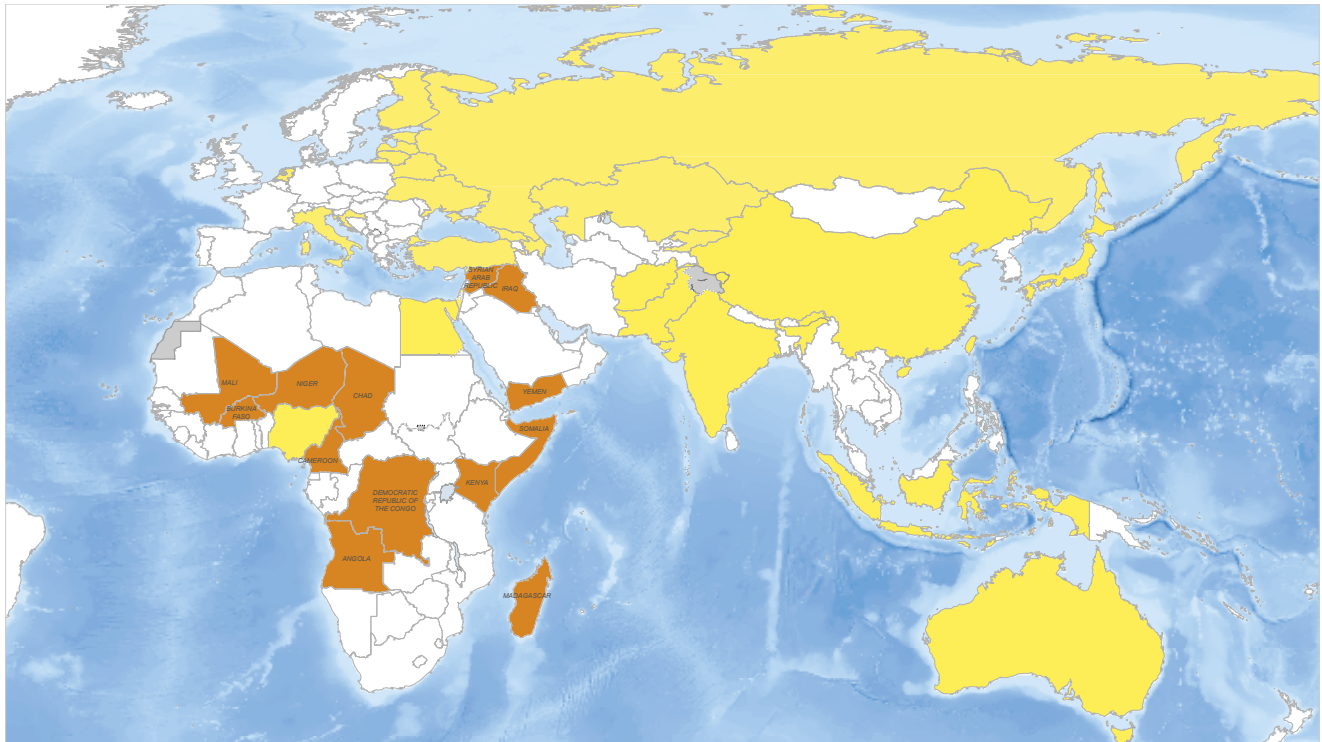
- ES will be sustained through to the completion and certification of polio eradication, and will need to be sustained beyond the Plan's time frame.
- Although laboratory support costs vary by country, the GPLN has estimated that, in general, for a laboratory already involved in poliovirus isolation from clinical specimens, an additional US\$ 50 000 investment would be required for equipment and consumables to process environmental samples. A further US\$ 33 000 would be needed to cover the cost of analysing 100 samples.
- Existing laboratory capacity to cope with the extra sample workload will need to be expanded. From experience in Egypt, processing and analysing 100 sewage samples in the laboratory require additional staff trained at approximately the same level as those for processing and analysing stools from 200 AFP cases, with two specimens from each.

3.6 Legacy

- As with AFP surveillance, a successful ES programme will be a lasting legacy of the GPEI, providing a platform to enhance the surveillance and biosecurity assessment of waterborne illnesses.

ANNEX A. ES for polioviruses – status in early 2014 and future expansion

Figure A1: Existing and proposed environmental surveillance plans



■ Countries known to have existing ES at end of 2013

■ Planned expansion of ES by April 2016

ANNEX B. Containment safeguards

Primary safeguards of containment reduce the likelihood of poliovirus release from an essential facility. Key elements include:

- facility management, which practises continuous risk assessment and strict observance of biosafety and laboratory biosecurity procedures;
- the containment facility, which incorporates appropriate biosafety design, construction and operating principles;
- immunization (IPV) of facility personnel, which can reduce the risk of infection in the facility and intra- or extra-household transmission, should infection occur;
- reduction in the use of WPV and substitution with Sabin strains or further attenuated strains where possible;
- contingency plans for potential virus release or exposure, which specify actions and assign responsibilities for the facility, institution, ministry of health and other concerned government agencies.

Secondary safeguards of population immunity minimize the consequences of a poliovirus release into the community from an essential containment facility. They consist of a national routine childhood polio-immunization policy and the attainment of high national population coverage consistent with WHO policy and eventual post-eradication strategies.

Tertiary safeguards of facility location minimize the consequences of a release of highly transmissible WPV by placing essential facilities in areas with demonstrated low poliovirus reproductive rates. Such areas have good personal, domestic and environmental hygiene standards, as well as closed sewage systems with a minimum of secondary treatment of effluents.

Primary, secondary and tertiary safeguards are required for handling essential facilities and storing WPV materials after WPV eradication. Primary and secondary safeguards are required for handling essential facilities and storing WPV, OPV or Sabin materials throughout the poliovirus type 2 containment period and after cessation of routine OPV use, as summarized in Table B1:

Table B1: Containment safeguards required for essential poliovirus facilities, post-eradication

Poliovirus type	Safeguards		
	Primary	Secondary	Tertiary
WPV	Yes	Yes	Yes
VDPV	Yes	Yes	Yes
Sabin	Yes	Yes	No

**EVERY
LAST CHILD**

The text "EVERY LAST CHILD" is arranged in three lines. The word "EVERY" is on the top line, "LAST" is on the middle line, and "CHILD" is on the bottom line. Two orange footprints are integrated into the design: one is positioned to the right of "LAST" and the other is to the left of "CHILD".

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