

# Report of the 23<sup>rd</sup> Informal Consultation of the Global Polio Laboratory Network (GPLN)

Venue and dates: WHO Headquarters, Geneva, Switzerland, 15 - 16 March 2017

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## List of abbreviations used

AFP	acute flaccid paralysis
bOPV	bivalent oral polio vaccine
CAG	WHO Containment Advisory Group
cVDPV	circulating vaccine-derived poliovirus
cVDPV2	circulating vaccine-derived poliovirus type 2
CVID	common variable immune deficiency
CWG	Containment Working Group
ESIWG	Environmental Surveillance Implementation Working Group
fIPV	fractional dose of inactivated polio vaccine
GAPIII	WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use
GCC	Global Certification Commission for the eradication of polio
GPEI	Global Polio Eradication Initiative
GPLN	Global Polio Laboratory Network
GPLNMS	WHO Global Polio Laboratory Network Management System
IPV	inactivated polio vaccine
ITD	intratypic differentiation of polioviruses
iVDPV	vaccine-derived poliovirus from immunodeficient individuals
iVDPV2	vaccine-derived poliovirus type 2 from immunodeficient individuals
mOPV2	monovalent type 2 oral polio vaccine
NGS	next generation sequencing
OPV2	oral polio vaccine type 2 component
PCS	post-certification strategy
PEESP	Polio Eradication and Endgame Strategic Plan 2013-2018
PEF	Polio Essential Facility
PHEIC	public health event of international concern
PID	primary immune (B-cell or combined B/T-cell) deficiency disorders
PolIS	Polio Information System
PT	proficiency testing
rRT-PCR	real-time reverse transcriptase polymerase chain reaction
SIA	supplementary immunization activities

SL2	Sabin-like poliovirus type 2
SOP	standard operating procedure
TIMB	Transition Independent Monitoring Board
tOPV	trivalent oral polio vaccine
VDPV	vaccine-derived poliovirus
VDPV2	vaccine-derived poliovirus type 2
WPV	wild poliovirus
WPV1	wild poliovirus type 1
WPV2	wild poliovirus type 2

## **Background**

The Global Polio Laboratory Network (GPLN) was established in 1990 by WHO and national governments, and currently includes 146 laboratories in a three-tiered structure. The primary roles and responsibilities of the GPLN have steadily evolved as progress has been gained towards the goal of global polio eradication. As the prospect of global polio eradication approaches, and appropriate changes have been made to global immunization and polio surveillance strategies, the main responsibility of the GPLN is to ensure that laboratory procedures and work practices are in line with the objectives of the Polio Eradication and Endgame Strategic Plan 2013-2018 (PEESP). The GPLN meets every year in an informal consultation to develop recommendations for improving performance and coordination and determine the research and resource needs of the network laboratories.

The 23rd Informal Consultation of the WHO GPLN was held in Geneva, Switzerland, from 15 to 16 March 2017. The meeting included participants from laboratories of the six WHO geographical regions including WHO Laboratory Coordinators, and for the first time included WHO Regional and Headquarters staff responsible for field surveillance for polio. A full list of participants is provided in Annex 1.

## **Scope and objectives**

The main objectives of the 23rd Informal Consultation of the GPLN were to:

- a. review recent advances in global polio eradication with emphasis on laboratory support to the programme;
- b. review the overall performance of the GPLN and report on the GPLN's quality assurance programme and capacity building;
- c. discuss alignment of polio diagnostics with the Programme needs and make appropriate recommendations to the GPLN and field surveillance officers;
- d. discuss implementation of the Global Environmental Surveillance Expansion Plan and make appropriate recommendations to the GPLN and field surveillance officers; and
- e. review poliovirus type 2 detection, reporting, investigations and response, and make appropriate recommendations to the GPLN and field surveillance officers.

An agenda for the meeting is provided in Annex 2.

## **Opening Remarks**

The meeting was opened on behalf of WHO by Mr Michel Zaffran, Director of Polio Eradication, and Dr Ousmane Diop, Coordinator of the Global Polio Laboratory Network. Dr Mark Pallansch was nominated as chairman for the meeting and Dr Ray Sanders as rapporteur.

This was the first consultation of this type to bring together colleagues from the GPLN and WHO polio field surveillance at Global and Regional levels. This represents a change in format for the GPLN informal consultations and reflects the shift in challenges facing the GPLN. Many of these challenges now occur at the WHO Regional level, requiring Regional and local solutions, and the focus of the GPLN at global level is shifting further towards strategic considerations.

## **SESSION 1: Progress towards detection and interruption of Wild Polio Virus (WPV) and vaccine-derived poliovirus (VDPV) transmissions**

### **Progress and Challenges towards Eradication – Global Update**

The first objective of the polio endgame and endgame strategy is the detection and interruption of transmission of poliovirus, and the past 6 months has seen a continued decline in the number of wild poliovirus (WPV) and circulating vaccine derived poliovirus (cVDPV) cases detected. As of the beginning of March 2017 there were 11 WPV cases in Pakistan/Afghanistan and 2 cVDPV cases, 1 in Nigeria and 1 in Pakistan, detected over the previous 6-month period. However, environmental surveillance has continued to detect both WPV and cVDPV in Pakistan and Afghanistan where polio cases have not been detected. Detailed assessment of the situation in Pakistan has concluded that the major risks to interruption of transmission include continued failure to vaccinate all accessible children, failure to detect and track poliovirus in high risk mobile populations, and continued performance pressure on programme staff and programme monitors. In Afghanistan in 2016 WPV was predominantly detected in only 2 restricted areas, both on the border with Pakistan, and confidence in the quality of surveillance in Afghanistan is high. In Nigeria in 2016 four WPV type 1 (WPV1) cases were detected together with 2 cVDPV type 2 (cVDPV2) isolates, all orphan viruses from a total of 4 states. Following a large-scale outbreak response targeting over 40 million children with multiple vaccine rounds, no additional viruses have been detected since September 2016. Despite the achievements made, safe access to susceptible populations remains a major challenge to the programme in Nigeria and the suspicion exists that poliovirus may continue to circulate undetected.

The second objective of the polio endgame and endgame strategy is the effective withdrawal of trivalent oral polio vaccine (tOPV) and further introduction of inactivated polio vaccine (IPV). All countries previously using OPV have now switched from tOPV use and provided appropriate validation data on the switching process to WHO. Unfortunately, 21 countries have been required to delay introduction of IPV due to the global vaccine shortage caused, in part, by the massively increased global demand. Supply of IPV will continue to be restricted for the remainder of 2017 and into 2018.

To make most effective use of vaccine available through the UNICEF Supply Division countries have been assessed according to the risk they pose for virus circulation and placed in one of four tiers for prioritising vaccine supply. All tier 1 countries, assessed as being at highest risk, have been supplied with IPV, while tier 2 countries will be supplied in the second quarter of 2017. These countries have been warned of possible further interruption to supply throughout 2017 and have been encouraged to review their routine vaccine usage requirements. Tier 3 and 4 countries, considered to be at lowest risk, will not be supplied with IPV in 2017 and it remains uncertain if they will receive vaccine in 2018. The grading system used to allocate countries into at risk tiers is currently under discussion and it may be possible to afford some of the tier 3 and 4 countries a higher priority for IPV supply. Any country making the decision to introducing a fractional IPV (fIPV) vaccination schedule will be prioritised and would be supplied as soon as adequate IPV becomes available.

Vaccine-derived poliovirus type 2 (VDPV2) and cVDPV2 detections have been closely tracked since 2015 and isolates were detected in 10 countries in 2016. There are believed to be 2 ongoing outbreaks of cVDPV2, one in the Sokoto area of Nigeria and the other in Balochistan, Pakistan, both eliciting widespread supplementary immunization activities using monovalent type 2 OPV (mOPV2).

The occurrence of Sabin-like type 2 polioviruses (SL2) have been closely monitored by the GPLN through AFP and environmental surveillance through the periods leading up to, during and after the switch from tOPV use. While SL2 isolates were detected in 17 countries not using mOPV2 in the 3 months immediately after the switch, detections have declined markedly in the following months. However, continued detection of SL2 isolates into 2017 together with the results of in-country investigation has demonstrated that limited stocks of tOPV remain in some countries. Any detection of SL2 or of tOPV stocks has been followed-up with thorough investigation, and plans are being developed for a targeted sweep of facilities and private clinics in some countries searching for remaining tOPV vials. As expected, SL2 isolates were detected in countries using mOPV2 in response to cVDPV2 outbreaks, but detections declined over time following the vaccination response. Development and use of the WHO global stockpile of mOPV2 has worked well and countries requiring the vaccine have very rapidly been supplied with stocks for outbreak response activities. Not all countries have been fully receptive to the proposal to use mOPV2 in response to an outbreak.

The third objective of the polio endgame and endgame strategy is laboratory containment of poliovirus infectious materials and global certification of polio eradication. A Global Certification Commission (GCC) will take responsibility for oversight of compliance with the WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (GAPIII). A Containment Working Group (CWG) has been established to support the GCC in the new containment certification role. In addition, the WHO Containment Advisory Group (CAG) is in the process of being established to address specific technical issues related to GAPIII. The CAG will report directly to the WHO Director General. To date 30 countries have provided notification that they intend establishing designated Polio Essential Facilities (PEFs) as defined in GAPIII. These countries have reported a total of 78 intended PEFs.

The fourth objective of the polio endgame and endgame strategy is to establish the post certification legacy of the polio eradication initiative and develop a transition planning process. At the Global level there will be a significant decline in available funding from 2017 to 2019 and countries that have depended on these funds to develop and maintain the initiative have been supported in the process of planning for transition to polio-free status. Post-certification strategy development is underway and a Transition Independent Monitoring Board (TIMB) has been established to monitor implementation and effects of the transition process. In the WHO African Region necessary staff reduction activities have been initiated and a Regional Transition Officer recruited. The WHO African and Eastern Mediterranean Regional Offices are developing a business case for immunization in Africa to strengthen funding support for immunization services in the absence of funds for polio eradication.

The primary goal of transition planning is to maintain and mainstream polio-essential functions after certification of eradication and the Transition Guidelines (June 2015) have defined the polio-essential functions in broad terms. There is, however, a need to develop a strategic plan (PSC) to detail the specific functions, policy decisions, mechanisms and financial requirements to protect a polio-free world and define how polio-free status will be maintained.

### **Overview of the performance of the Global Polio Laboratory Network**

At a time of rapid change within the polio eradication initiative and the global polio landscape it is well recognised that laboratory and field surveillance components of the programme need to be

even more effectively working in concert to firstly achieve global polio eradication, but also to determine the characteristics and respective roles and responsibilities for effective and sustainable polio surveillance immediately pre- and post-certification.

In rising to the challenges presented by the final phases of global polio eradication the GPLN has consistently evolved to be faster, more focussed and fully accountable. The target times for poliovirus detection and response to WPV outbreaks has been reduced through introduction of new testing algorithms, increasing capacity for intratypic differentiation (ITD) and by arranging faster shipment of isolates for genomic sequencing. The Network has become more focussed through implementation of comprehensive quality assurance procedures at all levels, provision of enhanced technical assistance to laboratories where needed and establishment of extensive environmental surveillance systems. Network accountability has been increased through systematic improvement of all aspects of laboratory management and introduction of real time laboratory performance tracking. Of the 146 laboratories in the GPLN, 47 conduct virus isolation alone, 73 conduct virus isolation and ITD, and 26 conduct virus isolation, ITD and genomic sequencing. It is planned to increase the number of laboratories conducting ITD and genomic sequencing prior to global certification.

Development and implementation of environmental surveillance of poliovirus has been a major innovation in recent years. The GPLN is currently working on standardized monitoring indicators to track the effectiveness of environmental surveillance and provide guidance and recommendations on the management, analysis and reporting of environmental surveillance data. Global expansion of environmental surveillance is being driven by programmatic needs, but the surveillance process remains lengthy in terms of selection of appropriate sites, procurement of materials and provision of training, and faces a number of procedural challenges. These include the need for close monitoring and supervision, development and improvement of methodologies, effective data sharing and analysis and ensuring sustainability. Despite the challenges there has been a significant incremental increase in the number of environmental samples collected and processed since 2014, particularly in the WHO African, Eastern Mediterranean and South East Asian Regions. A quality assurance programme for environmental surveillance is in development with a checklist for accreditation to be pilot tested and a proficiency testing scheme to be introduced.

Laboratory containment of poliovirus infectious materials has been an ongoing function of the GPLN and laboratories have played a key role in driving the programme towards improvement of laboratory biosafety and biosecurity. Biorisk management training for GPLN members has been completed in all WHO regions and operational guidance papers on the management of laboratory materials following OPV2 withdrawal developed.

As the trend towards a declining number of WPV cases since 1998 has progressed, there has been a general stepwise increase in the number of samples from AFP cases processed in GPLN laboratories. In 2016 in excess of 245,000 stool samples from AFP cases, contacts or other sources were processed in GPLN laboratories. Of these the vast majority had poliovirus isolation results reported within 14 days of receipt and greater than 90% had ITD and/or sequencing results reported within 7 days of isolate receipt.

The GPLN has played a central role in virological monitoring of poliovirus type 2 viruses post OPV2 withdrawal and rapid and effective laboratory reporting of type 2 isolations has been a key trigger

for determining an appropriate outbreak or event response from the programme. The number of countries reporting SL2 isolates has declined from 28 in March 2016 to a persistent 3 or 4 in February 2017.

The Global Polio Laboratory Network Management System (GPLNMS) has been further developed as a way of improving communications between the members of the GPLN and there are now over 200 users accessing the web-based system. Users can now share content including resource files, news, an events calendar and discussion topics.

The main threats to GPLN performance include the increasing workload faced by the laboratory coordinators which is having a negative impact on laboratory performance by decreasing provision of routine monitoring and guidance. There is also the threat of complacency setting in as the final stages of global polio eradication approach. There have been an increasing number of non-coordinated demands on the GPLN from the GPEI and National authorities seeking laboratory information required to mount specific programmatic responses to events. There is an urgent need to align and consolidate the GPEI partners' visions of the future of the GPLN, and questions over the transition process need to be answered sooner rather than later.

### **Detection and molecular epidemiology of WPV in 2016 - Report from the Eastern Mediterranean Region**

There has been a dramatic decline in the number of polio cases detected in the Region since 2014, with only 2 countries, Pakistan and Afghanistan, having cases since 2015. There is a well-supported and effective Regional laboratory network that includes two laboratories capable of conducting polio genomic sequencing. The laboratory workload for the Region is, however, very high. In 2016 there were specimens processed from more than 18,000 AFP cases and contacts, requiring ITD testing of 753 isolates and genomic sequencing of 70 polio isolates. Most of the specimens came from Pakistan and Afghanistan.

To date, the most recent case detected in Afghanistan was on 21 January 2017 while the most recent case in Pakistan was 13 February 2017. These cases were detected in the same endemic foci as seen in previous years. Several of these endemic foci span the border between Pakistan and Afghanistan, underlining the need for control and outbreak response activities to be conducted simultaneously on both sides of the border. In addition, in Pakistan there are a number of areas from which no AFP cases are reported, but where WPV is being detected in environmental samples. Clearly WPV has continued to circulate in these areas despite the very low number of polio cases detected and there is no room for complacency in the programme.

Six countries in the Region have now established environmental surveillance in support of AFP surveillance, Jordan and Lebanon as a direct response to the refugee situation. Environmental surveillance laboratories have been established in Iran, Sudan, Syria and Iraq to begin implementation in 2017. Environmental surveillance data clearly demonstrates that in several areas of Pakistan, including Baluchistan, Punjab and Islamabad, Sindh and Peshawar, WPV continues to circulate in the absence of reported AFP cases and that significant susceptible populations exist in these areas. The situation in Afghanistan is far more promising with very few WPV positive environmental samples detected to date.

Evidence has been accumulated to demonstrate poliovirus transmission routes in Pakistan, with closely related variants spreading from endemic foci in the south of Pakistan in 2014 to re-emerge in January 2017 in the Punjab showing signs of sustained circulation. The continuing detection of orphan viruses with divergence of between 1.6% and 2.5% from closest known isolates demonstrates that viruses can circulate undetected for periods of more than 2 years in the communities between the southern city of Karachi and the Punjab. There is also molecular evidence for the spread of virus lineages circulating in Peshawar across the border into Afghanistan and further spread there. Another virus, circulating in Quetta, Pakistan in 2016 was imported into Afghanistan and circulated in Kandahar and Helmand provinces there. It is clear that despite the large number of supplementary immunization activities (SIA) being conducted, WPV continues to circulate in Pakistan and is capable of being exported across the border to Afghanistan. Molecular data suggests that virus reservoirs are being sustained in the Karachi area through the low season and are being transmitted to more northerly areas of Pakistan in the high season.

Estimates of virus isolate genetic diversity indicate a decline in the number of detected virus variants across the 2015 - 2016 low-season, reaching an all-time low. However, average genetic diversity slightly increased during the peak high-season and into the 2016 - 2017 low-season, with the discovery of extended genetic linkage between cases together with a number of orphan viruses. These discoveries indicate gaps in the surveillance system that urgently need to be filled if eradication is to be achieved.

### **Molecular epidemiology of WPV to inform progress towards eradication - Lessons learnt from India**

The last case of polio due to WPV in India was detected in January 2011 and Region was certified polio-free in March 2014. There are >40,000 health facilities that report polio, and >165,000 active surveillance visits are conducted by SMOs each year. Approximately 50,000 AFP cases are investigated annually, and around 100,000 stool samples are collected and tested in the 8 WHO-accredited polio laboratories. Environmental sampling is conducted in 7 States with large migrant populations.

Before interruption of transmission Bihar and Uttar Pradesh were sources of virus for the whole country, with export to other States usually resulting in short chains of transmission that resulted in only a few AFP cases. Environmental surveillance, first introduced in Mumbai in 2001, was used to document the repeated importation of virus from endemic foci in Bihar and Uttar Pradesh into polio-free populations in the initial absence of detected AFP cases. Similar observations were later made in Delhi. In 2003 an outbreak of WPV1 in Karnataka was linked through genomic sequencing to importation of virus from western Uttar Pradesh. The virus spread to neighbouring States of Andhra Pradesh and Tamil Nadu, but transmission was halted within one year. Until 2006, WPV from western UP was predominantly linked to the reintroductions into other States, but from 2007 onwards, WPV from Bihar was increasingly isolated in other States including Punjab, Delhi and Maharashtra. All WPV1 isolated in India in 2010 were linked to those circulating in Bihar in 2009. Molecular epidemiology has shown that these viruses were also being exported to other countries; to Bangladesh and Angola in 2006, to Nepal on multiple occasions, and to Tajikistan in 2010.

An outbreak of WPV3 was detected starting in Uttar Pradesh in 2004 and steadily increasing to 2009, but also occurring in Bihar from 2007 to 2009. Routine immunization coverage with tOPV had been



poor in Uttar Pradesh and Bihar and immunization was supplemented with immunization campaigns. In 2005 the vaccine used for these supplementary campaigns was switched to mOPV1, allowing accumulation of susceptibles to WPV3. From 2008 to 2010 the outbreak virus was transmitted from Bihar to other major centres, such as Mumbai and Delhi, and detected through the environmental surveillance systems in place.

The experience gained in India demonstrated how genomic sequence data could be effectively used to provide information for action. Whenever a WPV was detected in a low risk area it could be linked to an endemic reservoir area and SIAs were carried out in both areas. In addition, SIAs were carried out in all areas known to have experienced repeated re-introductions at the same time as they were undertaken in Bihar and Uttar Pradesh. After several years spent conducting SIAs it was concluded that WPV transmission chains could not be stopped using the existing strategy despite OPV campaigns, high quality surveillance and availability of molecular data. A comprehensive review of field and molecular epidemiology was undertaken in 2009 and it was concluded that 107 blocks in Bihar and Uttar Pradesh were the high risk areas from which all WPV in India spread. A comprehensive plan was developed to address polio associated risk factors through improved routine immunization coverage and address a series of public health issues in underserved populations. Molecular data was also used effectively to provide evidence of final elimination of endemic WPV.

#### **Detection and molecular epidemiology of VDPV in 2016 - Overview, genetic characteristics, and clues for categorization of VDPV**

The emergence of VDPVs, particularly VDPV2s, in recent years has posed the question of whether there are specific genetic characteristics of viral capsid protein 1 (VP1) sequences that can be used to differentiate cVDPVs from iVDPVs and so provide a more rapid and dependable laboratory diagnosis. Genetic variations between iVDPVs and cVDPVs may reflect the differences in the selective pressures during person-to-person transmission compared with chronic infections in immune-deficient patients. Reported key properties distinguishing iVDPV from cVDPV include the level of mixed virus populations, more-extensive antigenic divergence from OPV than cVDPV and the tendency for non-recombinant or vaccine/vaccine-recombinant genomes. Systematic quantification of these key properties is underway to determine if there are specific genetic characteristics that can differentiate cVDPV from iVDPV.

The approach taken was to conduct analysis of the amino acids transcribed from the genomic sequences, looking for the degree of conservation and the incidence of mixed bases (nucleotides) that may indicate a common characteristic. Use has been made of publicly available sequence information from GenBank, which provides a reasonable number of cVDPV2 sequences (576) but fewer iVDPV2 sequences (21). Initial analysis suggested that no single nucleotide or amino acid position consistently differentiated cVDPV2 from iVDPV2. However, looking at the number of nucleotide substitution numbers for specific amino acid substitutions suggested there are more amino acid substitutions with increasing nucleotide substitution in iVDPV than in cVDPV. For isolates with a low or moderate number of nucleotide differences in the VP1 region it is difficult to differentiate iVDPV from cVDPV, but if the number of nucleotide substitutions is  $\geq 22$  then iVDPV and cVDPV appear to form two distinct clusters, and the model works best if the number of amino acid substitutions is  $\geq 5$ .

The next steps include expanding the dataset beyond the current type 2 VP1 data from Genbank by adding more sequences available from CDC and other GPLN laboratories, using available complete capsid sequences, and including additional iVDPV sequences. Different modelling approaches will also be attempted looking at available data on poliovirus types 1 and 3, and determining if additional information can be gleaned from complete genome sequencing data.

### **Summary of outcomes of the GPLN's *Ad Hoc* Small Working Group meeting**

Representatives from the Global Specialised Laboratories together with Global and Regional Laboratory Coordinators meet 3 times a year in an *Ad Hoc* Small Working Group to discuss a range of laboratory-associated topics. The main topic of discussion in recent meetings has been adaption of GPLN diagnostic procedures to meeting GAPIII requirements as polio eradication approaches and the need to contain laboratory stocks of poliovirus-infectious materials increases. This group met, in conjunction with the Informal Consultation, on 14<sup>th</sup> March.

- **Inactivation of poliovirus.** Basic laboratory diagnostics can be safely conducted in a Biosafety Level 2 (BSL-2) laboratory, but once a poliovirus type 2 virus is identified the isolate must be moved to a containment laboratory for further processing. While viral RNA extraction can be conducted safely in a containment laboratory, few facilities site their sequencers within a containment laboratory, so there is a need to safely pass RNA for PCR and sequencing out of the containment laboratory. Further work is needed on developing an effective method to ensure virus inactivation prior to RNA extraction. A protocol for virus inactivation by heat treatment followed by viral RNA isolation has been developed and validated at CDC and is due to be pilot tested in Global Specialised Laboratories.

Information from labs receiving FTA cards on the quality of RNA extraction, recovery, ITD and sequencing has been gathered by laboratory coordinators as a component of monitoring the quality of FTA card processing.

- **Needs for polio serology in the endgame and post-OPV era.** All GPLN and Polio Essential Facility (PEF) staff should be tested for immunity against polio, particularly type 2 in the first instance. There may be ongoing programmatic needs, such as seroprevalence studies and clinical trials of new candidate vaccines that will require safe serological techniques.

Current recommendations are that serological testing for type 2 virus only be conducted in PEFs and that only polio types 1 and 3 are tested in other laboratories. Alternative assays are being developed, using 'safer' strains of poliovirus or use of a non-infectious pseudo-virus system.

Further questions include the additional work necessary to evaluate or validate any new methodologies and the need for CAG to endorse alternative methods as suitable to be used at a lower containment level.

- **Polio diagnostics – current status and future prospects.** An evaluation of real-time reverse transcriptase polymerase chain reaction (rRT-PCR) intratypic differentiation (ITD) assays to different platforms has been conducted. The ABI 7500 standard and 7500 Fast systems represent the gold standard for rRT-PCR but are expensive to use due to high maintenance requirements. Three alternative machines (Cfx-96 BioRad, Stratagene MX3000, and RotorGene Q) have been tested for possible use by GPLN laboratories. A final report on the findings is in preparation.

- **Analysis and reporting of sequencing results.** A standard process for reporting PV2 (VDPV2) sequencing results is being finalized. Work continues at CDC on VDPV classification based on nucleotide sequence.
- **Environmental surveillance.** A recommended protocol for processing and analysis of environmental samples will be finalized before the next Small Working Group meeting. A revised version of the environmental surveillance accreditation checklist is being considered for final endorsement by the Small Working Group. Plans for environmental surveillance proficiency testing have been developed, and proficiency testing samples have been prepared and will soon be pilot tested. It is not clear at present how to evaluate environmental surveillance sites and identify those most suitable to monitor PV circulation although potential markers have been identified that may aid in this process.

A bag-mediated filtration system (BMFS) for environmental surveillance has been developed and pilot studies have shown promising results. Further refinement and scale-up is feasible in next few months depending on Programmatic needs.

- **Direct detection of PV in stool samples.** This approach, if possible, would greatly facilitate safer and timelier laboratory detection of polioviruses. A number of different methods are being tested and protocols for their use are being finalised. Logistics and costing of these methods have been evaluated but quality assurance/quality control methods have yet to be established. Work has already started for direct detection of poliovirus in environmental samples and additional methods are being considered.
- **Next generation sequencing (NGS) for sequencing poliovirus isolates.** NGS is being considered for wider use because of the complex virus mixtures found in environmental samples and the increase in sequencing sensitivity required in support of direct virus detection. NGS provides data on complete genomes in a single run and is capable of detecting mixtures of components and virus variants. The required technology is becoming more widely available, at least in institutional core facilities. An NGS pilot study is being conducted.
- **Quality assurance (QA) and proficiency testing (PT).** PT continues to be critical to ensure optimal function of GPLN, helping to identify and aid laboratories that may have issues with performance. PT panels have been summarized by laboratory, by region, and by sample to guide discussions in the SWG and detailed explanations of reasons for points deducted are given in PT reports.

The 2015-2016 sequencing PT went well overall, despite some issues in a few laboratories. Three failing laboratories passed on second attempt; two have not received a second panel; one returned results months later. There has generally been a good response to the FTA card sample. Sequencing laboratories should perform a sequencing run at least once a month to maintain proficiency. The 2017 sequencing PT will include 2 FTA card samples that will be graded.

## Summary of session discussions

The global IPV supply situation is not favourable, and concerns were expressed over the criteria used for prioritising countries for supply through UNICEF, and questions asked over how existing criteria may be modified. There are only 2 global suppliers of IPV, both have faced difficulties in meeting demand but only one has made substantial efforts to work with the international partners to develop a sustainable and effective supply position. It is possible that in the near future there will be only one global IPV supplier. At present countries in tiers 1 and 2 are assured of vaccine to meet their needs in 2017. Supply is not guaranteed to countries in tiers 3 and 4 before 2018. There is some flexibility of supply for countries that choose to adopt a fIPV schedule, or countries considered to be at increased risk of VDPV emergence.

The last remaining reservoirs of WPV1 in Pakistan are probably in Quetta block and the Khyber-Peshawar corridor. Karachi continues to be affected by a large mobile population introducing virus into the urban area. Evidence from improved surveillance activities, particularly environmental surveillance, in Pakistan suggests that virus continues to circulate in small sub-populations in endemic areas but the programme has yet to fully identify the sub-populations of susceptibles that need to be reached by vaccination. Community-based vaccination has been introduced in Quetta to improve vaccine coverage, but immunization activities need to be continued with targeted rounds of SIAs.

There is evidence that older age groups, including adults, can be infected in the context of local circulation, but any role in transmission of virus, especially to other communities, remains unclear. This type of data is often not systematically collected. While it remains true that adults may have a minor role to play in maintaining transmission, it is unclear how to address the problem, since responding to older age groups effectively would require substantial additional resources and funding. It is clear that the most significant age group responsible for continuing transmission are the <5 years group, and available resources should be targeted primarily on this age group.

Final case classification of iVDPV or cVDPV depends not only on the laboratory results but on the field epidemiological information. There is a need for clear guidance on the level of sequencing data necessary to make the classification, particularly at the beginning of an event when the appropriate level of response must be determined. The new protocol for VDPV2 allows for response to be initiated once sequence data is available identifying the isolate as VDPV2. Sequence data will rapidly allow determination of any relationship to other current VDPV2s; if there is an obvious link the isolate, depending on supporting evidence from field investigations, becomes a cVDPV2. Most of the VDPV2 isolates detected in the past year have not been genetically linked to any other isolates and final classification has been determined on the basis of field epidemiological and antibody testing for immunodeficiency.

Possible parallels between the situation seen in India leading up to 2010 and the current situation in Pakistan and Afghanistan include use of molecular data to detect transmission associated with mobile populations and the repeated re-seeding of areas where polio has been eliminated. In Pakistan this should allow the focusing of resources on the highest risk populations and identification of at-risk populations, as was successfully accomplished in India. Use of environmental surveillance in Pakistan has been more extensive than in India, making direct comparison difficult, but there needs to be more effective systematic programmatic use of all of the

surveillance data available in Pakistan. Genetic variability of isolates and geographical distribution of positives were significantly less in India one year prior to elimination than is the current situation in Pakistan. In Afghanistan the parallels with the situation in India in 2008 -2009 are clearer and available data should be more effectively used to monitor the mobile populations, both the short trans-border populations and long-distance travellers.

While the molecular epidemiology data is undoubtedly of use to the programme in identifying pockets of continuing virus circulation and importations from elsewhere, there is a tendency on the part of the programme to attempt over-interpretation of the data being provided. Complete transparency on the part of the laboratories is accompanied by the requirement to provide explanations of how the data can be best interpreted and used as information for action. Not all sequence data will have programmatic implications or require any change in programme activity.

Methods for direct detection of poliovirus in samples are close to becoming equivalent to current laboratory methods, but when and how these methods are introduced depends on the programmatic requirements for comparable sensitivity for finding poliovirus. Current methods are not 100% sensitive for detection of poliovirus, but the programme needs to decide on the level of comparability that is acceptable.

If poliovirus serology in its current format is performed post-eradication it will need to be conducted under containment in a PEF. It is possible that new techniques, not requiring containment, will be available by that time. Exact requirements will be decided by the CAG.

## **SESSION 2: Field Surveillance and Polio diagnostics: Programme needs during the Endgame**

### **Integration of iVDPV surveillance to AFP Surveillance: Egypt experience**

A project was established in Egypt starting in 2011 to estimate the prevalence of VDPV excretion among persons diagnosed with primary immune (B-cell or combined B/T-cell) deficiency disorders (PID) and to genetically characterize VDPVs isolated from persons with PIDs. Subjects tested positive for VDPV excretion were followed-up to determine duration of virus excretion. An individual excreting VDPVs for over six months was considered to be a 'long-term' or prolonged excretor and those with an excretion period >3 years was considered to be a chronic excretor.

The project started in 3 focal sites and was expanded to four other governorates in 2014. A total of 10 cases were confirmed as iVDPV positive; 8 of iVDPV2, 1 of iVDPV1 and 1 of iVDPV3. Of the cases detected, 4 presented with AFP. A total of 6 cases were successfully followed up with repeat stool collections. The most recent case, diagnosed as PID and reported as AFP, was detected in February 2017. A VDPV2 was detected with 17 nucleotides sequence variation in VP1 genomic region.

The project concluded that iVDPV excretion rate among PIDs in this population was 5% among those with at least 1 sign from the Jeffrey Modell list. It also concluded that integration between AFP and PID surveillance was less than optimal, with many gaps in the collection and sharing of critical information and instances of cases that are missed or lost to follow-up. Integration of AFP

surveillance with PID surveillance will require more supervision, training and funding, with the inclusion of more university-based focal points for PID.

PID cases were shown to be excreting Sabin-like viruses and follow-up of these cases demonstrated a progressive shift in the viruses excreted from Sabin-like to VDPV, underlining the need to sequentially sample these cases for poliovirus excretion. The PID surveillance system sensitivity was increased by reducing the number of Jeffrey Modell signs from an initial 3 to 1. It has now been agreed that stool samples should be collected from all detected PID cases, and those shown to be positive for poliovirus excretion should be followed-up.

### **Coordination of virological and immunological investigations of iVDPVs: Tunisia experience**

There is a relatively high incidence of PID in Tunisia with 60 to 70 newly diagnosed cases each year, possibly linked to the high level of consanguineous marriage. There are 3 major referral centres for clinical investigation in the country and a unique referral centre for advanced immunological investigation in the Pasteur Institute of Tunis, connected with almost all health centres throughout the country. No national registry for PID exists but an extensive database is available through the immunology laboratory and information in this database has been used in studies on PID patients.

A national study was conducted in the 1990s to assess the risk of community-acquired infection with OPV strains in PID patients in the context of mass vaccinations during NIDs. This study found that poliovirus was isolated from 4 of 16 PID patients, indicating a high susceptibility for poliovirus infection in these individuals; however no evidence was detected for establishment of chronic excretion. Tunisia also contributed to an international study on PID patients conducted from 2008 to 2013. This study demonstrated the very high susceptibility of PID patients to enterovirus infections, with 13% of all study patients in Tunisia positive for enterovirus excretion, and 20% in patients with IgG deficiency. The background rate of enterovirus infection in Tunisia is usually 1 to 4%. Several PID patients had iterative enterovirus infections with sequential infections with different enteroviruses.

A recent iVDPV case in Tunisia, detected in 2016 had an onset of fever in November, became hospitalized and was reported as an AFP case. Stool samples collected at the end of November were positive for Sabin-like (SL) type 3 virus by ITD and negative by rRT-PCR VP1 VDPV screen and the laboratory result reported as SL3. The physician in charge of the patient was contacted for additional information, follow-up sampling and immunological investigation. Immunological investigation confirmed MHC Class II deficiency and a follow-up stool was positive for type 3 poliovirus and positive by rRT-PCR VP1 VDPV screen. A fourth stool sample collected was also rRT-PCR VP1 VDPV positive, showed 10 mutations on screening and was reported as iVDPV3-positive.

Capitalising on the collaboration between the immunology laboratory, virology and national polio surveillance programme, the desire is to establish routine surveillance of PID patients for polio excretion. All PID patients attend healthcare facilities in Tunis on a frequent basis and it should be possible to establish a quarterly screening system to monitor for polio excretion.

### **WHO-coordinated database on iVDPVs: lessons learnt**

The WHO-coordinated iVDPV registry attempts to capture all cases of vaccine-derived poliovirus excretion among immunodeficient patients regardless of reporting source and paralysis status and includes both prolonged (> 6 months excretion) and chronic (> 5 years excretion) cases. Most cases

are 0 to 5 years of age, correlating with the time of OPV administration. As age increases, survival rate for PID patients decrease and OPV exposure reduces. There is a larger variation in age in high income countries, possibly due to differences in life expectancy of PID patients with patients having lower life expectancy in middle and lower income countries and longer life expectancy in high income countries. Distribution by countries represented is largely affected by the strength of VDPV surveillance and PID diagnosis and the survival rate of PID individuals, and countries with strong surveillance and PID diagnosis may be overrepresented, for example Iran and Egypt where VDPV studies have identified many iVDPV cases. The apparent increase in iVDPV cases over the past 10 years is largely due to the strengthening of surveillance and VDPV sequencing in countries continuing to use OPV. The vast majority of cases have paralysis, but this mainly reflects the source of case reporting through AFP surveillance. Approximately 25% are not AFP, suggesting a large number of iVDPV cases that are not detected.

In the registry the highest prevalence is of iVDPV2 exclusively (67%) but the incidence is expected to decline after OPV2 withdrawal, and type 1 and 3 may increase. For individuals excreting for >6 months, half (51%) stopped excreting, many spontaneously, and 23% developed prolonged ( $\geq 6$  months and  $\leq 5$  years) excretors. Only 2 individuals (4%) have been excreting for more than 5 years. The excretion period for 21% of cases is unknown. Known chronic excretors have tended to be diagnosed with Common Variable Immune Deficiency (CVID), characterized by low levels of serum immunoglobulins and antibodies, and almost invariably have come from high-income countries. No new chronic excretors have been detected since 2000. Survival analysis using available data suggests that except for CVID cases, the excretion period of poliovirus is short (6 months to 5 years).

Attempts have been made to model the iVDPV data suggesting that iVDPV excretors constitute a significant risk to trigger outbreaks in under immunized populations post OPV cessation, particularly in lower middle-income countries with high population densities. Provision of a polio antiviral drug combination should dramatically reduce the risk of outbreaks, but will require surveillance to identify asymptomatic excretors. It has been proposed AFP surveillance be expanded to include a second screening case definition, to be used by AFP surveillance staff to detect children with suspected PID. The case definition should include the presence of at least 2 of the 10 Jeffrey Modell signs for PID. All detected 'suspected PID' patients should be fully investigate with the collection of two stool specimens to test for PV, and referral to an immunology centre wherever possible. Initially, the expansion will be implemented as a pilot test in up to five countries in the Middle East. This approach has been endorsed by SAGE.

### **Field surveillance strategies during the endgame**

Field surveillance activities need to be fast and fully accountable during the endgame period. To develop strategies to achieve this WHO has established a Surveillance Task Team (STT), with attention focussed on outbreak and polio-free countries, tasked with developing a Global Surveillance Action Plan, strengthening polio surveillance at Regional and Member State level, and coordination of surveillance resources.

Outbreak response guidelines call for a measure of increased surveillance and outbreak response periods offer the potential for surveillance strengthening, including opportunities for advocacy. These opportunities can be integrated into new outbreak response standard operating procedures (SOPs) at country level.

A surveillance risk register for a small number of priority countries is being developed based on an assessment of surveillance performance criteria and risk factors. Risk predictions are limited by the indicators used and performance data available, and it is becoming clear that there is a need to look beyond classic indicators of surveillance performance, to include variables based on population movements, quality of active surveillance and validation of case classification. The Independent Monitoring Board (IMB) requested the GPEI to conduct a deep assessment of surveillance in a number of countries including Nigeria, Pakistan and Afghanistan to review the strengths and weaknesses of the national systems. One approach to the assessment was to look at classical indicators, such as timeliness of stool collection, but rephrase the question to assess the number of districts with 100% stool collection timeliness and percentage of cases with second stool collection >14 from onset. This approach permits investigation of the quality of surveillance that may not be obvious using standard assessment of the classic indicators.

The STT has raised a series of possibilities for further discussion, including the implementation of active surveillance in the context of an outbreak scenario, relevance of healthy child stool sampling in specific instances and community-based surveillance. The potential for more accurate geolocation of cases, including use of handheld devices and GPS coordinates should be discussed as a possibility. The use of environmental sweeps, using a single, one-time environmental surveillance event, offers the potential to collect information from even the smallest community sites.

Another area of development is to extend the Stop Transmission of Polio (STOP) Program to include surveillance, possibly by engaging former STOP team members for long-term surveillance strengthening.

### **Laboratory surveillance prospects during the endgame**

The programme needs to find ways to supplement AFP surveillance, to cast a wider net to minimize missed infections and not just AFP cases. It also needs to reduce the time interval from case identification to response, and improve sample collection, transport, and processing methods.

The move to expanding environmental surveillance must balance resource commitments between AFP surveillance and environmental surveillance and expanded use has significant implications for both field and laboratory activities. Expanding environmental surveillance, particularly to countries without GPLN laboratories or those facing security issues, presents serious challenges for the surveillance system. There are few standard quantitative metrics for environmental surveillance site selection or site monitoring, and the programme is dependent on both detailed technical information and local knowledge to identify promising sites.

There is a constant demand for better assay sensitivity and specificity, to rapidly identify viruses for sequencing or to directly identify WPV. There is a need for methods to identify VDPV in sea of Sabin viruses (e.g. in sewage) and for direct screening during outbreak. There are a series of evolving diagnostic questions raised by WPV2 eradication and OPV2 cessation and the need to detect cVDPV2s. As the programme moves into the endgame phase it cannot afford to miss a WPV or VDPV in a homotypic mixture.

Opportunities to improve laboratory methods include the possibility of reducing even further the laboratory turn-around time through use of new ITD assays and improved sequencing methods, and



through direct detection of poliovirus in stool or sewage, thus eliminating the need for virus isolation. There is a role for new methods to analyse complex virus mixtures, particularly those found in environmental samples, and there may be a programmatic role of NGS in this.

There has been continuing evolution of molecular ITD methods, beginning in the early 1990s and now using version 5.0, reflecting the increasing technical capabilities available and the evolving needs of the programme. The algorithm for use of ITD 5.0 has been simplified so that any isolate identified as non-SL or in any way discrepant goes straight to sequencing.

A great deal of development has been carried out on methods for direct detection of poliovirus in stool and sewage, including application of some of the methods in specific settings. Direct detection potentially saves 3 to 7 days, but poliovirus culture is now well established, the viruses grow rapidly and efficiently in culture and direct detection requires much more sample processing. Current assays are at the sensitivity limits of PCR. Sensitivity limitations may be overcome by adding more material for each PCR reaction but that would risk carryover of additional PCR inhibitors, or simply increasing the amount of stool extracted. There is an added complication in that there is usually an insufficient amount of virus per unit volume in sewage to detect without a concentration step.

Any new direct detection method must be easily implementable in existing GPLN labs, especially those that serve high-risk areas, and be implementable in laboratories with no molecular biology experience. At present sequencing methods are less sensitive than rRT-PCR by 100- or 1000-fold, raising the question of how to get quality sequence data directly from stool. In addition, any new approaches may have implications for PV2 containment now, and broader containment considerations later.

One example of a new technology is the PATH diagnostic tool for rapid detection of poliovirus in stool. This tool has been developed for potential deployment to first- or second-tier labs, not necessarily GPLN laboratories, and requires a minimum of laboratory equipment to perform. The initial focus has been on detection of WPV1 and VDPV2, but on evaluation has been shown to have low sensitivity and specificity, with less than 50% concordance with the standard ITD assays.

Laboratory methods continue to evolve to rapidly identify polio isolates in need of sequencing, but complex mixtures, including many associated with VDPVs and environmental samples remain a problem for sequencing. For any new methods introduced account must be taken of the need for laboratory databases to possess the flexibility to accept data from new assays and algorithms and for additional training and re-training requirements. It must also be born in mind that referral patterns, and laboratory capacities associated with referral, may need modification as the programme moves through the endgame.

## Summary of session discussions

In addition to testing 'suspected PID' cases for polio excretion, all known PID cases should be tested on a frequent basis. However, the capacity to diagnose PID cases is highly variable between countries.

AFP surveillance teams are well trained for collection of stool samples, and could be trained in evaluation of the Jeffrey Modell signs, but significant questions remain over how the proposed definition of 'suspected PID' could be made to function for field use. It is possible that the definition will require modification. In some countries in the Eastern Mediterranean Region diagnosis of PID depends on the immunological centres, and these centres can be effectively integrated into the AFP surveillance system. However, for many countries there needs to be a carefully considered systematic approach to implementing any expanded AFP surveillance system, including an assessment of existing diagnostic and treatment facilities.

The extent of the risk to polio eradication posed by polio excretors with PID has still to be determined and many research questions remain to be answered. However, the programme should be ready to begin implementation of additional screening should the current studies suggest it is necessary. This preparation will include an assessment of the additional resources required to identify suspected cases, collect and test stool samples, and fully characterize any poliovirus isolates detected. It should also be considered that in some countries there will be few resources available to provide treatment for identified PID cases, raising ethical issues over providing diagnosis without offering treatment.

A persistent challenge within the surveillance system is the lack of a simple credibility check to assess the likelihood that existing data is providing a realistic picture of the presence or absence of polio transmission in a given location. Evaluation of surveillance indicators at sub-national level is useful for assessing reliability of surveillance data, but is not always available in every country. In addition, almost all countries have some inaccessible populations that do not necessarily reflect the polio status of the country as a whole and surveillance indicators for these populations should reflect this.

One approach to areas with security challenges may be to conduct healthy child stool surveys, but there are, as yet, no specific local guidelines on how to accomplish this, or a systematic assessment of the resources required.

A key challenge for surveillance remains the requirement to provide real-time analysis of data to provide information for action. This has always been a challenge, but it increases as we enter the endgame period. Surveillance strategies must be directed to providing improved case investigation, stool collection, and analysis and reporting of data. Some activities, such as collection of contact stool samples, may be very low sensitivity for a very high workload, and should be assessed in terms of effectiveness for the programme. There needs to be careful consideration of both favourable and unfavourable aspects of any surveillance activity, bearing in mind that the requirements for surveillance may be different in different circumstances and time, and relative advantages and disadvantages may change.

As a general rule, older technologies tend to be less expensive and newer technologies tend to be more expensive, but there have been no systematic assessment of cost-effectiveness of using the newer methods. Differential cost components have become clearer over time, but more complex costings, including replacement of laboratory equipment provided much earlier in the programme now need to be considered. Cost effectiveness studies can now be undertaken and specific questions on the relative cost of introducing new methodologies can now be asked. While the financial cost of surveillance is a relatively small component of the overall GPEI budget, it would be useful to have an assessment of the real cost per specimen tested. Included in any consideration of cost effectiveness should be an assessment of how new methodologies or approaches will improve surveillance.

### **SESSION 3: Environmental Surveillance of Poliovirus**

#### **Update on implementation of the Global Environmental Surveillance Expansion Plan**

The Polio Eradication & Endgame Strategic Plan 2013–2018 developed by the GPEI in response to a directive of the World Health Assembly is a comprehensive, long-term strategy that addresses what is needed to deliver a polio-free world by 2018. The Plan calls for environmental surveillance enhancement and expansion to help identify any residual transmission in endemic areas, provide early indications of new importations or emergence of VDPV and document the elimination of Sabin viruses following the withdrawal of OPV2.

The Global Environmental Surveillance Expansion Plan has been developed by WHO. Priorities for the first phase of the expansion have included endemic countries, those recently infected by poliovirus, those at high risk of poliovirus importation either because of geographical proximity to infected areas or past history of repeated poliovirus importation, and areas at risk for emergence and circulation of vaccine-derived polioviruses. Initial work, started in 2013, supported sites in Nigeria, Kenya, India, Pakistan, Afghanistan, and Egypt. The Expansion Plan was finalized in 2015 and support extended to additional sites in Nigeria, Afghanistan, and Pakistan. New sites were also established in Cameroon, Chad, Niger, Burkina Faso, Guinea, Madagascar, India, Jordan and Lebanon.

The second phase of the expansion includes a broader assessment of risk based on 5 parameters: global risk assessment for WPV1 risk, as determined by the Eradication and Outbreak Management Group (EOMG) Risk Assessment Task Team (RATT); tiering used for IPV introduction for cVDPV2 risk; non-polio AFP rate at national level for overall surveillance risk; risk arising from conflict leading to inaccessibility or surveillance gaps (based on reports of deaths from armed conflict 2013-14 from Uppsala University); and, risk arising from having type 2 poliovirus containment facilities.

Based on assessment of these 5 parameters the highest risk countries included Ethiopia, South Sudan, Equatorial Guinea, Iraq, Somalia, Yemen (however, experience has shown that environmental surveillance is not currently feasible in these countries), Myanmar (commencing), Indonesia (for expansion), Timor-Leste (but environmental surveillance is probably not feasible), and Philippines. High priority countries included Democratic Republic of Congo, Gabon, Burundi, Mali, Central African Republic, Guinea-Bissau, South Africa (assuming it will have a type 2 poliovirus essential facility

(PEF), Syria (however, experience has shown that environmental surveillance is not currently feasible), Iran, Sudan, Laos, Vietnam, and Papua New Guinea (but environmental surveillance is probably not feasible). Another eleven countries have been listed as medium or low priority, many on the basis of proximity to high risk countries. The Expansion Plan is considered to be a 'living document' and the tiering is not fixed but open to review and revision.

Additional tasks of the Environmental Surveillance Implementation Working Group (ESIWG) include developing standardized indicators to monitor and track the effectiveness of environmental surveillance, provide guidance and recommendations on management, analysis, and reporting of environmental surveillance data, and review resource requirements for full integration of environmental and AFP surveillance to ensure sustainability. The 2017-2018 budget for expansion is USD 13,699,300 and includes set up and running costs, specimen collection, transport, in-country coordination, and monitoring for new sites. It does not include existing costs in established countries.

Challenges to expansion include the tight timeline, as experience has shown that it can take a year or more to fully establish environmental surveillance in a new site or country. In addition, ensuring the quality of surveillance requires close monitoring, both by the national and regional levels. Establishing and maintaining confidence in the system can be a challenge, particularly with regard to data sharing and confidentiality. The increased burden of environmental surveillance on the sequencing laboratories needs to be taken into account, as does the burden placed on countries to respond appropriately to positive detections.

#### **Implementation of environmental surveillance: What does it take? Experience from Nigeria.**

Environmental surveillance started in Nigeria, in Kano state in July 2011 following recommendations from the Expert Review Committee (ERC). Since the start of environmental surveillance, silent wild poliovirus transmission was confirmed in a number of areas including Lagos in 2012, Sokoto in 2013, and Kaduna in 2014. At the end of 2016 environmental surveillance was being conducted in 15 States, with a total of 56 sampling sites. There is a plan to add an additional 4 sites in 2017. There has been a steady rise in the number of environmental samples collected, from 25 in 2011 to 815 in 2016. Despite the expansion there is currently only one environmental surveillance laboratory serving the country, although there are plans to establish a second.

Key requirements for establishing and maintaining environmental surveillance include detailed planning, involving all stakeholders with strong buy-in from government authorities. There is a need for strong logistics support including adequate funding for sample collection, transportation and laboratory testing. There is also a need for training, both of sample collectors and their supervisors, and of laboratory personnel.

Major drivers of the expansion in Nigeria have been leadership from the Government, at National and State level, and WHO through provision of logistics support and training. Partnership with security personnel in some parts of the country has been crucial in States experiencing unrest, including Borno, Adamawa and Yobe. The programme has been dependent on strong supervision and monitoring, making use of local knowledge to select sample collection sites. Feedback has been provided through regular meetings with sample collectors and an annual review meeting.

The main challenges encountered have been the absence of well-designed closed sewage system in many of the highest priority States. Security challenges exist in the Northeast zone (especially Borno, Yobe and Adamawa states) that threatens safe sample collection and transportation. Reliance on erratic public transportation to get the samples to the laboratory at Ibadan causes delayed delivery, and a fragile infrastructure causes power outages that threaten the capacity to keep samples cold. Lack of local environmental protection legislation permits local industry to pollute drainage channels and sampling sites with chemical effluent discharges and blockage of water flow by refuse, road construction activities, irrigation and mining activities.

The way forward is seen as further expanding based on risk assessment considering AFP surveillance performance, population dynamics and poliovirus epidemiology. A second environmental surveillance laboratory will be established in the Maiduguri Polio Laboratory and a new algorithm for laboratory testing will be adopted to facilitate faster laboratory reporting of results.

### **Managing workload in an environmental surveillance laboratory: Constraints and limitation in Pakistan**

Pakistan has also seen a significant level of expansion in environmental surveillance. Surveillance began in 2009 in two cities (Karachi and Lahore) with 8 sites, and has steadily expanded to 53 sites in 28 cities in 2016. In Afghanistan environmental surveillance began in 2013 with two sites in Kandahar, and has subsequently been expanded to 17 sites in 6 cities. The Virology Department, National Institute of Health, Islamabad hosts the laboratory responsible for testing environmental surveillance and AFP surveillance samples from Pakistan and Afghanistan.

There has been a huge increase in the number of environmental samples received in the laboratory, from 46 in 2009 to 715 in 2016. Projections for 2017 suggest as many as 900 may be received for the year. The increase in number of samples has been matched by an increase in the number of ITD tests required. In 2009 a total of 136 ITD tests, using probe hybridization/ELISA, were conducted. In 2016 a total of 2337 ITD tests, using qRT-PCR, were conducted; the projected workload for 2017 is 3480. Sequencing workload increased from 43 in 2009 to a peak of 655 in 2014, but has declined since 2014 due to the decline in polio-positive isolates detected. Laboratory staff is expecting another increase in 2017 following the OPV switch and the requirement to sequence every poliovirus type 2 isolate detected.

Expansion of environmental surveillance has required improved planning for laboratory consumables and reagents, including critical review of additional laboratory required for the proposed expansion. Necessary reagents and consumables were provided as required, and for 2017 laboratory supplies have been ordered with a 6 months buffer zone to allow for unexpected increases in laboratory testing or difficulties in obtaining materials. In addition, new laboratory staff were recruited before the expansion began, trained and allocated to the various laboratory sections. The laboratory space has also been expanded to take account of the increased workload.

The main constraints and limitations include the lack of a reliable power supply and the absence of backup support and servicing for critical equipment. There are also limitations in the current data management system with no options for analysis of weekly progress reports, line listing of positive samples or reporting on pending results. It is clear that an improved environmental surveillance data management system is urgently required.

### **Environmental surveillance data and information management: gaps and way forward**

A key component of any surveillance system is a data management system that not only permits the storage of data but also presents data in a format that can be easily analysed. Data management systems in use within the polio programme were established to meet the needs of AFP surveillance, and environmental surveillance presents some very different data management requirements. Country-specific data management systems for environmental surveillance, meeting the immediate data needs of the country, have been established as surveillance has been established and expanded, but there is no global process for reporting data and transforming them into information required at international level.

Raw data was initially reported to WHO, primarily from the laboratories, in the form of spreadsheets, but effort has gone into developing a more integrated system. Work is ongoing in EMRO to develop a more integrated database for information sharing. WHO headquarters attempts to manage the data and information provided through the Polio Information System (PoliS) integrated data management system that aims to harmonize existing data management and reporting systems. Work is currently underway to update country management systems from a series of unwieldy spreadsheet files to a common data entry and management system that can be reported to WHO without the requirement to harmonize data in different formats. PoliS provides standard tabular views of positive sample results, and results can be converted into calendar view and sit-specific information. There is also a mapping function. Main objective of PoliS is to harmonize and consolidate GPEI data from various sources allowing the user the ability to visualize multiple layers of information.

A number of gaps still exist at global level that would make PoliS fully functional. There is no common definition of what constitutes an environmental surveillance site, or guidelines on how to establish a site. There is no common site naming policy, or common system for numbering or identifying samples from a particular site. There are no guidelines on how to manage sit-specific data if the site changes, or on what the minimum common data variables should be captures for each site. There is no global process for the standardized laboratory data management for environmental surveillance, no definition of a minimum reporting dataset or clear process for managing referred isolates. There is no defined regional/global system for managing the environmental surveillance process, with non-coordinated regional initiatives offering a range of different approaches.

It has been proposed that the ESIWG define and promote the processes for environmental surveillance site management and standardized laboratory data management, and request GPLN endorsement for the development and implementation of one GPEI online environmental surveillance information system based on the defined processes. Important considerations include the capacity for standardized reporting across regions using a one-time data entry system (no longer relying on emailing weekly files). The system should permit integration with PoliS and allow a user-friendly searchable interface with secured and controlled access of information. Knowledge and experience gained in the Regions should be utilized to develop the global system.

### **Field investigations following detection of PV2: India experience**

India switched from tOPV to bOPV on 25 April 2016 as a part of globally synchronized withdrawal of the type 2 component of OPV. AFP and environmental surveillance have been ongoing since then,

with environmental surveillance conducted at 35 sites in 8 States. Detection of Sabin-like type poliovirus type 2 isolates from AFP cases declined very rapidly immediately following the switch, with the last positive cases detected in May 2016. Sabin-like type 2 isolates have continued to be detected from environmental samples, however, up until December 2016. A total of 7 Sabin-like type 2 isolates were detected, all showing very limited genomic variation from Sabin type 2 virus, suggesting continued illicit use of tOPV in at least two locations (Ahmedabad and Hyderabad).

Following detection of Sabin-like type 2 viruses in environmental samples field investigations were launched in Hyderabad and neighbouring districts in September 2016, and in Ahmedabad in September and November 2016. Field investigations included re-verification of cold chain points that were listed under switch validation exercise, visits to all AFP reporting sites in the district including extensive search in medical colleges and other big institutes, and physical verification of all private stockists and vaccine distributors on priority, in coordination with state drug controller. Street-by-street physical verification of all small private clinics or health facilities that were not part of reporting sites was conducted and visits made to the OPV manufacturer in the area for type 2 OPV bulk storage. On location of any identified vials of tOPV the source and time of supply was traced and safe disposal of vaccine vials ensured.

In Hyderabad 37 vials of tOPV were located at a total of 17 private clinics, the majority of which were very small local clinics not affiliated with any medical association. Of the 37 vials, 22 were unopened and 15 were partially used. All vials had been procured before switch date and 6 were time-expired expired; the remaining 31 had expiry dates from December 2016 to November 2017. Eighty percent of the vials came from a single manufacturer. In Ahmedabad 44 vials of tOPV were located at a total of 31 health facilities, all small private practitioners. Thirteen of the vials were unopened and 31 partially used. All had been procured before the switch, and the majority came from a single manufacturer.

Following the discoveries in Hyderabad and Ahmedabad a follow-up search for remaining tOPV was made across India. During the polio NID conducted in January 2017 vaccination teams and supervisors searched 261,448 health facilities, mostly small private clinics, for remaining vials of tOPV. Of these, 36,130 administered vaccines, and 65 held remaining stocks of tOPV. A total of 116 vials of tOPV were recovered. These 65 health facilities, of which 2 were government facilities, ranged across 9 States. The majority of tOPV recovered was from one manufacturer. The Drug Controller General for the Indian NRA visited the manufacturer and confirmed that no tOPV manufacturing took place after then switch. The nation-wide search for tOPV will be repeated during the April round of NID, and any vial of tOPV discovered will be replaced with 2 vials of bOPV.

### **Summary of session discussions**

The matrix of 5 parameters used to prioritise countries for expansion is at present an empirical model and has not formerly been assessed for feasibility of establishing environmental surveillance in the countries. This will be the next step, for which input from the Regional Offices will be crucial, as it will to review any relative weighting of the different parameters in the final assessment. Communication between WHO and Member States should be through the Regional Offices, who are responsible for supporting their countries in assessing the feasibility of establishing environmental surveillance and working with countries to develop an implementation plan. The global budget does include a component for human resources at both country and Regional level, and this should be

used to support staffing to assess feasibility and implement the plan. Although the budget is allocated for activities in 2017-2018 the likelihood is that it will be extended to cover a longer period.

These presentations have been highly instructive in describing the realities of establishing and expanding environmental surveillance, particularly with regard to increasing workload, and should be instructive to the programme as it considers further expansion. The presentations have highlighted the importance of infrastructure and the limitations that lacking or unreliable infrastructure places on surveillance and the need to address issues related to infrastructure logistics if expansion is to continue.

Environmental surveillance is currently largely dependent on external funding with little recognition given to the need for sustainability. A vision statement will be prepared by WHO on projected future funding and sustainability of the system beyond the year 2020, but there remain many unknowns at this point. It is of concern that the Regions and Member States have been given somewhat mixed messages over funding reductions and requests to increase surveillance. WHO is investigating ways in which current capacities and essential functions can be maintained, but there remains significant uncertainty over how this will be funded.

Site selection, monitoring and review of sites remain major concerns for the programme. The rationale for adding more sites within a country, for giving some sites preference over others, or for maintaining sites that are non-productive, remains unclear in many countries. It is clear that in most countries only a small percentage of the population is under environmental surveillance. One way to expand environmental surveillance would be to monitor the periodic and predictable mass gatherings that occur around the world on a regular basis, many for religious reasons. The science of environmental surveillance remains at an early stage in its development, and more needs to be done to make it more systematic, more accountable and easier to interpret the results. More assessment and review of existing environmental surveillance is required for general guidelines to be established. It will then be up to individual Member States to implement the guidelines in a way most appropriate to their circumstances.

There is an obvious programmatic advantage in harmonizing regional and country data at global level to achieve standardization. While it is clearly possible to use the existing data management systems, established on an *ad hoc*, country-by-country basis, and through a process of data harmonization and consolidation arrive at a global database. This process can be cumbersome, resource intensive and time-consuming. In this instance, diversity is a major challenge to attaining a global picture of the epidemiological situation. A balance needs to be struck, however, between the immediate needs of the laboratories at country level and the programmatic needs at regional and global levels. The process of development of a global system is at the point of determining what can be agreed with regard to key components of the system, such as a standardized methodology for naming and identifying a site, possibly in a format similar to the Epld format used in AFP surveillance. There are two major components to the discussion: the data most desirable to be captured and; the processes necessary to achieve standardization. There needs to be a comparison of what already exists in the different WHO Regional systems, and a comparison of the older established systems with the new systems being established under the expansion. The WHO Regional Offices are fully prepared to share their information and experiences to arrive at a common position.



Defining the process for harmonization and standardization clearly falls within the remit of the ESIWG, and the group will be discussing how best to accomplish this at a later date. The question of whether the process could or should be integrated with the GPLNMS is more difficult to answer, and more work is needed to look at the potential value added to the GPLN in integration. GPLNMS was developed as a mechanism for annual reporting, primarily for laboratory performance monitoring, rather than real-time programmatic monitoring. The system permits hierarchical aggregation of laboratory data on AFP cases from laboratory to country, to Region, to WHO headquarters. It is not immediately clear how the system could be configured to permit real-time accessibility of laboratory-specific environmental surveillance data at global level for programmatic action.

There is currently no mandate, structure or funding to manage environmental surveillance sites within the GPLN. However, the global programme is not content with the way environmental surveillance data is currently being managed. One potential solution is for resources to be provided, at global level, for development and maintenance of a system that would meet the needs of the laboratories, countries, Regions and the global programme. This will have important implications for the transition process and polio legacy issues.

The detailed street-by-street search of smaller health facilities conducted by the vaccinators and supervisors provides an impressive example of what needs to be done to ensure all stocks of tOPV have been removed. The continued isolation of Sabin-like poliovirus type 2 in environmental samples when not detected in AFP cases also demonstrates the value of environmental surveillance. The search process revealed that many of the individual practitioners in small private health facilities were not aware of the national and international programme, and not aware of the global switch away from tOPV. It was also apparent that some of the manufacturers were not fully aware of the schedule for tOPV withdrawal and continued to provide vaccine until close to the switch date. There is a clear need to establish a structured arrangement to ensure communications and information exchange with all relevant health facilities, and this will be essential when a global decision to withdraw all OPV is made.

#### **SESSION 4: Events and Outbreaks management**

##### **Events and Outbreaks: Standard Operating Procedures and lessons learnt**

The revised GPEI Standard Operating Procedures (SOP) for polio outbreak response were developed in 2015, with further revision in preparation for April 2017. The latest revision (version 2.2) includes response strategies after OPV2 cessation, VDPV notification and classification and use of the mOPV2 stockpile. The guidelines provide a recommended timeline of events from when notification of virus isolation is received from the laboratory (Day 0) to when the outbreak can be declared over. There are strict guidelines for responses expected from Member States as the nature of the event is determined and sequential activities are implemented.

Under Article 6 of the International Health Regulations 2005 (IHR) all Member States are required to notify WHO of events likely to constitute a Public Health Event of International Concern (PHEIC), including poliomyelitis due to WPV and cVDPV. Detection of Sabin-like type 2 polioviruses after September 2016 is also considered to be a PHEIC requiring notification. Evidence of poliovirus

circulation distinguishes an 'event' from an 'outbreak', and an event is defined as detection of a single isolate without evidence of circulation, which may present a low to medium risk for transmission. An outbreak presents evidence of circulation and a high risk for further transmission.

With reference to VDPV2 isolation, the recommended process for risk assessment, outbreak grading and vaccine release include 3 steps. The first step is an immediate review of available information within the WHO headquarters Polio Team, followed the same day by a discussion with Regional and country authorities to assess the risk posed and advise on further investigation according to the scenario. The laboratory plays a key role in this step and in any further investigations required. Requirements for mOPV2 used will be determined and if necessary the mOPV2 Advisory Group to the WHO Director General will be convened and notice given to UNICEF Supply Division. The second step includes Advisory Group discussion to determine the level of risk presented, the need for mOPV2 or IPV use, provide recommendations to the WHO Director General and Member States, and liaise with UNICEF Supply Division to make the appropriate vaccine available. The third step is a grading of the outbreak by the EOMG into one of 3 grades to determine the risk and level of support required.

If it is decided an immunization response is required it is now generally recommended that 2 SIAs are conducted in outbreak and high risk areas, but if there is no evidence for circulation in low and medium risk areas resources be focused on investigation and surveillance. The target for SIAs should be children <5 years of age unless there is evidence for circulation in older age groups. The SIA should target approximately 1 to 2 million children, based on risk assessment and country capacity to deliver, and coverage must be  $\geq 80\%$  with no evidence for persistently missed children. The first SIA should be conducted within 14 days of the laboratory report of the sequencing data and subsequent SIAs should be conducted at 2-3 week intervals. An immediate and adequate response to cVDPV2 is now required even where WPV1 still circulates. Discussions will be required on how best to time bOPV rounds with mOPV2 rounds where it is required.

There have been 31 VDPV emergencies since April 2016, requiring 51 meetings of the Advisory Group. The Advisory Group recommendations have usually been implemented on time, within 14 days, although this has not always been the case. Detection of Sabin-like type 2 polioviruses is now very closely monitored and a rapid response initiated, including assessment of the laboratory data and additional field investigation.

Outbreak response assessment occurs every 3 months following a notification and is conducted by independent experts. They assess the evidence for a sensitive surveillance system, high population immunity and interruption of poliovirus transmission. They review the quality of the response plan and implementation of response activities. New guidelines for outbreak response are being drafted and the role of laboratories in consultation and implementation of response assessments will be increased.

### **Molecular epidemiology of polioviruses to inform investigation and response to events/outbreaks**

All WPV, VDPV and poliovirus type 2 isolates are currently subjected to sequencing of a 900 nucleotide stretch of VP1. Results are supported by a well-developed quality assurance and quality control programme providing a high level of confidence. There are currently 28 accredited sequencing laboratories within the GPLN that have been subjected to proficiency testing for the past

5 years, with an accreditation checklist and regular monitoring. Programmatic actions can be based on as little as a single nucleotide difference, 6 nucleotide changes rather than 5, for example, so confidence in the accuracy of sequencing results is essential.

One area of recent development is the standardization of information and methodologies for better communication, including evolving tools to link genetic sequence data with epidemiological data, and standardization in the reporting of sequencing results. In another development sequencing laboratories have been provided with protocols for selecting specific primers for amplifying individual components of virus mixtures and for determining whether a new sequence is a VDPV (poliovirus type 1 or type 3) based on the number of nucleotide changes. A protocol has also been developed for determining if two sequences are genetically linked. Sequencing methods continue to evolve as new requirements arise, including the extension from VP1 sequencing to complete genome sequencing, and development of more sensitive methods to match the increased ITD sensitivity when investigating complex mixtures of viruses.

VDPV classification and reporting continue to pose a challenge, both technical and in terms of accurate communication with the programme. There remains a need to improve communication and coordination between the laboratories and epidemiology, possibly through the development of a standardized process within each WHO Region. For poliovirus type 2 events and outbreaks the laboratory information is critical for understanding the event and assessing the risk, and this information usually needs to be interpreted and explained by a virologist. To meet these challenges, activities are underway to harmonize VDPV reporting from the sequencing laboratories, to adopt standard text for notes accompanying sequencing reports and use of a standard template for line-listing of results to reduce the amount of extraneous, non-essential information accompanying the laboratory results.

### **Summary of session discussions**

Further collaboration with the Regional Offices will take place shortly in consideration of the need for greater laboratory involvement in the planning and evaluation process, particularly the steps that result in an increased laboratory workload, and in developing and refining indicators and timelines. There is also a need to increase involvement of the laboratories in the risk assessment and planning of response activities in the field; at present the laboratories are often not adequately consulted. Programme managers at country level should be further encouraged to include laboratory staff in the assessment and response planning processes.

There is concern that responding to a cVDPV2 outbreak with mOPV2 in a population with low immunity to poliovirus type 2 will increase the risk of generating further cVDPV2 outbreaks. A balance is required between the need to respond to a potential outbreak and the need to mitigate against generating additional cVDPV2s. Review of data collected over the past year has indicated that the information available to assess risk posed by secondary spread of mOPV2 is generally sufficient to be consistent with the outcomes predicted by modelling. Even though population immunity to poliovirus type 2 will be declining with time, for the immediate future the risk posed by cVDPV2 remains greater than the risk from secondary spread from mOPV2.

The new SOPs place greater emphasis on the role of risk assessment and permit WHO Regional Offices greater flexibility in not responding to an event until clear evidence can be gathered to

demonstrate circulation. Technical updates on the revised protocol will be available by the middle of April 2017, with a further revision of the entire document being made available by the end of September.

There is a large stockpile of bulk mOPV2 vaccine that can be filled and finished as required. There is currently no shortage of mOPV2 and none is envisaged for the near future, but there are currently no plans for producing more bulk.

As more laboratories are now providing sequencing results there is a clear need for improved consistency in the reporting of sequence information, together with recognition for the need for transparency in the way sequencing results are interpreted and reported back to the programme. There is also a need for the programme managers to understand the implications of molecular epidemiological data and consistently act on the laboratory results provided. This may require additional training in programmatic interpretation of critical laboratory information, aimed specifically at programme managers, if the scope of the need for additional training can be defined.

## **SESSION 5: Planning Polio Transition**

### **GPEI Transition Planning and the Post-certification Strategy: Challenges to sustain integrated field and laboratory poliovirus surveillance**

This is a critical time for GPEI transition planning as the world at the point of developing and evaluating new approaches to managing high risk public health events, and discovery of poliovirus transmission after global certification will constitute a major public health event. Transition planning has already been initiated at country level, but some countries are remain unclear over the requirements, the level of external funding available to implement activities, and the length of time funding will remain accessible. Improved communication is required to ensure that countries are fully aware of their responsibilities and the support available for them to implement activities, and also which activities will be phased out, which will need to be maintained, and which can be transferred to other authorities.

The post-certification strategy (PCS), beginning at the time of certification, will define the essential components required to maintain a global polio-free status. It will outline the strategic options, particularly at the global and regional levels, and describe the funding requirements. Four essential goals have been defined; containing all sources of poliovirus, detecting and responding to any poliovirus introductions, immunizing populations against unexpected events, and ensuring polio functions are sustained post-certification. A key milestone in the process will be the cessation of use of OPV, with the requirement for enhanced surveillance for the subsequent one-year period. Guidelines on how this will be accomplished will be covered in the PCS.

A sensitive surveillance system will be required to promptly detect any poliovirus in a human or in the environment during the post-certification period. This will require revision to the concept of poliovirus surveillance as conducted over the past 25 years, possibly with new methodologies, but building on what has already been established. It will also require mechanisms to sustain the established technically qualified laboratory and surveillance infrastructure capacity, including information systems, together with identifying possible future outbreak risks and responses required. As a starting point for discussions it has been assumed that the core components of

surveillance systems will be continued, including the GPLN with all of its current functions. However, surveillance for an eradicated pathogen will require a different surveillance system to that required for a controlled pathogen, and it will be essential to understand the evolution of primary risks over time and the changing implications for the sensitivity and specificity of surveillance. It has also been assumed that there will be a mix of surveillance strategies and operational priorities that will differ by geography, degree of risk, and time after certification. Synergies with other surveillance or laboratory diagnostic systems are also assumed, but it will be necessary to sustain polio prioritization and core capacities for poliovirus detection and characterization.

Changing surveillance requirements can be conceptualized more easily if future requirements are allocated into stages of time after certification of polio eradication. Stage one would be the period from certification to cessation of bOPV use; stage two would be 0-4 years post-cessation; stage three would be 5-9 years post-cessation; and stage four would be 10 years plus. Key questions for consideration now include which surveillance functions and systems would be required for each stage at each level (global, regional and national), which surveillance structures would be most sustainable, efficient and effective, and optimize polio assets, and what are the foreseen challenges, and opportunities, for implementation.

#### **A way of life post-certification: the WHO Europe experience**

The WHO European Region encourages Member States to provide polio surveillance data from three primary sources; AFP surveillance, environmental surveillance and enterovirus surveillance. Given the broad heterogeneity of countries in the Region, many of which do not conduct AFP surveillance, the Regional Office has strongly encouraged the collection of detailed supplementary surveillance data in the form of environmental and enterovirus surveillance information. Experience has led to the conclusion that the supplementary surveillance used in the Region has a high probability of detecting polioviruses in the target population, but may not be sensitive enough to identify the index case or initial excretor. One challenge facing the Region is that most of the data is generated through the laboratories and there is a lack of available epidemiological data from enterovirus and environmental surveillance systems, particularly for systems that are not directly under the authority of the Health Ministries.

#### **Summary of session discussions**

Although technically feasible, it may not always be cost effective to conduct some forms of surveillance in some countries in the post-cessation period. Increasing infrastructural development in some current high risk countries will also reduce the risk of polio transmission in future, partially reducing the requirements for ongoing surveillance, paradoxically while increasing the capacity of the country to conduct sophisticated sustainable surveillance. There are some surveillance components and capacities that will be required as a constant for the long term, and others that may only be applicable during particular periods under specific circumstances. Further discussion is needed on what these components may be, how they can be developed and implemented and, if necessary, sustained for the long term.

Experience in Europe and the United States suggest that routine enterovirus surveillance, as a system for detection of poliovirus, is relatively insensitive, but is capable of detecting poliovirus in a general target population. The level of sensitivity is comparable with that of a healthy child stool survey. The level of sensitivity is dependent on the rate of sampling of the population, which in turn, often depends on the laboratory capacity available to process samples. Enterovirus surveillance is only of value for poliovirus surveillance if the capacity exists for the laboratories to differentiate poliovirus-positive samples from other enterovirus-positive samples, a capacity that may not always be available with some of the automated screening tests, particularly as we move towards a polio-free future.

There are 16 priority countries for Polio Transition and each of these countries is expected to develop a national polio transition plan. As part of the planning process these countries are investigating how decreasing international funding will impact current polio assets and what opportunities exist to 'mainstream' future polio surveillance activities into national government systems or integrating polio into a broader disease surveillance system. This aspect of the transition process will be discussed at the next WHA meeting and input from the laboratory group will be essential in guiding the discussion on future scenarios.

### **Conclusions - summary of discussion points**

Objective 1: current views and thoughts on evolution of field surveillance and laboratory strategies for polio diagnosis pre- and post- certification

- The changing GPEI landscape necessitates greater exchange between the laboratories and the programme, particularly with surveillance staff;
- Detailed genomic sequence information on isolates generated through the GPLN can be used to drive programmatic responses, but may also be over-interpreted and disproportional reliance placed on them by programme. Genomic sequence information must be considered in conjunction with classic epidemiological information;
- Developments in field surveillance, including introduction of environmental surveillance, has resulted in increased laboratory workloads that need to be adequately resourced;
- The laboratories provide the sequence data essential to make final classification of VDPV isolates, but surveillance information is required to determine possible linkages with other cases.

Objective 2: current views and thoughts on evolution of field surveillance and laboratory strategies for polio diagnosis pre- and post- certification

- iVDPVs present an increased risk post OPV cessation and there is a clear need for continued surveillance, particularly in lower middle-income countries;
- Surveillance for PID can act as a supplement to AFP surveillance and has been shown to be capable of detecting iVDPV excretors. However, questions remain over how to integrate PID surveillance with existing polio surveillance systems;

- The development of a case definition of 'suspect PID' and any attempt to establish routine surveillance for suspect PID are expected to result in an increase in laboratory workload that may not be cost effective;
- There is a need to review the current case definitions for PID and the Modell signs and to analyse currently available data to determine surveillance for PID could best be integrated into poliovirus surveillance;
- All identified PID cases should be screening for polio excretion as a matter of routine and results reported to the polio programme;
- There are clear poliovirus containment concerns surrounding laboratory handling of iVDPV2 materials and need to review GAPIII for requirements for handling samples from known poliovirus excretors;
- In outbreak situations surveillance needs to provide rapid results and be resource efficient. To achieve this consideration must be made of both favourable and unfavourable characteristics of current surveillance systems and the limitations of any particular system clearly understood;
- Proposed new strategies for poliovirus surveillance must be assessed for added value, with consideration of the effectiveness with regard to laboratory workload. There is a need to consider the costing of proposed new surveillance systems and methodologies and to establish the cost effectiveness;
- There is a need to continue the discussion on surveillance requirements and development of additional systems, particularly for use in the post certification period.

Objective 3: (i) review and define roles and responsibilities of all environmental surveillance stakeholders, and (ii) define needs and obtain consensus on data/information management for environmental surveillance of PV

- The rationale for the expansion matrix developed for the environmental surveillance Expansion Plan requires further clarification and discussion. There is a need for clear guidelines on criteria for environmental surveillance sampling site selection, with emphasis placed on the use of existing surveillance information;
- Expansion of environmental surveillance implies an increased workload for the sequencing laboratories and increased laboratory costs. There is an urgent need to review the logistics issues and implementation challenges;
- Further discussion is required on methods for systematic reporting and sharing of laboratory results from environmental surveillance;
- Consideration should be given to short-period environmental surveillance at specific mass gatherings, such as religious festivals and celebratory gatherings;
- Further discussion on is needed on the practical outcomes from environmental surveillance, particularly with regard to quality versus quantity. A better understanding of the underlying science with regard to adequate population coverage, sampling frequency, site distribution and number of sites needs to be developed;
- Further discussions are required on the management and harmonization of environmental surveillance data, the role and function of a centralized database at WHO headquarters, integration with the POLIS system and integration of environmental surveillance data into existing AFP surveillance systems;

- The WHO Regions have already made significant progress in developing their own systems for management of environmental surveillance data and this should be referred to in attempts to develop a standard process for referring environmental surveillance data. Further discussions are required on the data that need to be captured in a standardized system and the processes required for standardization;
- PV2 has been detected for a considerable time after the withdrawal of Sabin type 2 containing tOPV, with detections being made in environmental surveillance samples long after last AFP PV2 positive case detection. Continued use of tOPV after the global cessation event demonstrates the need to conduct additional tOPV sweeps in selected countries to locate and remove continuing stocks of tOPV, particularly those that may be held in small the private sector health facilities. There is a continuing need to monitor PV2 isolations very closely;
- Documenting the tOPV withdrawal event has parallels with the inventory process used for polio laboratory containment validation, and the experience gained should be made use of.

Objective 4: establish common understanding on pre-requisites for efficient detection and response to outbreaks/events of VDPV and WPV

- An increased laboratory workload should be expected to result from a PV2 event and plans should be in place to provide adequate laboratory resources;
- With regard to the elimination/eradication timeframe for VDPV detection, the clock should be reset to zero after mOPV2 use. Use of mOPV2 in response to a PV2 event has some profound implication for some countries, and national authorities may choose not to use this response;
- More laboratories are now generating poliovirus genomic sequencing data and there is a need for more discussion on consistent reporting of sequence information;
- There is an increasing burden of responsibility placed on laboratories for identifying an outbreak accompanied by an increasing need to be fully confident of the laboratory information being provided;
- There is a need for further training of programme staff in interpretation and uses of complex sequence data, and a general requirement for better communications between the laboratories and rest of the programme to avoid confusion and misinterpretation of data;
- Methodologies for the rapid field detection of poliovirus are being developed but are not yet ready for widespread use due to generally sub-optimal levels of sensitivity.

Objective 5: planning Polio Transition

- Some surveillance components and capacities will be required as a constant for the long term, and others may only be applicable during particular periods under specific circumstances. Further discussion is needed to determine what these components may be.



- Availability of international funding for polio surveillance will decline in the short-term, and polio assets will either need to be taken over by national authorities or polio surveillance integrated into broader disease surveillance systems.
- Although technically feasible, not all potential polio surveillance systems will be cost effective, and further discussion is required on how systems can be made sustainable.

## Annex 1

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## Annex 2

### Agenda of the meeting

#### Wednesday 15<sup>th</sup> March 2017

**Objective** is to present current status of the GPEI, the GPLN and technical updates on molecular epidemiology of WPV and VDPV

#### SESSION 1: Progress towards detection and interruption of Wild Polio Virus (WPV) and vaccine-derived poliovirus (VDPV) transmissions

08:30	Welcome remarks and Nomination of Chairman and Rapporteurs	O. Diop
08:35	Administrative announcements	D. Renard
08:40	Progress and Challenges towards Eradication	M. Zaffran
09:10	Overview of the performance of the GPLN	O. Diop
	<i>Detection and molecular epidemiology of WPV in 2016</i>	
09:40	Report from the Eastern Mediterranean Region	H. Asghar
	<i>Molecular epidemiology of WPV to inform progress towards eradication</i>	
10:00	Lessons learnt from India	J. Deshpande
	<i>Detection and molecular epidemiology of VDPV in 2016</i>	
10:20	Overview, genetic characteristics, and clues for categorization of VDPV	C. Burns
<b>10:40</b>	<b>Coffee-break</b>	
11:00	Summary of outcomes of the GPLN's Ad Hoc Small Working Group meeting	J. Martin
11:30	Round table discussions: VDPV/WPV diagnosis and molecular epidemiology	All participants
<b>12:00</b>	<b>Lunch</b>	

#### SESSION 2: Field Surveillance and Polio diagnostics: Programme needs during the Endgame

**Objective** is to present current views and thoughts on evolution of field surveillance and laboratory strategies for polio diagnosis pre- and post- certification

	<i>Regions/Countries experience</i>	
13:00	Integration of iVDPV surveillance to AFP Surveillance: Egypt experience	L. Bassioni
13:15	Coordination of virological and immunological investigations of iVDPVs: Tunisia experience	H. Triki
13:30	WHO-coordinated database on iVDPVs: lessons learnt	R. Sutter
13:50	Round table discussions: integration of epidemiological, virological and immunological investigations of iVDPVs	All participants
<b>15:30</b>	<b>Tea-break</b>	
	<i>Strategies to adapt and strengthen Surveillance during the endgame</i>	
15:50	Field surveillance strategies during the endgame	A. Anand
16:10	Laboratory surveillance prospects during endgame	S. Oberste
16:30	Round table discussions: Mapping strategies and milestones	All participants

18:00 **Wrap-up and adjourn**

Chair

*Cocktail***Thursday 16<sup>th</sup> March 2017****SESSION 3: Environmental Surveillance (ES) of Poliovirus**

**Objectives** are (i) to review and define role and responsibilities of all ES stakeholders, and (ii) define the needs and get consensus on data/information management for ES of PV.

09:00	Update on implementation of the Global ES Expansion Plan <i>Regions/Countries experience: Implementation of ES</i>	G. Tallis
09:20	Implementation of ES: What does it takes, Experience from Nigeria.	H. Abdullahi
09:35	Managing workload in an ES laboratory: Constraints and limitations in PAK	S. Sharif
09:50	Round table: Roles and responsibilities at country, regional and global levels	All participants
<b>10:30</b>	<b>Coffee-break</b> <i>Data and information</i>	
10:45	ES Data and Information management: Gaps and Way forward	P. Chenoweth
11:05	Round table discussions: Standardized capture of ES data and strengthening ES analytics	All participants
<b>12:00</b>	<b>Lunch</b> Regions/Countries experience: Investigations of viruses of programmatic interest	
13:00	Field investigations following detection of PV2: India experience. by Webex.	S. Bahl
13:20	Round table discussions: Investigations' guidelines and standards	All participants

**SESSION 4: Events and Outbreaks management**

**Objective** is to get common understanding on pre-requisites for efficient detection and response to outbreaks/events of VDPV and WPV

14:20	Events and Outbreaks: Standard Operating Procedures and lessons learnt	R. Lewis
14:50	Molecular epidemiology of polioviruses to inform investigation and response to events/outbreaks	C. Burns
15:10	Round table discussions: Alignment of virological and epidemiological assessment and response to PV event/outbreak	All participants
<b>15:40</b>	<b>Tea-break</b>	

**SESSION 5: Planning Polio Transition**

**Objective** is to discuss opportunities and challenges to sustain Polio Surveillance pre- and post-certification

16:00	Update on GPEI SC work on post certification strategy agenda	B. Burkholder
16:20	Way of life post certification: EUR experience	E. Gavrilin

16:35	Round table discussions: Post-certification surveillance, what are the challenges to sustain Polio Surveillance and integration of field and laboratory operations.	All participants
17:30	Summary of recommendations	Chair/ Rapporteurs
18:00	<b>Wrap up and Adjourn</b>	

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