Global Polio Laboratory Network

Guidance Paper 9

Reporting polioviruses of programmatic interest detected using methods not-recommended or not-accepted by the GPLN-SWG

Document version (date)	Description of substantive revisions
Version 1 (May 2023)	

Purpose

The purpose of this document is to provide a framework for standardized reporting of poliovirus and/or part thereof by the Global Polio Laboratory Network (GPLN) to the Global Polio Eradication Initiative (GPEI). This guidance will reiterate and clarify steps to be taken by any laboratory within or outside the GPLN which reports a poliovirus of programmatic interest (poi) i.e., wild poliovirus (WPV), vaccine-derived poliovirus (VDPV) and oral polio vaccine-related viruses (Sabin-like or nOPV2-like).

Rationale

At the inception of the GPEI, an agreed scheme to report laboratory results had allowed proper monitoring of poliovirus epidemiology to trigger public health activities aiming to stop polio outbreaks. Indeed, after setting clear standards and comprehensive quality assurance programs, only polio diagnostic results issued by a WHO-accredited laboratory are accepted by the program. However, recently this situation has become more complex, with technologies have evolving, and other public health programs testing biological materials where poliovirus can be found (e.g., sewage samples used for SARS-Cov-2 monitoring). Consequently, it is forecast that more polioviruses of programmatic interest will be detected inside or outside the GPLN using diagnostic methods different to those recommended or accepted by within the GPLN after due validation by the GPLN small working group (SWG), which was established by the GPEI to research and develop new methods, reagents and approaches for poliovirus diagnostics. It is therefore important to formalize and clarify the confirmation and reporting processes for all detected polioviruses of programmatic interest, in order to provide timely and accurate results to the GPEI.

Reporting the detection of poliovirus and/or sequences of polioviruses generated by a WHO-accredited sequencing laboratory, which is member of the GPLN, had been streamlined and made consistent over the years. There had been several instances where a poliovirus of programmatic interest had been detected outside the GPLN, however final validation and official reporting of results had always been done through the GPLN and GPEI channels. This must remain the rule, including after the global eradication of poliovirus.

Objectives of the Guidance Paper

The objectives of this document are as follows;

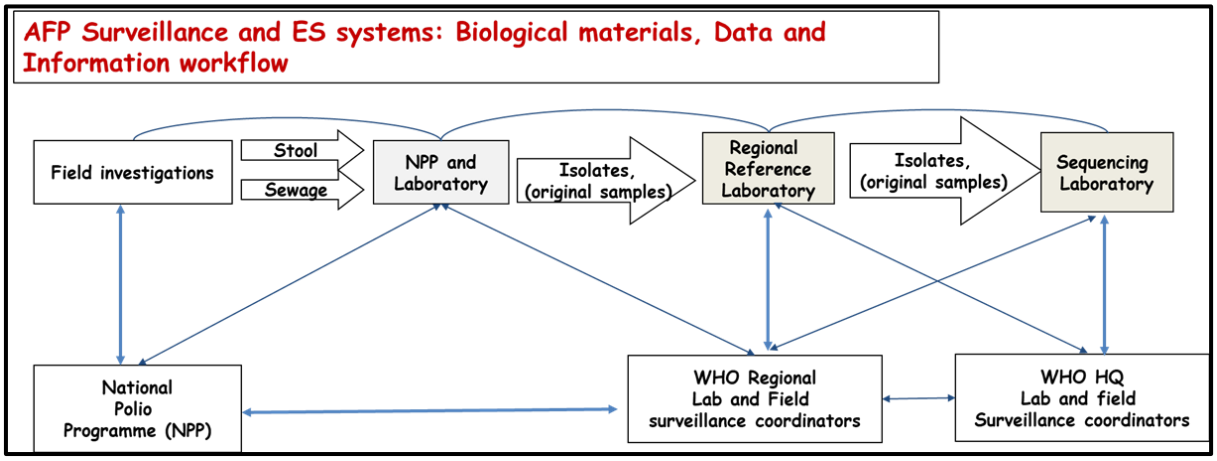
1. Briefly describe the reporting process of poliovirus sequence results for Polio Reference Laboratories within the GPLN; and
2. Clarify the notification steps for the national, regional and global Polio Reference laboratories which receive poliovirus sequences obtained using methods or test algorithms that are not-recommended or not-accepted by the GPLN SWG.

Applicability

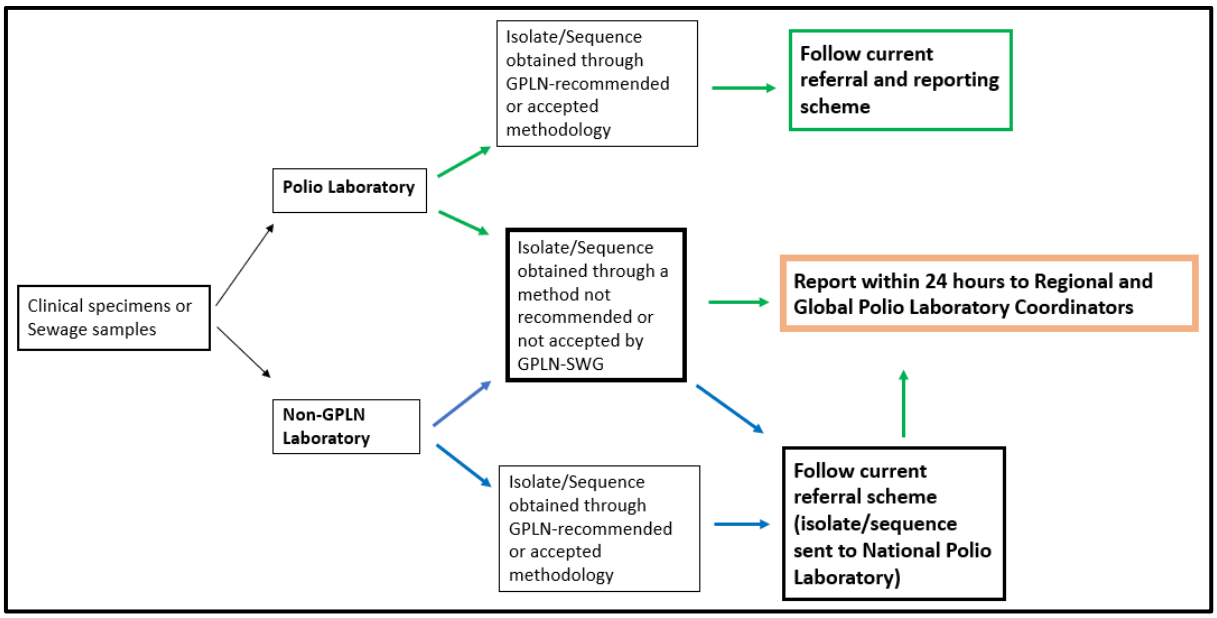
The guidance applies to any poliovirus sequence reported by a member of the GPLN (145 Laboratories) where a WPV or VDPV sequence has been obtained or received from a referring laboratory within or outside the GPLN as per the GPEI's recommendation. Indeed, only WHO-accredited Polio laboratories must report polioviruses detected in an acute flaccid paralysis (AFP) case, an AFP contact, a specimen from the community, an individual diagnosed with a primary immunodeficiency disorder (whether associated or not with AFP), and an environmental sample. The poliovirus and/or the sequence of the poliovirus can originate directly from a member of the GPLN but may also have been first communicated by a non-GPLN laboratory, which subsequently referred poliovirus materials/data to the

GPLN Laboratory as per national guidance based on the WHA resolution 41.28, adopted by the member states in 1988.

❖ Current generic workflow



❖ Workflow to be implemented by Polio laboratories, for all PV sequences detected using a methodology not-recommended or not-accepted by the GPLN SWG



Note: Green arrows refer to the workflow for GPLN laboratories; Blue arrows refer to the workflow for non-GPLN Laboratory.

❖ Step by step notification and reporting process

1. The first notification from a non-GPLN Laboratory or a GPLN Laboratory, which used a methodology not-recommended or not-accepted by the GPLN SWG must include

a. All metadata linked to the sample, including all dates from sample(s) collection to receipt of sample(s) in the laboratory;

b. Detailed description of the methodology used and the dates for all steps of the procedure;

c. Complete raw and edited (if applicable) sequence data, and QA/QC procedures applied during the procedure; and

d. Alignment of the sequence with reference sequence (if applicable) and interpretation of the findings.

2. After receiving the notification, the global and regional WHO Laboratory Coordinators will liaise with the GPLN SWG and relevant Global Specialized Laboratories for a joint analysis and critical review of:

(i) The genetic data;

(ii) The available metadata;

(iii) A comprehensive comparison with relevant poliovirus sequences already reported by the GPLN; and

(iv) The interpretation of their findings. If metagenomic approaches are used, poliovirus sequences must be accurately identified based at least on a fragment of the capsid region.

At this stage, the laboratory which produced the data/information may be asked by the Global and the Regional polio laboratory Coordinators to provide additional data and/or biological materials for further analysis.

3. The findings, interpretation and conclusions from the assessment described in points 1 and 2, supplemented with the necessary epidemiological data, are then discussed with field surveillance officers based at the WHO Regional and Headquarter offices.

4. If the findings are unequivocal, and only in this case, then formal reporting can occur, with the key message(s) from the results. WHO Laboratory Coordinators will share the report with the relevant National Polio Laboratory, which will forward the report to national public health officers, and non-GPLN laboratory if relevant, that initially referred the sample to the National Polio Laboratory, copying relevant GPEI colleagues involved in the Program's response.

Note: Steps 1-4 should be documented by WHO Laboratory Coordinators for records.