Global Polio Laboratory Network

Guidance Paper 7

Evaluation and Adoption of New Polio Diagnostic Methods and Procedures

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Evaluation and Adoption of New Polio Diagnostic Methods and Procedures by the *GPLN's Small Working Group on development and evaluation of new methodologies, diagnostic reagents and approaches to testing*

The Global Polio Laboratory Network (GPLN), is a laboratory network of 145 laboratories spanning all WHO regions with the purpose to detect and identify polioviruses in human specimens or environmental samples, while complying with poliovirus containment requirements, in support of the Global Polio Eradication Initiative (GPEI). The success of the GPLN in providing consistent and robust results for the GPEI has been achieved through broad validation and standardization of methods and procedures. The GPLN has provided programmatic support structures at global and regional level; laboratory capacity building, both human and material; training and technical assistance; logistic networks; quality assurance, quality control and safety protocols; and annual accreditation. The laboratories within the GPLN are accredited by WHO, on a yearly basis, to perform the methods and report the results as described in the Polio Laboratory Manual. The other key to sustaining the quality of the results over more than three decades has been the continual evolution of methods using new technologies that are broadly applicable and assuring their successful adaptation in all GPLN laboratories.

The GPLN *ad hoc* Small Working Group on development and evaluation of new methodologies, diagnostic reagents and approaches to testing (aka GPLN SWG) is the guiding group for poliovirus diagnostics within the GPLN. It consists of GPLN stakeholders with extensive knowledge of laboratory procedures and processes within the laboratory network of each WHO region. The SWG leverages the experience and knowledge of each region to plan and implement technical and operational improvements, review QA/QC parameters, and respond to issues facing the GPLN through different stages of polio eradication globally. Within this context, new methods and procedures, along with supporting information, are reviewed and assessed for diagnostic validity, performance and programmatic feasibility and feedback provided for implementation in the GPLN. The SWG may determine a method to be either recommended or accepted, or not recommended or not accepted for use by and within the GPLN.

Changes and updates to recommended methods can be grouped into two categories: Minor or Major changes. Minor changes are updates to current assays or algorithms (e.g., ITD 4.1 to ITD 5.0) that do not fundamentally change laboratory procedures, reporting, or referral patterns, and have minimal impact on procurement of supplies and reagents. Major changes are anything that has the potential to significantly change the routine procedures and/or processes of the GPLN (e.g., molecular genotyping replacing serotyping) and often represent significant cost and time investments for successful implementation. Although minor changes are carefully weighed, analyzed, and discussed, the potential for disruption is minimal and will not be the focus of this document.

A WHO GPLN **acceptable method** fits all the criteria for "acceptable method" as specified in BOX 1. An **acceptable method** indicates the method or procedure is not inferior to the current procedures and the results are reliable. Acceptable methods are methods from which the results are accepted by GPLN SWG, but the methods will not be endorsed or recommended, indicating that no support from the GPEI or the GPLN is given or implied. Acceptable methods can be incorporated into the general GPLN workflow in specified laboratories or regions, but due to logistics, cost, complexity, or robustness (robustness in this context is defined as broad applicability around the world) will not be recommended, or supported, by the GPLN. Laboratories using

acceptable methods are responsible for documentation of QA/QC protocols, including proficiency testing, and still must meet annual accreditation requirements.

BOX 1: Criteria for Acceptable New Methods or Procedures in the GPLN

1. **Proof of concept**: Preliminary data with a finalized protocol must show non-inferiority relative to existing recommended poliovirus diagnostic methods.
2. **Programmatically relevant data**: The new method should provide results that can be reported to and has meaning for the GPEI.
3. **Non-inferiority in parallel testing**: Improvement or non-inferiority compared to current procedures or methods must be shown based on a head-to-head comparison (e.g., parallel testing) against the existing recommended methods in multiple GPLN laboratories, with selection concurrence by the SWG. An adequate number and diversity of samples should be tested to identify issues or variability that may negatively affect or limit implementation.
4. **Diagnostic algorithms:** Diagnostic algorithms for sample testing, analysis, and referral are provided.
5. **Quality assurance:** A QA/QC procedure for the new system or method to insure reliable and reproducible results must be available/provided.

A WHO **recommended method,** as described in the WHO Polio Laboratory Manual, fits all the criteria for "acceptable method" within the GPLN (listed in BOX 1) and must meet several additional requirements, as specified in BOX 2.

BOX 2: Additional Criteria for Recommended New Methods or Procedures in the GPLN

1. **Availability**: Reagents or supplies are globally available, and with at least wo suppliers.
2. **Algorithm**: Diagnostic algorithms for sample testing, analysis, and/or referral are provided and will work broadly within the GPLN.
3. **Workflow**: The work can be performed by currently available GPLN personnel and/or support for recruitment of staffing needs are identified.
4. **Cost-benefit analysis**: The cost-benefit analysis (e.g., burden of laboratory time/capability/expertise of personnel) has been performed and is in favor of the new method.
5. **Training**: Workshops and training materials are available to the GPLN.
6. **Implementation**: Pilot testing within GPLN laboratories in all WHO regions has been performed and results are approved by the GPLN SWG.
7. **Quality assurance program**: An acceptable quality assurance program, including a quality control plan, process, supply of reagents and procedures (proficiency testing, accreditation checklist), is available and feasible.
8. **Support**: Support for implementation of the new recommended method is, or can be, secured/provided.

Most additional criteria (summarized in Table 1) for a new method to become a Recommended method do not concern the diagnostic quality of the method: the diagnostic quality should be based on non-inferiority relative to the existing recommended method. The additional criteria aim at managing worldwide implementation of the new method and sustained surveillance system performance.

Table 1. Summary of Requirements between Acceptable and Recommended Methods and Procedures

	Acceptable	Recommended
Proof of concept	X	X
Programmatically relevant data	X	X
Analytical non-inferiority	X	X
Non-inferiority in parallel testing	X	X
QA/QC procedure	X	X
Global reagent availability		X
Clear compatible algorithm		X
Workflow		X
Cost-benefit analysis		X
Training		X
Implementation		X
Quality assurance program		X

Current Global Polio Laboratory Network *Ad hoc* Small Working Group Members, as of March 2021

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