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The Global Polio Laboratory Network: A Model for Good Laboratory Practice

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The Global Polio Laboratory Network: A Model for Good Laboratory Practice

A Study of the Quality Principles Practiced within the Global Polio Laboratory Network

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INTRODUCTION

This report was developed in response to a request from the United States Agency for International Development (USAID) to demonstrate how the Global Polio Laboratory Network (GPLN) could support other global public health initiatives and serve as a model for public health programs. A key purpose was to identify the quality principles subscribed to by the GPLN that have contributed to its success in creating a network that demonstrates good laboratory practice and determine whether these principles and GPLN's operational approaches could be applied to other health programs or systems to improve outcomes.

USAID selected the University Research Co., LLC (URC) to conduct the study and develop and prepare this report because of its expertise, through its Quality Assurance (QA) Project, in assessing the methods and principles used to increase and sustain quality in healthcare programs in the developing world.

The QA Project has cast its analysis of the GPLN's success in providing diagnostic virology support to the World Health Organization's (WHO) Polio Eradication Initiative (PEI) in terms of the QA and Quality Management (QM)[1] techniques and principles the network deploys to ensure high quality performance in detecting and tracking the wild poliovirus. All measures endorsed by the GPLN to improve laboratory efficiency, effectiveness, and performance were analyzed through the lens of QA and QM.

Offering the QA Project's view of the GPLN in QA and QM terms will provide other laboratories and health programs with an analytical framework that may serve as a benchmark for assessing their own programs' performance. This report may also spur other global public health initiatives to consider grafting their own laboratory networks onto the GPLN or developing independent networks to support their own goals. This report seeks to demonstrate that although the GPLN was developed to support the PEI, it not only has developed capacities, but also serves as a model to other global laboratory networks and health programs that will last after the goal of polio eradication has been reached.

THE GLOBAL POLIO LABORATORY NETWORK

The Global Polio Laboratory Network's primary mission is to provide diagnostic virological support to the PEI sponsored by WHO. GPLN is the investigative and diagnostic leader in the PEI strategy, and takes part in worldwide surveillance and detection of the wild poliovirus in populations from all areas of the world. The network is the PEI linchpin for effective worldwide polio eradication.

Detection and identification of the virus' geographic origin are crucial to polio's eradication. The GPLN consists of 148 laboratories that are distributed throughout the world and conduct scientific testing to isolate and identify the wild poliovirus in stool specimens collected from patients who manifest poliomyelitis symptoms. This testing is critical to the PEI strategy. The deployment of a sophisticated science to track the virus' geographical origins provides the catalyst (i.e., scientific confirmation of a polio case) to trigger the PEI mop-up[2] operations that concentrate on the populations at risk for poliovirus

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[1] For the purpose of this report QA refers to those activities that enable a healthcare organization to meet or exceed their expectations of quality, namely activities that contribute to defining (setting standards), measuring (monitoring programs) and improving quality. QM is the structural processes and activities that facilitate the application of QA, such as supportive leadership, commitment to teamwork, and staff participation in improvement activities. Additionally QM is viewed as responsible for selecting quality health personnel, allocating resources to support QA, and overseeing performance monitoring.

[2] Mop-up is an intense house-to-house immunization in a designated high-risk geographical area. All children in a specified age group (usually 0-59 months) are immunized during the mop-up regardless of their immunization status. High risk is defined as those children where poliovirus is still circulating or is likely to circulate. For example a mop-up immunization campaign might be conducted immediately after a case is confirmed as polio for given geographical area to interrupt poliovirus transmission in a focal area.

infections. Linking diagnostic activities with surveillance is what makes the work of the GPLN so vital in efforts to eradicate polio. This model of linking the laboratory performance with surveillance in fighting a public health disease is a new approach in program planning. The design and implementation strategies for the GPLN were modeled after the Pan American Health Organization's (PAHO) Latin American Polio Laboratory Network. The success of PAHO's network has been a beacon for the GPLN as they help us move towards a polio-free world**.**

Genesis: The Latin American Model

In 1985, PAHO and the Centers for Disease Control and Prevention in Atlanta (CDC) established the Latin American Regional Polio Network, which became the genesis and the model for other regional networks in the GPLN. These collaborators devised a strategy for developing the Latin American network, beginning by establishing criteria for network laboratory performance. They decided to be highly selective in incorporating laboratories into the network, deliberately restricting the number of laboratories to optimize standardization of laboratory methods, proficiency, communications, and logistics that included training and allocation of resources. The leadership selected laboratories to constitute the network based on their high-level performance and strategic location, ensuring healthcare facilities had reasonable access and timely response from a functioning polio laboratory.

They planned to add laboratories to this web methodically, as particular laboratories demonstrated that their performance could meet the established criteria. Since the network's beginnings, a key strategy of PAHO has been to maintain a high level of oversight and support (mentoring and coaching) for network laboratories. A conscious decision was made to keep the network small and focus on quality, defined as accurate and timely reporting.

The Latin American network proved its merits, enabling WHO to certify the Western Hemisphere as polio-free on September 29, 1994, the successful culmination of the nearly ten-year effort.

GPLN's Organizational Structure

Many of the successes and lessons learned from the PAHO Polio Laboratory Network were infused into the design of the GPLN, which was launched in 1991. The GPLN includes three types of laboratories worldwide, grouped according to the complexity of the polio diagnostics they perform. These laboratories are strategically located in countries with pre-existing laboratory infrastructure, where communications and logistics enable timely completion of the diagnostic process. The groupings include **National Laboratories,** which receive stool specimens from the field and perform virus isolation and type the poliovirus isolates.

Regional Reference Laboratories further study the isolates and determine whether the viruses are wild. The Regional Reference Labs, in turn, send wild viruses identified to **Specialized Laboratories** which perform genetic sequencing, a process that can detect epidemiological links between polio cases, identify reservoirs sustaining polio endemicity and monitor progress toward eradication of wild polioviruses. All laboratories have a minimum of one virologist; several Regional Reference Laboratories have more than one.

Criteria for Network Inclusion

The criteria used for selecting a laboratory for the network were based on the standards of the PAHO network. Criteria used for selection included an assessment of the laboratory resources—people, materials, and funds—it would take to guarantee the laboratory would be a successful member of the network. For example, if the laboratory's building structure was in a state of disrepair, it might not be considered if it lacked funds to bring the building up to functioning capacity or to build a new laboratory. Another key acceptance criterion was the ability of a laboratory to demonstrate its capacity, with training and support from WHO, to conduct proper laboratory science methods on the specimens, adhering to the standard operating procedures established. Laboratories selected were equipped with the necessary equipment needed to conduct the proper laboratory procedures. Selection of individual laboratories was a

collaborative process with the Ministries of Health to ensure the needs of the GPLN would be supported, at the same time meeting the needs of the local ministry. Likewise the GPLN considered the strategic location of all laboratories to ensure that healthcare facilities had reasonable access and timely response from a functioning polio laboratory.

Like PAHO, GPLN aimed to keep the network small to ensure proficiency and quality control, handle logistics, and provide a high level of oversight and ongoing mentoring for the network laboratories. Table 1 displays the criteria for accepting a laboratory into the network.

Table 1

Criteria for Accepting a Laboratory into the Network

The goal was to keep the network small and manageable, to oversee standards, and to provide frequent coaching and mentoring. Considerations evaluated were:

1. **Resources** required for renovations and upgrading the existing laboratory to meet standards
2. **Training** and education required to have a full complement of laboratory staff to perform all aspects of the specimen testing
3. **Acquisition of equipment** required to adhere to the Standard Operating Procedures (SOP)
4. **Geographical location**: The GPLN considered strategic locations of all laboratories looking at access, turn-around time, and transportation to and from the laboratories
5. **Political** support for the program, both from the ministries and the laboratories

GPLN's Roles and Responsibilities

WHO's technical oversight and support of the GPLN: Oversight for the network is assumed by WHO headquarters (WHO/HQ). It coordinates the standards development process, oversees communications, ensures consensus agreement for the adoption of new methodologies, conducts the accreditation processes, and provides coaching and mentoring for all the laboratories within the network. Key to the WHO/HQ's role has been its ability to lead the network by demonstrating a strong commitment to quality management principles such as teamwork and participation, allocation of resources to support QA activities, and a demonstrated commitment for capacity building among laboratory personnel. The headquarters staff set the tone for quality results—accuracy and timeliness—and has guided the development of a network infrastructure to support the needs of laboratories within the network.

Regional roles and responsibilities within the GPLN: To support the geographical size of a global network, WHO/HQ utilizes the WHO regional structure to secure oversight and consistent monitoring through the development of a Regional Coordinator position. This position has been key to the development and ongoing operations of the network. The Regional Laboratory Coordinators are responsible for the regional design, management, and maintenance of the regional network. The regional networks were developed independently of each other, with individual laboratories following global guidelines and standard operating procedures designed at WHO Headquarters in Geneva using the lessons learned and merits of the PAHO Polio Laboratory Network.

National Polio Laboratories' integrated role: Laboratory functions and field surveillance for wild polio transmission are integrated operations, a strategy that has been the hallmark of the Latin American Regional Network's success in attaining certification that the region had become polio free.

- The basic procedure GPLN laboratories use to diagnose poliomyelitis includes isolation of the wild poliovirus in cell culture from appropriate stool specimens collected from acute flaccid paralysis (AFP) patients and sometimes their contacts.

- Field surveillance personnel collect the specimens from hospitals and rehabilitation centers. However, laboratory staff also sometimes collect specimens, not only because surveillance is integrated, but because National Laboratory personnel are dedicated to getting the work done and will do whatever task needs doing. As one staff member said, "We even go to the hospitals to collect the specimens. This is our connection with the field personnel." This is concrete evidence of the value of having one common program vision shared by all.
- There are standard, established scientific methods for isolating the poliovirus and typing it, and those methods are based on classical virology, agreed upon by the network through consensus and an iterative process for standards development. The standard operating procedures are written and distributed to every polio laboratory in the network
- Once the isolates are typed and characterized, Specialized Laboratories conduct the genetic sequencing of the isolates to pinpoint their geographical origins and to exclude the possibility of laboratory contamination. The Specialized Laboratories deploy medical technology that is sufficiently sophisticated to produce accurate results in a timely fashion, to trigger mop-up operations to immunize all potential victims against the virus, a key PEI program strategy.

GPLN's Benefit to the Polio Eradication Initiative

The network's proficiency in providing virological support to the PEI translates into benefits to the WHO polio eradication effort in that it has produced global standardization of what science deems "Good Laboratory Practice,"[3] despite diversity in laboratory institutions throughout the world. The GPLN's techniques and procedures for isolating and tracking the wild poliovirus are uniform worldwide. This achievement is verified annually for each laboratory in the network through the GPLN's accreditation process. All laboratories practice ongoing quality improvement (problem solving) with results from their activities forwarded to WHO/HQ for dissemination throughout the network for the benefit of all regions and laboratories. Subscribing to a philosophy of continuous improvement helps to ensure that laboratory performance standards are maintained. The network continuously demonstrates uniformly high performance in detecting and tracking the wild poliovirus with accuracy, while meeting defined timelines. This agility and proficiency in tracking the presence of the wild poliovirus among populations at risk worldwide is no accident. The network's success is the result of careful planning, network design, and standardized high-level global performance.

STUDY METHODOLOGY

A Senior Quality Assurance Advisor and a Senior Advisor for Laboratory Practice and Management from the QA Project visited the network headquarters at WHO, attended a GPLN Laboratory Director's annual meeting in Geneva, Switzerland, and conducted on-site visits to five network laboratories. This team's objective in visiting those laboratories and the WHO/HQ was to gain first-hand knowledge of the laboratories' functions and practices, and to examine them from the perspective of QA and QM. They compared the functions and capacity of the laboratories prior to being involved in the network to their current level of functioning and productivity. These site visits took the two senior advisors to Atlanta, Georgia, in the U.S., and then to the Indian sub-continent and Africa, where large areas and populations remain at risk for polio transmission. The QA Project team visited the following:

- The U.S. Centers for Disease Control and Prevention in Atlanta (Specialized Laboratory)
- The African Regional Reference Laboratory in Johannesburg, South Africa
- The Ugandan National Laboratory in Entebbe, Uganda
- The Indian Regional Reference Laboratory in Mumbai, India

[3] A laboratory receives "Good Laboratory Practice" standing when they regularly perform laboratory investigations using state-of-the-art standard operating procedures, and their reports are consistently reliable and accurate.

- The Indian National Laboratory in Chennai, India
- WHO GPLN Headquarters, Geneva, Switzerland
- GPLN Laboratory Director's annual meeting, Geneva, Switzerland

The QA Project Senior Advisors developed their working knowledge of these laboratories through discussions with WHO/HQ staff, Regional Coordinators, and observation of laboratory practices and interviews with laboratory staff, including:

- Laboratory directors
- Laboratory managers
- Laboratory supervisors
- Virologists
- Laboratory technicians
- Data managers

The knowledge attained by the team enabled them to evaluate laboratory performance in QA and QM terms in order to develop a framework for analyzing the network's success factors. In so doing, the QA Project can pass on the framework in a clear, practical form with management science underpinnings, to laboratory managers and other public health programs throughout the developing world. It is WHO, USAID and the QA Project's hope and intent that laboratory managers in regions where other vaccine-preventable diseases are prevalent may use this report as a point of departure for developing other effective laboratory networks and public health programs. This would be an important step toward making the world free of these other diseases**.**

THE GPLN THROUGH THE LENS OF QUALITY ASSURANCE

Quality Assurance: Key to Good Laboratory Practice

"Quality assurance can be viewed in its broadest sense as encompassing all those activities that are carried out to assure that health services meet or exceed expectations of quality," according to David Nicholas, MD, MPH, Director of the URC's Quality Assurance Project.[4] QA is a goal-oriented, systematic process for closing the gap between actual performance and the desirable outcomes.

More specifically, quality assurance has proven to be significant for program development and management in achieving desired outcomes. In this context, QA can be defined as all activities that contribute to defining, measuring, and improving the quality of healthcare services, such as developing and communicating standards, measuring the level of compliance with standards, and applying quality management methods to continually improve quality.[5] In addressing the GPLN, these activities can be performed as part of the accreditation of laboratories, supervision of laboratory staff or other efforts to improve the performance of the laboratory personnel and raise the quality of services to meet the GPLN overall goal.

The challenges of managing a global network can be daunting. When QA principles and practices are applied uniformly within the network, it can provide laboratory managers and staff with objective data and information to help narrow the gap between current and optimal laboratory performance.

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[4] Nicholas, David. *QA Brief,* "Organizing for Quality," The Quality Assurance Project, University Research Co., LLC, Center for Human Services, Bethesda, MD, January 1999, Volume 8, Number 1.

[5] "Institutionalization of QA," QA Project II Report to USAID, July 2000.

The establishment and maintenance of QA activities is clearly a management responsibility, and unless management is committed to QA, it will not happen. The GPLN conducts many QA activities on a regular basis, such as supervision visits, data tracking and accreditation activities, and their standards' development process, which is founded on the principle of using current evidence supported by consensus within the network's virology team. The results of these activities objectively demonstrate to the network's nuclei and others their successes as investigative and diagnostic leaders in WHO's Polio Eradication Initiative. QA methods can also be used to measure the progress and success of the GPLN as a whole.

Overview of Findings

The QA Project team found that the GPLN successfully achieves its high-level performance and ultimate success in facilitating PEI's achievements toward a polio-free world with the QA activities they utilize and conduct. "The QA practices that we witnessed during our site visits were impressive. These practices have served the network well as it continues to improve and strengthen the strategic Polio Eradication Initiative," one Senior QA Advisor said.

Laboratories' Evolution

To demonstrate the changes in laboratory capacity due to the inception of the GPLN, it is important to understand what the capacity and nature of the laboratories were before the network and their involvement in the PEI program (see Table 2). The Global Polio Laboratory Network now contains almost 150 laboratories organized into a three-tiered system of national and Sub-National Laboratories, Regional Reference Laboratories, and Specialized Global Laboratories. Many of these laboratories existed before the network was established; very few were created specifically for polio eradication. However, the nature of these laboratories has changed dramatically since their inclusion in the PEI. Many were primarily research laboratories, and most of these have retained at least some of their research activities. Others were clinical diagnostic laboratories linked to a single or limited number of medical or health facilities. Some played a role, either full-time or part-time, in providing laboratory diagnoses for public health programs, but these programs were often limited in scope with little or no direct feedback into public health interventions.

Table 2

Changes in Laboratory Practices after Inclusion in the Network

Prior to the Network	After Inclusion in the GPLN
Laboratories were primarily independent entities characterized by the following: • Standards developed for their laboratory • Internal communication • Public focus was geographically limited • Limited funds for capacity building to support standards • Were not part of a surveillance program • Laboratories principally identified wild viruses from clinical assessments	As a result of being a GPLN Laboratory the following characteristics are seen: • Operate with global standards that are supported by an accreditation program. • Operate with a global public health initiative • As part of the GPLN they have access to more funds directed at capacity building • Laboratories function as part of a surveillance program, which drives standards and policies • Case definition is based on both virology and clinical criteria

Technical capacity in many laboratories was limited to very specific research-oriented or clinical diagnostic tasks, with little or no concept of standardization of methods or of reporting results. In 1991, when the GPLN was initiated, few laboratories in the world had the capacity to accurately, rapidly, and reliably isolate and characterize polioviruses from stool samples. Recent experience with the capacity of enterovirus laboratories not included in the GPLN support this statement.

GPLN's Outcome: Good Laboratory Practice

There is a coordinated network of efficient and proficient public health laboratories performing the same activities to the same high standard. They are integrated with the case investigation and immunization services to provide laboratory diagnostic information that can be used immediately by national and international public health authorities. Specific laboratory functions carried out are as follows:

Pre-analysis: It is very important that collection of specimens be done under standardized conditions, because the analyses preformed by health laboratories are subject to biological and technical factors and environmental effects. The GPLN's influence helped to improve the quality of specimen collection through the support of the following practices, which when followed, minimized pre-analytical factors that can negatively influence laboratory investigations:

- Method of transport
- Utilization of a reverse cold chain process
- Established transit time to meet specimen guidelines for analysis
- Chain of specimen custody
- Quality criteria for specimens pending analysis, including storage

Analysis/specimen testing: The GPLN had a direct effect on the analysis phase, overseeing the development of the following:

- Standard Operating Procedures (SOP) manuals
- Routine checks and balance
- Audit system
- Turn-around-time
- Accuracy of results and reporting

This Good Laboratory Practice environment was achieved through strategic planning and methodical design based on current scientific evidence in the literature and effective management practices. The QA Project witnessed a devoted commitment to QA and QM practices in daily operations, starting with WHO/HQ and continuing through the Regional Coordinators and the country laboratories. It found that the GPLN has followed seven **quality principles** in the clinical laboratory setting to achieve, according to international scientific standards, its Good Laboratory Practices.

THE PILLARS OF SUCCESS: SEVEN QUALITY PRINCIPLES

The QA Project's Senior Advisors identified seven quality principles through discussions at WHO/HQ, observing the team process at an annual laboratory director's meeting and visiting the five GPLN laboratories. The advisors believe that these principles not only demonstrate how the laboratories have achieved their high quality of service; they are also the factors that have led to the GPLN's success in bringing WHO's polio-free world goal within reach by 2002.

These quality principles exemplify QA and QM in practice throughout the network and support the QA Project's belief that other public health initiatives may use the framework and its contents to benchmark their own laboratory network or health program's performance. The seven quality principles are shown in Table 3 and described below.

Table 3

Seven Quality Principles Demonstrated by GPLN

1. Leadership commitment
2. Network-wide communication
3. Utilization of quality assurance methods: defining, measuring, and improving quality
4. Functioning accreditation program
5. Ongoing capacity building
6. Documentation standards
7. Responsible allocation of resources

Quality Principle #1: Leadership Commitment

Quality Traits for Principle #1

Create a vision, collaborative management, limited bureaucratic behavior, a sense of partnership, actively committed leaders, timely and frequent communication

Management science posits that an organization's leaders set the tone. "In a learning organization, leaders are designers, stewards, and teachers. They are responsible for building organizations where people continually expand their capabilities to understand complexity, clarify visions, and improve shared mental models–that is, they are responsible for learning."[6] In this regard, WHO/HQ's leadership of the GPLN is exemplary and is replicated in style and substance at every level of the network.

WHO leadership has succeeded in creating a vision, communicating it throughout the network and instilling in GPLN staff the vision of a polio-free world by the year 2002 and achieving global certification by 2005.[7] This vision is simple and clear, and it has provided a beacon for all members of the GPLN. This vision was articulated repeatedly by personnel of all ranks and positions in each of the National, Reference, and Specialized Laboratories the Senior Advisors visited.

This vision is at once compelling and, more importantly, perceived as within reach. It has given the laboratory personnel throughout the world a common purpose and a goal that motivates high performance and an uncommon degree of personal dedication to both individual and teamwork. "We cannot afford to miss a single poliomyelitis case, since in many situations the transmission of the virus is silent and the infection already may have spread," said the Director of a Polio Laboratory.

The management of the GPLN is characteristically professional, approachable, collaborative, and friendly. While there is a specific chain of command in the network, staff members worldwide are on a first-name basis. There is a marked absence of pressure to pay homage to hierarchy so often characteristic of a global operation of the GPLN's dimensions. This informality and the anti-bureaucratic behavior are direct results of GPLN's management and philosophy. The beneficial effects are palpable among laboratory staff. As one staff member said, "This gives us a sense that we are a family, which makes it easier to deal with difficult situations and conflicts."

The resulting attitude that "we are in this together" is all-pervasive in the labs, and because of it, staff are more willing to articulate work concerns and pinpoint problems openly. They are more willing to "go the extra mile" to address them.

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[6] Senge, Peter M., *The Fifth Discipline*, New York, Doubleday. 1990.

[7] Certification is granted when a "polio free" status is maintained for three years.

Laboratory staff members are passionate when speaking about their personal commitment to polio eradication. For example, a laboratory manager in Mumbai, India, said that for her, just knowing that her grandchildren will be able to grow up and not worry about polio, as she did not have to worry about smallpox for her children, is what drives her everyday.

They feel that they belong to a partnership, characterized by a sense of participation, association, and joint interest in a global public health initiative of consummate human value. Network members have bonded with each other in their dedication to achieving a polio-free world. The effect is a feeling of "oneness," heightened by trust.

Quality Principle #2: Network-Wide Communication Plan

Quality Traits for Principle #2

Freedom from rigid, vertical, or horizontal channels of communication and commitment to interpersonal communication, opportunity to exchange views.

While the GPLN's Regional Coordinators principally communicate with WHO/HQ, country/regional laboratories' communication within the GPLN is not exclusively **vertical** or **horizontal.**

The staff at GPLN laboratories experiences a freedom of purpose as they manage their work within their individual spheres of expertise. They also communicate without inhibition with other laboratories in their region or others in the network, solving problems, discussing technological or other scientific matters, or just exchanging views or information.

Strong interpersonal relationships exist from laboratory to laboratory cutting across country borders, staff positions, and rank. For example, these relationships exist among laboratory directors and virologists at laboratories elsewhere within their countries or on other continents.

Every time the question was asked, "How does the network function and succeed?" The response was, "It is the relationships we have with each other." This belief reverberated from the CDC in Atlanta, to the Indian and African labs. Though land and sea separate the laboratories, close contact and interpersonal relationships bind the network, giving the GPLN marked vibrancy and cohesion.

Quality Principle #3: Utilization of QA Methods: Defining, Measuring, and Improving Quality

Key Words for Quality Principle #3

Developing standards, monitoring performance, quality improvement

The use of QA methods to improve quality of healthcare and services has significantly increased over the last several years. Healthcare program managers have come to recognize the merits of applying QA methods and principles to promote quality outcomes. The GPLN consistently employs three core QA activities to achieve high performance in detecting and tracking the poliovirus with accuracy, while meeting defined timelines. The QA activities are developing and communicating standards, designing and implementing a performance monitoring system, and improving quality.

GPLN's QA Activities: Defining Quality (Standards)

The QA Project's definition: Defining quality is clarifying what is needed to produce quality. This includes defining, setting, and updating clinical and administrative standards for health services (based on

the best scientific evidence currently available); communicating these standards; and designing accreditation, licensing, or certification programs. Stakeholders' perception of quality (including client and community input) is an important contribution to defining quality.

Observed activities within the GPLN: The GPLN, under the stewardship of the WHO/HQ uses a consensus process for developing standards, drawing on the expertise and knowledge of the team to develop standards that meet current scientific evidence and that are feasible with the resources available for all laboratories within the network. Once a standard has been adopted, communication and necessary training are carried out, again supported by WHO/HQ and Regional Coordinators oversight. The venue for developing or adopting new standards is the Annual Laboratory Director's meeting, where current state-of-the-art technology is presented and discussed followed by an iterative process leading to consensus on new or revised standards to incorporate into the GPLN's standard operating procedures. The GPLN's ability to meet WHO's scientific and performance standards is ensured by WHO's methodical, systematic accreditation process, which takes place annually for all network laboratories. WHO's accreditation has produced uniform standards for laboratories to meet, and the resulting proficiency demonstrated by accredited laboratories is a leading quality principle for the GPLN. (Refer to quality principle # 5 - Functioning Accreditation Program for a detailed description of the GPLN's accreditation process.)

GPLN's QA Activities: Measuring Quality

The QA Project's definition: The systematic identification of what level of quality the system is currently producing. Measuring quality includes the collection and analysis of data that provide information about the level of adherence to established guidelines and standards; problems encountered that limit adherence, and opportunities for quality improvement through audit, supervisory assessments, self-assessment, or other methods.

Observed activities within the GPLN: While accreditation is the overall mechanism for monitoring the quality of laboratory performance, on-going internal measures were used at all laboratories between the accreditation visits for both the pre-analytical and analytical phases of laboratory investigation. Such monitoring included assessing for the following: improper specimen collection, faulty specimen container labeling, improper transportation of specimens, lack of reverse cold chain, inadequate specimen volume, old or dried specimens and, finally, ongoing proficiency testing.

When gaps in performance are noted, immediate steps are taken to rectify the situation. This includes assigning a second laboratory to verify all specimen results until the laboratory in question can satisfy the standard's requirements, and sending out an interim laboratory manager to oversee the process.

GPLN's QA Activities: Improving Quality

The QA Project's definition: A systematic process for improving the quality of care by reviewing the processes and addressing the gaps between current practices and desired standards. Quality improvement activities include management decisions, process re-designing, and team-based problem solving. These activities are based on objective data obtained through monitoring activities.

Observed activities within the GPLN: Early on, the network adopted a philosophy and a process for continuously improving in order to achieve its goal. Even as they approach the final stage of the eradication effort, the network strives to improve upon methodologies, communication, and turn-around times. They continue to monitor and evaluate their processes and conduct routine regional and global meetings, with the goal of "continually improving" and a sense of "You can always do better!" Quality improvement activities were carried out in all the facilities with results passed on to other laboratories, or the GPLN Regional office or headquarters as appropriate.

The accreditation visit is approached from a problem-solving perspective, involving the laboratory staff at every level and as a learning experience for both laboratory personnel and peer reviewers.

Quality Principle #4: Capacity Building (Training and Education for Staff, Supervisors, and Managers)

> 550 laboratory staff received specific training between 1991 and 1999

All polio laboratory personnel have received specific training for their work. Training sessions have occurred in all regions with support from the Specialized Laboratory Virologists. Between 1991 and 1999 more than 550 laboratory staff received training in the isolation and characterization of poliovirus. This commitment to training and education has created a network of laboratories fully conversant with the requirement of Good Laboratory Practice and laboratory biosafety, and a cadre of technically competent laboratory staff providing a public health resource available for use beyond the requirements of the polio eradication initiative.

The network has a strong commitment to field team training. As an example of the GPLN's integrated surveillance and diagnostic operations, personnel from the Entebbe National Laboratory routinely go into the field to train surveillance teams in proper specimen preparation and in transport timetables for the specimens. This training has enhanced the quality of the specimens upon arrival and the timeliness of their delivery to the labs. Laboratory personnel also train community healthcare workers in proper handling and transportation of laboratory specimens. Regional Reference laboratories work with the National Laboratories when requested regarding collection and transport of specimens.

Quality Principle #5: Functioning Accreditation Program

> Accreditation becomes an interactive learning experience for all participants–both laboratory personnel and the peer reviewers. "At first I wasn't excited about the accreditation process. It was just more work, but every time they come, we learn something else."

Recognition of an individual network laboratory's compliance with WHO standards is achieved through accreditation by WHO headquarters. Accreditation standards are usually regarded as optimal and achievable and are designed to promote continuous improvement within each lab. The accreditation process is a QA activity that has underpinned the network's strong global performance. As of March 2001, of the 148 laboratories in the network, 79 percent (117) are fully accredited, with another 7 percent (11) having received a provisional standing. Five laboratories are pending accreditation, and 15 have not been able to achieve accreditation status. When a laboratory is pending accreditation or is not accredited, a second accredited laboratory must verify its samples until they receive accreditation status. The process for accrediting the six Specialized Laboratories has been completed. (See Appendix A for WHO table with laboratory accreditation standings.)

GPLN accreditation is a formal process conducted annually. A team of qualified peer reviewers from GPLN Headquarters in Geneva, Switzerland, and virologists from a Specialized Laboratory and a Regional Reference laboratory make annual visits to individual laboratories in the network for on-site evaluation. Following the evaluation a determination, based on criteria, is made whether the laboratory is ready to achieve accreditation.

A variety of factors can prohibit a laboratory from achieving accreditation status. Common problems affecting accreditation status are:

- Failure to pass the proficiency test
- Sensitivity and specificity of results do not match reference laboratory results

- Inability to comply with laboratory methods and standards
- Laboratory management either are not present or lack the ability to lead
- High turnover of trained staff or an inadequate number of laboratory staff to handle the workload
- Limited resources to support the required turn-around time and transportation criteria established for specimens
- Inadequate implementation of quality control procedures

The accreditation process is specifically tailored to polio investigation and detection, in that it addresses specific programmatic needs and standards that are crucial to the diagnostic testing of a stool specimen. (Refer to Appendix B for accreditation criteria and process.)

The peer reviewers intend their visits to be problem-solving opportunities involving laboratory staff at every level, whereby accreditation becomes an interactive learning experience for all participants. As one laboratory member stated, "At first I wasn't excited about the accreditation process. It was just more work, but every time they come, we learn something else."

A laboratory receiving accreditation status has a positive effect on staff, the laboratory, and the community. Staff members in a laboratory in Chennai, India identified the following ways in which the accreditation process positively impacted their work:

- Increases efficiency within the laboratory
- Strengthens the public confidence in the laboratory
- Integrates laboratory services
- Promotes staff training
- Creates a comparative database for the Network
- Provides recognition for the staff
- Creates individual pride
- Gives a sense of belonging
- Quality outcomes are achieved

Quality Principle #6: Documentation Standards

Data, when accurately collected and recorded, provide essential information for program managers to assess their level of achievement in meeting program goals. Without data to translate into information, managers and staff cannot make decisions based on fact. Data management for the GPLN has been a focus and strength of the GPLN. As a result, most of the GPLN laboratories have been supplied and trained to use specific software to track data (Regional GPLN EPI-Info software). The software program was customized to meet the GPLN's documentation needs, and data managers in each laboratory have been trained to use it. Most importantly, daily, weekly and monthly reports are submitted to Regional Directors and GPLN/HQ. This allows the leaders to spot "red flags" or variances quickly and follow-up on the information.

Laboratory data management systems are quite elaborate. The network laboratories manage records in a variety of ways determined by the technology available and laboratory preference. There were data sheets that were hand-written, typed, or computer generated; they were kept in file cabinets, bound registers, and loose-leaf binders. Certain areas had duplicates and triplicates. Reports of work performed are generated on a weekly basis and are sent to the Regional Director who compiles, analyses, and produces a consolidated report, which is distributed to all concerned.

Records in the national laboratories visited indicated that close to 90+ percent of their results were sent to the submitting agency within 28 days of receiving the specimen. In the regional reference laboratories, this number was nearly 100 percent. Refer to Appendix C for a construct of the data flow process and timetable within the network.

Quality Principle #7: Responsible Allocation of Program Resources

Health programs require resources to make their guiding vision a reality. The resources the PEI has received from donors to support the GPLN's work have played a critical role in facilitating improvement in each lab's quality and efficiency. This includes meeting deadlines, handling an increasing volume of specimens, and testing the specimens accurately. Resources include such items as computers, freezers, incubators, microscopes, autoclaves, tubes, pipettes, reagents for typing, which assures no false positive reporting, and staff training. See Appendix D for a comprehensive list of required laboratory equipment to perform laboratory investigations in compliance with the SOP.

All laboratories are furnished with minimum equipment; for example, many laboratories have only one computer to use for data tracking and e-mail. What is remarkable is that while the resource requirements to handle the GPLN's workload exceed available funds, the laboratories consistently produce timely and accurate test results. A confident spirit is omnipresent in the network, and this attitude compensates for limitations resulting from inadequate funding and supplies, although these were serious concerns among all the staff interviewed.

Cost to Operate the Network

Between 1991 and 1999 more than US$6,000,000 was spent on providing laboratory equipment and upgrading laboratory facilities, and more than 550 laboratory staff have received laboratory science training. At the time of this report, annual operating costs for the GPLN were approximately US$ 4,000,000 (the breakdown is shown in Table 4).

Table 4

Annual Operating Costs for the GPLN

Category	Related Annual Cost in US$
• Regional and global coordination, including specimen and isolate shipping costs	1,500,000
• Accreditation and quality control	500,000
• Supply of essential reagents and equipment maintenance and/or replacement	1,000,000
• Training and trouble shooting, including consultant support	1,000,000
Total Annual Costs	**US$4,000,000**

GPLN Donors

While GPLN personnel at all levels are proficient and personally committed to optimal performance—free to carry on their work under GPLN's benevolent guidance—WHO cannot operate the GPLN without

the strong support it receives from donors. These donors provide resources, time, and expertise to the PEI, particularly to strengthen the GPLN and enhance its effectiveness.

Donors' contributions ensure that each laboratory is sufficiently equipped and staffed to handle the multiple responsibilities and urgent tasks entailed in fulfilling WHO's vision of a polio-free world by the year 2002. Staff, united by this vision, could not produce such effective work without the fundamental contributions made by these donors. "There are no luxuries here, as you can see, but we are trying to meet our responsibilities with the best intentions," an epidemiologist from one of the African laboratories emphasized to the QA Project Senior Advisors.

GPLN laboratory members work toward the vision, and anticipate the time when future network operations will include the eradication of the other vaccine preventable diseases. Donors' participation and generosity support the efforts of the GPLN and foster their hopes.

CONCLUSION

It is WHO's and the QA Project's hope and intent that laboratories and other health program personnel reading this report can recognize the GPLN's most compelling aspect: with a unity of purpose, laboratory networks and healthcare programs can succeed at the global level, regardless of the environment for these efforts. Although the GPLN operates with minimal resources, its staff's dedication, will, and tenacity have made WHO's vision of a polio-free world by the year 2002 credible and achievable.

The substantive and numerous quality principles found in the GPLN may serve as benchmarks for closing performance gaps in other laboratories or health programs. The GPLN's QA practices can serve as a point of departure for developing strategies to raise laboratory performance and/or program performance elsewhere to higher yet achievable levels.

Although the goal of PEI is to rid the world of Polio, it is hoped that the lessons learned through the effort, particularly those of the GPLN, will continue on to become part of other public health endeavors. The laboratory network itself could be used in efforts against other infectious diseases. The expertise gained at the National Laboratories has transformed many of them from small research facilities into state-of–the-art public health laboratories that can support national health programs. The principles used by the GPLN can serve as a model for health programs both large and small.

LESSONS LEARNED FROM THE GPLN

The network staff has learned many lessons along the road to building a successful network. The following stand out as significant, and hopefully others can benefit from these lessons learned.

- **Concentrate on logistics**: Never underestimate the challenges that logistics will present. Detail planning is the linchpin of success. Logistic preparation requires adequate time and a keen eye for strategic planning and details.
- **Prepare realistic** budgets for operational success.
- **Direct energies and resources toward a network-wide communication plan:** In the beginning, communication and the role it would play in supporting the network's outcomes were underappreciated. The network management found that unsolved "nagging problems" often were solved when communications were addressed.
- **Build a dynamic program through on-going problem solving:** The GPLN program would not be successful if operations and methods remain static. Adopting a philosophy of continuous improvement has been key to the program's success.
- **Develop a sense of belonging:** The network continually benefits from the synergy that results from almost 150 laboratories being part of something that has become bigger than the sum of its parts. The power of being part of a "Global Team" has tremendous influence and impact over laboratories and

their individual commitment. The network simply could not exist if the individual national laboratories were not committed to the vision the PEI. Being part of the GPLN, as one member stated, has helped many "fence sitters" to jump off the fence and join the team.

- **Develop a leadership team that can "walk the talk":** The GPLN management team has strong field experience as virologists and laboratory managers. In essence they know the science behind the vision. This background, combined with a "hands-on" philosophy of overseeing field operations, is key to establishing a partnership with the laboratories.
- **Developing standard methodologies** that can be applied in a reasonably flexible way as long as basic requirements for sensitivity and specificity are met has been the mainstay of the GPLN's success. It has also understood the importance of developing standards that are feasible and achievable in many different environments.
- **The value of having quality control activities** both for individual network laboratories (proficiency testing and accreditation) and for the wider GPLN system (performance monitoring and progress tracking) has contributed to success. This concept, which was difficult to develop, has allowed the GPLN to compare results and ensure that within the network they are all speaking the same language.

APPENDICES

Appendix A: WHO GLPN Accreditation Data (as of March 2001)

Appendix B: WHO GPLN Accreditation Criteria

Appendix C: Data Flow for Polio Eradication

Appendix D: WHO GPLN Essential Equipment List

Appendix A: WHO GLPN Accreditation Data (as of March 2001)

Type	Accredited	Provisional	Failed	Pending	Totals
Global	7	0	0	0	7
RRL	13	2	0	0	15
NL	68	8	6	4	86
Totals	88	10	6	4	108
%	**81%**	**9%**	**6%**	**4%**	
Sub-NL	29	1	9	1	40
%	73%	3%	23%	3%	
All Labs	**117**	**11**	**15**	**5**	**148**
%	**79%**	**7%**	**10%**	**3%**	

Region	Labs	Accredited	Provisional	Failed	Pending	Totals	% Accred.
AFRO	RRL	1	2	0	0	3	100%
	NL	7	3	2	1	13	77%
AMRO	Global	1	0	0	0	1	100%
	RRL	1	0	0	0	1	100%
	NL	7	1	0	0	8	100%
EMRO	RRL	4	0	0	0	4	100%
	NL	7	1	0	0	8	100%
EURO	Global	4	0	0	0	4	100%
	RRL	2	0	0	0	2	100%
	NL	26	3	4	1	34	85%
	Sub-NL	0	1	8	0	9	11%
SEARO	Global	1	0	0	0	1	100%
	RRL	3	0	0	0	3	100%
	NL	11	0	0	2	13	85%
WPRO	Global	1	0	0	0	1	100%
	RRL	2	0	0	0	2	100%
	NL	10	0	0	0	10	100%
	Sub-NL	29	0	1	1	31	94%
Totals		117	11	15	5	148	86%

Appendix B: WHO GPLN Accreditation Criteria

Surveillance of acute flaccid paralysis (AFP) at an annual non-polio rate of >1/100,000 in children under 15 years of age is the standard for certifying polio eradication in all countries. The ultimate goal is establishment of a poliomyelitis classification system based on virologic evaluation of all AFP cases.

Virologic evaluation consists of tests on two adequate stool specimens collected 24 to 48 hours apart from each AFP patient within 14 days of onset of paralysis. Supplemental virus surveillance may be required where appropriate that includes specimens from special surveys of healthy children, contacts of AFP cases, and the environment. For certification purposes, laboratory results are accepted only from a WHO accredited poliovirus laboratory.

Accreditation provides documentation that the laboratory has the capability and the capacity to detect, identify, and promptly report wild polioviruses that may be present in clinical and environmental specimens. The accreditation process also provides a learning opportunity, a mechanism for identifying resource and training needs, a measure of progress, and a link to the Global WHO Laboratory Network.

The accreditation of National Poliovirus Laboratories is reviewed annually by the WHO Regional Office and is based on laboratory performance during the 12 months immediately preceding the application, accompanied by complete data, usually from 13 months to 1 month prior to evaluation. Accreditation is given for the upcoming calendar year.

There are seven criteria for accreditation:

1. **Test results are reported by the laboratory on at least 80% of AFP specimens within 28 days of receipt.**

This criterion may be met for all virus negative specimens after 2 passages in 14 days. Similarly, viruses that demonstrate cytopathic effect (cpe) within the first week of incubation may be identified within the 28-day time frame. Viruses that appear late in passage, are virus mixtures, or present typing difficulties may require longer than 28 days. In such situations, the laboratory may meet this criterion by providing interim test results to the EPI program within 28 days and full results within 14 days thereafter.

2. **Virologic tests are performed on at least 150 stool specimens annually.**

Fully active virus laboratories that maintain the appropriate cell cultures weekly and annually test 150 stool specimens of any origin for any enteric viruses are deemed to meet this criterion. Laboratories anticipating fewer than this number may collaborate with the EPI staff to develop protocols for sampling stools from healthy children in high-risk areas, for routinely testing specimens from meningitis cases, or for other epidemiologically sound virus surveillance activities.

3. **The accuracy of poliovirus detection and identification among all virus isolates is at least 90%.**

Accuracy is determined by agreement in test results on all poliovirus isolates submitted by the National Laboratory to the Regional Reference Laboratory (RL) during the 12-month review period.

4. **At least 80% of poliovirus isolates from AFP cases forwarded to the RRL for ITD within 14 days of obtaining typing result.**

It is essential that the polio eradication programme be aware of wild poliovirus isolations as soon as possible. All poliovirus isolates from AFP, AFP contacts, and suspected polio cases must be forwarded without delay to the Regional Reference Laboratory for intratypic differentiation.

5. **Internal quality control (QC) procedures for L20B and RD cell culture sensitivity are implemented at least quarterly in accord with WHO protocol.**

Original QC data sheets and summaries of corrective action are retained for documentation and discussion with reviewer.

6. **The score on the most recent WHO-approved proficiency test is at least 80%.**

Proficiency test (PT) results must be reported within 42 days of panel receipt to receive full credit.

7. **The score from the annual on-site review of laboratory operating procedures and practices is at least 80%.**

For laboratories with consistently high annual scores, the Regional Laboratory Coordinator may waive the on-site review upon the laboratory's satisfactory completion of the annual checklist.

The annual non-polio enterovirus (NPEV) isolation rate from all stool specimens is not a criterion for accreditation because of the variability of findings influenced by a number of factors, including the season of the year, elevation, and population hygienic levels. However, the rate may be a useful indicator of laboratory performance and should be discussed with the reviewer. The annual NPEV isolation rate in most tropical countries typically exceeds 10%.

A laboratory that achieves less than the passing score on any one of the applicable criteria will work with the Regional Laboratory Coordinator to:

• Identify areas where improvement is needed

• Develop and implement a work plan

• Monitor laboratory progress

• Provide for re-testing where required

• Continue steps to achieve full accreditation

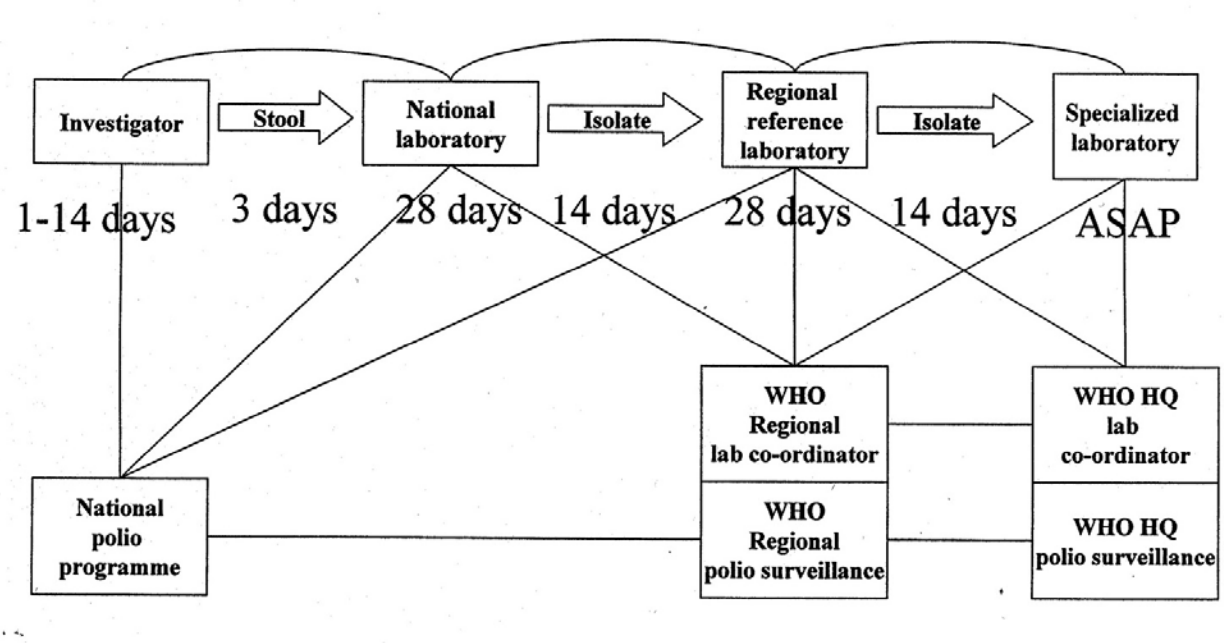
A laboratory that fails to achieve a passing PT test score within 6 months after annual review is deemed non-accredited and must make arrangements with an accredited laboratory to perform duplicate tests on all specimens.

The checklist to be filled out annually by laboratories is designed primarily for use in countries that perform AFP surveillance. Applicable components of criteria 2-7 may be used for laboratories in other public health-related activities.

The checklist consists of four parts. Part I summarizes the findings of the review and the data on which accreditation is based. Part II provides a worksheet to calculate and record laboratory performance for criteria #1 through #6 for the immediately preceding 12 months if data are complete. (Selection of the most recent 12-month period as a basis for calculation, rather than the most recent calendar year, provides an assessment of current performance and permits review of laboratories at any time during the calendar year.) Part III provides a profile of the laboratory and serves to identify resource needs. Part IV is a checklist for evaluation of laboratory operating procedures and practices for criterion #7.

The checklist does not include all laboratory activities or all situations. It is intended to serve as a guide only. The experienced reviewer is expected to ask detailed questions and make additional suggestions as appropriate to assure high-quality laboratory performance.

Appendix C: Data Flow for Polio Eradication



Appendix D: WHO GPLN Essential Equipment List

ITEMS	Recommended	
	Quantity	Total Cost (US$)
Autoclave, large, (or bench top for small lab)	1	14000 (1,000)
Balance, with power adaptor	1	1295
Cabinet, class II safety and replacement filter	1	7000
Centrifuge, low speed, refrigerated	1	7710
Computer, with software	1	1700
Counting chambers	2	180
Pipetors, 100-1000 µl	2	400
Displacement pipettes, 20-200 µl	2	300
Dispenser, repeated	2	200
Fax machine	1	600
Freezer, -20°C, household, non-frost free, chest type	2	1200
Incubator, standard	2	6400
Liquid nitrogen container, 25 L for reserve nitrogen	1	2600
Liquid nitrogen storage system – low evaporation	1	1930
Media filtration system and accessories	2	3255
Meter, pH, hand held with spare electrodes	1	610
Microscope, inverted	1	3530
Microscope, standard	1	1670
Mixer, vortex	1	200
Oven, hot air sterilizing	1	580
Refrigerator, household, 4°C	2	1200
Stirrer, heated, magnetic with bars	1	300
Storage system for chest freezer	1	600
Test tube rack for 16 mm tubes	12	315
Thermometers	12	85
Thermometers, 0-100°C	6	300
Water distiller, double or triple, glass	1	2500
Water deionizer (cartridge)	1	2650
Water bath	1	865