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Integration of Quality Management Systems in a Rural, Low-Resource Environment: The Experience at Phebe Hospital in Bong County, Liberia

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ABSTRACT

Laboratory strengthening programs have been limited to clinical testing for prioritized diseases such as Ebola Virus Disease (EVD), Lassa Fever, COVID-19, Multidrug Resistant Tuberculosis, Malaria, and Human Immunodeficiency Virus (HIV). While patient outcomes are key concerns, limited efforts have been directed at improving Quality Management Systems (QMS). The benefits of QMS are correlated to improved patient care in resource-limited settings. This article examines the ability of a laboratory in a low-resource setting to integrate QMS into clinical care, describes its challenges, and measures its benefits on improved treatment outcomes. Gap analysis was conducted to implement QMS at Phebe Hospital, Bongo county, Liberia. We prioritized the framework of workflow processes and reorganization, equipment and inventory management, and documentation as challenges hampering the effective implementation of QMS. As a stepwise intervention strategy, laboratory workflow and infrastructure were remodeled, staff retrained, partners managed, and system changes were communicated to strengthen the laboratory systems. Improvement in communicating goals to clinicians, following work plans, managing staff time, delegating responsibilities, allocating resources, and strategically managing the presence of multiple partners as effective strategies to improve QMS were observed. We demonstrated that improving QMS strengthens the laboratory systems at Phebe Hospital. To sustain such initiative, Phebe Hospital must focus efforts on building sustainable laboratory systems and structures. We propose future studies to evaluate the short- and long-term benefits of such interventions.

Keywords: Laboratory; Liberia; Quality Management System; Rural Hospital; Resource-Limited Setting

INTRODUCTION

The quality of laboratory services, including systems and structure, is one of the major factors that directly affect national health care. As such, Quality Management System (QMS) is an ongoing auditing process that seeks to ensure that a clinical laboratory is of the best quality to meet patient care requirements. To determine the effectiveness of the national standards, QMS must holistically examine all areas of the laboratory where any neglect could translate into increased costs in time, personnel efforts, and ultimately treatment outcomes. Accordingly, there are 12 quality system essentials (QSE) in QMS that evaluates the effectiveness of the laboratory in delivering quality care. They include organization, personnel, equipment, purchasing and inventory, process control, information management, document and records, occurrence management, assessment, process improvement, customer service, facilities, and safety [1].

Laboratories in Sub-Saharan Africa (SSA) must be encouraged to create national tools in the form of quality standards and employ guidelines to strengthen laboratory services. According to global statistics, laboratory results influence up to 70% of medical diagnoses and are therefore required as essential tools for the provision of safe and effective patient treatments [2]. Prevalent methods to integrate QMS in SSA include the WHO checklist, created in 2009, which is an accreditation checklist based on international quality documents [1]. Also, ISO 15198, the “gold standard” for laboratory quality in clinical care, proves challenging for low-resource environments to reach [1].

The challenges associated with the implementation of QMS in Liberia have been attributed to the lack of leadership and governance structure, policy and regulation and sustainable programs [2-6]. For example, there is no defined national government or local health facility budget set aside for laboratory system strengthening, and budgetary decisions are generally made by the National Legislature largely composed of individuals having limited knowledge of health and associated matters. Therefore, it is imperative to adapt appropriate standards in order to address critical gaps and strengthen laboratory systems.

Until recently, the strengthening of laboratories by most international organizations within the framework of improving health care in resource-limited settings has been one of the least prioritized areas. Most laboratory strengthening strategies have traditionally been limited to clinical testing programs for prioritized diseases such as HIV, TB, and Malaria [3-4]. Most of the funding for laboratory services in Liberia, for example, have

traditionally been limited to vertical programs [3]. Over time, it has been recognized that vertical programs are not generally effective for patient outcomes without holistically integrating the laboratory environment and related elements that are crucial for the full operation of the laboratory [7].

Furthermore, effective disease surveillance requires functional public health systems and clinical laboratories for the early detection of epidemics such as COVID-19, Ebola, and Marburg. Collectively, surveillance determinants serve as catalysts to recognize, differentiate, and define the respective roles of public health and clinical laboratories. In a recent disease outbreak in April 2017 in Liberia, the ability of the country's public health systems to identify and detect emerging infectious diseases (EIDs) was re-examined [8]. The need to ensure adequate laboratory responses at the hospital level became glaring during the post-Ebola period. Although Ebola was ruled out, the inability of clinical laboratories to rule out some basic pathogens, as outlined in the Essential Package of Health Services (EPHS), was a significant limitation [8]. Eventually, laboratory networks must be equipped to address both individual patient care and public health needs from the peripheral to the national level, and efforts in laboratory systems strengthening require a focus on speedy decision making and quality services in order to predict reliable outcomes.

For example, National political will and technical leadership could be considered, based on the recent EVD outbreak in Liberia, as fundamental components to strengthen and sustain health care delivery systems and advocate for laboratory services in low resourced environments. Governance and leadership are essential requirements to accelerate the daily operations of laboratories through coordinated allocation of appropriate resources and minimum standards for the effective functioning of clinical laboratories. Standards and priorities are being instituted in Liberia through dedicated teams that align partners' organizational goals with those set by institutional leaderships. Whether or not those goals are outlined in a written strategy, or utilized as a framework to institute structured plans, remain unknown.

One of the limitations in quality care is misdiagnoses of diseases as experienced during the EVD outbreak in Liberia [8]. This was highlighted as one of the key challenges during the 2014 EVD outbreak in Liberia. With basic microscopy, the lack of continuing education leads to misdiagnosis of malaria. Also, many personnel in the laboratory may not have received adequate

continuing education and neither are they professionally licensed. For example, at a recent Laboratory Week Conference focused on highlighting diagnostics in Liberia, 95% of the fifty-seven medical laboratory technicians (MLTs) had limited access to continuing education, while 82% of the technicians were also alarmed that Widal test, which is commonly used in Liberia for the diagnosis of Typhoid, has been eliminated from testing centers around the world [9]. It is well known that the absence of technicians in the laboratory during the Ebola outbreak signaled a lack of confidence in the clinical laboratory environment, not only by physicians, but also by technicians. Efforts by the Ministry of Health (MoH) to increase inputs like hardware, knowledge and skills of technicians must include a focus on continuing education.

A recent pre-service workshop on Good Clinical Laboratory Practice (GCLP) reflected pre-workshop test scores of 44% while the average post-workshop scores were 77% [10]. Several studies have shown that pre-analytical phase (patient preparation, specimen collection and identification, transportation, preparation for analysis and storage) is the most error-prone process in laboratory medicine [11]. This is likely seen as the smallest percent of work that happens in laboratory medicine. The lack of quality management systems can have a negative impact throughout all phases of laboratory or clinical specimens and the results generated ultimately impact patient care. Through partnerships, the MoH continues to address these gaps, but how these opportunities are managed should be applied at the facility level where the impact occurs. However, without data on the impact of partners at the national level, the impact of their programs and activities on Liberia's laboratory system strengthening cannot be readily assessed. A more critical examination regarding the management of partners at the facility level may likely provide insights into the extent of the integration of QMS at Phebe Hospital.

METHODOLOGY

Project Setting

The project was implemented at Phebe Hospital and School of Nursing in Suacoco, Bong County, Liberia. It is a 156-bed hospital with an equipped laboratory for basic biochemical tests and microbiological investigations, electronic x-ray machine, IV infusion unit and oxygen plant. It provides basic surgical, medical, obstetric and gynecological, and pediatric cares. Presently, the hospital also host residents from the Department of Obstetrics and Gynecology of the Liberia College

of Physicians and Surgeons (LCPS) as its community rotation site, supervises medical interns during clinical rotations and serves as clinical sites for nursing students from Cuttington University and other nursing programs in the country. The Phebe Hospital School of Nursing provides diploma in five different programs: Professional Nursing, Professional Midwifery, Nurse Midwifery, Nurse Anesthetics and Medical Laboratory Technology [12]. The hospital caters to over 300,000 population within its catchment area consisting of Bong County, the surrounding political subdivisions of Liberia, and the bordering towns and cities of the neighboring country of Guinea [13]. As part of Liberia's public health system, it is the third largest hospital in the country that delivers diverse services to approximately 52,000 persons per year [14-15].

Pre-Planning Phase

In preparation for the QMS integration at Phebe Hospital, the first step was to perform an audit of the facilities, ongoing procedures, and current policies in order to identify and categorize the gaps impeding the quality standards of the laboratory. For the second step, we reviewed the findings from the 2017 Strengthening Laboratory Management Toward Accreditation (SLMTA) baseline audit conducted by the Academic Consortium to Combat Ebola in Liberia (ACCEL). Third, one of the hospital partners audited the laboratory based on the WHO-AFRO framework during which time the laboratory got a score of zero stars [16]. Then, we assembled a team of Laboratory Technicians, Medical Doctors, Hospital Administrators and Mid-Level Health Workers to review the data extracted from the primary audit of the hospital and examine the second analyses of the two baseline audits, respectively. The mandate of the team was to categorize and prioritize the findings from the gap analyses in order to implement a stepwise intervention strategy. Accordingly, the team identified the key priority areas for improvement in the laboratory as (1) workflow processes and reorganization, (2) equipment and inventory management, and (3) documentation, respectively.

Intervention Strategies: Integration of QMS at Phebe Hospital

In collaboration with the hospital and a laboratory-based partner, we identified the most suitable intervention strategies, based on the key priority areas, geared toward the strengthening and sustainability of QMS at Phebe Hospital. Accordingly, we described the step-by-step interventional measures to mitigate the associated gaps and challenges in order to improve the

laboratory systems and structures, including capacity enhancement, at Phebe Hospital.

A. Priority Interventions

- i. **Workflow Process: Facility Renovation and Reorganization.** The main laboratory space was utilized for testing purposes, while the blood bank and the other three rooms were used for offices and storage. Due to the limited space, the main laboratory space was reorganized into sections with chemistry, hematology and urinalysis in the main laboratory space, and microbiology in two of the office spaces with the blood bank in its current location. The testing areas were minimally renovated using Phebe Hospital's Maintenance Department for functional reorganization of the laboratory space. Where suitable non-porous surface materials could not be sourced in-country, large tiles were used and then covered with laboratory grade epoxy. Each space was then reorganized to remove nonfunctional or unnecessary equipment. For example, a distiller was previously installed in the blood bank but not utilized due to the non-availability of water. Accordingly, it was subsequently relocated to an area between the main laboratory and the Microbiology Laboratory with water supply, whereas additional lines and sink were installed. Additionally, there was a lack of organized storage space. A "hallway" between the main laboratory and the microbiology rooms was outfitted with a wall of shelves made by the Maintenance Department and utilized as a repurposed shelf for storing and organizing laboratory supplies as part of the inventory management plan.
- ii. **Equipment and Inventory Management.** With the purchase or refurbishment of new equipment, Phebe Hospital created equipment and inventory master lists. Maintenance schedules were defined for various equipment based on the manufacturer's specifications and, along with the validation or verification records, deposited into the "Book of Life" for each equipment. Also created was a service sheet to request extensive technical support. Finally, quality control (QC) check logs were created for all equipment. The QC logs are visibly posted above the equipment to remind laboratory technicians of the regularly scheduled dates for checks. Additionally, whenever forms are completed, they are stored in the "Book of Life" for the specific equipment [17]. The Book of Life, maintained for the life of an equipment, contains the equipment inventory sheet, service of

contract information, vendor's installation records, laboratory's validation plan and record, calibration, maintenance and service schedules, and manufacturer notification inserts and alert [17]. This makes it easier to review equipment history and helps the technicians with troubleshooting. Supplies stored in the laboratory have the necessary bin cards on the shelf and the process for inventory management documented in accordance with the Standard Operating Procedure (SOP).

- iii. **Documentation.** A key component of the QMS integration at Phebe Hospital revolved around documentation. A quality manual was started with one of the microbiology mentors and continually updated. The SOPs were revised and, in some cases, especially in microbiology, developed afresh. The QC check forms and associated SOPs were created, including SOPs for the newly acquired equipment. The requisition and reported processes for the laboratory were updated, SOPs written, and new forms created and shared with the clinical staff to ensure that all necessary information was included. While the documents and records being generated in the laboratory are currently paper-based, strategies are being instituted to gradually transition to a laboratory-based information system.

B. Secondary Interventions

- i. **Monitoring.** As the improvement projects were being prioritized and scheduled accordingly, the laboratory assembled a core quality team and introduced weekly Quality Management meetings. The purpose of the team was to provide internal monitoring of projects and regular review of ongoing projects. The team has been grouping items arising from the meetings into nine of the 12 QSEs: facilities and safety, documents and records, personnel, equipment, purchasing and inventory, process control, information management, occurrence management, and process improvement. During these meetings, new items were assigned to a member of the laboratory staff as a measure to ensure participation and ownership for the effective integration of the quality management system.
- ii. **Reorganization.** When evaluating strategies to reorganize laboratories and improve process workflow, there is a need for the changes to be initiated around specialization of

duties and responsibilities. As a result, the laboratory staff was reorganized into a new organizational chart with members of the team given additional responsibilities. The new roles included a Quality Manager, Safety Officer, Inventory Manager and five section heads (Chemistry, Hematology, Microbiology, Urinalysis and Parasitology, and Blood Bank). These new roles were filled by existing staff with leadership characteristics. Additionally, the laboratory technicians were given specialized training competencies based on the assigned sections while maintaining their generalized multi-purpose competency in the laboratory. Finally, the work schedules were adjusted within the framework of the revised organizational structure.

- iii. **Partner Interventions: Automation and Microbiology.** Due to the lack of funds from the hospital, partner interventions were instrumental in completing a significant proportion of the improvement projects. Phebe Hospital leverage their existing relationships to secure materials for the renovations of the laboratory facility while it provided the necessary labor. Partner relationships were instrumental in the acquisition of new semi-automated analyzers for Chemistry, Hematology and Urinalysis. Research partnerships also enabled Phebe Hospital to have on-the-job-training and long-term mentorships for the re-integration of the microbiology program. Finally, relationships were leveraged to provide laboratory leadership with SLMTA training and the entire staff with QMS training.

RESULTS AND DISCUSSION

Due to the limited number of trained personnel and inadequate incentives from the national level, laboratory technicians perform multiple functions across different areas of the hospital. As is common in most low-resourced settings, Laboratory Technicians have multiple roles. For example, Laboratory Technicians serve as instructors at the Medical Laboratory Technician Training Institution on the hospital campus, MoH Trainers for advancing testing techniques for other Laboratory Technicians, and County Diagnostic Supervisors of Bong County for the MoH, among others. Additionally, there is a lack of alignment in training programs by sectors, MoH and partners. Accordingly, the combination of multiple roles across multiple organizations, lack of training opportunities and inadequate alignment frequently results in replication, duplication and/or irrelevant training events received by similar staff over the

years. The laboratory team adjusted the work schedules of the Laboratory Technicians to match with the availability and expertise of trainers and/or mentors to alleviate scheduling conflicts. However, without a comprehensive system similar to the Rwanda Model, this issue will continue to persist [18-19].

Communication is an integral part of overall laboratory management and is one of the keys to quality management. Miscommunication has negative consequences and contributes to adverse clinical events and treatment outcomes. This plays a role in the dissemination of information within the laboratory system and also between the laboratory and laboratory service users. Consequently, there is increasing interest in, and use of, communication technologies to support laboratory medicine. There have been setbacks pertaining to communication within and outside the laboratory at Phebe Hospital. In recent times, there has been marked improvement in communication. Caller-user group (CUG) cell lines have been installed in the laboratory and then wired to the various departments. This mode of communication has combated the issue of poor communication between the laboratory and clinical services with regards to delayed sample collection, transport, and reporting of results [5-6]. An alert bell has also been placed in the laboratory entrance to alert the laboratory personnel of the arrival of patients for collection of samples or the provision of results. This has gone a long way in reducing the unnecessary presence of non-laboratory personnel in the laboratory and consequently improving infection control measures and contamination of the laboratory.

As demonstrated in low-resourced settings, equipment and inventory management has proven and continues to be a challenge. Persistent electrical issues have been a challenge to the continuous use of the new analyzers and the storage requirements of the reagents. Lack of spare parts and in-country service technicians contribute greatly to equipment downtime in the laboratory. This has also proven to be longer than usual lead time in getting supplies into the country and out to the facilities. Working with various partners also means multiple avenues for ordering and receiving laboratory supplies, a process which has yet to be streamlined and properly managed by Phebe Hospital. The laboratory team is currently working with partners to streamline the ordering process from partners and create SOPs for ordering supplies from both the MoH and respective partners.

Another challenge to the implementation of quality management has been the adjustment of the team attitude to a quality minded strategy. The

integration of quality management generally means additional routine work, especially around documentation, which does not endear it to the already poorly incentivized laboratory team. It has been found that consistent daily review and reinforcement of QC checks and other documents and records have worked best with reinforcing new practices. Also, the provision of training on QMS can be very instrumental in creating awareness regarding its importance. Plans are also being considered to incentivize the Laboratory Technicians.

Most importantly, sources of funding for sustained quality management are a major challenge in QMS integration. Currently, as in most SSA countries, laboratory services are administratively grouped with pharmacy and other clinical services of priority usually given to essential medical services over the laboratory [1]. As such, laboratory supplies and other necessities are usually neglected at both the local and national levels [20]. While Phebe Hospital and the MoH have leveraged available partners' relationships to provide for capacity building in the laboratory, the entire process must be continuous in order to be sustainable. This means that eventually Phebe Hospital leadership will have to establish dedicated funding for the laboratory and organizations such as the Liberian Association of Medical Laboratory Technicians will have to advocate on the national level for laboratory representation on budgetary decision-making bodies.

In summary, the implementation of quality improvement projects and QMS in general has helped to transform the laboratory at Phebe Hospital. Despite the challenges, the laboratory has improved since the introduction of QMS. The growing motivation and dedication of the laboratory staff, as well as the commitment of the hospital management, will be critical in sustaining the ongoing quality improvement projects. On the national level, efforts regarding equipment standardization, partners' mapping and coordination at the MoH level have commenced. However, additional efforts need to be instituted, particularly in the areas of supply chain management, equipment management and overall dissemination of the commitment to laboratory quality [20]. This will create the platform for international accreditation of Phebe Hospital Laboratory, as well as other laboratories in the country.

In conclusion, laboratory strengthening systems in Sub-Saharan African have traditionally been limited to clinical testing programs for prioritized diseases. Interventions in limited resource settings must be customized and focused on building sustainable laboratory systems to

positively impact gradual improvement in laboratory services.

AUTHOR CONTRIBUTIONS

The concept for the development of the manuscript was conceived by CBE. The coordination of the manuscript development team to ensure timeliness of writing assignments, collating and compiling information, and following up was performed by GKS. All authors participated in the development of the final concepts for the manuscripts, attended manuscript development team meetings, and the writing, reviewing, and editing of assigned components. The final editorial reviews were performed by EAR and SBK, and the formatting and submission performed by SBK, respectively.

DISCLAIMER

The views expressed in the submitted article are those of the authors and do not in any way represent the views or positions of their respective affiliating institutions.

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