CME/SAM

Measurement of Improvement Achieved by Participation in International Laboratory Accreditation in Sub-Saharan Africa

The Aga Khan University Hospital Nairobi Experience

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ABSTRACT

Objectives: *As part of the ISO 15189:2007 accreditation process, the Aga Khan University Hospital Nairobi laboratory became the first internationally accredited hospital laboratory in sub-Saharan Africa outside South Africa in 2011 through the South Africa National Accreditation System.*

Methods: *Seven preanalytic, 10 analytic, eight postanalytic, and five administrative performance parameters were monitored from 2009 to 2012 to measure the impact of the accreditation process.*

Results: *Most measures in all four categories showed substantial improvement. The seven preanalytic measures all showed major improvement—between a quarter and a half sigma. Real but less dramatic improvement appeared in analytic and postanalytic measures, but greater than one sigma decrease in analytic "procedure violations" and a three-quarter sigma decrease in excessive turnaround time were noted in these categories. Administrative improvements included dramatic decreases in misdirected and missing reports and complaints.*

Conclusions: *This study demonstrates the correlation of the accreditation process with improvement in quality measures in a low-resource region.*

Upon completion of this activity you will be able to:
- apply quality management system processes and quality monitoring to improve laboratory performance.
- list preanalytic, analytic, and postanalytic laboratory quality indicators that can be compared to external benchmarks.
- list additional challenges of achieving laboratory accreditation in resource-poor regions.

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Questions appear on p 292. Exam is located at www.ascp.org/ajcpcme.

Clinical laboratories are important components of patient diagnosis and public health programs.[1] In many resource-challenged settings, including most of sub-Saharan Africa, laboratory services have suffered from inattention and chronic underdevelopment,[2] leading to the lack of availability of accurate laboratory results. This has led to underutilization of laboratory testing for diagnosis. Thus, syndromic and algorithmic approaches have replaced etiologic diagnosis and treatment. These syndromic approaches result in frequent misdiagnoses. For example, a syndromic approach led to a greater than 30-fold overdiagnosis of cerebral malaria in a study from Tanzania.[3] In another study of children presenting with fever in Ghana, a high rate of bacteremia with a mortality of 39% was found in patients with a clinical diagnosis of malaria.[4] However, in recent years, ministries of health have increasingly prioritized the quality of testing services by implementing

quality management systems (QMSs) and building quality improvement activities into laboratory service work plans.[5-7] To support improvement of the quality of laboratory services, the World Health Organization (WHO) established the WHO-AFRO laboratory accreditation process and laboratory management training programs, such as Strengthening Laboratory Management Towards Accreditation[1] in 2009, and supported the launch of the African Society for Laboratory Medicine in 2011.[8] The WHO-AFRO laboratory accreditation process was subsequently replaced by the WHO-AFRO Strengthening Laboratory Quality Improvement Process Towards Accreditation in 2011. The WHO, the Centers for Disease Control and Prevention, and the World Bank are also supporting efforts to strengthen national laboratory systems in Ethiopia, Nigeria, Tanzania, and other countries through implementation of QMSs.[9]

Accreditation of medical laboratories is an established practice for quality improvement in developed countries,[10-13] but very few countries in sub-Saharan Africa have significant accreditation experience.[14,15] A search of the online registers of the College of American Pathologists (CAP), South African National Accreditation System (SANAS) and Kenya National Accreditation Service for accredited laboratories in sub-Saharan Africa showed that only five laboratories in Kenya were accredited, all of which were research laboratories or subsidiaries of commercial laboratories based outside Kenya. Moreover, the list did not include any hospitals in sub-Saharan Africa outside South Africa. Hospitals seldom pursue accreditation because of the perceived cost and unavailability of qualified personnel. In Kenya, most medical technologists are trained only at a diploma level. During the training, their laboratory exposure is limited to a 3-month laboratory attachment that they must find on their own. Thus, when they begin hospital-based work, they have usually not received training in a setting that includes QMSs.

Established in 1958, Aga Khan University Hospital Nairobi (AKUHN) is a private, not-for-profit teaching and referral institution that provides tertiary- and secondary-level health care services and is a component of the global Aga Khan Development Network (AKDN). The AKUHN Department of Pathology has established itself as a reputable diagnostic laboratory performing approximately 1.5 million billable procedures annually in the following laboratory disciplines: routine and special chemistry, hematology, blood bank, microbiology and mycobacteriology, and histopathology including immunohistochemistry, cytology, and molecular pathology. The main hospital laboratory employs technical staff numbering approximately 100 full-time equivalent (FTE) employees and also supervises more than 30 outreach centers throughout Kenya. The main hospital laboratory is also the key teaching facility for residencies in clinical and anatomic pathology that are housed in the Department of Pathology.

The laboratory has a vision of being the reference center and leader in providing medical diagnostic laboratory services of the highest quality in Kenya as well as the rest of East Africa. This vision fits with the emphasis that the entire AKDN places on quality and capacity building throughout East Africa. The clinical and educational programs of AKUHN strive toward a level of quality that meets international standards. As part of the goal of providing this level of excellence, the AKUHN laboratory decided to pursue international accreditation and, in August 2011, became the first hospital laboratory in sub-Saharan Africa to achieve ISO 15189 accreditation, through the SANAS.

Upon the decision to undergo the accreditation process, a timeline of critical activities was developed ▮Table 1▮. The quality manager conducted gap analysis and reviewed all systems that were currently in place in 2008. The audit matched the gaps with potential solutions for meeting accreditation requirements and became the basis for the quality plan and implementation strategy. Quality indicators and process metrics were identified in each section of the laboratory, and a monitoring and evaluation process was developed. Continuous professional education sessions were delivered by faculty

▮Table 1▮
Accreditation Activities

Step	Activities	Duration (d)	Year
1	Explanation of road map by clinical director	½	2008
2	Selection and appointment of key people	2	2008
3	Gap analysis with implementation plan	5	2009
4	Staff awareness training on ISO quality principles	½	2009
5	Training the trainers	4	2009
6	Process mapping for each department to identify essential QMS processes and opportunities for improvement	5	2009
7	Documentation of quality policy, quality manual, and compulsory procedures	180	2009/2010
8	Identification, training, and certification of QMS internal auditors	4	2010
9	Assessment of preparation for accreditation visit, including compliance and effectiveness of the QMS	7	2010/2011
10	External audits shortly before official accreditation visit	3	2011
11	Corrective actions for any deficiencies found during the accreditation visit	15	2011

ISO, International Organization for Standardization; QMS, quality management system.

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and management to create awareness among staff and educate them on the importance of the accreditation process. The implementation of the accreditation process began formally in January 2009 with a three-phase plan.

Materials and Methods

Design and Implementation of the Three-Phase Model

Phase 1: Delineation of Management Responsibilities

The hospital and laboratory management had two major roles: (1) shaping organizational values and (2) establishing a managerial infrastructure that would bring about sustainable change. The quality manager was responsible for implementing and monitoring processes (periodic audits and random checks) with regular communication to the laboratory management regarding the QMS progress. We used process mapping techniques (value stream mapping) to come up with a step-by-step description of the actions that were to be taken by our staff to ensure that our process complies with ISO 15189:2007.[16] We walked through the flow, writing down the process steps as they existed then. The staff members doing the process mapping acted as the patient or sample. We recorded the process, decision points, inventory/storage points, number of operators, responsibilities, transportation methods, and process parameters for each step (flow chart).

Phase 2: Ensuring Effective and Efficient Resource Utilization and Implementation of Quality Processes

The laboratory management identified knowledge and performance gaps among personnel and provided them with the requisite training in scheduled weekly sessions. In addition, criteria were developed to assess the knowledge and skills of personnel.

A technical committee composed of laboratory management and members from the hospital procurement department was created to oversee the selection and qualification of equipment. An equipment maintenance schedule was put in place to provide guidance on corrective, routine, and preventive maintenance. Biannual comparison was performed for multiple machines doing similar tests.

Phase 3: Establishing Monitoring and Evaluation Systems

Quality indicators were identified in each section to measure and analyze progress. We monitored error rates in the preanalytic, analytic, and postanalytic phases of testing. The seven measures of preanalytic performance were as follows: (1) sample collected and not required, (2) requisition errors, (3) outpatient data entry errors, (4) patient identification errors, (5) sample recollections, (6) specimens with delayed collections, and (7) sample rejections. The 10 measures of analytic performance were (1) performance of tests that were not requested, (2) not performing tests that were requested, (3) repeated tests, (4) equipment malfunction, (5) sample mix-ups, (6) analytic interference, (7) failed external quality assessments (EQAs), (8) random errors, (9) quality control failures, and (10) procedure violations. The eight postanalytic metrics were (1) lack of dispatching results on time, (2) duplicate reports, (3) lack of critical value reporting, (4) excessive turnaround time (TAT) for in-house tests, (5) excessive TAT for referred tests, (6) reports that were missing, (7) reports sent to the wrong location, and (8) reports amended due to error. Finally, the managerial metrics included number of FTEs, number of complaints and compliments, and value of reagent wastage.

To track results, we used Six Sigma metrics, initially developed for the manufacturing sector but subsequently applied to the clinical laboratory setting.[17,18] Processes for handling complaints and client satisfaction surveys were established to ensure that the service provided by the laboratory met the expectations of users. Corrective action procedures were established to identify and eliminate the causes of nonconformities and identify root causes. Our performance evaluation began with benchmarking by using CAP Q-Probes[19] and Q-Tracks[16] measures or by setting in-house targets. Corrective measures were instituted rapidly if negative trends or defects in performance were detected.

Bench audits were coordinated by the section heads, who set timetables for the areas to be audited at least 1 month in advance. The auditors included the section head and experienced technologists, who were briefed on the audit procedures and the benches to be audited. During the audit, all QMS-noncompliant findings on the checklists were recorded and discussed with the section and with management. The section head made the final decision as to whether the findings were legitimate and presented the final report to the audited staff and laboratory management, including the laboratory director. Corrective actions were completed within 30 days of the date of the finding, and the root cause was analyzed as needed. An example of the internal audit list used for the microbiology bench is shown in **Table 2**. Additional audits included daily random checks by the quality assurance unit and annual audits of one section by another section within the laboratory.

Data Analysis

Data were collected for a set of defined quality performance metrics from the year 2009 (preaccreditation) to 2012 (postaccreditation). Data were retrieved from manual registers and the laboratory's information system. For each of the evaluable parameters, comparisons of 2009 and 2012 were assessed for significance using Yates corrected two-tail χ^2 analyses **Table 3**. In addition to comparing the raw numbers

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Table 2
Bench Audit for Microbiology

Category	Specific Tasks
Organization	Organization and management, organizational structure, planning process, monitoring
Personnel	Staff training and competency assessments, continuing education, annual staff performance appraisals
Equipment	Equipment: Selection, acquisition, installation, inventory, training of operators, retirement and disposal, calibration/validation, maintenance plan, preventive maintenance
	Records of maintenance information: Charts, logs, checklists, graphs, service reports, equipment corrective maintenance and repair form, equipment decontamination before service and/or repair
Purchasing and inventory	Reagents, supplies, and services: Receiving, inspecting, storing, maintaining inventory, controlling expiration periods
	Records of: kit validation, reagents/kit lot to lot validation
Process control	Sample management policies for test requisition, collection and preservation, labeling, transport, rejection, processing, storage, retention, disposal, referral, tracking system
	Coordinate and monitor QC activities for: Reagents, procedures, stains
	Prepared stain/reagent information on labels: Name of stain/reagent, concentration, date prepared, expiration date/shelf life, preparer's initials
	Maintain log books/files for recording information on each prepared stain/reagent
	QC failure investigation, corrective and preventive action
	Culture media preparation and QC
	Prepared media information on labels: Name of media, date prepared, expiration date/shelf life
	QC of antibiotic disks, Api strips, Vitek cards
	Maintain log books/files for recording information on each prepared media: Date and preparer's name; name of the medium; powder lot number; number of prepared plates, tubes, or bottles; sterility test results at 24 and 48 hours; growth test results
	Stocking and inventory of frozen isolates and QC strains
	Method validations
Documents and records	SOP preparation and review, alert box
	SOP ALERT box
	Microbiology files catalogue including the orderly arrangement of the files to hasten accessibility
	Section's meeting minutes
	Archiving of patient test reports/worksheets/request forms in retrievable form
	Design/creation of forms, charts, and worksheets for use in the microbiology section
	Bench instructions
Information management	Accurate and timely posting of results on the electronic medical record, delivering written reports, phone communication of critical values
Occurrence management	Identification and handling of errors to prevent their recurrence
Assessment	Audits: Section representative in external and internal audits, corrective and preventive actions arising from external and internal audits
	Bench audit coordination
	EQA: Schedule of challenges, receiving of challenges, assigning challenges, review of EQA reports, proficiency testing process, documentation of results, submission of results, failures, investigation, corrective and preventive action
Process improvement	Monitor turnaround of routine urine analysis and stool microscopy tests ordered from emergency department and selected outpatient clinics
Service and satisfaction	Complaint resolution-documentation and closure
	Client satisfaction survey, work plans for improvement
	Compliments
Facilities and safety	Adequate supply/good working condition of PPE, biosafety cabinets, fire extinguishers and fire blankets, appropriate storage and cabinets for flammable and toxic chemicals, eye washers and emergency shower, waste disposal supplies/equipment, MSDS and labeling of reagents/chemicals, first aid box
	General cleanliness of the section
	Standard safety practices
	Vaccinations

EQA, external quality assessment; MSDS, material safety data sheet; PPE, personal protective equipment; QC, quality control; SOP, standard operating procedure.

from year to year, the information was converted to defects per million opportunities and converted to a sigma metric, in which the sigma value indicates the number of standard deviations (sigma) better than the mean value. Thus, the lower the error rate, the higher the sigma value.

Results

Preanalytic performance was monitored by following the error rates of seven different parameters, including (1) unrequired sample collection, (2) requisition errors, (3) outpatient data entry errors, (4) patient identification errors, (5) sample recollections, (6) timeliness of sample collection, and (7) sample rejection. All seven parameters improved, with an average reduction to 33% of the preaccreditation error rate (Table 3). These seven parameters were charted by using a sigma plot so that a 4-year trend could be followed **Figure 1**. In a specific evaluation of errors most directly related to patient safety, requisition errors fell threefold, whereas patient identification and outpatient data entry

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errors decreased to less than half the baseline (Table 3). The least improvement was in timeliness of sample collection, yet a nearly 40% decrease was still seen in the number of specimens not collected in time.

A total of 10 analytic measures were monitored (Table 3). Eight of the metrics showed significant improvement, with an average sigma improvement from 4.75 before to 5.08 after accreditation **Figure 2**. The most remarkable improvement was in frequency of protocol violations, which were reduced to 2% of their preaccreditation values. This dramatic improvement in following protocol represented a culture change in the laboratory, with an emphasis on consistency and quality. No change was seen in the rate of equipment malfunction, which may be because routine service contracts had been used even before the accreditation process. No statistically significant change was found in the frequency of failed EQAs, but there was a trend toward improvement, with 40% fewer failed EQAs in 2012 than in 2009.

Performance on eight indicators of postanalytic quality and efficiency was monitored throughout the accreditation process, including four measures of the accurate and timely generation and delivery of reports, critical value reporting, excessive TATs for in-house or referred tests, and reports that were amended due to errors. The average for these eight metrics improved from a sigma of 4.66 to 5.07 after accreditation **Figure 3**. The rate of unreported critical values is a major quality indicator of the postanalytic metrics, so it is notable that this value was reduced to 33% of its preaccreditation value. Critical value reporting improved through sensitization of staff, zero tolerance to missed reporting of critical values,

Table 3
Preaccreditation to Postaccreditation Changes in Performance Parameters

Performance Measure	Preaccreditation (2009)	Postaccreditation (2012)	Denominator for Comparison	*P* Value
Preanalytic indicators				
Sample collected and not required	90	30	Samples	<.001
Errors in requisition	451	150	Requisitions	<.001
Outpatient data entry errors	248	120	Patients	<.001
Patient ID errors	14	6	Patients	.01
Sample recollections	113	60	Samples	<.001
Specimens not collected on time	4,918	3,089	Samples	<.001
Sample rejection	10,625	5,908	Samples	<.001
Analytic indicators				
Tests not done but requested	203	120	Tests	<.001
Tests done but not requested	20	15	Tests	.05
Repeat test analysis	600	235	Tests	<.001
Equipment malfunction	7.5 equipment days per 360 days	6.25 equipment days per 360 days	NA	NS
Sample mix-ups	23	12	Samples	.003
Analytic interference	20	12	Samples	.015
No. of failed EQAs	20	12	EQA	NS
Random errors	2,211	1,530	Tests	<.001
QC failures	3,158	2,339	Tests	<.001
No. of procedure violations	2,256	58	Tests	<.001
Postanalytic indicators				
Results not dispatched on time	248	196	Reports	<.001
Duplicate reports issued	164	51	Reports	<.001
Critical values not reported	128	43	Tests	<.001
Excessive TAT (referred tests)	46	18	Tests	<.001
Reports sent to the wrong location	38	12	Reports	<.001
Missing reports	47	8	Reports	<.001
Amended reports due to errors	46	29	Reports	<.001
Excessive TAT (in-house tests)	80,600	30,429	Tests	<.001
Managerial indicators				
No. of complaints	431	64	Patients	<.001
No. of tests per FTE	1,017	1,049	Tests	NS
No. of compliments	12	14	Samples	NS
Reagent wastage (US$)	43,256	3,993	Reagent expenditure	<.001
Laboratory volumes				
Tests	1,047,436	1,584,429		
Samples	116,382	176,048		
Total patients	38,794	58,683		
Reports	349,145	528,143		
Reagent expenditures (US$)	693,807	2,594,855		
EQAs	936	936		
Requisitions	58,191	88,024		

EQAs, external quality assessments; FTE, full-time equivalent; ID, identification; NA, not available; NS, not significant; QC, quality control; TAT, turnaround time.

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and strict monitoring. It is also notable that the number of tests with excess TAT for both in-house and referral tests decreased to less than 40% of the preaccreditation values. Because these are raw numbers and the laboratory volumes increased by 50% during that time, the improvement as a percentage of tests is even greater.

Four criteria of managerial performance were monitored, including number of tests per FTE, complaints, compliments, and reagent wastage **Figure 4** (Table 3). No attempt was made to increase efficiency by reducing the number of FTEs, so the number of tests per FTE remained constant. The managerial performance indicators also improved through the

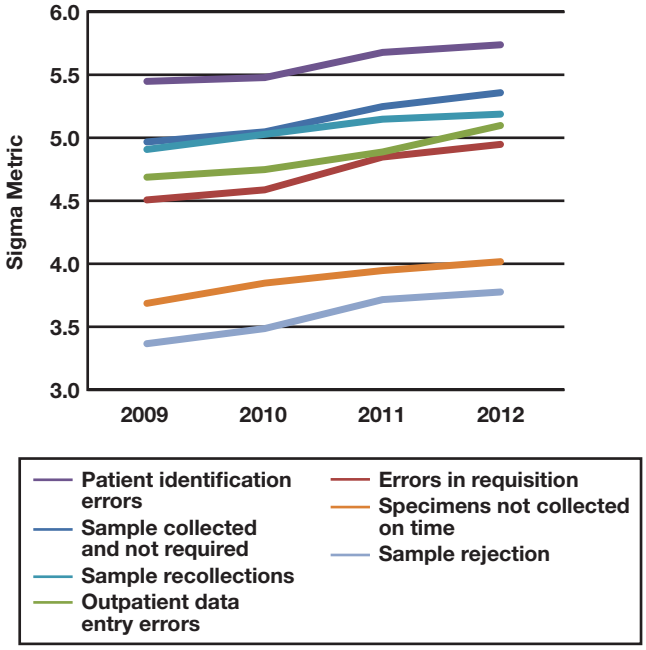

Figure 1 Preanalytic performance metrics.

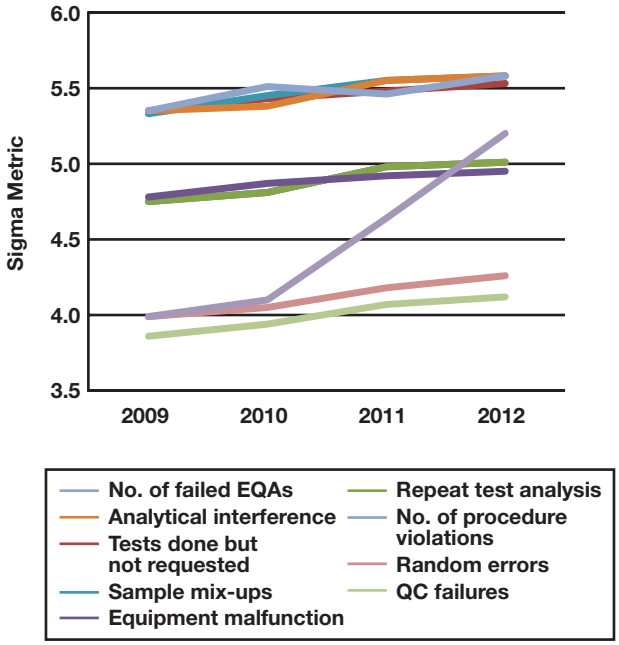

Figure 2 Analytic performance metrics. EQAs, external quality assessments; QC, quality control.

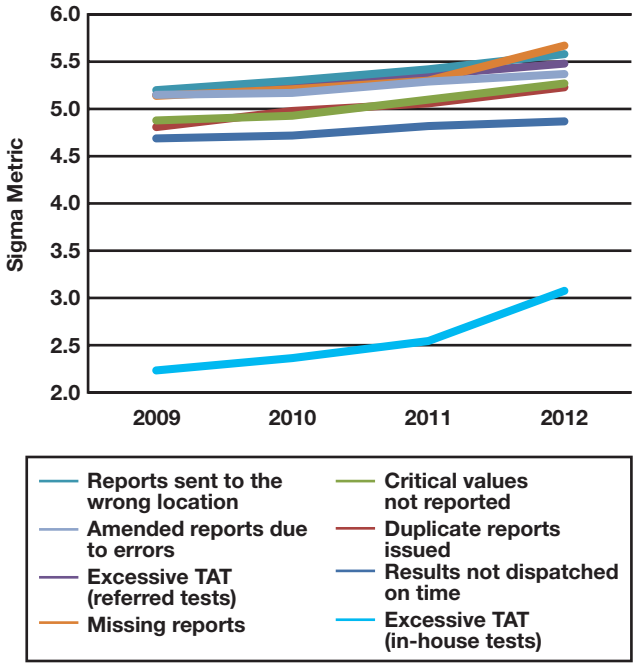

Figure 3 Postanalytic performance metrics. TAT, turnaround time.

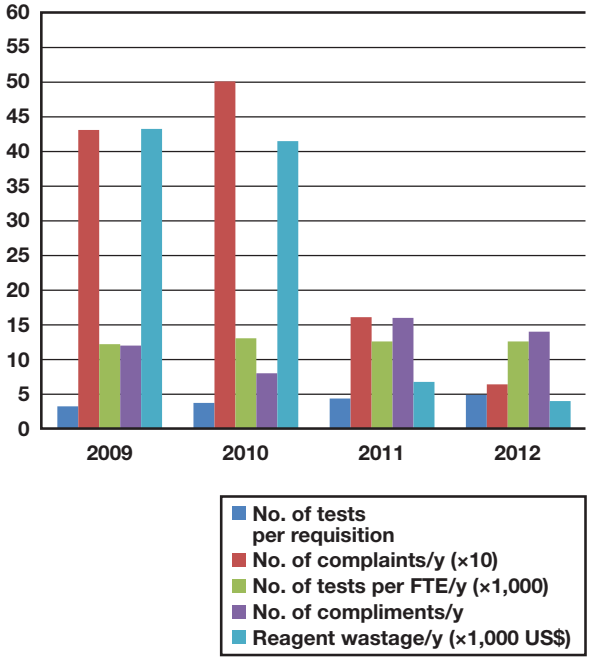

Figure 4 Managerial performance indicators. FTE, full-time equivalent.

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process of accreditation (Figure 4). Perhaps most notably, the number of complaints decreased to 15% of baseline, whereas the number of compliments remained constant. The cost savings of nearly US $40,000 per year occurred because of the implementation of a more effective communication process between procurement and the laboratory; these savings were realized because of reduced loss of reagents due to expiration or repeat sample testing. These savings offset the cost of maintaining accreditation.

Discussion

Accreditation is commonly expected of hospitals and laboratories in developed regions but is rarely acquired in the resource-poor countries of sub-Saharan Africa. The facility and personnel costs involved in going through accreditation processes are high enough to be a major deterrent for laboratories in resource-poor areas. It is also of interest to know whether accreditation is merely a marker for certain aspects of quality or whether the preparation for and process of acquiring accreditation results in quality improvement. The accreditation process at AKUHN has provided a platform for assessing the impact of the process itself on quality measures. We documented an improvement in nearly all of the seven preanalytic, 10 analytic, eight postanalytic, and five managerial parameters from 2009 through 2012. In fact, all but two of the 25 measures (equipment malfunction and failed EQA) showed significant improvement; EQA showed a trend toward improvement that was not statistically significant. In fact, the curves for the individual measures showed steady improvement from year to year, consistent with an ongoing impact of the quality efforts.

Overall, the results of the quality monitors from the AKUHN laboratory compare favorably with results reported in the literature. A review of laboratory quality indicators reported in the literature included several parameters that could be directly compared with our own results.[20] The standards reported in their study included (1) test requested but not done, 1.4% in comparison with our result of 0.008%; (2) test done but not requested, 1.1% in comparison with our result of 0.001%; (3) reporting errors or amended reports, 0.05% compared with our result of 0.005%; and (4) failed EQA, 1.4% compared with our result of 1.3%. Patient identification errors are particularly serious, and our result of 0.003% (sigma value 5.5) compares favorably with the reported standard of 0.08%[20] or a sigma value of 3.4.[21] Consistent and timely reporting of critical values is also given significant emphasis in the literature.[20,22] Our critical value reporting has continued to improve even after laboratory accreditation; for the first 5 months of 2013, 100% of critical values were reported within an average of 3 to 4 minutes. For comparison, a study of 623 laboratories participating in CAP programs reported averages of 6.1 and 13.7 minutes for inpatients and outpatients, respectively,[23] and another study of 121 laboratories participating in CAP programs reported a median of 4 minutes.[24]

We believe that the training environment played a major role in the improvement process. Within Kenya and the rest of East Africa, there is frequently little interaction between clinical pathologists and medical technologists; in fact, some interventions from other countries aimed at improving laboratory capacity in the region have ignored the role of the clinical pathologist. During the accreditation effort at AKUHN, the clinical and anatomic pathologists as well as residents in clinical and anatomic pathology worked closely with the technical staff to raise expectations and improve performance throughout the laboratory. Thus, it is important to ask whether a similar effort can succeed in the laboratory of a nonteaching hospital. We believe that it is possible provided there is an intentional and sustained interaction between the pathology and technical staff, with a common goal of sustained improvement.

Our success in attaining sustained improvement can be attributed to the leadership and resources for addressing these challenges. Weekly laboratory quality improvement meetings and monthly advisory meetings focusing on policy formulation and deployment were avenues through which issues were channeled and addressed. Perhaps the key success of the accreditation process was the adoption of a continual improvement culture in the laboratory, which has resulted in enhanced staff competency, improved operational consistency and reliability, and better teamwork.

The entire accreditation process cost approximately US $90,000 in the initial phase, with an additional US $30,000 required annually to maintain accreditation. However, the annual maintenance cost is mostly offset by improved efficiency in the laboratory, including reduced reagent expiration and less frequent need to repeat tests. These costs for initial accreditation and maintenance were lower than those published by Zeh et al,[25] who attributed the high cost to lack of local QMS trainers, making it necessary to bring trainers from abroad. In contrast, our laboratory hired an experienced local quality manager to train staff and lead the process. Furthermore, all their equipment was placed on preventive and corrective maintenance service contracts, which were also costly. For all our major equipment, maintenance is included as part of the placement contract.

In conclusion, the positive trend seen in our preanalytic, analytic, postanalytic, and management performance metrics is a clear indication of how the accreditation process has improved our laboratory performance and quality. Our experience highlights both the challenges and value of accreditation in sub-Saharan Africa. We have subsequently used the same

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model to achieve accreditation for the Aga Khan Hospitals in Mombasa and Kisumu. As the demand for quality grows in the region, we believe the AKUHN experience will encourage other institutions to also pursue accreditation. Our experience supports a previous recommendation[5] that well-structured laboratory education, training, and mentorship programs will accelerate the process of laboratories achieving accreditation in developing countries.

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