**The power behind quality management system implementation and sustainability at Bungoma district hospital laboratory in Kenya**

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**Abstract**

Introduction:

The improvement of quality testing services in public laboratories is a high priority in Kenya, and currently the National Laboratory Strategic Plan calls for laboratories to become internationally accredited. To that end, the Strengthening Laboratory Management Toward Accreditation (SLMTA) program was rolled-out to national, regional, and district labs throughout Kenya to prepare laboratories for the accreditation process. After 16 months in the SLMTA program, Bungoma District Hospital Laboratory (BDHL) rose from a zero- to 4-star rating and saw an improvement in Quality System Essentials, quality indicators, and proficiency test results.

Discussion:

While BDHL saw an increase in its star rating during SLMTA, it recognized that integrating quality improvement processes into its daily operations would ensure sustainability long after the training program ended. The lab undertook a process of changing its internal culture to align all hospital stakeholders—including upper management, clinicians, laboratory staff, and maintenance staff—to the mission of sustainable quality practices at BDHL.

Lessons Learned:

Management is key in engaging staff, creating an inclusive environment, and developing processes to sustain a culture of quality improvement.

Recommendations:

To build sustainability, the authors recommend total hospital management involvement and using progress-monitoring tools and feedback systems. BDHL incorporated SLMTA Improvement Project processes into routine daily activities, and considers this important in quality improvement.

**INTRODUCTION**

Laboratory is one of the core capacities that countries must develop for the implementation of the international Health regulations since laboratory services play a major role in key processes of detection, assessment, response, notification and monitoring of events [1] Medical laboratory are partners in patient safety. Laboratory results influence 70% of medical diagnosis. Quality of laboratory is major factor which directly affects the quality of health care [3].Therefore laboratory improvement is a stepping stone toward achieving good and quality patient care. Transforming health care begins with improving the quality of laboratory service.

The word accreditation is a catch and sometimes confusing. The confusion is invited by the various interpretations which have been attached to the word as well as misconception of what it means and what is involved in it. Accreditation is a procedure by which an accreditation body gives formal recognition that a body (laboratory) or person (signatory authority) is competent to carry out specific tasks (scope). [[4]](http://www.ijmm.org/article.asp?issn=0255-0857;year=2012;volume=30;issue=2;spage=131;epage=140;aulast=Wadhwa" \l "ref7) The procedure imparts official credit, authorization and registration of a laboratory and that it has demonstrated its capability, competence and credibility to carry out its specified scope. [5]

Laboratory’s improvement is a long term rise in capacity to supply increasingly diverse quality services to its clients hence, the concept of "Quality" will need to be understood and implemented. Total quality management (TQM) in a laboratory is an integrated program involving all laboratory staff and management. TQM is a framework to operate and it is aiming for integration, consistency, increase in efficiency and a continuous drive for improvement. [9]

The Strengthening Laboratory Management towards Accreditation (SLMTA) programme was launched concurrently with the stepwise WHO–AFRO–SLIPTA process in Kigali, Rwanda in 2009. SLMTA, a task-based curriculum, assists countries in the training of laboratory managers to implement the quality management system requirements of the WHO–AFRO–SLIPTA process, with the aim of granting them eventual international accreditation. [8]

The improvement of the quality testing services in public laboratories is a high priority in Kenya at the moment. Consequently, initiatives to train staff on quality management have been implemented using the WHO-AFRO stepwise approach. Three SMLTA workshops, one mentorship visits in between workshops and weekly conference call follow ups approaches have been used. Bungoma district hospital laboratory was one of the laboratories that under went through this programme.

SLAMTA mentorship process was implemented at Bungoma District Hospital in February 2010. The laboratory realized improvement which however stalled for some time.

The laboratory realized that a change in culture of encouraging the staff in participating in improvement activities, adopting hard work attitude and participating in laboratory planning; engaging total hospital management in the process; engaging other stakeholders like hospital maintenance unit, procurement/supplies unit, clinician and nurses; integrating SLMTA into routine work processes; and having a succession plan by appointing deputies to key positions would augment sustainability of the quality improvement.

The laboratory sought to change management processes such that it involved all laboratory staff in planning; held regular meetings with all stakeholders including maintenance unit, procurement unit, clinicians and nurses and engaged hospital management such that it participated in regular laboratory meetings. All these were geared towards achieving sustainable quality improvement.

The laboratory moved from zero stars rating to four stars rating within sixteen months and maintained it nine months after exit audit.

**DESCRIPTION**

**SLMTA MODEL**

The process started by an orientation meeting which included hospital management, laboratory in charge and the quality officer. After which a baseline assessment was conducted followed by three workshops attended by the medical superintendent (Hospital management), quality officer and one other laboratory staff. The laboratory performed three mandatory improvement projects among others which included:

* SOP writing
* Labeling of equipment and reagents
* Customer satisfaction
* Result validation
* Time management(punctuality)
* Room temperature monitoring
* Creation of personnel files
* Lab organization
* TAT (Turnaround time),
* Stock outs
* Creation of an archive
* ,EQA performance
* Equipment down time
* Test statistics

There was a one week on -site visit mentorship in between workshops by an external mentor. There was weekly conference call follow up by the mentor one week after every visit to ensure monitoring.

**SLMTA results**

In sixteen months, Bungoma district hospital laboratory saw increase in all twelve quality essentials (QSEs) as shown in figure 2.The laboratory baseline midterm and exit audits scores improved from 96 points to 185 points then to 230 points respectively as shown in figure 1. The laboratory maintained the four star rating of 219 points, although with a drop of 11 points in the in the surveillance audit eleven months after the exit audit.

The laboratory saw improvement in three improvement projects as shown in figure 3. Punctuality of its staff improved from 54% to 72% while customer complaints and sample rejection rate reduced to 2% and 9% respectively.

The laboratory noted improvement in external quality assurance (proficiency testing) performance to over 80% in both Hematology and chemistry which is the acceptable percentage as shown in figure 4.

**Total hospital laboratory involvement**

There was total hospital management involvement in the process by giving the laboratory support and attended monthly laboratory meetings which assisted deal with staff attitude. This came about when the laboratory justified why it needed the hospital management support by providing data on how much was lost when the analyzers could not perform well due to high temperatures. The laboratory also justified how quality improvement could assist in proper patient management; when reliable results are provide. The laboratory shared with the hospital management external quality assurance results compared to the mortality rate and how improvement in quality would reduce the mortality rate. The laboratory shared with the hospital management how long queues would be reduced if it could deal with staff on time management. The hospital management came on board and played the role of coordinating the links between laboratory and other key departments in the hospital. This made staff in the whole hospital staff change their attitude such that they were in support of laboratory quality improvement activities. The hospital management introduced an annual awards scheme for the entire hospital which brought competition among staff. It also played a role in sourcing for financial support from partners who donated air conditioners making the laboratory able to control room temperature.

**Regular laboratory meetings with internal stakeholders**

1. **Laboratorian- Clinician meetings**

The laboratory held quarterly laboratorian- clinician meetings in which rejection rates were discussed, where the clinicians feel the laboratory could improve and where the laboratory felt the clinicians could improve.

1. **Meeting with other stakeholders (maintenance and procurement unit)**

The laboratory introduced meetings with other stakeholders including hospital maintenance and procurement/supplies units respectively .In this meetings, the importance of ensuring periodic maintenance of laboratory equipment, procurement of specifications provided by the laboratory and monitoring of temperature in the hospital main store was discussed .This ensured procurement of proper supplies and reduced equipment down time. The reduction in equipment down time increased the efficiency of the laboratory. Before these meetings, the laboratory experienced long equipment down time as the hospital engineers could not respond promptly when conducted or could suggest the equipments be repaired by contracted engineers for even a minor repair. This also reduced the cost involved in paying contracted engineers when the hospital engineers were brought on board.

**Staff behavior change**

1. **Time management (punctuality)**

The laboratory ensured proper time management by introducing clocking in –clocking out and a permission grant form for its staff. This reduced number of hours wasted by staff. Before this the laboratory staff reported on duty late and left early before required time and did a technical appearance on duty and disappeared. All these were at the expense of the client in need of the laboratory services.

1. **One -on- one mentorship**

The laboratory management conducted one-on-one mentorship by which staffs were reminded the laboratory objective, thanked of their strongholds and requested to look at their weak points. This helped the staff remain focused to the laboratory set objectives.

1. **Wall of fame and shame**

The laboratory introduced the wall of fame and shame respectively. This was a management skill to deal with staff attitude, where the best performer was placed on wall of fame while the poor performer on wall of shame. The best performer was rewarded from as little as 500grams soap to a laboratory coat while the poor performer was expected to perform nine good things including proper daily equipment maintenance, performing daily internal quality control, punctuality, proper work station arrangement, and proper management of bench consumables, among others to move from wall of shame. This cultivated the culture of competition among staff and ensured conformity to the set standards.

**Sustainability of the process**

**1. Transformation of SLMTA process into daily routine activities**

To achieve sustainability the laboratory ensured proper training and transformed all its improvement projects into daily routine activities performed usually by the entire laboratory staff. After end of each improvement project, the laboratory adapted it in its routine activities after training of staff.

**2. Involvement of staff in planning and budgetary allocations**

The laboratory ensured entire involvement of its staff in budgetary planning which aimed at improvement of laboratory staff customs, beliefs and attitude such that they are in support of laboratory quality improvement activities. For instance it looked forward in encouraging the staff in participating in improvement activities, adopting hard work attitude and participating in laboratory planning. This made staff fill to be part of the quality improvement process.

**3. Monitoring of the process**

The laboratory achieved sustainability also through monitoring of its processes through regular planned internal audits. All non – conformances established during the audit were sealed and improvement projects initiated where needed.

**4. Succession plan**

The laboratory ensured continuity of the process by appointing deputies to all key posts in the laboratory who succeed the key personnel like the quality officer or laboratory in charge incase of their absence in the laboratory. This ensured the process to run smoothly even in absence of the key personnel.

**5. Customer survey**

The laboratory conducted and still does weekly customer survey using three forms, “How do you rate us form”, “complaint form” and “compliment form”. This helped the laboratory get both positive and negative feedbacks which it used to improve on its systems. All feedbacks were discussed in the staff meetings, positive feedbacks celebrated while corrective initiated on all negative feedbacks.

**6. Surveillance audits**

The laboratory liaised with external auditors to track the maintenance of improvement. This was used to test the efficacy on the implementation on the implementation with absence of a mentor for some time. During this audit; not only the quality system and analytical competence was examined but also if there was a real contact between laboratorian and clinicians and if the results are clinically validated.

**Table 1**

|  |  |  |
| --- | --- | --- |
| **ACTION** | **WHY** | **RESULTS** |
| Total hospital management involvement. | 1. Laboratory support.  2. Provide link with other hospital departments. | 1. Financial support.  2. Total hospital team involvement. |
| Meeting with procurement and maintenance units. | 1. To ensure proper supplies  2. Ensure periodic equipment maintenance. | 1. Supplies with required specifications.  2. Reduced equipment down time. |
| Laboratory-clinician meetings. | Provide link between laboratory and clinical department. | 1. Reduced complaints.  2. Reduced rejections.  3. Won confidence in the laboratory by clinicians. |
| 1-on-1 mentorship. | Remind staff laboratory objective and handle individual weaknesses. | Staff focused on quality improvement |
| Time management. | Reduce time wasted by staff | Staff available to perform assigned tasks. |
| Wall of fame and shame. | Improve staff attitude | Completion among staff that have improved quality |
| Succession plan. | Ensure continuity of improvement process | Continuous improvement even in absence of key personnel |
| Customer survey. | Get positive and negative feedback. | Feedback used for further improvement of the laboratory process. |
| Internal audits. | To ensure monitoring of the system. | Gaps identified and sealed |
| External surveillance audit. | To track maintenance of improvement. | Tested the efficacy of implementation/sustainability in absence of the mentor. |

**Lessons learned**

The laboratory learned that time management is a key to laboratory quality improvement. Before the SLMTA process there was no clocking in- clocking out for its staff and a lot of time was wasted.

Apart from the mentorship other management factors on the ground such as involvement of all staff in the entire process from planning could stimulate staff to sustain and even improve the system further. Initially staffs were not involved in the planning or budget allocation and this showed lack of motivation among the staff.

The laboratory improvement requires and involves some direction, regulation and guidance to generate the forces of expansion and maintain them i.e. this involves hospital management intervention, through options and setting of planning targets.

Laboratory’s improvement is a long term rise in capacity to supply increasingly diverse quality services to its clients hence, the concept of "Quality" will need to be understood and implemented. SLMTA in a laboratory is an integrated program involving all laboratory staff and management. SLMTA is a framework to operate and it is aiming for integration, consistency, increase in efficiency and a continuous drive for improvement.

Efficacy on the implementation on the implementation can only be tested through monitoring by regular planned internal audits, during this audit; not only the quality system and analytical competence must be examined but also if there is a real contact between laboratorian and clinicians and if the results are clinically validated.

FIGURE 1: RESULTS FOR BASELINE, MIDTERM, EXIT AND SURVEILLANCE AUDITS

FIGURE 2: PERFORMANCE BY QUALITY ESSENTIALS IN % (BASED ON WHO- SLPTA ACCREDITATION CHECKLIST) FOR THE BASELINE, MID TERM AND END TERM ASSESSMENTS

FIGURE3: SOME OF THE QUALITY INDICATORS IN THE YEAR; 2012

FIGURE 4: EQA PERFORMANCE2011-2013

**Recommendations to build sustainability**

For quality management system to be effectively implemented and sustained there must be total hospital management involvement; therefore justification by the laboratory to why they need management support is a necessary starting point. For laboratories planning to implement and sustain quality management system, considerable training of staff to incorporate improvement processes into daily routines must be put into account.

Time management by staff is critical to the quality improvement cycle, therefore it is recommended that the laboratory monitor how its staff their time.

Bungoma district hospital laboratory experience shows that when there was improvement in punctuality by its entire staff, other quality indicators also improved.

In spite of a slight decline in the surveillance audit, Bungoma district hospital can attest that sustainability could have come about by bringing on board all hospital stake holders and that the implementation and sustainability has brought back the confidence in the laboratory by its clients as noted by reduction in number of complaints

The implementation and sustainability of quality system in Bungoma district hospital, a primary with very limited resources, truly represents how team work and participation of all key and non-stake holders can help sustain the process.

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**Competing interests**

The authors declare that they have no financial or personal relationship(s) which may have inappropriately influenced them in writing this paper.

REFERENCES

1. Masanza M M, Ngobile N, Mukanga D,Gitta SN;Laboratory capacity building for international health regulation(THR[2005])in resource-poor countries:the experience of the African Epidemiology Network (AFENET);BMC Public Health,2010 Dec 3;10 suppll:58
2. Aoyagi T ;ISO 15189 Medical Laboratory accreditation;Rinsn Byori.2004 oct;52 (10):860-5
3. Guzei O,Guner EI;ISO 15189 accreditation Requirement for quality and competence of medical laboratories,experience of a laboratory l;clin Biochem.2009 mar.42 (4-5)274
4. ISO store,purchase 15189:2007 document on line2007:available from <http://www.iso.org/iso/iso>.
5. Kanaagasabapathy AS, Raop;Laboratory accreditation procedural.guidelines;Indian J clin. Biochem 2005:20:186-8
6. Kubono K;Outline of revision of Iso 15189 and accreditation of medical Laboratory for special health check up;Rinsn Byori2007 Nov;55(11):1029-36
7. Gershy-Damet G M;The World Hea3lth organization Africa region lLaboratory accreditation process:Improving the quality of laboratory systems in the Africa region;Am J pathol 2010 sep;(34 )393-400
8. David Mothabeng,Talkmore Maruta,Mathobo Lebina,Kim Lewis,Joe Wanyoike,Yohannes Mengstu;Strenghtening Medical Magegement towards accreditation: The Lesotho experience;African journal of Laboratory medicine
9. Tbbet MW,Gormez R,Kannangai R,Sridhan G;Total quality Management in clinical Virology laboratories;Indian J;Med Mcrobiol2006 oct;24(4):258-62
10. [Handoo A](http://www.ncbi.nlm.nih.gov/pubmed?term=Handoo%20A%5BAuthor%5D&cauthor=true&cauthor_uid=22727005), [Sood SK](http://www.ncbi.nlm.nih.gov/pubmed?term=Sood%20SK%5BAuthor%5D&cauthor=true&cauthor_uid=22727005). Quality Management Department, BLK Super Speciality Hospital, Pusa Road, New Delhi, India.
11. [Young DS](http://www.ncbi.nlm.nih.gov/pubmed?term=Young%20DS%5BAuthor%5D&cauthor=true&cauthor_uid=21736001). Department of Pathology and Laboratory Medicine, University of Pennsylvania, Philadelphia, PA, USA.
12. [Barth JH](http://www.ncbi.nlm.nih.gov/pubmed?term=Barth%20JH%5BAuthor%5D&cauthor=true&cauthor_uid=22422153). Association for Clinical Biochemistry, London SE1 2TU, UK. [julian.barth@leedsth.nhs.uk](mailto:julian.barth@leedsth.nhs.uk)
13. Abdullah Alkhanizan, Charles shaw: The attitude of health care professionals towards accreditation;A systematic review of the literature.