Implementing ISO 15189 Standard (Medical Laboratories- Particular Requirements for Quality and Competence) in Clinical Laboratory Services, LSD, ICDDR,B, Bangladesh

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Background:
Laboratory services are the cornerstone of health care programs as 70% of the clinical decision making are directly influenced by laboratory test results. The importance of quality medical laboratory services is recognized globally; quality and reliability are important for ensuring appropriate case management. Poor quality of laboratory services and unreliable test results can lead to inappropriate action or inaction such as over- or under-treatment when health care providers act upon inaccurate laboratory results. In an era of potential and infectious disease epidemics or pandemics, laboratory facilities of poor quality or limited capacity may lead to a severe under-detection of disease cases, allowing epidemics to gain a critical mass and spread. Several international organization including (US FDA, WHO, and The International Organization for Standardization (ISO)) and individual countries (UK, Canada, Thailand and Kenya) has developed quality systems to ensure the quality of laboratory results and patients welfare. Among these, ISO 15189: 2007 standard (Medical Laboratories- Particular Requirements for Quality and Competence) is most relevant to medical diagnostic laboratories. Medical laboratories around world are now working towards ISO 15189 standard implementation regardless of their own country standards.

Clinical Laboratory Services (CLS) of ICDDR,B is one of the trusted laboratories in Bangladesh and provides diagnostic support to ICDDR,B hospital, various research studies, clinical trials and referrals by clinicians and other hospitals. CLS is comprised of microbiology, hematology, biochemistry, molecular and sero-diagnostic laboratories and blood bank facilities. The laboratories performs 260 test parameter by using 600 test methods. The laboratories process 270,000 specimen and perform 630,000 tests annually. To ensure the quality and reliability of test results and to further enhance the quality of laboratory services CLS, ICDDR,B, committed to implement ISO 15189 standard across all laboratories. However, like many laboratories in Asia and elsewhere, CLS found the standard challenging to apply due to lack of proper guidance and technical support for implementation. Key components of the program were to build capacity of the laboratories staff on quality management system implementation and to ensure sustainability of the program.

Objective:
To implement ISO 15189 standard in CLS, ICDDR,B laboratories to improve the overall quality of laboratory testing and service provided to customers.

Methods:
In order to implement the standard in a timely manner ICDDR,B partnered with FHI to assist on ISO 15189 implementation project. For the success of the implementation key components of the program included

- Gaining support for the program from higher management
- Baseline assessment of the laboratories against ISO 15189 standard
- Gap analysis, recommendations for improvement
- Development of action plan and agreed upon timeline
- Formation of a Laboratory Management Committee to oversee implementation and practice of quality standards
- Training of laboratory staff, laboratory management on ISO 15189 and its implementation
- Support with generic quality documents (management and technical) and its adaptation into document control system
- Periodic monitoring of the implementation, mentoring and off-site and on-site technical support
- Pre-accreditation assessment
- Support in submission of the application for accreditation

To implement ISO 15189 standard and achieve accreditation usually takes 12-18 months for a committed laboratory with adequate resources. As a part of the accreditation program laboratory staff received 2 training and additional 4 trainings with a focus for management. The laboratories received 5 TA/monitoring visit from FHI. Exposure visits to accredited laboratories in the region as well as meeting with accreditation authorities were organized.
Results:

1. Thorough Training Provided for Staff:

Table 1: Training provided by FHI

| Quality System for Medical and Diagnostic Laboratories (all staff) |
| Safety Standards for Diagnostic and Research Laboratories (all staff) |
| Document Control and Quality Management (management) |
| Measurement of Uncertainty (management) |
| Equipment Management (management) |
| Internal Audit, Non-conformance, Corrective Action, Management Review (management) |

2. All Processes Were Documented:

A document control system was developed to maintain all of the processes and procedures performed by the laboratories. The purpose of the document control system is to ensure that employees are working with the most recent version of a document, insure regular review cycle of the documents and track the number of documents issued and location of the documents when retrieval is necessary. It has also served as way to align practices in laboratories and serves as a training tool.

Table 2: Improvement to the document control system.

<table>
<thead>
<tr>
<th>Aspects of Document Control System</th>
<th>Before 2009</th>
<th>After 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Management Documents</td>
<td>No Management Documents</td>
<td>131</td>
</tr>
<tr>
<td>Number of Technical Documents</td>
<td>229</td>
<td>464</td>
</tr>
<tr>
<td>Number of Technical Forms</td>
<td>25</td>
<td>72</td>
</tr>
<tr>
<td>Annual Review Schedule</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Standard Format for Documents</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Unique Document Coding</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Approval Process for Developing Documents</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Controlled Distribution</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Archive of Older Document Versions</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Access to Documents</td>
<td>Documents stored in locked cabinets in lab managers offices</td>
<td>Documents stored in main lab and accessible to all staff</td>
</tr>
</tbody>
</table>

3. Regular Planned Equipment Maintenance:

Equipment servicing has shifted from breakdown maintenance to planned maintenance and calibration for each piece of laboratory equipment. All servicing and issues are tracked in the equipment files, which is useful in identifying system errors.

4. Comprehensive Proficiency Testing is Maintained:

As part of good quality practice all tests now incorporate a daily QC. Furthermore, External Quality Assurance Scheme (EQAS) and inter-laboratory testing provide additional external QC evaluation of the performance of testing method, equipment and staff.

5. Annual Internal Audit:

An audit team is responsible for conducting annual auditing and when a corrective action requires an audit to insure corrective measures are effective. It not only provides the assessment, but cross sharing ideas among the laboratories.

6. Annual Customer Satisfaction Survey:

Each year the Specimen Reception Unit conducts a survey to determine areas for improvement and how we can better serve patients, researchers, doctors and clinicians. This was initiated in 2009 and continues to provide ICDDR,B relevant information and the opinion of our clients.

7. Measureable Key Performance Indicator (KPI):

KPI’s are critical in monitoring the performance of the laboratory. Data is collected periodically and continuously evaluated to assess laboratory performance. The periodic evaluation provides almost monthly information on our performance. KPI’s include an assessment of turnaround times, IQC & EQAS testing review, reporting accuracy and incidents.

8. Formation of Laboratory Management Committee (LMC)

The LMC is monthly meeting for management to review the monthly work, discuss current issues, approve documents and to provide overall direction to the laboratories. With the formation of the LMC it has created a forum to discuss issues and to come up with resolutions as a group. This fosters communication, coordination and team work.

9. Annual Management Review:

Management review allow an opportunity for all the staff to be informed of years progress. It is useful in identifying areas for improvement to the quality system and receiving staff input for planning improvement activities.

10. Staff Assessment:

As required, staff undergo annual assessment. If performance is below what is expected by management, staff are provided with study material, training and re-assessment to insure the staff performance is adequate to provide quality testing.

11. Accreditation Assessment:

As part of ISO 15189 accreditation by a certifying body under International Laboratory Accreditation Cooperation (ILAC) assessed CLS, ICDDR,B. As required follow up assessments are scheduled to insure that standards are being applied and maintained.

Conclusion:

CLS, ICDDR,B is the first laboratory in Bangladesh to implement and gain ISO 15189 accreditation. Implementation ISO 15189 standard improved the overall quality of CLS laboratories, not only for tests under the scope of accreditation, but all tests performed in the laboratory. Furthermore, accreditation of CLS has spurred an interest in other ICDDR,B laboratories to improve their quality. With adequate resources and support from management, ISO 15189 compliance is an achievable and sustainable goal for medical laboratories in developing countries, where national standards might not be developed.