LABORATORY QUALITY MANAGEMENT SYSTEMS STEPWISE IMPROVEMENT PROCESS (LQMS-SIP) TOWARDS ACCREDITATION

REPORT ON PILOT STUDY

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# Table of Contents

EXECUTIVE SUMMARY ............................................................................................................................................. 3

INTRODUCTION ........................................................................................................................................................... 4
  Pilot Study Background ....................................................................................................................................... 4
  Laboratory Selection Criteria .......................................................................................................................... 5
  Pilot Study Duration ......................................................................................................................................... 7
  LQMS-SIP Checklist ....................................................................................................................................... 7
  Pilot Study Laboratory Assessments ............................................................................................................. 7

RESULTS ................................................................................................................................................................. 8
  Pilot Study Data Analysis ................................................................................................................................. 8
  Summary Reports and Key Issues ...................................................................................................................... 17
  Lessons Learnt from the Pilot Study ............................................................................................................... 18

CONCLUSION ......................................................................................................................................................... 19
  Summary of LQMS-SIP Performance ............................................................................................................... 19
  Positive Outcomes from the LQMS-SIP Pilot Study ......................................................................................... 19
  Challenges Experienced in the LQMS-SIP Pilot Study ................................................................................. 20
  Suggested Strategies for Overcoming Challenges .......................................................................................... 20

Appendices: Percentage of Non conformities in the ISO 15189:2012 clauses in the Pilot Laboratories...22
EXECUTIVE SUMMARY

The Laboratory Quality Management Systems-Stepwise Improvement Process (LQMS-SIP) towards Accreditation has advanced significantly with the completion of a comprehensive and detailed Pilot Study. This Stepwise Improvement Process provides for recognition of the implementation of Quality Management systems in regional laboratories and acknowledges achievement of such in a three tiered approach. The Pilot Study was well received by all of the participating laboratories and the LQMS-SIP Checklist, developed against the requirements of the ISO 15189:2012, was noted as an excellent, user friendly tool to evaluate quality systems progress.

Ten laboratories from across the region were nominated by their Ministries of Health to participate in this ground breaking pilot study, which was successfully conducted from July to September 2014. The criteria developed to guide the study allowed a wide variety of different labs to participate including two privately owned, one in the final stages before accreditation, at least 3 who have had technical assistance for QMS development and 2 who had no prior support from external partners within the past 5 years. The laboratories also ranged in size and complexity from very small, less than 10 staff to very large of more than 50 staff, with highly complex services (example Molecular testing). The Study considered the individual laboratory’s needs and characteristics, and provided clear communication between the LQMS-SIP Secretariat and the laboratory staff to ensure that they were fully informed about and understood the assessment process. The total cost of the exercise, including airfare and per diem was $38,017.69 USD, resulting in an average cost per assessment of $3,802 USD.

The results showed that in general all of the participating laboratories were able to achieve some proportion of the requirements in each of Tier 1, 2 and 3. No laboratory obtained 100% of the requirements for any of the individual Tiers. The best performing laboratory succeeded in getting 71.1% of Tier 1, 66.7% of Tier 2 and 69.7% of Tier 3 requirements. An analysis was also performed to determine how many nonconformities were obtained by each laboratory across the Management and Technical requirements of the standard and the results showed that the average percentage of nonconformities ranged from a low of 29% to a high of 94%.

The final results of the pilot study including the analysis of the results from each laboratory, cost of implementation, opportunities for improvement and lessons learnt will be presented at a stakeholder meeting. This data will be very useful for all interested parties to appreciate how the LQMS-SIP can be used in the region and what will be required to roll the process out in all the CARICOM countries to the benefit of the Laboratory community.
INTRODUCTION

The Laboratory Quality Management System –Stepwise Improvement Process (LQMS-SIP) Towards Accreditation is a comprehensive approach to strengthen medical and public health laboratory services and systems throughout CARICOM. It is designed to recognize laboratories in the process of quality improvement assess their progress and recognize milestones towards meeting requirements of the ISO 15189:2012.

The LQMS-SIP is a U.S. CDC and PAHO joint initiative. It is supported by the President’s Emergency Fund for AIDS Relief (PEPFAR) through the United States Centers for Disease Control and Prevention, Caribbean Regional Office (CDC CRO) and is implemented by the Caricom Regional Organization for Standards and Quality (CROSQ). CROSQ is working with the CDC CRO, through its PEPFAR Laboratory Implementing Partner, the African Field Epidemiology Network (AFENET) to coordinate the LQMS-SIP activities in the region. The secretariat is the activity focal point, and provided and facilitated the laboratory assessments. It is managed by a project coordinator, who maintains supporting documentation and ensures that policies and procedures are compliant with the Caribbean guidance document for the LQMS-SIP and that its processes are adequate, transparent, fair and rigorous.

To examine the functionality of the LQMS-SIP, its requirements and determine the resources needed to expand the process at a regional level; a pilot study was designed and implemented among selected laboratories in the region.

Pilot Study Background

The implementation of the LQMS-SIP in the Caribbean commenced with a pilot study among selected laboratories. This was intended to identify issues to be corrected prior to the official roll out of the framework regionally. The study will also help to raise awareness among stakeholders and policy makers, on the benefits and potential of the LQMS-SIP as an important process for monitoring the continued improvement of quality management systems in clinical and public health laboratories. Beyond the pilot study, laboratories willing to enroll in this stepwise process toward accreditation will be encouraged to register and participate in the program from Tier 1 through to achieving Tier 3 recognition.

A detailed pilot study methodology was developed in concert with regional stakeholders taking into consideration the needs of the region.
The objectives of the LQMS-SIP pilot study were to:

1. Critically examine how the LQMS-SIP will work on the ground
2. Test its integrity and feasibility
3. Refine methods and procedures
4. Test logistics and costs of the assessments, application and enrollment procedures
5. Test the LQMS-SIP Checklist and other administrative procedures

**Laboratory Selection Criteria**

The CARICOM region is made up of fifteen member countries, all of whom had an equal opportunity to participate, since all public and private sector laboratories were eligible to be considered.

A total of ten laboratories were selected based on the responses received from the member countries to the call for participants to meet the selection criteria described below:

1. Each laboratory must have been designated as a medical or public health laboratory and fully recognized by the Ministry of Health of the participating country
2. At least one (1) of the selected laboratories must have been fully accredited by an accreditation agency or licensed by an independent local government regulatory body
3. At least one (1) of the selected laboratories must NOT be enrolled or have participated in a lab quality improvement program and is NOT receiving or have received partner support within the past 5 years
4. At least one (1) of the selected laboratories must have benefited from external support to improve their laboratory service quality within the last 5 years.
5. At least one private laboratory offering a range of services e.g. analysis of body fluids, imaging and biopsy
6. Laboratory scope of work could have included either low, medium or high complexity testing services, as described below:

**Low Complexity Laboratories**

Staff: ~ 1 to 5

Staff Skill Level: Lab aides, Phlebotomists, Lab Technologists

Testing Methods – Mostly manual with some automated

Tests offered:

- Limited or no Biochemistry and Haematology
Basic Serology (HIV, VDRL), Point of Care Testing for Glucose, Hemoglobin etc., Urinalysis (dip stick)

**Medium Complexity**

Staff: ~10-15

Skill Level: Mixed (Lab Aides, Lab Technicians, Phlebotomists and Medical Technologists)

Testing methods: Some manual but mostly automated

Tests offered:

- Basic Chemistry
- Basic Hematology
- Urinalysis and Microscopy
- Urine Culture
- Serology (HIV, VDRL, HepB etc.)
- TB Smear Microscopy
- Blood Banking (Grouping and Cross Matching)
- Flow Cytometry (CD4)

**High Complexity**

Staff - ~10 to 20 (or more)

Skill level: Medical Technologists, Pathologists, Consultants

Testing methods: Automated, State of the Art equipment

Tests offered:

1. Special Chemistries
2. Advance Hematology
3. Molecular Diagnostics (HIV Viral Load, DNA PCR, TB etc.)
4. TB Culture and Sensitivity Testing
5. Histology

Laboratory Managers/ Directors from selected laboratories were required to complete enrolment forms and forward them on to the MOH LQMS-SIP/Accreditation focal point, which shared the form with the LQMS-SIP Secretariat for processing and approval. The LQMS-SIP Secretariat also requested that laboratories propose a date for their laboratory assessment. Funding for the pilot assessment was provided entirely through the LQMS-SIP Secretariat using PEPFAR funds. This included the cost of Airfare and per diem for the Assessors and any internal travel costs incurred in accessing the Laboratory's premises during the visit.
Pilot Study Duration
The pilot study was undertaken during the months of July-September 2014. CROSQ worked closely with the Ministers of Health, Permanent Secretaries and Chief Medical Officers in country, to identify suitable laboratories which met the stated criteria and were interested in participation.

LQMS-SIP Checklist
The LQMS-SIP Checklist which is based on the ISO 15189: 2012 Medical Laboratories - Requirements for Quality and Competence was used to capture the data during the assessments. This Checklist was developed jointly by CROSQ, CDC CRO, PAHO and key regional stakeholders. The text of the Checklist adapted from the ISO 15189:2012 standard, was reproduced with copyright permission from the International Organization for Standardization, ISO.

The Checklist contains 15 sections on Management requirements and 10 sections on Technical requirements based upon the structure of the International Standard. All the requirements are separated into 3 distinct tiers, based upon relative importance/complexity. The first Tier represents the minimum requirements which is supposed correspond to the mandatory criteria required for the granting of a license based on legislation enacted by the Ministries of Health (in countries which have this structure) and the second and third tiers correspond to quality improvement milestones based on the agreed criteria for QMS implementation. Requirements noted in “black” represented Tier 1, requirements noted in “blue” represent Tier 2 and requirements noted in “green” represent Tier 3.

The Checklist was also produced in an electronic format as an Excel Spreadsheet which was useful for collecting assessment results, tallying the non-conformities identified in each clause and generating a summary of the totals for each Tier requirement. This was then used to create a convenient Action plan and Corrective Action Report to be shared with participating laboratories.

The laboratory assessors and the laboratories were provided with the Checklist in both formats. By providing the Checklist to the laboratories, they were able to familiarize themselves with the tool and some laboratories took the opportunity to “self-test” using the Checklist, before their formal visit.

Pilot Study Laboratory Assessments
The LQMS-SIP secretariat coordinated all laboratory assessments during the pilot. The Secretariat selected the technical and management assessors from a pool of trained assessors and communicated with the enrolled laboratory to find suitable dates for the assessment visit and coordinate the logistics of the assessment team. Technical and management assessors were
selected according to the requirements of each pilot laboratory and it was ensured that there was no conflict of interest with any of the laboratories.

Each assessment was conducted by a team of two persons with one functioning as the Technical Assessor and the other as a Management systems assessor. All visits were completed over a period of two – three days, depending on the size and complexity of the Lab. The assessors visited the laboratories and had short opening meetings with key personnel to give an overview of the planned process before commencing the assessment. Following this meeting, the assessors visited key areas of the laboratory, recorded observations using the checklist described above and conducted one-on-one discussions with staff. Upon completion of the assessment, the assessors met with key personnel once more to give a general summary of the visit. Pilot laboratories were encouraged to take necessary corrective actions to address deficiencies noted in their assessment. Findings from the assessment and feedback on the pilot were submitted to the LQMS-SIP Secretariat and formally communicated to the laboratory and the Ministry of Health.

RESULTS

Pilot Study Data Analysis
The analysis of LQMS-SIP pilot study was performed in accordance with the stated objectives of the study. All of the data collected during the assessment as well as the information provided on the administrative forms was analyzed and used to evaluate how well the LQMS-SIP had met laboratory goals. The parameters collected included: types of tests, proficiency test providers, number of staff, number of tests conducted monthly and instruments used in the laboratory.
<table>
<thead>
<tr>
<th>Lab Number</th>
<th>Types of Tests</th>
<th>Proficiency Test Provider</th>
<th>No. Of Staff</th>
<th>Approx. Number of Tests Per Month (Rapid/Specialized)</th>
<th>Instruments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Clinical Chemistry, Hematology, Immunoassay, Serology / Immunology, Urinalysis, HbA1c</td>
<td>One World Accuracy</td>
<td>6</td>
<td>800-1200</td>
<td>Blood Analyzer, Chemistry Analyzer, Chemistry Systems, Electrolyte Analyzer, Haematology Analyzer, Immuoassay Analyzer</td>
</tr>
</tbody>
</table>
| 4 | Clinical Bacteriology  
Enterics and Parasitology  
Food microbiology and *Salmonella* serotyping  
Mycobacteriology  
Mycology  
Syphilis, serological and other antigen/antibody testing  
Water quality | • American Proficiency Institute  
• Institute for Quality Management in Health Care (IQMH)  
• CDC Inter Laboratory Branch Proficiency Testing  
• Health Canada  
• One World Accuracy  
• College of American Pathologists (CAP)  
• LGC Standards  
• WHO GFN EQUAS | 16 | 5107 | • Chemistry Analyzer  
• Haemoglobin Analyzer  
• Spectrophotometer |
|---|---|---|---|---|
| 5 | Clinical chemistry  
Haematology  
Histocytopathology  
Histopathology  
Immunology  
Microbiology (Routine bacteriology, food, water and TB)  
Air Pollution  
Inorganic chemistry  
Microbiology  
Organic chemistry | • CDC Inter Laboratory Branch Proficiency Testing  
• EQAS  
• In Country HIV- DTS  
• NML  
• One World Accuracy  
• QASI | 62 | 2275 | • Chemistry Analyzer  
• Flow Cytometry Analyzer  
• Genetic Analyzer  
• Haematology Analyzer  
• Immunology Analyzer  
• Infectious Disease Analyzer (Diagnosis HIV1/ HIV2 Infection)  
• Real-Time PCR Analyzer |
| 6 | Bacteriology  
Blood Banking,  
Clinical chemistry/special chemistry,  
Cytology  
Hematology  
Histology  
Serology | • One World Accuracy  
• UKNEQAS  
• CDC Inter Laboratory Branch Proficiency Testing | 16 | 30 000 | • Chemistry Analyzers  
• Coagulation Analyzer  
• Haematology Analyzers  
• Immunossay Analyzer  
• Real Time PCR Analysis  
• Tissue Embedding System  
• Tissue Processing System |
| 7 | Bacteriology  
Mycology  
Parasitology  
PCR  
Serology | • CDC Inter Laboratory Branch Proficiency Testing | 158 | 1000- 1500 | No Data |
All of the laboratories participating in the pilot conducted a variety of testing in different speciality areas. The maximum number of testing areas was nine and the minimum number was five. All of the laboratories participated in proficiency testing except for one laboratory and several proficiency testing providers was utilized. Chemistry and Haematology analyzers were the most frequently used instruments in the laboratories, indicating that these are frequently requested services that are required at a minimum.

<table>
<thead>
<tr>
<th></th>
<th>Haematology-CD4</th>
<th>CDC Inter Laboratory Branch Proficiency Testing</th>
<th>One World Accuracy</th>
<th></th>
<th>25</th>
<th>2275</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HTLV and Syphilis (EIA &amp; Western Blot) RPR &amp; HIV rapid tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Molecular Biology</td>
<td>Serology/Immunology, Tuberculosis –Microscopy(IFA), Culture and DST</td>
<td></td>
<td></td>
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<tr>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>CDC Inter Laboratory Branch Proficiency Testing</td>
<td>One World Accuracy</td>
<td></td>
<td>25</td>
<td>2275</td>
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<tr>
<td></td>
<td>One World Accuracy</td>
<td>One World Accuracy</td>
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<td>25</td>
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<tr>
<td>9</td>
<td>CDC Inter Laboratory Branch Proficiency Testing</td>
<td>One World Accuracy</td>
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<td>25</td>
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<tr>
<td></td>
<td>One World Accuracy</td>
<td>One World Accuracy</td>
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<tr>
<td>10</td>
<td>CDC Inter Laboratory Branch Proficiency Testing</td>
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<td>2275</td>
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<td></td>
<td>One World Accuracy</td>
<td>One World Accuracy</td>
<td></td>
<td>25</td>
<td>2275</td>
<td></td>
</tr>
</tbody>
</table>

All of the laboratories participating in the pilot conducted a variety of testing in different speciality areas. The maximum number of testing areas was nine and the minimum number was five. All of the laboratories participated in proficiency testing except for one laboratory and several proficiency testing providers was utilized. Chemistry and Haematology analyzers were the most frequently used instruments in the laboratories, indicating that these are frequently requested services that are required at a minimum.
Please note that a logarithmic scale is used.

The number of rapid and specialized tests conducted per month in the laboratories ranged from 200 – 100 000. The greatest number of staff employed in the pilot laboratories was 158 and the least number was 2.
Eight (8) of the laboratories in the LQMS-SIP Pilot Study satisfied some of the requirements in Tier 1, Tier 2 and Tier 3 of the Checklist whilst two (2) laboratories satisfied requirements in Tier 1 and Tier 2 only. Laboratory 5 satisfied the majority of the requirements of the Checklist whilst Laboratory 3 satisfied the least of the requirements. Overall, more requirements were satisfied for Tier I across all laboratories, whilst Tier 3 requirements were the least satisfied.

Laboratory 5 attained the highest percentage of Tier score across all three Tiers, whilst Laboratory 3 attained the lowest percentage of Tier score.

*The Ideal Test Lab represents the maximum scores that a laboratory can obtain in each Tier if it did not fulfill any requirements*
Figure 3: Total Number of Management and Technical Non-conformities for each Laboratory in the Pilot Study

*The Acme Test Lab represents the maximum number of non-conformities that a laboratory can obtain if it did not fulfil any requirements.

A higher number of non-conformities indicate that the laboratory is only satisfying a small number of the requirements of the ISO 15189: 2012 whilst a low number of non-conformities indicates that the laboratory is satisfying a larger number of the requirements of the ISO 15189: 2012.

Overall Laboratory 3 had the highest total number of non-conformities (130) whilst Laboratory 5 had the lowest number on non-conformities (40). The data also shows that the majority of laboratories performed better in the management requirement, whilst several of them had a high number of nonconformities in the technical requirements.
The highest percentage of non-conformities across all the laboratories per ISO 15189: 2012 Management requirements was observed in Clauses 4.4 (Service Agreements), 4.5 (Examination by Referral Laboratories), Clause 4.10 (Corrective Action) and Clause 4.12 (Continual Improvement). This indicates that these clauses appear to be more difficult for the labs to meet. The lowest percentage of non-conformities per ISO 15189: 2012 Management Requirements was observed in Clauses 4.9 (Identification and Control of Non-Conformities), Clause 4.11 (Preventive Action) and Clause 4.13 (Control of Records).
Figure 5: Average percentage of non-conformities per Technical Requirements clauses for all pilot laboratories combined

The highest percentage of non-conformities across all the laboratories per ISO 15189: 2012 Technical requirements was observed in Clauses 5.5 (Examination Processes) and 5.6 (Ensuring Quality of Examination results). The lowest percentage of non-conformities per ISO 15189: 2012 Technical Requirements was observed in Clause 5.2 (Accommodation and Environmental Conditions).
Figure 5 shows the percentage of total nonconformities in both Management and technical requirements for each laboratory in the study. The data shows that Laboratory 3 obtained the highest percentage of total non-conformities (94.2%) in all the labs assessed, closely followed by Lab 9 at 93.5% and Lab 10 at 91.3%. This means that they have many areas which can benefit from quality improvement and corrective actions. Meanwhile Laboratory 5 obtained the lowest percentage of total non-conformities (29%). The next closest laboratory was Lab 8 at 50.7%, which is a 21.7% difference.

Summary Reports and Key Issues
The assessment teams generated individual country reports after each visit which were forwarded to the LQMS-SIP Secretariat. Each participating Laboratory received a summary report and Action plan from the Secretariat detailing their performance in the Pilot Study. The major issues recognized by the assessors relative to the laboratories operations that need to be addressed are summarized below:

1. Occupational health and safety in laboratory operations
2. Waste management and disposal
3. Conducting appropriate risk assessments
4. Accepting and managing complaints to the laboratory
5. Procedures for control of quality and technical records including retention times
6. Procedures for the review and validation of results  
7. Procedures for the use of the laboratory information systems and prevention of unauthorized access  
8. Continuing education and staff training  
9. Competency assessments and performance assessments for staff  
10. Agreements with referral laboratories  
11. Validation of equipment  
12. Availability of equipment manuals and calibration and service records for equipment  
13. Monitoring Quality Indicators  
14. Appropriate choice and use of personal protective equipment  
15. Adequate monitoring of stock to prevent "stock outs"  
16. Management review of the quality management system at planned intervals and the establishment of procedures for Management Review  
17. Use of appropriate biological reference intervals  
18. Inappropriate storage and segregation of reagents and media  

Lessons Learnt from the Pilot Study  
The development of the LQMS-SIP framework and the institutional arrangements for managing its implementation in the Caribbean region were tested during the pilot study. As part of the process of refining the system, lessons learnt were collected in order to keep track of the experience gained. These lessons are summarized below:  

1. Receipt of information such as quality manuals from participating laboratories is critical to allow laboratory assessors to review in advance of the laboratory assessment  
2. A large pool of experienced trained technical and management assessors is necessary to adequately service all the laboratories requiring assessments  
3. The LQMS-SIP Checklist should include a section that specifically addresses laboratory safety, even though it is not addressed in the ISO 15189  
4. The Tier requirements in the Checklist should be revised and the Checklist should be scored to allow easier interpretation of results  
5. The LQMS-SIP Enrolment Forms should be revised to make the sections dealing with staff qualifications, training and job descriptions be requested for senior staff only
CONCLUSION
The Pilot Study has generated valuable information which will be applied to the LQMS-SIP Programme to assist with critical decisions about how the program can be implemented regionally. The LQMS-SIP Pilot Study was well received by the participating laboratories as well as the in-country policy makers. The implementation of the LQMS-SIP and the execution of the pilot study had a positive impact on the development of quality management systems in medical laboratories.

Summary of LQMS-SIP Performance
The objective of the LQMS-SIP is to support the strengthening of medical and public health laboratory services and of quality improvement. The LQMS-SIP Checklist was a new tool developed based on the ISO 15189: 2012 and pilot laboratory management and staff noted that it was useful and easy to use for auditing their laboratories. The inclusion of a “what to look for section” which simplified the evidence needed to show if the requirements of a particular section of the standard was being met, was welcomed by users.

The administrative tools used in the pilot study were the LQMS-SIP Brief, Laboratory Application Process Guidelines, Laboratory Enrolment Forms (General, Laboratory Organization, Laboratory Testing, Quality Assurance, Laboratory Staff), Laboratory Terms of Reference for Technical Assessors and Lead Assessors and Confidentiality Agreements. All of these tools were reported as simple and easily used.

Positive Outcomes from the LQMS-SIP Pilot Study
1. The pilot study reached the target population of medical/public health laboratories in CARICOM countries
2. A range of laboratories (private, public, licensed, non-licensed) participated in the LQMS-SIP
3. Data was gathered to inform the future development of the LQMS-SIP
4. Pilot laboratory progress towards meeting internationally accepted standards (ISO 15189: 2012) was documented
5. The pilot generated an increased awareness of the importance of quality management systems and the need to adopt the ISO 15189:2012 and its requirements
6. Pilot laboratories expressed interest in improving their technical/management systems and correcting non-conformities
7. Policy makers in CARICOM countries (Ministers of Health, Permanent Secretaries, Chief Medical Officers) were sensitized to the benefits of improving laboratory quality management systems
8. The LQMS-SIP Checklist was updated from the ISO 15189: 2007 to the ISO 15189: 2012
9. The ISO granted copyright permission to CROSQ to use the ISO 15189: 2012 in the LQMS-SIP Checklist
10. The LQMS-SIP Checklist was field tested in medical laboratories and its applicability, “ease of use” and validity was documented
11. The PDF and electronic versions of the LQMS-SIP Checklist were well received by laboratory staff as an easy to use simple tool for auditing their laboratory
12. Data was gathered which would allow for the improvement of the LQMS-SIP Checklist and the refinement of the Tier requirements

Challenges Experienced in the LQMS-SIP Pilot Study

1. The pace of communication and response from stakeholders to LQMS-SIP Secretariat dispatches was slow
2. The time taken to identify suitable laboratories to participate in the pilot study by in-country policy makers exceeded the time allotted
3. The receipt of incomplete pilot study documentation from laboratories e.g. enrolment forms, quality manuals and description of laboratory activities hampered assessment planning
4. A limited pool of experienced trained technical and management assessors was available to conduct all of the assessments
5. Scheduling of assessments to satisfy both laboratory and assessor needs presented difficulties since laboratories were tardy in providing dates
6. A language barrier between assessors and laboratory staff in one assessment necessitated an interpreter which slowed the time taken to complete the assessment
7. The ISO 15189: 2012 Medical Laboratories-Requirements for Technical and Management Competence does not directly address issues regarding safety (ISO 15190: 2003 Medical Laboratories Requirements for Safety) and some laboratories did not have adequate measures to establish and maintain a safe working environment
8. No pilot laboratory satisfied all the requirements for any one Tier; all laboratories satisfied different percentages of requirements for all three Tiers.
9. The LQMS-SIP Checklist was not scored

Suggested Strategies for Overcoming Challenges

1. Improvement of communication with stakeholders and laboratories
2. Increased use of the CROSQ website to disseminate project information
3. Developing a training program to increase the number of experienced assessors in concert with regional stakeholders e.g. JANAAC, TTlabs and CARPHA
4. Reorganization and simplification of the pilot study enrolment forms to capture salient data more easily
5. Allotting additional time for assessments and scheduling
6. Review of the LQMS-SIP Checklist Tier Requirements in conjunction with stakeholders
7. Development of an addendum to the LQMS-SIP Checklist which addresses major safety issues in medical laboratories
8. The LQMS-SIP Checklist should be scored
Appendices: Percentage of Non-conformities in the ISO 15189:2012 Clauses in the Pilot Laboratories

Figure 7: Percentage of Non-conformities over the ISO 15189: 2012 Clauses in Lab 1

![Graph showing percentage of non-conformities for Lab 1](image)

Figure 8: Percentage of Non-conformities over the ISO 15189: 2012 clauses in Lab 2

![Graph showing percentage of non-conformities for Lab 2](image)
Figure 9: Percentage of Non-conformities over the ISO 15189:2012 clauses in Lab 3.

![Lab 3 Graph](image-url)

Figure 10: Percentage of non-conformities over the clauses in Lab 4.

![Lab 4 Graph](image-url)
Figure 11: Percentage of Non conformities over the ISO 15189: 2012 clauses in Lab 5

Figure 12: Percentage of Non conformities over the ISO 15189: 2012 clauses in Laboratory 6
Figure 13: Percentage of Non-conformities over the ISO 15189: 2012 clauses in Lab 7

Figure 14: Percentage of Non-conformities over the ISO 15189: 2012 clauses in Lab 8
Figure 15: Percentage of non conformities over the clauses in Lab 9

![Lab 9 graph]

Figure 16: Percentage of non conformities over the clauses in Lab 10

![Lab 10 graph]