Understanding Quality Management System: Essential Strategies to Improve Laboratory Performance

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Presentation Outline
• Quality Management System (QMS) background information
• Overview of international QMS standards and guidelines
• Comparison of ISO 15189 and CLSI
• Challenges to QMS Implementation
• Describe the stepwise approach to QMS
• Describe the “Laboratory Quality Continuum” as a tool to achieve quality excellence
• Describe the sources of laboratory errors
• Describe the culture of quality, relation to the patient safety and the role of leadership
• Describe the excellence in quality awards

Our Common Goal
Quality Excellence in Clinical Laboratory Practice

Principles of high-quality laboratory testing are the same anywhere in the world. It is one area of health care that can be, and should be, highly standardized.

The Quality Management System (QMS)
Provides a framework for managing and monitoring activities to address quality standards and achieve organizational goals.

Standardization in the Medical Laboratory
The right laboratory test at the right time with the right result leads to quality diagnostics, improved patient care, and improved public health around the world.

IFCC gratefully acknowledges financial support from Abbott Diagnostics Division

Standardized Test ➔ Standardized Procedure ➔ Standardized Reporting ➔ Improved Outcomes

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Standardization International Bodies

ISO – International Organization of Standardization
- World’s largest developer and publisher of international standards
- Standards are applicable to many kinds of organizations including clinical and public health labs
- Use consensus process in developing standards

CLSI – Clinical and Laboratory Standards Institute
- Global, nonprofit, standards-developing organization
- Developed standards apply specifically to medical labs
- Documents are developed by experts working on subcommittees or working groups (consensus process)

CEN – European Committee for Standardization
- Founded by the national standards bodies in the European Economic Community and associated countries
- General terms include openness and transparency, consensus, and integration

WHO – World Health Organization
- Developed several standards for disease-specific diagnostic labs, such as polio, H1N1 influenza, measles
- Provides with Laboratory Quality Management System Tool Kit

Quality Systems Models

There are two major models for QMS used globally.

ISO 15189:2012
- Broad – based
- Overarching standards
- 15 Management requirements
- 10 Technical requirements (Section 5)
- Both are based on the same concepts, but differ in the amount of specificity described.
- ISO is broader and CLSI is more specific.
- ISO = what to do; CLSI = how to do it

CLSI GP26-A4
- Specific – standards, guidelines, and best practices for quality in medical lab testing
- Practical implementation – detailed; applies specifically to medical labs
- 12 Quality system essentials
- 10 Technical requirements (Section 5)

ISO 15190:2003
- Medical laboratories -- Requirements for safety

ISO 10012:2003
- Measurement management systems – Requirements for measurement processes and measuring equipment in medical laboratories

ISO/IEC 17025:2005
- General requirements for the competence of testing and calibration laboratories

ISO 22870:2006
- Point-of-care testing (POCT) -- Requirements for quality and competence

ISO/TS 22367:2008
- Medical laboratories -- Reduction of error through risk management and continual improvement

ISO 15189:2012
- Medical laboratories – Particular requirements for quality, and competence

ISO 15197:2013
- In vitro diagnostic test systems -- Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus

CLSI
- CLSI in US developed the quality management framework and organized the topics as the "12 Quality System Essentials" model based on ISO 15189 and CLSI GP26-A4 standards

QMS is a simple, systematic approach of organizing all key work processes around the path of workflow in the laboratory.

CLSI – 12 QSE

Quality System Essentials: The Building Blocks

Preexamination
- Organization
- Customer Focus
- Facilities and Safety
- Personnel
- Equipment

Examination
- Process Management
- Documents and Records
- Information Management
- Equipment Maintenance
- Facility Improvement

Postexamination
- Continual Improvement

CLSI QMS and How Quality System Essentials (QSE) fits within the QMS

International Standards Applicable to Medical Laboratories

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<tr>
<th>International Standards</th>
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<td>ISO 15189:2003</td>
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<td>QMFA</td>
<td>Effortless laboratory Quality Improvement Process Towards Accreditation and Capability, RML in Africa</td>
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A QMS View of Laboratory Accreditation Standards

Principles of ISO 15189

ISO 15189: Where we are today

What are the advantages of test accreditation according to ISO 15189?

The pros can be summarized as:

- The only global standard for the accreditation of medical laboratory results
- Based on good laboratory practices
- Focused on technical specifications in medical laboratory
- Process approach matching the pre-analytical, analytical, and post-analytical phases
- Oriented to support accurate clinical decisions
- Identification and traceability information of the different phases of the medical laboratory process
- Monitoring and measuring of devices that significantly contribute to the trueness and uncertainty of the reported results
- Training and competence assessment of the staff which is critical to good management and good laboratory practices; and:
- Infrastructure to correctly support the operation practices.

Let’s Think outside the Box!
What are the drawbacks of test accreditation according to ISO 15189?

- The accreditation is expensive when compared to the ISO 9001 certification.
- Its value is not well understood by the physician and the customers of clinical decisions
- It is not used by most of the medical laboratory agencies as the standard to accreditation
- It requires auditors with advanced matrix of skills
- It does not require sustainability
- The specifications sometimes are generic
- It does not standardize critical practices such as the validation, measurement uncertainty, IQC and EQA/PT of examination procedures, and;
- The safety specifications are basic.

Global Momentum Toward QMS Adoption

- 40+ countries have implemented, or are in some stages of national adoption, of the QMS model approach to their laboratory services
- The WHO has fully adopted the QMS approach on a global basis and is in the process of education and training.
- In the US, the Centers for Medicare & Medicaid Services is encouraging labs to adopt a QMS approach to laboratory licensure and accreditation

What is happening with ISO 15189 implementation on a global perspective?

- 85% South Africa
- 56% rest of the world
- 90% of European countries
- 90% of Latin America
- 75% of other countries

What is happening with ISO 15189 implementation on a global perspective?

- Currently, ISO 15189 is obligatory in Australia and Latvia.
- Since 2011, all new French medical laboratories must be accredited. Since November 1, 2016, all other public or private laboratories in France must be accredited on at least 50% of the tests, expanding to 70% of tests by 2018, and all tests by 2020.
- In the Netherlands, the COKL accreditation has been changing to the ISO 15189 standard under the direction of the Dutch ‘Raad voor Accreditatie’ (RvA), with a target deadline of January 1, 2018.
- Belgium – only molecular tests
- Germany – only newborn screening
- Legal requirements exist in most countries.

Does your laboratory currently have a Quality Management System (QMS) based on the ISO 15189 standards?

1. Yes
2. No
The Stepwise plan is constructed such that, even when a laboratory does not reach full implementation of the QMS, it has already improved its quality service provision from Phase 1, and as such has benefitted already.

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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Quality Management System</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Equipment</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>PHASE 2 Operation Program</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Upgrading laboratory's</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>PHASE 3 Communication with clients</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>PHASE 4 Communication with clients</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

How to improve quality systems for a specific laboratory

What are the Challenges to QMS Implementation?

Knowledge
- Uncertainty about starting point
- How the regulatory process works

Awareness
- Defining roles and responsibilities
- Personnel qualifications and associated records
- Competency assessments
- Cost and mobilization of resources
- Proficiency testing – enrollment (all regulated analytes) to review of results to corrective actions to maintain records

Good Management Practices
- Perception of lack of time
- Lack of management commitment and practical support
- Method comparisons
- Calibration verification
- Equipment maintenance and associated documentation
- Resistance to change and managing change in evidence-based system

The formulation for improvement

Take into account:
- The laboratory’s current level of quality, which involves an assessment of the culture of quality;
- The existing quality management system (QMS) framework;
- The lab’s ability to effectively implement a quality program.

According to what you know today about QMS:

1. My existing QMS will need major revisions
2. My existing QMS will need moderate revisions
3. My existing QMS will need minimal revisions
4. My existing QMS is not based on a QSE model
5. I do not have a QMS yet

Audience Response
What are the essentials of quality excellence and how to achieve it?

**Phase 1: Analytical Quality (AQ) – Focus on Quality of the Analytical Phase**
- Activities that ensure analytical quality:
  - Quality Control
  - Validations and Verifications
  - Instrument-to-instrument comparisons
  - Linearity
  - Proficiency Testing

**Phase 2: Quality Assurance (QA) – The Checklist Mentality**

**Phase 3: Quality Management (QM) – A Formalized Quality Management System**

**Phase 4: Total Quality Management (TQM) – Incorporating the Voice of the Customer**

**Phase 5: Performance Excellence – The Pursuit of Excellence**

**Total Testing Process**
- Pre-analytical: Ordering, Collection, Identification, Transportation, Preparation, Analysis
- Analytical: Interpretation
- Post-analytical: Reporting

**The Iceberg Model of Sources of Error**
- Preanalytical still retains the largest source of error:
  - 45% – 62.2% (2016)
- Analytical:
  - 7% – 13% (1996), 15% (2016)
- Post-analytical:
  - 18.5% – 47% (2016)

**Diagnostic Errors vs Medical Errors**
- What is Diagnostic Error?
  - An IOM committee defines diagnostic error as the failure to:
    1. Establish an accurate and timely explanation of the patient's health problem(s) or
    2. Communicate that explanation to the patient.

**The Course of Lab Quality Continuum towards for excellence**

**Activities that ensure analytical quality:**
- Quality Control
- Validations and Verifications
- Instrument-to-instrument comparisons
- Linearity
- Proficiency Testing
Diagnostic Errors vs Medical Errors

A Framework for Thinking About Medical Errors

There are many possible ways to categorize medical errors, but no universally accepted taxonomy. Classifications have included:

- Type of healthcare service provided (e.g., classification of medication errors by the National Coordinating Council for Medication Error Reporting and Prevention).
- Severity of the resulting injury (e.g., sentinel events, defined as "any unexpected occurrence involving death or serious physical or psychological injury" by the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]).
- Legal definition (e.g., errors resulting from negligence [Institute of Medicine, 1999]).
- Type of setting (e.g., outpatient clinic, intensive care unit).
- Type of individual involved (e.g., physician, nurse, patient).


Diagnostic Errors: What is the role of laboratory?

A Framework for Thinking About Medical Errors

Diagnostic Errors: The Laboratory Viewpoint

Quality Assurance (QA) – The Checklist Mentality

- Labs are focused on meeting minimum regulatory requirements and nothing more.
- The de facto goal at this level is to keep the lab in business and pass inspections, not necessarily to provide the best patient care and service possible.
- Labs at this phase are often reactive, waiting for problems to surface before addressing deficiencies.
- The quality professional is seen more as a compliance officer – a sheriff that polices compliance with requirements.

Quality Management (QM) – A Formalized Quality Management System

- The Lab’s QMS has taken shape – requires a lab-centric QMS.
- CLSI’s 12 QS Essentials and other standards and guidelines are incorporated into the quality program with policies and procedures describing the quality framework.
- The key element is lab’s QMS is not merely aimed at meeting minimum regulatory requirements and inspections become the outlets to demonstrate achievements and to identify opportunities to further elevate the lab’s quality program.
- Labs begin to track the costs associated with quality, both good and bad, and can demonstrate a return on investment (ROI) for their quality program and initiatives and trend a comprehensive set of metrics.

“…when you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind…”

- Lord Kelvin

Stages of Quality
(CLSI HS1-A2:2004)

<table>
<thead>
<tr>
<th>Hierarchical Level</th>
<th>Activities Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Quality Management</td>
<td>Total management approach centered around customer satisfaction</td>
</tr>
<tr>
<td>Quality Cost Management</td>
<td>Activity to identify, measure, &amp; control cost of quality</td>
</tr>
<tr>
<td>Quality Management System</td>
<td>Systematic process-oriented approach to meet quality objectives</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>Organized activities to provide confidence that organization meets requirements for quality</td>
</tr>
<tr>
<td>Quality Control</td>
<td></td>
</tr>
</tbody>
</table>

Cost of Good Quality:

- Appraisal Costs
- Rejected Specimens Testing/Reagent Costs
- Attrition
- Training
- Lost Specimens
- Unused or Decreased Capacity
- Compromised Patient Safety
- Litigation
- Low Morale
- Inefficiency
- QI Projects

Cost of Poor Quality:

- Internal Failure Costs
- External Failure Costs

Sigma Levels and Cost of Quality

<table>
<thead>
<tr>
<th>Sigma Level</th>
<th>Detect rate (DPM)</th>
<th>Cost of Quality</th>
<th>Competitive Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>3.4</td>
<td>&lt; 10%</td>
<td>World Class</td>
</tr>
<tr>
<td>5</td>
<td>233</td>
<td>10-15%</td>
<td>Industry Average</td>
</tr>
<tr>
<td>4</td>
<td>6,210</td>
<td>15-20%</td>
<td>Non Competitive</td>
</tr>
<tr>
<td>3</td>
<td>66,807</td>
<td>25-30%</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>308,537</td>
<td>30-40%</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>690,000</td>
<td>&gt; 40%</td>
<td></td>
</tr>
</tbody>
</table>

How dramatically the cost of quality as a percentage of sales decreases if the process sigma improves.

What is Six Sigma?

- Systematic approach to reduce the occurrence of errors or mistakes in terms of defects per million (DPM).
- Six Sigma offers laboratories the way to make fewer mistakes in all their activities (ranging from filling in an order form to the most complicated analytical process and report delivery) by eliminating errors before they appear.
- If done properly, Six Sigma ensures that internal processes are running at optimum efficiency—i.e., DPM "before-and-after".

Quality Cocktail

Be it Lean, Six Sigma and/or ISO 15189
2017 Top Challenges and Priorities for Quality Management

Based on the survey results conducted by American Productivity & Quality Center

5/29/2017


Phase 4

Total Quality Management (TQM) – Incorporating the Voice of the Customer

- Lab’s QM program hits its stride and is characterized by the establishment of a culture of quality that permeates throughout the organization.
- No solitary quality manager, but a comprehensive, fully ingrained, top down culture of quality with all staff working toward the same goal.
- A culture of quality is fostered where employees are encouraged to report non-conformities in order to improve lab operations and quality.
- Labs in this phase may seek external validation for their quality achievements through accreditation programs which assess conformance to ISO 15189.

Potential Lab Customers

- Hospital - Based Lab: Emergency, Infection Control, ICU, Medical Staff, Nursing Staff, Outpatients, Pharmacy, Radiology, Referring Clinicians, Research labs, Suppliers/Vendors
- Reference labs: Clinicians, Government bodies, Pharmaceutical Companies, Referring labs, Suppliers/Vendors, University based research groups

"Culture is a little like dropping an Alka-Seltzer into a glass – you don’t see it, but somehow it does something."

- Hans Magnus Enzensberger

"Right" Culture Requires Shift in Thinking

<table>
<thead>
<tr>
<th>Not Effective Thinking</th>
<th>Effective Thinking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who did it?</td>
<td>What happened? Why?</td>
</tr>
<tr>
<td>Punitive</td>
<td>Fair and just</td>
</tr>
<tr>
<td>Bad people</td>
<td>Bad systems</td>
</tr>
<tr>
<td>Penalize the reporter</td>
<td>Thank the reporter</td>
</tr>
<tr>
<td>Confidential</td>
<td>Transparent learning</td>
</tr>
<tr>
<td>Investigation</td>
<td>Root cause analysis</td>
</tr>
<tr>
<td>Independent silos; no/little communication</td>
<td>Inclusive and interdisciplinary team; lots of communication</td>
</tr>
</tbody>
</table>

www.justculture.org

"Right" Culture Requires Shift in Thinking

<table>
<thead>
<tr>
<th>Not Effective Thinking</th>
<th>Effective thinking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thinking errors are rare</td>
<td>Realizing errors are everywhere</td>
</tr>
<tr>
<td>Great care</td>
<td>Great care in a high-risk environment</td>
</tr>
<tr>
<td>Lack of direction: staff make it up as they go along</td>
<td>Principles of fair and just culture, guidelines, algorithms, flow charts</td>
</tr>
<tr>
<td>Risk of disclosure/confidentiality</td>
<td>Moral duty, risk of non-disclosure</td>
</tr>
<tr>
<td>Great staff: poor systems</td>
<td>Great staff: great systems</td>
</tr>
<tr>
<td>Deliver care to patients</td>
<td>Partner with team, patients and families</td>
</tr>
</tbody>
</table>


Quality Strategy: Patient Safety Focus and Organizational Culture

The National Patient Safety Goals (NPSGs) were established in 2002 to help accredited organizations address specific areas of concern in regards to patient safety. The first set of NPSGs was effective January 1, 2003.

www.jointcommission.org/assets/1/6/NPSG_Chapter_LAB_Jan2017.pdf

ECRI Institute Names Top 10 Patient Safety Concerns for 2017

Since 2009, when ECRI Institute PSO began collecting patient safety events, the PSO and partner PSOs have received more than 1.5 million event reports and reviewed hundreds of root causes analyses. "The 10 patient safety concerns listed in our report are very real," says Catherine Pusey, RN, MBA, associate director, ECRI Institute PSO. "They are causing harm—often serious harm—to real people."

This year’s list includes:
• Information Management in EHRs
• Unrecognized Patient Deterioration
• Implementation and Use of Clinical Decision Support
• Test Result Reporting and Follow-Up
• Antimicrobial Stewardship
• Patient Identification
• Opioid Administration and Monitoring in Acute Care
• Management of New Oral Anticoagulants
• Inadequate Organization Systems or Processes to Improve Safety and Quality

https://www.jointcommission.org/assets/1/6/NPSG_Chapter_LAB_Jan2017.pdf

The difference between formal and informal leadership and the importance of informal leadership roles in managing quality

CLSI - GP38
Visit C-CLM Webpage

Phase 5 Performance Excellence – The Pursuit of Excellence

- The culmination of the laboratory quality continuum.
- Achieving excellence for the entire organization and all management systems, including leadership, strategy, customers, measurement systems and analysis, knowledge management, workforce, operations, and results.
- Labs foster innovation, continuous improvement, achieving exceeding benchmarks, and long-term success.
- Labs continuously strives to operate at a best-practice level and to achieve recognitions that differentiate their lab as world-class as the National Malcolm Baldridge Quality Award in US.

Excellence in Quality Awards

Performance Excellence – The Pursuit of Excellence

- DGMC Lab supports 325,000 annual patient visits and 6000 admissions.
- Largest POC testing program in the Air Force, managing 23 sites
- Serves in a 116-bed medical treatment facility
- Performs 1.2 million tests per year in Chemistry, Special Chemistry, Hematology, Coagulation, Immunology, Microbiology, POCT, Histology, Cytology and Transfusion Services
- MLO asked those submitting nominations for the 2017 Lab of the Year award to discuss their lab in terms of Six Criteria: Customer Service, Productivity, Teamwork, Education and Training, Strategic Outlook, and Lab Inspections

3 Questions to Ask About Your QMS in your laboratory

1. Are you cultivating quality management leaders in your organization - laboratory?
2. What is the proper ratio of corporate versus local quality management?
3. What is the role of technology in building a quality culture in your laboratory?

Audience Response

According to what you know about QMS from today’s presentation:

1. There is no change in my previous answer regarding the amount of revision necessary.
2. My existing QMS needs more revision than I previously thought.
3. My existing QMS needs less revision than I previously thought.
4. My existing QMS is not based on a QSE model.
5. I do not have a QMS yet.
The early physician’s laboratory was certainly more modest than the 21st-century POL.

The urinalysis was commonly performed not only at the bedside but also in the physician office laboratory during the nineteenth century.

Summary

- Standards form the basis for quality practices. They are developed by the organizations.
- QMS improve laboratory practice.
- Where to Start - Approaches to implementation for QMS will vary with local situation. Start with the easiest, implement in stepwise process.
- Raising Quality Awareness - Continuous progression along the lab quality continuum will reduce costs, result in the strategic advantage of differentiation in the marketplace through quality and offering the very best care for the patients.
- Embedding an emphasis on patient safety into the lab’s organizational culture can reap many benefits for the overall organization.
- Accreditation is an important step in the continual improvement of the QMS.
- The implementation case of ISO 15189 at a global perspective could be seen as currently unsuccessful, since only a few countries here and there have adopted it wholesale. This is very different than the rapid and widespread adoption of ISO/IEC 17015 in other science fields. On a harmonisation perspective of good laboratory practices, the slow uptake of 15189 is a major concern. Nevertheless, while ISO 15189 is not mandatory in most countries, this standard remains the most common global reference for quality in medical laboratories. Its influence around the world cannot be overstated.

Needless to say!

Committee on Clinical Laboratory Management Educational Workshop

Educational Workshop
“Intelligent Clinical Laboratory Management: Impacts on Quality System Improvement”
October 22, 2017 • Durban, South Africa
Everything is well, that ends well…

- Ioana Brudașca

Comments and Questions

Mulțumesc

Comments and Questions