Quality Management in the Laboratory

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Learning Objectives

• Define key elements of a documented quality management system (QMS)
• Describe the role of the laboratory director in developing, implementing and overseeing the program
• Identify criteria that evaluate a QMS for effectiveness
“Quality” Terminology

- Quality
- Quality Control
- Quality Assurance
- Quality Indicator
More “Quality” Terminology

- Quality Improvement
- Quality Management System
- Quality Management
Progression of Quality

• 1940s – 1960s: Laboratory quality control (QC)
• 1970s: Proficiency Testing
• 1980s: Quality Assurance (QA)
• 1990s: Quality Systems
History of the QMS

- 1995 - FDA Guideline for Quality Assurance in Blood Establishments
- AABB incorporated the quality management concepts into its accreditation standards
- 1999 - CLSI published guideline on QM concepts
- 2003 - ISO 15189, Medical Laboratories published
Why have a QM Program?

Enhances these outcomes:

• Ability to reduce or eliminate medical error;
• the likelihood of meeting customer requirements;
• the potential for successful governmental and accreditation assessments; and
• sustainable attainment of quality objectives.
Regulatory Requirement

- CLIA Regulations (§493.1200 - §493.1299)
  - Subpart K – Quality System for Non-Waived Testing

- CMS approves accrediting organizations
  - CAP
  - AABB
  - COLA
  - TJC
Choosing a QMS Framework

- Quality System Essentials (QSE)

- Similar elements described
  - AABB - CLIA
  - CAP - FDA
  - CLSI - ISO 15189
Components of a QMS: Attachment pages 3-4
The Quality Manual

- Defines and documents the QMS
- Tool for communicating operational guidelines to your staff and to external assessors
- Provides the opportunity for staff to see their integrated roles and responsibilities

- Quality Manual TOC: Attachment page 5
Quality Management Plan

• A document that describes the laboratory’s overall QM program
• Includes a statement of the laboratory's commitment to quality and patient safety
• Spells out the types of monitoring that will be performed
• Includes major planned quality improvement activities
• Specifies how quality and safety information is to be collected and disseminated
Quality Management Plan

• Required by CAP (GEN.13806)
• Provides reasonable assurance that the laboratory
  – Complies with laws and regulations
  – Meets defined standards of laboratory practice
  – Engages in quality improvement activities

• QM Plan and Program must be implemented!
Key Elements of a QM Program

- Written Quality Manual including a QM Plan
- Implementation
- Data collection
- Analyze and evaluate data
- Identify opportunities for improvement
- Implement improved processes
- Evaluate improvements
- Communicate results
Where can you get ideas for improvement?

- Incident reports
- Internal assessments
- Institutional goals, vision, and mission
- Lean or Six Sigma processes
- Customer feedback
- Employee suggestions
- Utilization reports
Monitoring Quality Indicators

• Select indicators which monitor the quality of performance
  – Pre-analytic variables: specimen submission and handling
  – Analytic variables: diagnostic accuracy
  – Post-analytic variables: report adequacy and integrity

• UCLA Quality Indicators: Attachment pages 6-7
Acting on Quality Indicator Data

- identifying opportunities for improvement;
- implementing corrective action;
- performing a root cause analysis;
- developing a quality improvement strategy;
- modifying targets or action thresholds;
- reporting to interested parties; and
- deciding to continue monitoring or stop monitoring the indicator.
Quality System Internal Audits

- Audits should be formally planned and organized
- Target operations that have the highest risk for non-conformance and impact on patient care
- Tracer methodology audits

- QSE: Organization self assessment: Attachment pages 8-9
- NY Dept of Health tracer audit: Attachment 10-12
Management Review

- The QMS shall include a management review
  - Quality indicator data
  - Quality system audits
  - Proficiency testing failures
  - Non conformities including complaints
  - Results of improvement processes
  - External inspection reports
Management Review

• Are corrective actions implemented?
  – Are problems investigated?
  – Are potential solutions discussed/evaluated?
  – Are changes instituted?
  – Are changes evaluated for effectiveness?

• QMS review activities must be documented
Quality System Cycle

1) Define Quality Goals & Process Objectives

Establish Policies / Procedures

delegation

Responsible Person(s)

2) Review and Approval

Implementation

Responsible Person(s)

Monitors

Quality Improvement Initiatives

3) Outcomes Analysis

**Director Responsibilities**
Evaluating Your QM Program

1. Is the QM program comprehensive?
2. Is the plan implemented as written?
3. Is data analyzed?
4. Are corrective actions implemented?
5. How are improvements evaluated?
6. How and to whom are results communicated?
Laboratory Director’s Responsibilities (CLIA)

- The laboratory director is responsible for the overall operation and administration of the laboratory… and for assuring compliance with the applicable regulations (CLIA “88)

- 14 items: Attachment page 13
Lab Director’s Role in a QM Program

- Development
- Ensuring implementation
- Assessment and reassessment of activities
- Monitoring improvements
- Communication
- Ensuring integration with institution’s program
- Strategic and proactive guidance
QM Suggestions for the Laboratory Director

- Communicate importance of the QM program
- Lead by example
- Lead the QM meeting
- Communicate with staff regarding changes
- Encourage discussion of problems
- Discuss unusual cases, aberrant results, etc.
- Cover all shifts
  - Make rounds on evening and night shifts
Key Points for the Laboratory Director

• Focus on those items that are
  – Meaningful
  – Patient centered
  – Problematic
  – Risk reducing
  – Director driven
  – Reflective of a culture of quality

• Be visible
• Be involved
• Communicate
Summary

• The quality management plan is a living document and requires ongoing review and improvement
• Active involvement of the laboratory director in the QM program is key to providing quality patient care and ensuring patient safety
• Developing and following a strategic plan focused on quality and service helps ensure the improvement of patient care and should be a key component of the QM Program.
Resources

• College of American Pathologists
  – Quality Management in Anatomic Pathology (2005)
  – CAP Laboratory General Checklist (6.17.2010)

• Clinical and Laboratory Standards Institute
Pathology & Laboratory Medicine
Quality Manual

Located on the Pathology website at:
http://www.intrapathnet.medsch.ucla.edu/
  Hosp_Compliance/QManual.php
Thank you