Standardization in the Clinical Laboratory Setting

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Today's Topics

- Clinical laboratory standardization
- Quality management systems (QMS)
- Cost of quality
- Impediments of standardization
- Development process of standards

Goals

- Understand how standardized procedures reduce errors, reduce laboratory costs, and improve the quality of test results and patient care
- Understand the fundamentals of a QMS and the available resources to help establish a QMS
- Understand and identify possible impediments to the adoption and implementation of clinical laboratory standards
- Understand the development process for clinical laboratory standards and guidelines

Why Standards Matter

- Raise levels of quality, safety, reliability, efficiency, and interchangeability
- Lower trade barriers
- Act as a base for legislation (or avoid the need for legislation)
- Aid in technology transfer
- Provide easy access to best-in-class practices
- Deliver benefits at an economical cost

Questions to Consider

- **Why standardize health care?**
- **What tools are available to standardize health care?**

Problems Standardizing

- Process standardization in health care has been slow
- Major challenges to standardization
- Effect of no standardization

Implementation of Standardized Protocols

- Eliminates unnecessary complexity of care processes
- Improves efficiency and safety
- Allows for direct comparison and interpretation of results

Standardization Barriers

Why has wide-scale standardization in health care taken so long?

Benefits of Standardization in Health Care

- Clearly, there are significant benefits to standardization

Resources for Standardization

- **What is a good starting point to standardize processes and procedures?**
  - **ISO 15189:2012. *Medical laboratories – Requirements for quality and competence***
  - **ISO 17025:2005. *General requirements for the competence of testing and calibration laboratories***
  - **ISO 9001:2008. *Quality management systems – Requirements***
- **ISO documents specify the requirements**

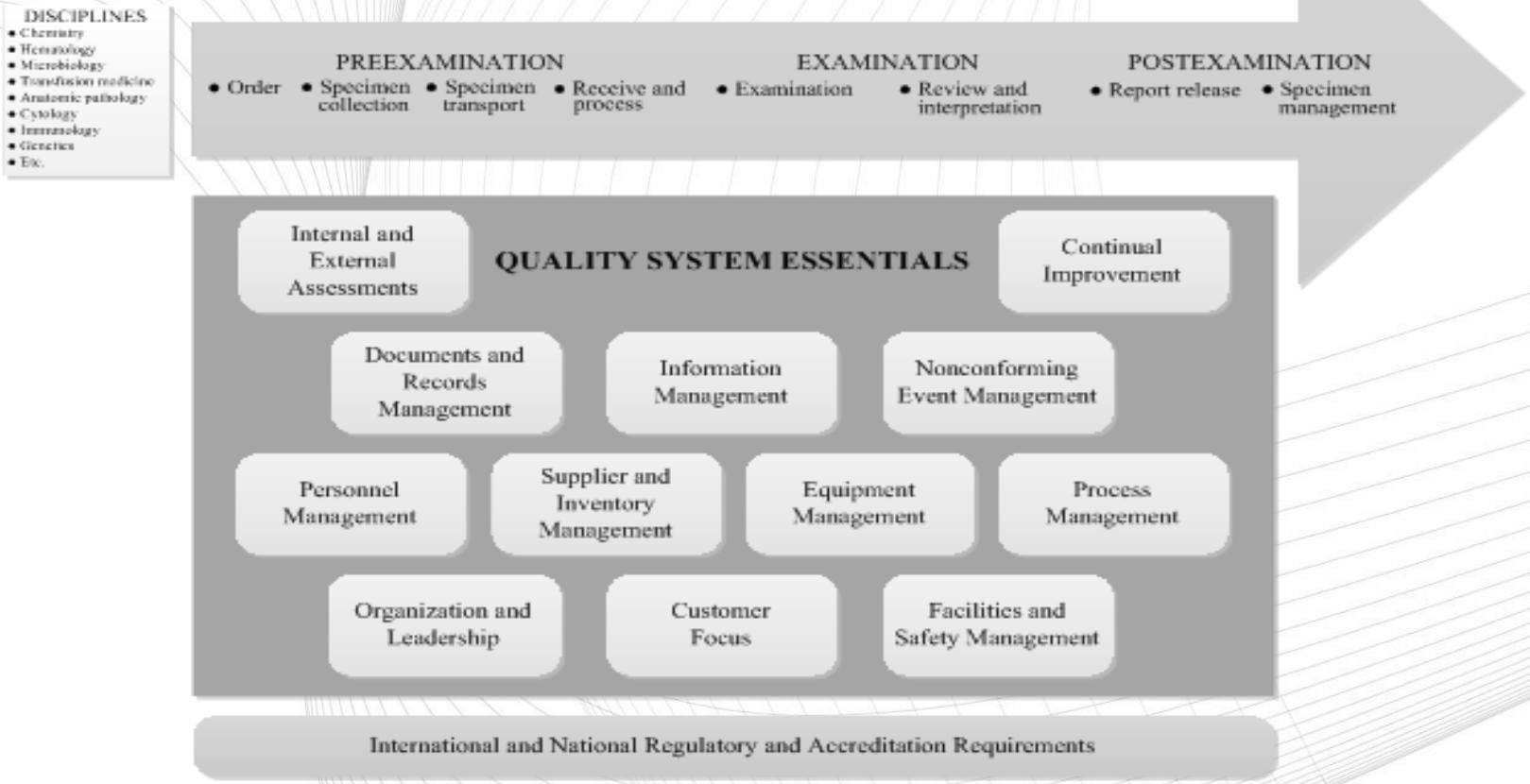
Resources for Standardization

- **Another resource to use**
  - **CLSI QMS01 – *Quality Management System: A Model for Laboratory Services*; Approved Guideline—Fourth Edition (2011)**

Quality Management System

- **What is a QMS?**
  - **From ISO 15189: management system to direct and control an organization with regard to quality (ISO 9000:2005 [3.2.3])**
  - **From CLSI QMS01: management system to direct and control an organization with regard to quality (ISO 9000 [3.2.3])**

QMS Framework: The CLSI Model



The Quality Hierarchy

Stage	Activities Performed
Total quality management	Management approach centered on sustained high quality, by focusing on long-term success through customer satisfaction
Quality cost management	Measurement system for the economic aspects of the "cost of quality"
Quality management system	**Systematic process-oriented approach to meeting quality objectives**
Quality assurance	Planned and systematic activities to provide confidence that an organization fulfills requirements for quality
Quality control	Operational process control techniques to fulfill quality requirements for regulatory compliance and accreditation

CLSI QSE Documents

- **CLSI has a published guideline for 10 of the 12 QSEs**
- **Documents for the QSEs Customer Focus and Information Management are in development**

The Cost of Quality

- How much money does your laboratory spend on supporting good quality?

- How much money does your laboratory spend on resolving problems and errors?

Quality Quote

“It’s cheaper to do the job right the first time than to recover from an error.”

– Philip Crosby

Determining the Cost of Quality

What is the cost of quality in *your* laboratory?

Fact

“…companies that adopt a cost of quality concept are successful in reducing failure cost and improving quality for customers.”

Schiffauerova A, Thompson V. A review of research on cost of quality models and best practices. *International Journal of Quality & Reliability Management.* 2006;23(4):674-679.

Premise

Laboratories are businesses; therefore, adopting a cost of quality concept will help reduce waste and improve quality to patients and customers.

What is a “Cost of Quality” Concept?

Costs connected with attaining the desired level of quality

Any costs expended when quality is not perfect

Types of Quality Costs

Prevention

Appraisal

Failure

- Internal Failure
- External Failure

Prevention Costs

- Quality planning
- Work process training
- Initial competence assessment
- Supplier capability
- Preventive maintenance
- Process validation or verification
- Quality management activities
  - QMS education
  - QMS implementation
  - Quality meetings
  - Quality projects

Appraisal Costs

- Surveying customers and users
- Conducting ongoing competence assessment
- Calibrating measuring equipment
- Conducting sample inspections:
  - Receipt
  - Examination
- Performing and reviewing quality control
- Participating in proficiency testing
- Measuring quality indicators
- Conducting internal audits
- Participating in external laboratory inspections and accreditations

Identifying Prevention and Appraisal Costs

Can you identify prevention and appraisal costs in your operating budget?

Failure Costs: Internal (Before Delivery)

- Sample problems in the preexamination phase
- Insufficient or expired reagents or supplies
- Rework, repair, retesting, reinspection
- Wasted blood and blood components
- Downtime
  - Computer
  - General unavailability of services

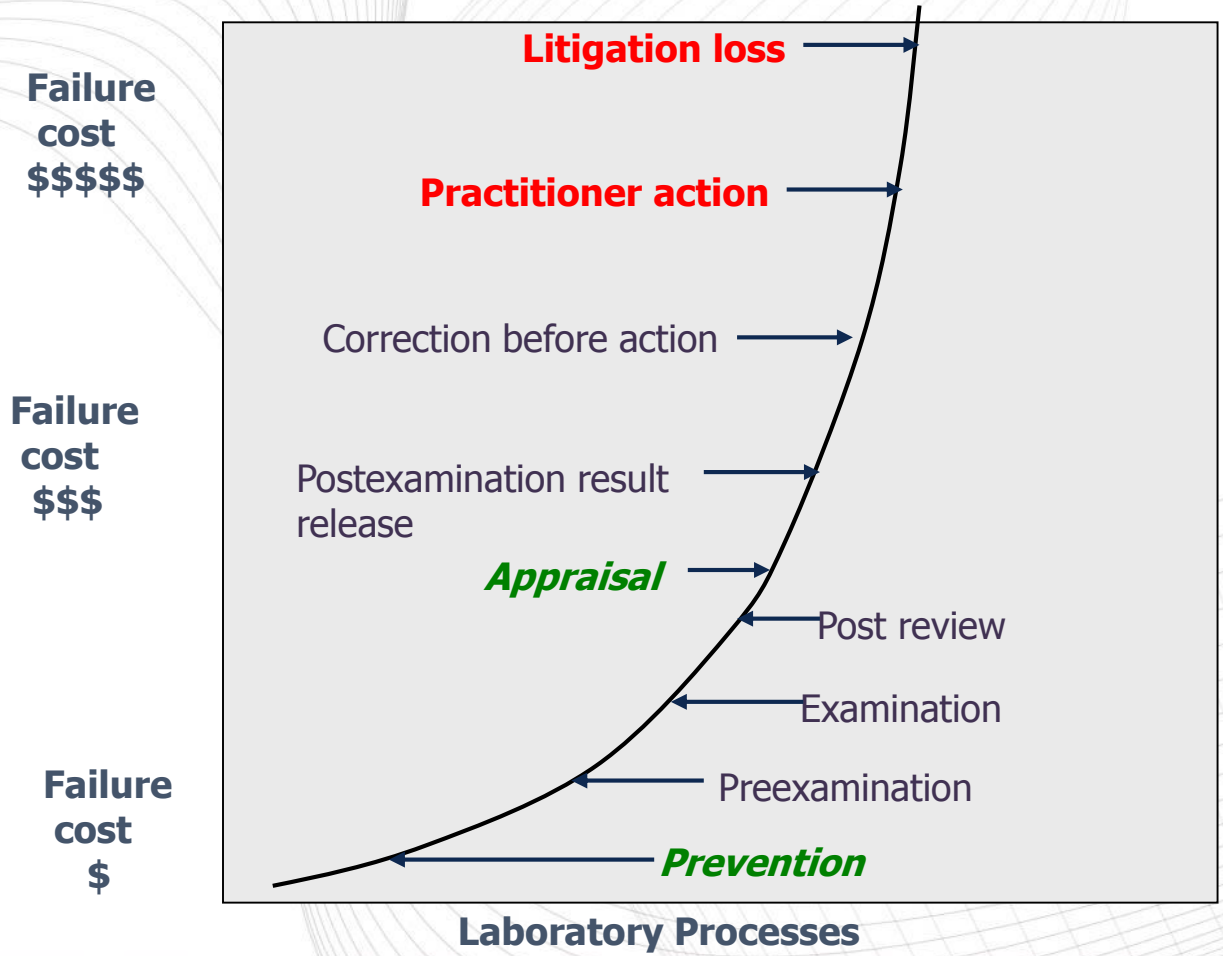
Failure Costs: External (After Customer Receipt)

- Lost reports
- Reporting errors
- Customer complaints
- Lost samples
- Misdiagnoses
- Lawsuits

Identifying Internal and External Failure Costs

Can you identify internal and external failure costs in your operating budget?

Failure Cost and Detection Point in Laboratory Processes



Berte LM. The cost of quality. In: Harmening DM, ed. *Laboratory Management: Principles and Processes.* 3rd ed. St. Petersburg, FL: D.H. Publishing & Consulting Inc., 2012:339-358; adapted for the laboratory from Wood DC, ed. *Principles of Quality Costs: Financial Measures for Strategic Implementation of Quality Management.* 4th ed. Milwaukee, WI: ASQ Quality Press; 2013. Reprinted with permission from D.H. Publishing & Consulting, Inc.

Why Cost of Quality?

- **Laboratories should measure the cost of quality for three important reasons:**
  - **Quantify the financial effects of process failures**
  - **Use failure cost data to identify and prioritize improvement efforts**
  - **Track progress of improvement initiatives**

Words of Wisdom

- For each failure there is a root cause
- Causes are preventable
- Prevention is *always* cheaper!

There is a greater risk in doing nothing than in trying something different.

Impediments to Adoption and Implementation of Standards

- CDC project – “Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics”
  - Used a modified Cabana model

Cabana MD, Rand CS, Pow NR, et al. Why don’t physicians follow clinical practice guidelines? A framework for improvement. *JAMA*. 1999;282(15):1458-1565.

What Did We Do?

- Surveys
- Focus groups
- Assessments
  - Development process
  - Laboratory practice guidelines

What We Learned

- **Survey and focus group results**
  - **Awareness of CLSI**
  - **Awareness of the specific publications**
  - **Contents**
  - **Communication**
  - **Price**
  - **Usability**

What We Learned

- **Development process assessment**
  - **Committee formation**
  - **Project idea generation and approval process**
  - **Document systematic review and revision process**

What We Learned

- **Laboratory practice guideline assessment**
  - **Reinforced several process change recommendations**
  - **More transparency is needed in creating laboratory practice guidelines**

The Standards Development Process

- Standards development process for ISO
  - PWI
  - NWIP
  - CD
  - DIS
  - FDIS
  - Publication

The Standards Development Process

- Standards development process for CLSI
  - Project proposal
  - Call for volunteers
  - Committee formation
  - Proposed Draft vote
  - Final Draft vote
  - Publication

Participation in Standards Development

- Participation in ISO
- Participation in CLSI

...so the truth about standards is...

- Standards are a part of your everyday life and enable:
  - Enhanced quality
  - Innovation
  - Process efficiency and design
  - Reduction of waste
  - Consumer confidence
  - Equity in commerce
  - Sustainability