Quality.

Yesterday. Today. Tomorrow.

*Where We’ve Been.*
*Where We Are.*
*Where Are We Going?*
• Key healthcare issues
  – Access to care
  – Quality of care
  – Controlling costs
  – Rapid information access/exchange
Physician
Mid-level clinician
Patient

Healthcare without the Doctor...

Cost
Convenience

Scott; 2009
Quality Buzzwords

- QC
- QA
- QMS
- Path of Workflow
- Continuum of care
- LEAN
- Six Sigma
- ISO
- TAT
<table>
<thead>
<tr>
<th>Year Period</th>
<th>Progression</th>
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<tbody>
<tr>
<td>1940’s-1960’s</td>
<td>Quality Control (QC)</td>
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<tr>
<td>1970’s</td>
<td>CAP Proficiency Testing program introduced</td>
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<tr>
<td>1980’s</td>
<td>Quality Assurance (QA) in healthcare advanced by JCAHO</td>
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<tr>
<td>1990’s</td>
<td>Quality systems introduced by FDA, AABB, NCCLS (CLSI) and ISO 9000</td>
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<tr>
<td>1999</td>
<td>National Quality Forum created</td>
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*Nevealaninen & Berte, 2000*
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2003</td>
<td>CLIA ’88 revised to include Quality Management System (QMS) guidelines</td>
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<tr>
<td>2004</td>
<td>Maryland General Hospital Scandal</td>
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<tr>
<td>2006</td>
<td>Un-announced inspections</td>
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<tr>
<td>2006</td>
<td>CAP launches ISO 15189 accreditation program</td>
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<tr>
<td>2010</td>
<td>FDA tightens standards for POCT</td>
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• 1999: Institute of Medicine (IOM) published report
• Medical errors = 8th leading cause of death in the US.
• Estimated 44,000 – 98,000 deaths each year due to preventable medical errors
• Raised the quality standards and expectations of healthcare providers, payors, and patients
• Subsequent follow-up reports by the IOM (2001 and 2003), have continued to make patient safety and the reduction of medical errors a key issue in healthcare.
To Err is Human

- Approximately 7 billion laboratory tests performed each year in the US
- Numerous opportunities for error
  - Specimen labeling
  - Specimen handling
  - Analytical
  - Reporting
- Patient safety initiatives and innovations just beginning to be implemented in laboratory industry
- AACC Patient Safety Group
  - Educational programs
  - Categorizing laboratory errors
  - Rule-based decision making built into LIS’
Other Patient Safety Reports

- Bell, McNaney, and Jones. *Improving health care through redesign.* 2006.
50/50 chance of proper healthcare

Elizabeth A. McGlynn, PhD, et. al.
Primary care
1.1 per 1000 visits
27% effect patient care

Nutting et. al. JAMA 275:8, 1996
Mis-identification of laboratory specimens:
> 160,000 adverse medical events each year

35% of high-severity transfusion medicine events and 25 deaths/year due to specimen labeling errors

Test order errors: 5% - 18% of all test orders
Impact of Errors on Patient Outcomes

24.4% of errors negatively impacted patient care

Inappropriate laboratory test repeats: 17%
Inappropriate laboratory investigations: 6%

Carraro & Plebani; 2007
JCAHO Patient Safety Goals

• 50 percent of Joint Commission standards are directly related to safety
  – medication use
  – infection control
  – surgery and anesthesia
  – Transfusions
  – restraint and seclusion
  – staffing and staff competence
  – fire safety
  – medical equipment
  – emergency management
  – security
• 2001: Additional patient safety standards
• 2003: Behavioral health care and long term care organizations
• 2004: Ambulatory care and home care organizations

http://www.jcaho.org/accredited+organizations/patient+safety/facts+about+patient+safety.htm
CLSI (NCCLS) Guidelines


JCAHO: Tracer Methodology

- Initiated end of 2004
- Traces a patient stay through-out the hospital
  - Point of entry through post-discharge
- “Focus less on paper, more on patients and patient experience”
- Follows a patient through the “continuum of care”

• First reported in 2004
• Inaccurate HIV and HCV results
• Initiated a GAO audit of lab inspection process
• Congressional hearings on lab safety
• CAP and its inspection processes came under heavy scrutiny
  – Initiated drastic changes to the inspection process
• JCAHO also criticized
• Reference Pathology Services of Maryland shut down to quality violations representing “immediate jeopardy”

- Project began in 2006
- Collaboration with the CDC to define laboratory measurement and reporting.
- Defined 6 preferred practices as national voluntary consensus standards to drive quality improvement efforts within the pre and post analytic phases of laboratory testing.
Laboratory Leadership

- Leaders of organizations that order tests and leaders of clinical laboratories should work together to ensure that specific expectations regarding communication to and from the laboratory are met.

Patient/Specimen Identification

- Standardized policies, processes, and systems should be implemented to ensure the accurate and legible labeling of laboratory specimens.

Sample Acceptability

- Collection and processing facilities should ensure that acceptable specimens are collected using appropriate techniques.
Test Order Accuracy

• Organizations should implement systems to ensure that all test orders are accurately communicated to laboratory staff in a timely manner.

Verbal Communication

• For verbal or telephonic reporting of critical test results, verify the tests results by having the person who is receiving the information record and read back the compete test result.

Critical Value/Result Reporting

• Communicate critical laboratory values/results to the individuals who require them and appropriately document them in a secure, confidential, accurate, and timely manner.
Leadership

- Encourage electronic communication
- Coordination of efforts to ensure communication of critical values
  - Investigation when the process fails
- Monitor verbal and electronic communication of results
Patient/Specimen Identification

- Verbal, self-identification of patients
- Use of at least 2 patient identifiers
  - Investigation when the process fails
- Specimen collection containers labeled at the time of collection and in the presence of the patient
- Safe labeling practices
- Sample rejection criteria for incomplete or inappropriately labeled specimens
Sample Acceptance

- SOP for specimen collection & processing
- Define maximum number of collection attempts
- SOP to address collection in specific patient populations
  - e.g. fingersticks, heel sticks
- Policies which reduce blood culture contamination
- Quality & appropriateness of the specimen determined before the patient leaves
Sample Acceptance

• Unacceptable specimens NOT TESTED
• Communication when specimens cannot be tested
• Specimen processing and transport consistent with producing quality results
• Track and monitor specimen collection failures
Test Order Accuracy

- Specific SOP’s for electronic, verbal, and telephone communication of test orders
- All non-written orders followed up with a written request
- Standard nomenclature
- SOP for add on’s which determines if the existing specimen is available and acceptable for testing
• International Standards Organization 15189:2007 is an internationally recognized laboratory accreditation standard.
  ➢ Originally proposed in 1994
  ➢ 1999 competency requirements for calibration labs
  ➢ 15189 published in 2003 and revised in 2007
• ISO 15189 specifies quality management systems and competencies unique to medical laboratories.
• Focus is on the quality management system and all of the elements that interact in all phases of testing.
• Outlines controls required to manage risks that impact lab quality.
• Provides tools to improve lab operations and customer service.
ISO 15189 Philosophy

- Continuous quality improvement.
- Issues represent opportunity for improvement.
- Staff at all levels are empowered to identify issues and participate in corrective action.
- Customer satisfaction is key.
- Job satisfaction is important.
- A safe clean lab is needed for quality.
Quality Systems Management

Pre-analytic → Analytic → Post-analytic
PATH OF WORKFLOW

QSEs
- Organization
- Personnel
- Equipment
- Purchasing & Inventory
- Process Control
- Documents & Records
- Information Management
- Occurrence Management
- Assessments
- Process Improvement
- Customer Service
- Facilities & Safety
ISO 15189: Patient-Centric

Clinician
- Test Awareness
- Requisition Completion
- Patient Preparation

Sample
- Collection
- Transportation
- Accession

Testing
- Preparation
- Equipment
- Reagents
- QC
- QA

Information
- Data Capture
- Data Interpretation
- Storage

Report
- Creation
- Routing
- Transport
- Storage

Patient
Our goal is to connect **policy** to **procedure** using **processes** which sustain the **Path of Workflow**.

These **actions** are supported by the **Quality System Essentials**
LEAN Principles

- **Value** is defined by the customer.
- Eliminate **Waste**
- Involve and **empower** employees
- **Continuous improvement**
The elements of production that do not add value.

- Overproduction: Producing too much, or producing too soon.
- Transportation: Any nonessential transport is waste.
- Inventory: Any more than the minimum to get the job done.
- Waiting: Waiting for an appointment, for signatures, for a printer that has a long queue.
- Processing: Over-processing, unnecessary steps, signatures, reviews.
- Motion: Any motion that does not add value, e.g. re-entering same information more than once.
- Intelect: Any failure to fully utilize the time and talents of people.

Persoon, Zaleski, and Freichs; 2006
Workplace Organization: 5 S

- Sort
- Set in Order
- Shine
- Standardize
- Sustain

Coons, TechSolve; 2009

http://www.laborequipment.com/uploadedImages/Markets/Lab_Safety/chart2_WEB_sm.jpg
• Procedures and work practices are defined and written to document the best practices as defined by the staff performing the work.
  – Not written to please a regulatory body.
Value Stream Mapping
LEAN: Continuous Improvement

1. Put the current process to the test every time you do a task.
2. Be thinking of a "better" way.
3. Put the "better way" to the test – experiment.
4. If it works, document it as the new process.
5. Begin using the new process as the current process.

The Eternal Round of Continuous Improvement
Today’s Quality Philosophy

Action Oriented Culture
“Healthcare must expand its view of quality beyond the departmentalized quality control and quality assurance activities of the last decades to keep pace with the growing role of total quality management in today’s competitive environment.”
Competitive Edge:

- Anticipation
- Action
- Communication
- Know your customer
- *Know thyself*
Use data to support quality and quality initiatives.

Use quality as a means to positively effect change in your laboratory.
What Does Quality Mean?

• Improving patient’s lives…………
  – Accurate results
  – Appropriate patient care
  – Excellent customer service
  – Employee satisfaction
  – Others??
Quality...... Why Do We Care?

- Professional obligation
- Promotes quality healthcare
- Competitive market demands
Quality CAREs

C Customer Service
A Action
R Results
E Enthusiasm

with
Progression of Quality

QA
Testing

QMS
Process

ISO
The Customer Experience
What face is behind that specimen?
What would Grandma say?
Quality Starts with YOU....

Get it started.

Pass it on.