How to Build the Quality Improvement Mindset and Sustained Effort into the Laboratory Organization

Bonnie Messinger
CPHQ, CMQ/OE (ASQ)
ARUP Laboratories, Inc.
“…appreciation of context is often the crux of improvement strategies.”


Emphasis on Patients

Mission

ARUP's mission is to continually improve patient care by building professional relationships through excellence in laboratory testing, service, education, and research.

Making the Best Better
Quality Indicators

The JCAHO 10-Step Process
1. Assign Responsibility
2. Delineate Scope
3. Identify Key Aspects of Care/Service
4. Identify Indicators
5. Set Thresholds
6. Monitor
7. Identify Improvement Opportunities
8. Take Action
9. Assess
10. Communicate

Responsibility

- Medical Director/Director is responsible for all aspects of the departmental indicator monitoring system
- Manager/Supervisor is responsible for oversight of all division/section quality monitoring activities
- Quality Specialist is responsible for division quality activities:
  - PT, audits, occurrence reporting, improvement support, QC, indicator monitoring, instrument validation, SOP’s.
Discover: What gets measured, improves!

• Anatomic Pathology and Oncology/Genetics
• Business Development
• Chemistry
• Quality & Compliance and Safety
• Human Resources and Institute for Learning
• R & D and Technology Transfer
• Immunology
• Strategic Services and Facilities
• Infectious Diseases
• Support Services
• Transfusion Services
• IT Systems
• University Healthcare Clinical Laboratory and Services

Identify Indicators

• Early Warning
  – Stat testing turn-around time
• Confirmatory
  – Bench-top cleaning log completion
• Critical Services
  – First attempt critical result notification success rate
• Critical Processes
  – Mislabeled specimens by patient care unit
• Latent Error
  – Number of understaffed shifts
• Human Behavior
  – Missed test orders by shift
• Compliance
  – Number of days between competency testing and major error
Examples of ARUP Indicators

**Structure Measures**
- Accreditation/ licensure issues
- Audits
- Correlation of results/ instruments
- Compliance with policy/ procedure
- Employee safety issues
- Hazardous waste minimization activities
- Instrument/ kit failures
- Performance appraisals
- Personnel competency
- Proficiency testing performance

**Process Measures**
- Accuracy/ clarity of laboratory reports
- Appropriateness of samples and labeling
- Appropriateness of transport conditions
- Critical value notification/ documentation
- Incident reports
- Test order accuracy
- Provision of adequate sample/clinical information
- Specimen handling accuracy
- Turn-around time

**Outcome Measures**
- Appropriateness of requests
- Client interaction/ consultation
- Clinical correlation
- Employee injuries/ safety issues
- Patient outcome
- Physician/ client feedback
- Lost samples
- Corrected reports
Set Thresholds

- Use current performance as a baseline and challenge the process.
- Use organizational goals.
- Establish criticality (may be 100% is only acceptable threshold).
- Use benchmarking, other organizations, literature, industry standards (Q-Probes).
- Use realistic targets.

Monitor

**Internal**
- Has the potential to affect product safety, potency and purity, but is caught and corrected before exiting the system.
- Deviation from standard, norm or established process that does not reach the client or patient.

**External**
- Testing not performed
- Result amended
- Reporting delayed
- Complaint
ARUP Quality Cycle

1. **Quality Indicator Monitoring**
2. **Quality Assurance Reporting**
3. **Project Implementation**

**WEEKLY REVIEW MEETING and DEPARTMENTAL QA MEETINGS**

- **Sentinel Event?**
- **Trend?**

**CQI Organization**

- **Root Cause/Failure Modes Analysis**
- **Quality Improvement/Project Team**

**Source, patient information, client information**
**Required billing adjustments**
**Requested follow-up**

**Discovery:**
Assigning only one tracking category for each occurrence report robs the organization of the incentive to fix all but the most obvious unsafe systems.

**Event #1**
- Story
- Dates
- Category
- Sub-category
- Outcome
- Root cause
- Severity rating
- Monitoring department
- Involved vendor
- Communication trail

**Event #2**
- Story
- Dates
- Category
- Sub-category
- Outcome
- Root cause
- Severity rating
- Monitoring department
- Involved vendor
- Communication trail

**Event #3**
- Story
- Dates
- Category
- Sub-category
- Outcome
- Root cause
- Severity rating
- Monitoring department
- Involved vendor
- Communication trail

**Summary of all discoveries and actions**
Mission
The mission of the Continuous Improvement Board (CIB) is to act as a facilitator to create an environment of quality teamwork at all levels of ARUP which continuously improves services and products we deliver to customers (both internal and external) and ultimately the patient.
Continuous Improvement Board

- Oversight committee for quality improvement activities
  - Uphold corporate quality philosophy
  - Train workforce members
  - Recognize efforts and reward success
  - Prioritize improvement projects
  - Form and mentor QIT’s
  - Support implementation
- Rotating membership ensured broad workforce engagement.

Discovery:
An Improvement Board should be composed of 90% committed members and 10% skeptics. With participation, the skeptics become committed.

CIB Working Teams

Discovery:
Throwing a carnival is unparalleled as an advertising strategy. Games, executive participation and popcorn are essential.

Education/Involvement
- Recognition
- Advertising
- Training
- Publications

Improvement Action
- QIT Request Approval
- Team Formation
- Team Tracking
A process that is failing or inefficient and is:

- Necessary for customer needs
- Critical for Operation
- Costing money because of poor quality
- Causing grief
- Continually exceeding thresholds
- Very complex
- Involving multiple departments

Discovery:
Formal improvement teams are resource intensive; choose wisely.
Scaling the team is more important than having broad representation.

Identify Improvement Opportunities

For identifying improvement opportunities, the Seven Basic Quality Tools are all you need.
Discovery:
The hardest part of improvement is implementing recommendations. Many implementations lead directly to another improvement opportunity.

Remedial Action
Corrective Action
Preventive Action
Implementation Teams
Documentation
Project Management

Assess
Internal Audits (Examples)
- Analytical Measurement
- Corrective Actions
- Equipment and Process Validation
- HIPAA Compliance
- Information Technology
- Labeling Accuracy
- Proficiency Testing
- Record Retention and Archiving
- Safety
- SOP’s and Document Control
- Specimen Trackability and Traceability
- QC and Preventive Maintenance
- Quality Program Effectiveness
- Training and Competency
**Communicate**

**Weekly**

**Agenda**

- Scheduled client visits and start-ups and client visit reports
- Compliments and successes, shared practices
- Discussion of significant issues from the previous week
- Client focus for selected clients or client groups
- Graphical displays of data trends
  - Performance over time for outcomes (misplaced samples, amended reports and significant issues)
  - A 10-week moving window for selected processes
  - Client trends

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**Monthly**

**Communicate**

Monthly data is reviewed in Section

**Monthly QA Meetings**

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**Communicate**

Monthly data is reviewed in Section

**Monthly QA Meetings**

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**Communicate**

Monthly data is reviewed in Section

**Monthly QA Meetings**
Communicate

Quarterly

Lost Specimens per Million Billed Units

Track Exception Handling
Specimen Processing
ASM Storage
Technical Section
In Transit
Unknown/Not Documented
Vendor Laboratory
Staging Area

Month B
Month A

Lost Specimens per Million Billed Units

Specimen Processing Errors

- Sample Mislabeled by Name
- Clinical Information Not Forwarded to the Testing Section
- Sample Mislabeled by Test
- Required Sample Temperature Not Maintained
- Sample Mislabeled by Date/Time
- Sample Mislabeled by Type
- Specimen Not pH'd During Processing
- Sample Mislabeled by Order Number

Type of Defect Count

- 0.0%
- 10.0%
- 20.0%
- 30.0%
- 40.0%
- 50.0%
- 60.0%
- 70.0%
- 80.0%
- 90.0%
- 100.0%

Annually

Communicate

Indicator Effectiveness Counts

<table>
<thead>
<tr>
<th>Number of indicators where monitoring was...</th>
<th>Improve Care</th>
<th>Measure Quality</th>
<th>Measure Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most Effective</td>
<td>452</td>
<td>428</td>
<td>298</td>
</tr>
<tr>
<td>Somewhat Effective</td>
<td>269</td>
<td>267</td>
<td>189</td>
</tr>
<tr>
<td>Not Effective</td>
<td>83</td>
<td>67</td>
<td>71</td>
</tr>
<tr>
<td>Not Applicable</td>
<td>16</td>
<td>21</td>
<td>222</td>
</tr>
</tbody>
</table>
Communicate with Customers

Discovery:
Transparency promotes collaboration and sharing.
Pairing the ARUP QA report with the client Exception report provides a clearer picture of quality than one or the other alone would provide.

Emphasis on Relationships

Through excellence in laboratory testing, service, education and research, ARUP’s mission is to continually improve patient care and support the mission of the University of Utah.

ARUP’s vision is to be the reference laboratory of choice for community health care systems, as the most responsive source of quality information and knowledge.
Discovery:
No single quality model or method will suffice over time to address the quality needs of a growing organization.

- 7 Basic Quality Tools
- 7 Management Quality Tools
- Automation
- Process Simulation
- Error-proofing/Innovation
- Lean
- Six Sigma
- Agile

Automation

ARUP’s automation initiative develops, implements and integrates systems, instruments and applications.

- Expert Specimen Processing
- Image Management
- Automated Core Laboratory testing platform
- Track delivery
- Automated Specimen Management
- Automated Endocrinology testing platform
- Shipment Tracking
- Thawing and Mixing Work Cell
Total Quality Management

Employee Break Room Improvement
Implemented immediately
• Ice machine
• A promise of continued improvement tied to financial success
Implemented in 1 year
• Larger vending machines with better selections
• Modular tables and chairs to save space
Implemented in 5 years
• Area for personal telephone calls
• Private area for nursing mothers
• Separate meeting rooms
• Recycling
Implemented in 10 years
• Improved ambience
• Cafeteria with subsidized meal options

Fault Tree Analysis

Identification Error Risk
• Assess event risk
• Assess cumulative risk

Denominator: Number of ARUP Draws…..Sept: 20638
Causal Tree

IT Communication
Response to a highly complex event
• The time sequence of the events was not linear.
• The communication requirements were complex.
• Each player was choosing downstream actions based on incomplete upstream information

Failure Modes and Effects Analysis
Misplaced Samples
• Revised the standard search checklist for all departments to include all possible locations for samples to “disappear” at each step in the sample delivery and storage process.
• New checklist approved and adopted October 2005.
Lean
Special Chemistry Work Area Redesign

• 31% reduction in distance traveled per test
• Gained 100 sq-ft bench space
• Reduced overall lab size by 10%
• Gained 17% lab bench top
• Increased workstations to add 3-5 FTE
• Created space for a larger capacity piece of equipment

Process Simulation
Meconium Sample Preparation Process

Process simulation VSM showed that travel time and non-standard work processes lengthened processing time.

• Redesigned the work area to improve efficiency and minimize travel time.
• Standardized steps to a best practice model.
• Changed to an alternate platform, eliminating labor intensive and lengthy sample preparation steps.
• Improved sensitivity with the new platform.
Six Sigma  
Gram Stain Turn-around Time Study

Time from Collect to In Lab

Process changed to schedule additional deliveries on nights and weekends

One-page Project Manager

Department Set-up Process

- Scope
- Business Model
- Objectives, Mission, Goals
- Budget
- Policies, Processes and Procedures
- Forms and Templates
- Evaluation and Monitoring Criteria
- Audits
- Risk Assessments
- Staff and Resources
Agile Software Development

Phase I: Replace DOS-based product (complete)
Phase II: Accessioning in the field (complete)
Phase III: Pre-accessioning in the field for interface clients
  Three sprints completed
Phase IV: Web-based System 2000

System 2000™ Phase III

Sprint Burn-Down Chart - System 2000 Sprint 3 - 7.13
"Test Order Cancels"

0 10 20 30 40 50 60 70 80 90 100
Work Left To Do (hours)

Dates

e-Solutions

ARUP Consult™

Laboratory test selection support tool:
  • lab tests categorized into disease-related topics
  • clinical background information, test ordering suggestions, and concise diagnostic advice
  • direct links to relevant references
  • algorithms to support clinical decision-making
  • available in both Web and PDA formats
Discovery:
Most organizations operate from an internalized Quality Plan. That was the case with ARUP. Putting the Plan in writing wasn’t so daunting as we imagined.

Quality Systems
• Organization
• Staff & Resources
• Equipment & Supplies
• Purchasing & Inventory
• Contract Management
• Product Development
• Process Control
• Documents & Records
• Information Management
• Occurrence Management
• Assessments & Compliance
• Process Improvement
• Service and Satisfaction
• Facilities and Safety

Emphasis on the Relationship Between Customers and Employees

ARUP’s Five Pillars
• To Provide Excellent Patient Care by Supporting Clients
• To Create a Good Working Environment
• To Do the Right Thing
• To Improve Continuously
• To Act Responsibly
Emphasis on Context

Basic principles
- Simple rules; cultural norms
- Executives as role models

Holistic quality
- Embracing who we are
- Planning for who we will be

Collegial relationships
- Patients, practitioners, suppliers and the community as partners

Organizational learning
- Mistakes as opportunities
- Workforce open to growth

Empowered Teams
- Characterized by accountability
- Driven by front line champions

“Management systems that conform to a rigid and complex “quality” blueprint in the hope of rubber-stamping success will fail.

The successful strategy is one that creates a unique culture of quality that has the ingenuity and intelligence to continually evolve.”
Needs of the organization evolved beyond those provided by the early organizational structure.

- Continuity
- Agility
- Responsiveness
- Ready and dedicated resources
- Feasibility analyses
- Tracking
- Implementation
- Communication

Discovery:

Quality is a systems property in that it is:

- Evolutionary
- Adaptable
- Embedded
- Emergent and
- Inherently ordered
Wedges are strategic priorities
Rings are stages in the improvement process
Tags are activities
- Name and ID Number
- Description
- Contact information
- Color-coded priority
- Beneficiary
Communication – the 10th Step

Discovery:
Communication is the thread that ties all the players together; it ties quality to culture and primes the organization for success.

With employees
With the end user—patients, clients, caregivers, payors
With vendors and suppliers
With peers

About successes
About challenges
About discoveries
Even about heartbreaks

And finally, back to context…

“Usually improvement cannot be accomplished or sustained without giving the messy business of social interactions, communication, power and organizational context its due.”

—Stephen R. Covey