Quality Management for the Medical Laboratory

Michael Noble MD FRCPC
Chair – Program Office for Laboratory Quality Management
Medical Director for Quality – LifeLabs BC
Books Worth Reading

• The Deming Method by M. Walton (1986)
• ISO 9001:2000 Essentials – CSA
• ISO 15189:2003 Essentials – CSA
• CLSI HS1- A Quality Management System Model for Health Care
• CLSI GP26:A3 - Application of a Quality Management System Model for Laboratory Services
Seventy percent of clinical medicine decision making is predicated upon, or confirmed by, or documented by medical laboratory test results.

Dighe, A. S., Medicolegal liability in laboratory medicine, Semin Diagn Pathol, 2007
Quality Management is not new

1922 - Walter Shewhart

Western Electric
Bell Telephone Laboratories
Statistical Process Control
1940 - J Edwards Deming - The Fourteen Points

1. Create **constancy of purpose** of product and service
2. Adopt a new philosophy (**mistakes are unacceptable**)
3. Cease dependence on mass inspection
4. Stop the process of awarding business on price alone.
5. **Improve constantly and forever** the production and service
6. Institute **training**
7. Institute **leadership**
8. Drive out **fear**
9. **Break down barriers** between staff areas.
10. Eliminate slogans and targets
11. Eliminate numerical quotas
12. Remove barriers to pride in workmanship
13. **Institute vigorous education and retraining**
14. **Take action to accomplish the transformation**
J Edwards Demining – The seven *deadly* diseases

1. Lack of constancy of purpose
2. Emphasis on short term profits
3. Evaluation by performance
4. Mobility of Management
5. Running a company on visible figures alone.
6. Excessive medical costs.
7. Excessive costs or warranty.
Philip Crosby
1926-2001
Doing it right the first time

THE FOUR ABSOLUTES
• Quality is conformance to requirements
• The system of Quality is prevention.
• The performance standard is zero defects
• The measurement of quality is the price of non-conformity.
Standards Development

BSI

ISO

ISO 9000
ISO 17025
ISO 15189

CDC
CLSI
WHO

THE WORLD

US Military

ABCA

NATO

Deming

Shewhart
The Quality Toolbox

- Surveys
- Six Sigma
- Lean
- Metrics
- RISK FMEA

The Quality Toolbox
Tools in the Toolbox

• Mega-Tools
  – Lean
  – Six Sigma
  – Priority Matrices and Risk Assessment

• Tools/Techniques
  – Balanced Scorecards
  – Brainstorming
  – Control Charting
  – Flow Charting
  – Quality Indicators
  – Surveys
A really good, inexpensive reference book
Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality: Proposed Guideline

**PLEASE**

This proposed document is published for wide and thorough review in the new, accelerated Clinical and Laboratory Standards Institute (CLSI) consensus-review process. The document will undergo concurrent consensus review, Board review, and delegate voting (in candidate for advancement) for 60 days.

Please send your comments on scope, approach, and technical and editorial content to CLSI.

**COMMENT**

This document provides guidance on development of quality indicators and their use in the medical laboratory.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.
Quality Indicators are Metrics (measured process information)

- Determine quality of services.
- Highlight potential quality concerns,
- Identify areas that need further study and investigation, and
- Track changes over time.
Metrics

- **Quality Indicators**
  - Count tests
  - Counting process time
  - Counting errors
  - Counting defects
  - Counting OFIs
  - Test Scores

- **Quality Control**
  - Temperature
  - pH
  - Concentration
  - Weight
  - Reaction time
  - Fluorescence
  - Colony Count
Assessing Quality Indicators

- Importance
- Scientific Acceptability
- Feasibility
- Usefulness

Potential for Improvement
Reliability and Validity
Implementation and cost
Comprehensive

Having Quality Quality Indicators
1. Diabetes monitoring (system)
2. Hyperlipidemia screening (system)

- Test Order Accuracy and Appropriateness (pre-analytic)
- Patient Identification (pre-analytic)
- Adequacy and Accuracy of Specimen Information (pre-analytic)
- Blood Culture Contamination (pre-analytic)
- Accuracy of point-of-care testing (analytic)
- Cervical cytology/biopsy correlation (analytic)
- Critical Values Reporting (post-analytic)
- Turnaround time (post-analytic)
- Clinician satisfaction (post-analytic)
- Clinician follow-up (post-analytic)
CLMA Survey
Pre-examination Phase Indicator List

- Ordered test is appropriate for patient care
- Patient consent appropriately collected
- Test utilization by clinician for best patient care
- Physician written order with every specimen
- Cost/benefit assessment for laboratory test menu
- Patient identification and its accuracy

- Preparation of patient for specimen collection
- Appropriate specimen container
- Timing of specimen collection
- Phlebotomy success
- Specimen integrity
- Specimen quantity
- Specimen transportation
- Accuracy of specimen identification
- Condition for specimen storage
CLMA Survey
Examination Phase Indicator List

- Quality Control
- EQA-external quality assessment
- Time to first result availability
- Specimen contamination

- Laboratory injuries or accidents
- Competency of testing personnel
- Vacancy of technical staff
<table>
<thead>
<tr>
<th>CLMA Survey</th>
<th>Post-examination Phase Indicator List</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Result reporting accuracy</td>
<td></td>
</tr>
<tr>
<td>• Adequacy of information</td>
<td></td>
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<tr>
<td>for interpretation of</td>
<td></td>
</tr>
<tr>
<td>laboratory tests</td>
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<tr>
<td>• Report delivery</td>
<td></td>
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<tr>
<td>turnaround time</td>
<td></td>
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<tr>
<td>• Consistency of critical</td>
<td></td>
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<tr>
<td>values reporting</td>
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</table>

|                                      |                                      |
| • Result interpretation             |                                      |
|   by physician                      |                                      |
| • Patient’s satisfaction            |                                      |
|   with laboratory services         |                                      |
| • Patient’s satisfaction            |                                      |
|   specifically with phlebotomy     |                                      |
|   services                         |                                      |
| • Physician’s satisfaction          |                                      |
|   with laboratory services         |                                      |
Seven Steps to Successful Indicators

Do not start data collection until these are addressed

1. **Objective**
2. **Methodology**
3. **Limits**
4. **Interpretation**
5. **Limitations**
6. **Presentation**
7. **Action plan**
Developing Indicators

<table>
<thead>
<tr>
<th>Objective</th>
<th>What are you trying to measure?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. Why am I collecting this information? Be specific</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Methodology</th>
<th>How to capture the data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. What data needs to be captured</td>
</tr>
<tr>
<td></td>
<td>2. Who (or what) to capture the data</td>
</tr>
<tr>
<td></td>
<td>3. How often to capture the data</td>
</tr>
<tr>
<td></td>
<td>4. Is it achievable (time, resources, revenue)?</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Limits</th>
<th>Can I preset levels for:</th>
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<tbody>
<tr>
<td></td>
<td>1. Acceptable, Concern, Unacceptable, Critical</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Presentation</th>
<th>Graphic or Text</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Interpretation</th>
<th>1. What does it mean?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Does it reflect on YOUR quality?</td>
</tr>
<tr>
<td></td>
<td>3. Can I compare it?</td>
</tr>
<tr>
<td></td>
<td>4. Can I trend it?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Limitations</th>
<th>1. Unintended variables</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. What does it not mean?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Action Plan</th>
<th>1. What will I do if it indicates acceptable performance?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. What will I do if it does not?</td>
</tr>
</tbody>
</table>
Quality Indicator Worksheet

OBJECTIVES:
Monitor physician overall satisfaction with interpretations provided on urine culture reports

METHODOLOGY:
An electronic survey has been developed and circulated to 100 randomly selected physicians receiving an interpreted urine culture report each month for 6 consecutive months. Physician identified by billing number. No physician more than 1 survey per month. Satisfaction question is scaled between 1 (low) and 5 (high). Mean score on responses is followed.

QL GRAPHIC

PRESET LIMITS
Mean threshold of 4 is considered as acceptable. Mean score monthly of 3.5 or lower indicates possible opportunity for improvement.

INTERPRETATION
Five months study suggests that random group with some concerns with interpreted reports.

LIMITATIONS ON INTERPRETIONS
Likert scale is arbitrary, may incorporate unintended bias.

ACTION PLAN FOR VARIOUS OUTCOMES AND INTERPRETATIONS.
If 3 or more months show consistent scores of 3.5 or less, consider focus group to examine value of interpreted reports to physician client group.
Consider repeat study in 12 months time.
Setting Relevant Limits and Ranges

- Set Objectively
- Validate by Study
- Clinical Relevancy
- Customer Expectation
- Matched Benchmarks
- Regulation
Some Easy Targets

- Patient identification and its accuracy
- Specimen container
- Specimen quantity
- Time to first result availability
- Report delivery turnaround time
- Critical values reporting
Tougher Fruit

- Patient consent appropriately collected
- Physician written order with every specimen
- Laboratory injuries or accidents
- Competency of testing personnel
- Result interpretation by physician
Many organizations spend thousands of hours collecting and interpreting data. However many of these hours are nothing more than wasted time because they analyze the wrong measurements, leading to inaccurate decision making.

– Mark Graham Brown.
Wasting Time and Energy

*Indicators that you can’t*

- Measure regularly
- Interpret
- Complete
- Change
  - Out of your control
  - Too many variables
The Secret to setting up Quality Indicators

ONLY MEASURE WHAT YOU CAN MEASURE.

ONLY MEASURE WHAT YOU CAN CHANGE.

MAKE MEASUREMENTS BEFORE YOU MAKE CHANGES.
in summary…
Developing Quality Indicators

• WRITE IT DOWN
  – What exactly do you want to measure?
  – How exactly do you want to measure?
  – What exactly are you going to do with the information?
  – Do what you can do. Don’t bother with the rest, yet…
Use an indicator only as long as it provides you with useful information.

Don’t get tied to your indicators.
Caution about patient outcome indicators

Theoretically, outcomes best assess quality, but they are the most difficult to measure

- too many variables and confusers
  - Age, underlying conditions, therapy, circumstance
- require high volumes of detailed data
- Need long collection periods.

David Hsia
Medicare Quality Improvement
Bad Apples or Bad Systems?
FACT:

Quality Indicators, Done Well, Will Consume More Time Than You Have

Don’t be an Indicators Glutton

- Set Priority
- Set Limits
- Drop Non-Productive Activity
- Target: 10-12
Engage the folks who do the work, because they know what they do!
Taiichi Ohno

- **1950: Head of Toyota Motor Products Visits the US to study Industrial Success**
  - *What he learns*
    - **Ford Motor Company**
      - Excessive inventory
      - Workload was excessive and uneven
    - **Piggly Wiggly Foods**
      - Reordering and restocking inventory when needed
      - Just in Time ordering.
  - *What he does*
    - **Design the Toyota Production System**
      - Remove overburden (muri)
      - Remove inconsistency (mura)
      - Eliminate waste (muda).
• **The right process will produce the right results**
  – *Build a culture of stopping to fix problems, to get quality right the first time*
  – *Standardized tasks are the foundation for continuous improvement and employee empowerment*
  – *Use only reliable, thoroughly tested technology that serves your people and processes.*

• **Add value to the organization by developing your people and partners**
  – Grow leaders who thoroughly understand the work, live the philosophy, and teach it to others.
  – Develop exceptional people and teams who follow your company's philosophy.
  – *Respect your extended network of partners and suppliers by challenging them and helping them improve.*

• **Continuously solving root problems drives organizational learning**
  – Go and see for yourself to thoroughly understand the situation.
  – Make decisions slowly by consensus, thoroughly considering all options; implement decisions rapidly;
  – *Become a learning organization through relentless reflection and continuous improvement.*
## TPS (LEAN) JARGON

<table>
<thead>
<tr>
<th>Muri, Mura, Muda</th>
<th>Overburden, Inconsistency, Waste</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seiri, Seiton, Seiso, Seiketsu, Shitsuke (Five S)</td>
<td>Sort, Straighten, Shine, Standardize, Sustain</td>
</tr>
<tr>
<td></td>
<td>Keep what you need; throw out the rest.</td>
</tr>
<tr>
<td></td>
<td>A place for everything and everything in its place.</td>
</tr>
<tr>
<td></td>
<td>Keep your workplace neat and clean.</td>
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<tr>
<td></td>
<td>Keep work practices consistent</td>
</tr>
<tr>
<td></td>
<td>Maintain and review your standards</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Value Streams</th>
<th>Tracing the Work Flow: Maximize Value – Eliminate waste</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kanban</td>
<td>“Pull” performance – Piggly Wiggly Performance</td>
</tr>
<tr>
<td>Kaizen</td>
<td>Reflection and Continuous Improvement</td>
</tr>
<tr>
<td>Poka Yoke</td>
<td>Error Proofing</td>
</tr>
<tr>
<td>Gemba</td>
<td>Go and See</td>
</tr>
</tbody>
</table>
Value Streams

Activity transforms - waiting is waste
Activity flows through pools of waste
Customers value active transformation and abhor waste
Value streaming:
IDENTIFYING PROCESS WASTE

- COLLECTION
  - ACCESS
  - AVAILABILITY
  - COMPETANCY

- INVENTORY PROCESS
  - MONITORING
  - AVAILABILITY
  - ORDER
  - DELIVER

- CHECKING PROCESS
  - VERIFICATION
  - VALIDATION

- TRANSPORT
  - ACCESS
  - AVAILABILITY
  - ACTIVITY
  - ACCURACY

- TESTING PROCESS
  - PERSONNEL
  - EQUIPMENT
  - WORKSPACE
  - ENVIROMENT

- INTERPRETATION PROCESS
  - CLINICAL
  - RELEVANCY
Process Mapping
Pre-Examination Procedures

**Physician**
- See patient
- Go to station
- Find chart
- Find order page
- Write order
- Flag chart
- Put in right pile
- Check order
- Transcribe order
- Contact lab

**Phlebotomists**
- Phlebotomist leaves
- Phlebotomist goes to ward
- Check room
- Find patient
- Check armband
- Check order
- Check requisition
- Check tubes
- Draw blood
- Check tubes
- Sign off requisition
- Time punch requisition
- Package Tubes
- Transport tubes

**Accessioning**
- Sample checked in
- Requisition time punched
- Sample unpackaged
- Tubes confirmed
- Tube numbers created
- Tubes number labeled
- Tube tops removed
- Centrifugation
- Aloquoting
IDENTIFYING WASTE IN LABORATORY TESTING

- WAITING for a test order
- WAITING for a requisition
- WAITING to collect a sample
- WAITING to transport a sample
- WAITING to accession a sample
- WAITING to start processing a sample
- MOVING to collect reagents at a distant location
- MOVING from one work station to another
- SEARCHING for an instrument or material essential for processing a sample
- WAITING to complete processing a sample
- WAITING to create a report
- CREATING an excessive report
- CREATING an non-interpretable report
- WAITING to transport a report
- WAITING for a report to be read
- WAITING for report-generated action
- WAITING to contact a report recipient
Reducing WASTE in the Medical Laboratory

- At-source Order Entry
- No-wait transport.
- Condensed workspace
- Structured workspace
- Continuous flow processing
- Automated Reporting
- Auto-released reporting
- Auto-interpreted reporting
Reducing WASTE in the Medical Laboratory

• At-source Order Entry
• No-wait transport.
• Condensed workspace
• Structured workspace
• Continuous flow processing
• Automated Reporting
• Auto-released reporting
• Auto-interpreted reporting
Reducing WASTE in the Medical Laboratory

- Faster data entry
- Faster transport
- Reduced motion
- Faster report release
- Less tech time

- More entry error
- More transport cost
- More inflexibility
- Less personal report
- More I.T. time
Eliminating waiting time: LEAN’s Kanban trigger system

• A “Piggly Wiggly” notification system that once activated triggers a response to start another process going.
  – Inventory management trigger alerts in advance when you will run out of materials. Time to order more.
  – In parasitology or other microscopic analysis, when unread slides start to build, have alternate plan to address overload.
Poka Yoke: Error Proofing

• Placing workable limits that prevent an action from going wrong.
• In mechanical systems, it means adding design features that allow two units to only work in one position.
• An example in ECG testing
ECG Poka Yoke

R Arm
L. Arm
Foot
Chest

Limb Lead Reversal
POKA YOKE reduces ECG Errors

RED RIBBON
RIGHT SIDE
RIGHT ARM
RIGHT WAY
Poka Yoke in the laboratory is **not** always successful

- **Reliable**
  - Safety needles

- **Not always reliable**
  - Bar Readers
  - Fill-line monitoring
  - Sharps Containers
  - Required Computer fields
Poka Yoke in the laboratory is not always successful

- Reliable
  - Safety needles
- Not always reliable
  - Bar Readers
  - Fill-line monitoring
  - Sharps Containers
  - Required Computer fields
Six Sigma: Quantitative Continual Improvement
Quality Management

- Organization & Management
- Facilities
- Personnel
- Documentation & Control
- Technical
- Assessment
- Continual Improvement
- Customer Satisfaction
A March through Quality History

BSI

ISO

ISO 9000
ISO 17025
ISO 15189

CDC

CLSI

NATO

ABCA

US Military

Deming

Shewhart
Galvin Manufacturing to Motorola

Motorola Inc.

GALVIN MFG.

Radio

Battery Eliminator

Television

Computer Parts

Cellular Telephones
Galvin Manufacturing to Motorola

Bill Smith – Senior Quality Assurance
Robert Galvin - CEO

1986
Six Sigma
Continual Improvement

Cellular Telephones
Computer Parts
Television
Radio
Battery Eliminator

Motorola
Six Sigma Cycle of Improvement

- **DMAIC**
  - **Define** process improvement goals that are *consistent* with customer demands and the enterprise strategy.
  - **Measure** key aspects of the current process and collect relevant data.
  - **Analyze** the data to verify cause-and-effect relationships. Determine what the relationships are, and attempt to ensure that all factors have been considered.
  - **Improve** or optimize the process based upon data analysis using techniques like Design of experiments.
  - **Control** to ensure that any deviations from target are corrected before they result in defects. Set up pilot runs to establish process capability, move on to production, set up control mechanisms and continuously monitor the process.
## Comparing Cycles

<table>
<thead>
<tr>
<th></th>
<th>PLAN</th>
<th>MEASURE</th>
<th>DO</th>
<th>CHECK</th>
<th>ACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shewhart</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Six Sigma</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
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</table>
## Definitions

<table>
<thead>
<tr>
<th>Role</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td><strong>Champion</strong></td>
<td>The Six Sigma Boss, assigns and is responsible for all projects.</td>
</tr>
<tr>
<td><strong>Master Black</strong></td>
<td>Hands on expert, mentors Black Belts and below.</td>
</tr>
<tr>
<td><strong>Black</strong></td>
<td>4-8 weeks of training, full-time team leader, lead at least 1 major project to completion</td>
</tr>
<tr>
<td><strong>Green</strong></td>
<td>2-4 weeks of training, part-time practitioner, implements 2-3 projects per year</td>
</tr>
<tr>
<td><strong>Yellow</strong></td>
<td>1 week of training, participates in a number of projects per year</td>
</tr>
</tbody>
</table>
Who Makes a Green Belt a Green Belt?

• The Company
• The Company can hire a Six Sigma company
• In industry Sigma Belts have:
  – Caché
  – Credibility
  – Ties to income
Six Sigma
Calculations

\[ f(x) = \frac{1}{\sigma \sqrt{2\pi}} e^{-\frac{x^2}{2\sigma^2}} \]
<table>
<thead>
<tr>
<th>Sigma</th>
<th>Defects per Million Operations (DPMO)</th>
<th>Efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>691,500</td>
<td>30.85</td>
</tr>
<tr>
<td>2</td>
<td>308,500</td>
<td>69.15</td>
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<tr>
<td>3</td>
<td>66,800</td>
<td>93.32</td>
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<tr>
<td>3.5</td>
<td>22,750</td>
<td>97.73</td>
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<tr>
<td>4</td>
<td>6,210</td>
<td>99.38</td>
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<tr>
<td>4.5</td>
<td>1,350</td>
<td>99.87</td>
</tr>
<tr>
<td>5</td>
<td>233</td>
<td>99.977</td>
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<tr>
<td>6</td>
<td>3.4</td>
<td>99.966</td>
</tr>
<tr>
<td>Sigma</td>
<td>Defects per Million Operations (DPMO)</td>
<td>Efficiency</td>
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</table>
What is improvement

• As DPMO goes down, Sigma goes up
• Operational goals should apply
  – What is desirable?
  – What is achievable?
  – What is affordable?
• A 1.5 short term Sigma Shift approximates an achievable long term expectation.
What Does Six Sigma Contribute?

• A reiteration of Shewhart and Deming for project oriented continual improvement.

• A structured method for continual improvement.

• A structured mathematical model for enumerating error and improvement.
And in summary…

- Quality Management is an active process.
- Quality Management is framed on a Quality System.
- Quality Management activities are improved by using the Quality ToolBox.
In conclusion:

• Medical laboratories have a requirement and an expectation for quality.
• Medical laboratories have a network of quality partners with whom to interact.
• Medical laboratories have a history of quality management from other sectors from whom they can learn.
• Medical laboratories have an international standard upon which they can base their quality management.
Every Laboratorian has a responsibility and an obligation to be informed about quality and its management.