


How Do You Know How Well You're Doing?

(Quality Indicators for Measuring Laboratory Performance)

Lucia M. Berte
www.LaboratoriesMadeBetter.com



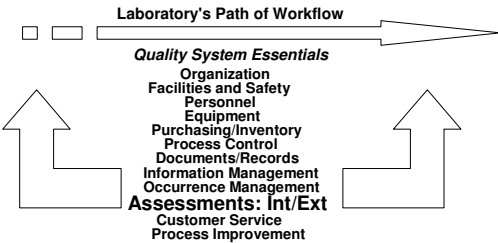
CLSI
CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE

- HS01-A2: *A Quality Management System for Health Care*
- GP35-P (new!): *Development and Use of Quality Indicators for Process Improvement and Monitoring Laboratory Quality*

2

CLSI Quality System Model

Laboratory's Path of Workflow



Quality System Essentials
Organization
Facilities and Safety
Personnel
Equipment
Purchasing/Inventory
Process Control
Documents/Records
Information Management
Occurrence Management
Assessments: Int/Ext
Customer Service
Process Improvement

3


To manage quality you must measure it.

Steven George

4

Why Measure?

- Early detection of unfavorable trends, patterns
- Rapid remediation
- Timely correction



5

Purpose of Measurement

- Monitor specific usually stable functions
- Monitor complex processes (PoW)
- Monitor effectiveness of planned improvements to work processes
- Compare to others to identify potential quality risks

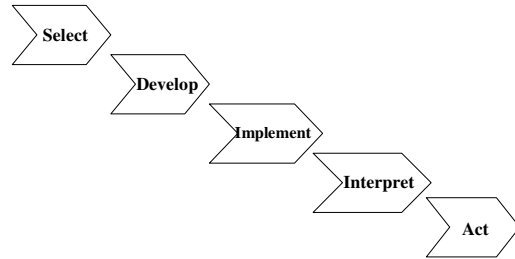
6

GP35 Outline for a Measurement Program

- Select indicators
- Develop indicators
- Implement indicators
- Analyze, present, interpret information
- Act on information

7

GP35 Outline for a Measurement Program



8

GP35 Outline for a Measurement Program



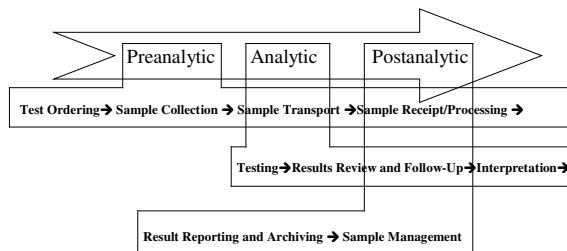
9

Types of Indicators

- Clinical outcomes
- Functional status/ADL
- Customer satisfaction
- *Process efficiency and effectiveness*
- Resource use and financial performance

10

CLSI GP26 Laboratory Path of Workflow



11

Preanalytic Processes

- Test ordering
- Patient preparation
- Sample collection
- Sample labeling
- Sample transport
- Sample receipt
- Sample processing

12

Measurements for Preanalytic Processes

- Incomplete requisitions
- Patient identification accuracy
- Phlebotomy efficiency
- Complications of phlebotomy
- Adequacy of collected samples
- Accuracy of sample accessioning



13

Analytic Processes

- Testing
- Results review and follow-up
- Interpretation

14

Measurements for Analytic Processes

- Incomplete test runs (i.e., technical problems)
- Invalid test results (i.e., controls out of range)
- QC failures
- Missed follow-ups
- Misinterpretations
- Missed diagnoses

15

Postanalytic Processes

- Results Reporting
- Results Archiving
- Sample Management

16

Measurements for Postanalytic Processes

- Timeliness of critical value reporting
- Reporting errors
- Disparities
 - in diagnosis
 - between preliminary and final reports
- Unavailability of archived samples

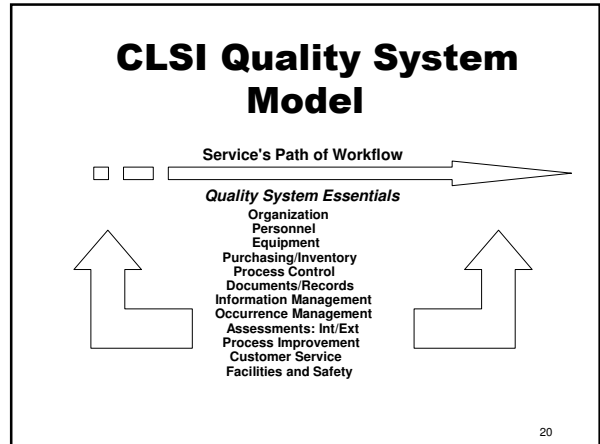


17

Indicators chosen by Lab Leadership from

- | | |
|------------------------------------|-------------------------|
| ● Organizational goals | ● Information |
| ● Mission | ● Indicators |
| ● Strategic ambitions | ● Nonconforming events |
| ● Customer needs | ● Customer complaints |
| ● Societal values and requirements | ● Known vulnerabilities |
| ● Patient safety | ● High risk |
| ● Accreditation issues | ● Failure prone |
| | ● Available resources |

18



- ### Quality System Essentials: CLSI HS1
- Organization
 - Personnel
 - Equipment
 - Purchasing and Inventory
 - Process Control
 - Documents and Records
 - Information Management
 - Occurrence Management
 - Assessment: Internal & External
 - Process Improvement
 - Customer Service
 - Facilities and Safety
- 21

- ### Measurements for QSE: Organization
- Financial performance
 - Overall compliance with quality management system
 - Balanced scorecard
-
- 22

- ### Measurements for QSE: Facilities and Safety
- Adequacy of facility maintenance services
 - Number and type of laboratory accidents
 - Needlesticks
 - Findings from safety audits
-
- 23

- ### Measurements for: QSE: Personnel
- Personnel turnover rate
 - Completeness of training
 - Competence evaluation outcomes
 - Completeness of personnel files
-
- 24

Measurements for QSE: Equipment

- On-time performance
 - Calibrations
 - Maintenance
- Downtime
 - Analyzers
 - Computers
- Frequency of unscheduled service and repairs



25

Measurements for QSE: Purchasing and Inventory

- Supplier performance
 - Backorders, delays
 - Incorrect shipments
 - Damaged shipments
- Inventory
 - Emergency orders
 - Outdating



26

Measurements for QSE: Process Control

- QC performance
- Turnaround times



27

Measurements for QSE: Documents and Records

- Document problems discovered
 - outdated
 - incomplete
 - incorrect
- Number and type of document deficiencies cited by inspectors



28

Measurements for QSE: Information Management

- Number and type of security breaches
- Inability to retrieve archived information
- Problems with data integrity
 - transfers
 - after downtime
 - after merges and purges



29

Measurements for QSE: Occurrence Management

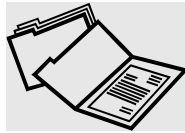
- Customer complaints
 - physicians
 - other health care staff
 - patients
- Numbers and types of nonconformances



30

Measurements for QSE: Assessments

- Findings from external assessments
- Proficiency testing performance



31

Measurements for QSE: Customer Service

- Employee satisfaction
- External customer satisfaction with
 - Phlebotomy
 - Quality of telephone responsiveness
 - Physician satisfaction with services
 - Physician satisfaction with report format and content



32

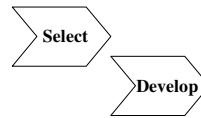
Measurements for QSE: Process Improvement

- Number and type of continuous improvement projects ongoing
- Results of follow-up evaluations of process improvement changes



33

GP35 Outline for a Measurement Program



34

Quality Indicator Development Form*

- Part 1: Identification of an indicator
- Part 2: Indicator development and data collection
- Part 3: Indicator analysis and interpretation

*CLSI HS1-A2, A Quality Management System Model for Health Care

35

Quality Indicator Development Form*

- Part 1: Identification of an indicator

*CLSI HS1-A2, A Quality Management System Model for Health Care

36

Development of an Indicator

- Operational definition
- Data collection process
- Setting of target, limit or action threshold

37

Operational Definition

- Indicator identifier – name or ref number
- Purpose – why we are doing this one
- Scope – activities and boundaries
- By whose authority
- Domain – map to QSE, PoW Lab section, etc.

38

Data Collection Process

- Who's responsible
- How often and for how long
- Collection method
- Data type
 - Attribute (#)
 - Variable (aspect)
- Sampling scheme
- Validation of data extraction programs
- External references

39

Target Setting

- Current performance baseline
- Target based on goals
- Criticality of target in improvement to
 - Patient safety
 - Clinical effectiveness
 - Service quality
 - Cost
- Feasibility
- Existence of evidence-based benchmark

40

Form Part 1: Identification

- What key quality characteristic is measured?
- What is the rationale?
- What is the specific name?
- To which functions does it apply?
- What core strategy is satisfied?
- Which dimension of excellence is measured?
- Are there literature references?

41

Quality Indicator Development Form*

- Part 1: Identification of an indicator
- Part 2: *Indicator development and data collection*

*CLSI HS1-A2, A Quality Management System Model for Health Care

42

Form Part 2. Data Collection

- Develop operational definition
- Define specific data collection method to be used
- Describe data collection plan
- Describe any sampling plan
- Are baseline data available?
- Is there a target or goal?
 - External
 - Internal

43

Capture the

- *Rate* of something that happens e.g., numerator and denominator
- *Source* of problems e.g., which locations have the most problems
- *Reasons* for a problem e.g., type of sample problem

44

GP35 Outline for a Measurement Program

```
graph LR; A[Select] --> B[Develop]; B --> C[Implement]
```

45

Implement Indicator

- Pilot trial to confirm
 - Objective, specific, achievable, collectible data, interpretation, and presentation
 - Prospective data collection
 - Revise plan, with document control
 - Go-live on large scale

46

GP35 Outline for a Measurement Program

```
graph LR; A[Select] --> B[Develop]; B --> C[Implement]; C --> D[Interpret]
```

47

Quality Indicator Development Form*

- Part 1: Identification of an indicator
- Part 2: Indicator development and data collection
- Part 3: *Indicator analysis and interpretation*

*CLSI HS1-A2, A Quality Management System Model for Health Care

48

Part 3. Analysis

- Analysis plan
 - Descriptive statistics
 - Mean, median, mode
 - Percentage, range
 - Standard deviation
 - Graphs
 - Bar or pie charts
 - Histogram
 - Control chart
 - Pareto diagram
- Data reporting plan
 - Who will receive results?
 - How often will results be provided?

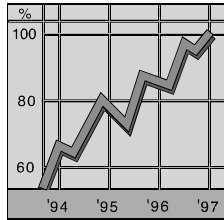
49

“See information where others see only data.”

Robert H. Waterman, Jr.

50

Analyze, Present, Interpret: Control Charts



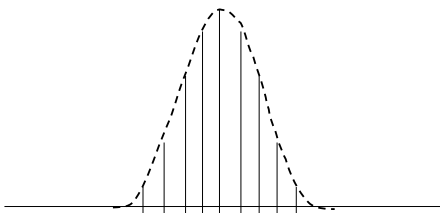
51

Analyze, Present, Interpret: Pareto Charts



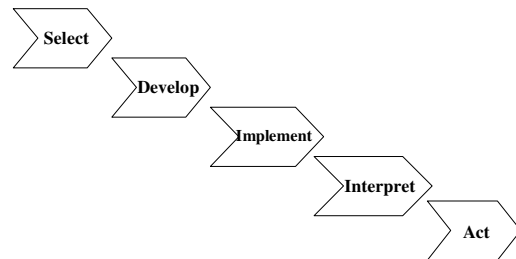
52

Analyze, Present, Interpret: Histogram



53


GP35 Outline for a Measurement Program



54

**It isn't what you find...
it's what you do about
what you find!**


Philip Crosby



55

Periodic Quality Report Contents

- Quality indicators results
- Internal audit findings
- External assessment deficiencies
- Results of customer satisfaction surveys
- Status or follow-up of process improvement projects



56


Indicator Reports include

- Data collected
- Time period
- Method of collection
- Presentation and interpretation
- Data limitations
- Needed actions and interventions

57

Quality Report Provides:

- Dashboard of how well the laboratory's processes are functioning
- Knowledge of where failure cost is occurring
- Assessment of compliance with
 - requirements
 - your established quality management system



58

Action Type Terminology

Remedial	Immediate action to rectify recognized nonconformance	Recollect lost samples
Corrective	Action to remove root cause	Flowchart sample transport process
Preventive	Proactive action to eliminate cause of potential nonconformance	Automated sample handling

59

Possible Decisions

- Continue to monitor, or stop monitoring
- Identify OFI
- Implement remedial action
- Perform Root Cause Analysis
- Implement corrective action
- Apply an improvement strategy
- Modify targets or action thresholds

60

Only Management can...

....make resource allocation decisions!



61

In Summary

- Measure and monitor your laboratory's process performance
- Use the CLSI GP35 guideline
- Identify opportunities for improvement
- Prioritize these opportunities
- Take action!

62

“The starting point for
improvement is to
recognize the need.”

Masaaki Imai

63