Quality Management in clinical laboratories

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What is Quality?

Quality is doing the right things and doing those things right

Philip Crosby (1970)
What is Quality in the lab?

“Establishing conditions such that the quality of all tests performed in the medical lab assists clinicians in practicing good medicine”

- Dr. Callum G Fraser
Quality Management System addresses all process

- The laboratory environment
- Quality Control procedures
- Communications
- Record keeping
- Competent and knowledgeable staff
- Good quality reagents and equipment
International Organization for Standardization (ISO) - History

ISO: from the union of two organizations
- the ISA (International Federation of the National Standardizing Associations), established in New York in 1926
- the UNSCC (United Nations Standards Coordinating Committee), established in 1944
History of ISO

October 1946:

Decision to create a new international organization, of which the object would be "to facilitate the international coordination and unification of industrial standards"

The new organization, ISO, officially began operations on **23rd February 1947**
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<td>Statistical Process Control</td>
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<td>W. Edwards Deming</td>
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<td>Joseph M. Juran</td>
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<td>Philip B. Crosby</td>
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<td>Robert W. Galvin</td>
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ISO Documents - Laboratory

ISO 9001:2000 Quality Management System Requirements
Model for QA in design, development production, installation, and servicing

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

ISO 15189:2012 Quality management in the clinical laboratory
ISO 15189:

- The foundation of international medical laboratory quality management
- Medical laboratories—Particular requirements for quality and competence
NCCLS / CLSI

NCCLS: National Committee for Clinical Laboratory Standards Institute

CLSI: Clinical and Laboratory Standards Institute

Important documents from CLSI:
“A quality management system model for laboratory services”
“Application of a quality management system model for laboratory services; approved guidelines – GP26 -13”
HS1-A2  A Quality Management System Model for Health Care
- describes quality system model, 12 essentials
- aligns to ISO 15189 and parallels ISO 9000
- applies to all health care systems

GP26-A3  Application of Quality Management System Model for Laboratory Services
- describes laboratory application of quality system model
- relates the path of workflow to the quality system essentials
- assists laboratory in improving processes
- relates to HS1-A2 and ISO 15189
Stages of Quality - Hierarchy

QUALITY MANAGEMENT
QUALITY SYSTEM
QUALITY ASSURANCE
QUALITY CONTROL
QUALITY CONTROL

- QC is the study of those errors, which are the responsibility of the laboratory and of the procedures used to recognize and minimize them.

- Lab personnel must know that QC is the obligation to the patient: It is designed to give confidence in the methods used and its purpose is not to find scapegoats or to punish mistakes.

- The watch word for reliability: Accuracy and Precision
Quality Assurance

- Planned and systematic activities to provide adequate confidence that requirements for quality will be met (ISO)

- Includes IQC, EQA, pre-analytic phase, test standardization, post-analytic phase, management, and organization (WHO)
QUALITY ASSURANCE

- QA is a comprehensive term that refers to all aspects of operation from preparation of the patient to sample collection, sample analysis, recording of the result and its dispatch.

- QA has two components:
  - Internal Quality Control (IQC)
  - External Quality Assessment (EQA)
Quality System

- Organizational structure, resources, processes and procedures needed to implement quality management (ISO, NCCLS)
Quality Management

- All activities of the overall management function that determine quality policy objectives, implement them by means such as quality planning, quality control, quality assurance, and quality improvement within the system (NCCLS)
Quality System Philosophy

- Say what you do
- Do what you say
- Prove it
Quality Assurance

All Activities Associated with the Attainment of Quality

- Organizational structure, responsibilities and authorities
- Staff recruitment, training, work allocation, development
- Leadership, motivation and supervision
- Documentation of procedures
- Test method selection, development and validation
- Equipment selection, management and calibration
- Control of accommodation and environment
- Control of consumable supplies and reference standards
- IQC & EQA
- Reception, labeling, processing and storage of samples
- Addressing complaints and other corrective actions
- Recording and reporting test results
- Accounting and administrative functions
- Audits, Management Review & follow-up improvements
ACCURACY

- Closeness of agreement between true value and the mean of measurement results obtained over large number of observations
- This can be quantitatively expressed as BIAS

\[
BIAS = \frac{\text{Observed value} - \text{True value}}{\text{True value}} \times 100
\]

- Good accuracy means least BIAS
PRECISION

- Closeness with each other of the large number of observations in measurement process, under prescribed conditions.

- This can be quantitatively expressed as coefficient of variation - % CV

- Good precision means least CV
REPEATABILITY

- Closeness of the agreement between the results of successive measurements of the same specimen with the following conditions:
  - The same measurement procedure
  - The same analyst
  - The same measurement systems used under the same conditions
  - The same location
REPRODUCIBILITY

- Closeness of the agreement between the results of successive measurements of the same specimen with the following conditions:
  - The same measurement procedure
  - Different analysts
  - Different measuring systems
  - Different locations and at different times
Quality assurance covers all aspects of laboratory tests

1. Pre-analytical
2. Analytical {Internal Quality Control (IQC) and External Quality Assessment (EQA)}
3. Post-analytical
Reasons for rejecting a sample

- Unlabeled sample
- Broken or leaking tube/container
- Insufficient patient information
- Sample label and patient name on test request form do not match
- Sample collected on wrong container
- Haemolysed sample
- Inadequate volume for the quantity of preservative
- Insufficient quantity for test requested
- Prolonged transport time/poor handling during transport
Method Validation

Precision
Accuracy
Range / Analytical Measurement
Range (AMR)
Reference Interval
Analytical Sensitivity
Analytical Specificity
Interferences
Facilities and Safety

Develop Lab Safety Management Program

- Develop a manual for safety and biosafety
- Organise safety training to staff – should include:
  - universal precaution
  - infection control
  - chemical and radiation safety
  - PPE
  - disposal hazardous waste
  - fire extinguishers
  - first aid equipment
- Set up process to conduct risk assessment, ongoing safety audits towards potential safety problems
Quality Indicators

- Specimen Container Information Error …
- Specimen rejection, acceptance …
- IQC… (Improvement in % CV of analytes over 12 month period)
- Proficiency Testing Performance … (% of PT values within the allowable criteria, eg. 2 SDI)
- Inpatient Laboratory Result Availability… (% of test results available for morning rounds as stipulated in the institution policy)
- Critical Values Reporting …
- Turnaround Time …
- Clinician Satisfaction With Laboratory Services..
- Complaints … (n of complaints received & n of complaints resolved)
- Telephone calls for results …
- Equipment downtime …
Sources of Error

- Analytical – Random & Systematic
- Non-analytical
What are Performance Standards?

• Performance standards define the required quality of lab results

• The two metrics that define the quality specifications:
  
  BIAS  (systematic error)
  
  % CV  (random error)
Understanding Analytical Errors

Systematic Error (SE) = Bias
*constant or proportional

Random Error (RE) = Imprecision

Total Error = Bias + Imprecision
= Bias + 1.65 CV_{analyt}
**TOTAL ERROR ALLOWABLE (TEa)**

- If TE present < TEa, patient results are considered reliable

- If TE present > TEa, the laboratory is failing to meet quality specifications for the test & is likely to be producing clinically unreliable patient test results
Sigma metric

- Do you know the Sigma metric for each of your test methods?
- Depends on
  - Tolerance limits or quality requirements for the test. (TEa)
  - Imprecision of the method (SD or CV)
  - Inaccuracy of the method (Bias)

Sigma metric = \frac{(TEa - Bias)}{CV}
Westgard Rules

- Six Commonly Used Westgard Rules –
  - Two - Warning
  - Four - Mandatory

- Violation of **Warning rules** should trigger a review of test procedures, reagent performance and equipment calibration.

- Violation of **Mandatory Rules** should result in rejection of the results.
Warning Rules

- Warning 1$_{2S}$ - Random Error
- Warning 4$_{1S}$ – Systematic Error/ Bias

Mandatory Rules

- Mandatory 1$_{3S}$ – Random Error
- Mandatory 2$_{2S}$ – Systematic Error
- Mandatory R$_{4S}$ – Random Error
- Mandatory 10x – Systematic Error
$1_{2S}$ Rule = A warning to trigger careful inspection of the control data
$1_{3S}$ Rule = Reject the run when a single control measurement exceeds the $+3SD$ or $-3SD$ control limit

$+3SD$

$+2SD$

$+1SD$

Mean

$-1SD$

$-2SD$

$-3SD$

$1_{3S}$ rule violation

Day
2\textsubscript{2S} Rule = Reject the run when 2 consecutive control measurements exceed the same +2SD or -2SD control limit.
$R_{4S}$ Rule = Reject the run when 1 control measurement exceed the +2SD and the other exceeds the -2SD control limit.
4s rule violation
10\_x Rule = Reject the run when 10 consecutive control measurements fall on one side of the mean.

Day
$7_T$ rule violation
L J CHART I-A ALBUMIN QC LEVEL-2

4.6
4.5
4.4
4.3
4.2
4.1
4.0
3.9
3.8
3.7

+2 SD
+1 SD
-1 SD
-2 SD
LJ CHART II  B  GLUCOSE LEVEL - 2

GLUCOSE LEVEL - 2
Thank you