EXTERNAL QUALITY ASSESSMENT PROGRAM (EQAP)

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TWO COMPLEMENTARY COMPONENTS OF TQM ARE

- Internal Quality Control (IQC)
- External Quality Assessment (EQA)
INTERNAL QUALITY CONTROL (IQC)

- Is necessary for the daily monitoring of precision and accuracy of analytical method.
- Only detects changes between present performance and previous stable performance (Baseline).
- Undetected systematic errors during baseline period would be included in the mean that was used to calculate the control limits.
EXTERNAL QUALITY ASSESSMENT (EQA)

- Is a process by which a laboratory uses an outside unbiased source to verify the quality of patients results
- Allows a laboratory to confirm that its results are consistent with those of other laboratories using the same or similar methods for an analyte and thus to confirm it is using a method correctly
- Is important for maintaining the long-term accuracy of the analytical methods
EQA HAS FOUR STAGES

- Providing and Sending Quality Control (QC) Material to Participating Laboratory
- Measuring Analyte(s) and Reporting Result(s) by Participating Laboratory
- Data Analysis and Sending Evaluation Report(s) to Participating Laboratory
- Interpretation of Evaluation Report(s) and Taking Corrective Action for Unacceptable Result(s) in Participating Laboratory
PROVIDING AND SENDING QC MATERIAL

- General Requirements
- Analyte Validation
- Homogenity (Uniformity) Testing
- Stability Testing
- Stress Testing
- Shipping Testing
MEASURING ANAYTE(S) AND REPORTING RESULT(S)

- Storage
- Reconstituation
- Measuring QC Material Like Patient Specimen
- Reporting Results and Method Characters
  1) Kit Producer
  2) Kit Lot No.
  3) Procedure
  4) Principle of Method
REASONS FOR REDUCING CONSISTENCY BETWEEN DIFFERENT METHODS AND PROCEDURES ARE

- Different Analytical Specificity
- Different Analytical Sensitivity
- Different Calibration
- Matrix Effect
Evaluation of performance of each participant needs to establish two values:

1) Assigned (target) value of the test material
2) Acceptable range

Different methods can be used to establish these estimates, but there is no standard protocol statistical parameters
WHAT ARE TARGET VALUE & TRUE VALUE?
Structures of Accuracy-Based System

Definitive Method

True Value

Traceability

Observed Value

Reference Method

Primary Reference Material

Method Validation

Secondary Reference Material

Method Validation & External Quality Assurance

Field Method

Control Material

Internal Quality Assurance
There are three methods

1) The addition of a known amount or concentration of analyte to a base material containing none

2) The use of a Consensus value produced by a group of expert or referee laboratories using best possible methods

3) The use of a consensus value produced in each round of EQA, and based on the results by participants
assigned value is consensus value (trimmed mean value) derived from all results submitted by participants in the scheme of that analyte.

Practical experiences has shown that the consensus value usually agrees closely with the true value in schemes with a large number of participants.

Consensus value may not be valid in two conditions: here are three methods.

1) Numbers of laboratories is small
2) A large proportion of participants have a significant analytical bias
VALIDATING THE CONSENSUS VALUE

- By analysing the control material by reference methods, which needs laboratories with adequate training and experience of such methods.

- The routine methods by participants in the scheme may also be used, but laboratories assigning the values must be confident of their bias and precision.

- To compare the consensus values obtained for the same control material from different schemes in for example different countries or regions.
After calculating method relating consensus value, acceptability criteria must be established.

For this, statistical parameters are calculated, including:

1) Mean ($X$)
2) Standard Deviation (SD)
3) Coefficient of Variation (CV)

\[
CV\% = \frac{SD}{X} \times 100
\]
Acceptability criteria may be:
1) Interval based on group SD (e.g. X +/- 2SD)
2) Fixed percentage (e.g. X +/- constant percent)
3) Fixed interval (X +/- constant amount)

Alternatively, scoring system may be used:
1) Bias Index Score (BIS)
2) Variance Index Score (VIS)
3) Standard Deviation Index or Interval (SDI)
Z Score

\[ Z = \frac{X_{\text{lab}} - X_{\text{peer}}}{SD_{\text{peer}}} \]

\[ SDI = \frac{X_{\text{lab}} - X_{\text{peer}}}{SD_{\text{peer}}} \]

\[ BIS = \frac{X_{\text{lab}} - X_{\text{peer}}}{X_{\text{peer}}} \times 100 \]
Chosen Coefficient of Variation (CCV)

- CCV are the lowest CVs obtained for particular determinations during first two years of the EQAS.

- It is kept constant so that improvements in the performance of laboratories can be detected.
Performance Indicators Resulting from Cumulation of BIS & VIS Over Time (typically 6 months or 10 scores)

- Mean Running VIS (MRVIS)
- Mean Running BIS (MRBIS)
- Standard Deviation of BIS (SDBIS)
Random Error

Systematic Error

Total Error

Imprecision

Untrueness

Inaccuracy

Random Bias

Systematic Bias

Random & Systematic Bias

SDBIS

MRBIS

MRVIS
Four Rules Usually Employed for SDI Evaluation

- 2/5
- X
- 1
- R
- 3
- 4
Peer GROUP PROGRAM

- Peer Group Program Is A Combination of Internal And External Quality Control
- When EQC Is Used In Conjunction With Daily IQC, This Program Will Give Laboratories Added Confidence in Their Patient Test Results
- All Labs Use The Same Control Material and Report Their Results Daily
- Data Are Analyzed And Reported Monthly As SDI and CVR
CAUSES FOR EQAP FAILURES

Problem with QC Materials

1) Analyte Unstability
2) Mishandling of Specimen during Shipping to Laboratory
3) Interfering Substance in QC Materials
CAUSES FOR EQAP FAILURES

- Incorrect Handling of QC Materials
  1. Incorrect Reconstituation
  2. Incorrect Storage Conditions
  3. Evaporation of Prepared QC Materials
CAUSES FOR EQAP FAILURES

- Technical Problem with a Method
  1) Calibration Problem
  2) Inadequate Maintenance Causing Increased Imprecision
  3) Deterioration of Reagents and Other Components
  4) Inadequate Environmental Control In Laboratory
CAUSES FOR EQAP FAILURES

Incorrect Procedure

1) Incorrect Dilution Process
2) Incorrect Mixing
3) Incorrect Calculation
4) Incorrect Unit
5) Transcription Error
CAUSES FOR EQAP FAILURES

- Incorrect Laboratory Grouping
- And Falling in Group Others
- Which Is Compared with Allover