Monitoring of Internal Quality Control System Using Patients’ Data

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Presentation Outline

• Internal quality control (IQC)
• Frequency of IQC and patient safety
• Monitoring of IQC
• Periodic monitoring of IQC using QC samples
• Continuous monitoring of IQC using Patients’ data
• Conclusion

Quality Control

• Quality control (QC) can be defined as the control of the testing process to ensure that the measurand results meet the expected quality requirements
• QC processes vary, depending on the methods
  • quantitative
  • semiquantitative or qualitative
• Data of semiquantitative or qualitative tests do not show a Normal distribution and therefore QC of these tests relies on nonparametric models

ISO 15189 (5.6.2.1)

“The laboratory shall design quality control procedures that verify the attainment of the intended quality of results”.

1

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Internal Quality Control (IQC)

- Internal Quality Control help us to detect, reduce, and correct errors in analytical process prior to report patients results.

Current practice of IQC

- Frequency of analysis of QC samples
  - Daily, weekly, monthly etc.
  - or once per shift, twice a day, three times a day, ...
  - Many labs prefer once a day

- Number of controls
  - Level 1, level 2, level 3 etc...

- The rules for acceptance or rejection of the results of QC samples
  - Westgard multirules, others.

Frequency of IQC, how often is “right”?

- ISO 15189 recommend that:
  - “Quality Control materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.”

  ISO 15189 (5.6.2.2)

Frequency of IQC testing

- The frequency of IQC are not standardized for tests performed in laboratory Medicine
- It is usually based on regulatory requirements
- CLIA regulations mandate the minimum frequency IQC evaluations in terms of time
  - CLIA regulation 493.1256 Standard: Control procedures.
    - (i) At least once each day patient specimens are assayed or examined perform the following for—
      - (i) Each quantitative procedure, include two control materials of different concentrations;
      - (ii) Each qualitative procedure, include a negative and positive control material;
Assessing the Impact of the Frequency of Quality Control Testing on the Quality of Reported Patient Results

E(N0) = ΔPE{(ARL_{ED}-1)E(NB)-(1-P_1)[E(NB) - E(N0)]}

**BACKGROUND.** The traditional measure used to evaluate QC performance is the probability of rejecting an analytical run that contains a critical out-of-control error of how frequently QC testing should be performed (1). The traditional approach to assessing quality control performance is based on the probability of...
Continuous Monitoring of IQC

- QC samples are not cost effective for continuous monitoring of IQC
- Patients’ data can be used for continuous monitoring

Patients’ data as a tool for continuous monitoring of IQC

Glucose, Example

Glucose, Example
Key Questions

- How can we calculate the target for patients’ data?
- How can we calculate truncation limits?
- How many patients’ data is required to detect errors?
- Can patients’ data be used to detect random and systematic errors?

Patient Data Algorithms

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Keywords
- Quality control • Quality assurance • Risk management • Total testing process • Delta checks • Laboratory errors

Key Points
- Algorithms using individual patient results can be a useful complement to routine quality control materials.
- Patient results can be used to detect error or identify potential testing complications at all phases of the total testing process (preanalytical, analytical, and postanalytical phases).
- Patient-specific data algorithms include delta checks, tests for verify specimen type, stability checks, and result-based reporting.

A statistical algorithms for monitoring IQC using patients data

- 1. Determine the target value for patients data
- 2. Determine the truncation limits
- 3. Calculate the mean, SD and CI of patients data located within truncation limits
- 4. If the CIs of patients’ data and target value overlaps, the difference is not significant, if they do not overlap the difference is significant.
- 5. Instead of CI model, alternative rates can be used for different tests.
Target value of patients’ data

- Mean of all data
- Mean of data within truncation limits
- Average of normals (AON)
- Moving average (MA)
- Exponentially Weighted Moving Average (EWMA)
- Medians of all data
- Moving median
- Others

Glucose

Mean of all data

Mean of data within truncation limits
Truncation Limits

- Reference intervals (RI)
- Between subject Biological Variation
- Others

Truncation limits based on Between-subject Biological variation data

- Between-subject of Biological variation data can be used to calculate the limits of patients data to monitor IQC
Between subject biological variation is the variability of a measurand between the homeostatic set points between different healthy participants.

Estimation of the homeostatic set point

\[ N_{HSP} = \left[ Z \cdot \sqrt{CV_A^2 + CV_I^2} \right]^2 \]

- \( N_{HSP} \): Numbers of samples required to estimate the homeostatic set points
- \( CV_A \): Analytical variation
- \( CV_I \): Within-subject biological variation
- \( D \): The allowed percentage deviation from the true homeostatic set point

\[ D = ??? \]

\[ D = Z \cdot \sqrt{CV_A^2 + CV_I^2} \]

\[ D \] can be calculated for the result of 1 sample.

\[ D = Z \cdot \sqrt{CV_A^2 + CV_I^2} \cdot \frac{1}{\sqrt{N_{HSP}}} \]

\( RCV \)
A Study of Various Estimators for the Derivation of Quality Control Procedures from Patient Erythrocyte Indices

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ABSTRACT

Bull, B. S., Elashoff, B. M., Heilbron, D. C., and Cooper, J.: A study of various estimators for the derivation of quality control procedures from patient erythrocyte indices. Am. J. Clin. Pathol. 41: 423–31, 1967. The derivation of quality control data from patient laboratory values presupposes, first, that the distribution of these values is stable over long periods of time; second, that it is possible to estimate accurately the mean of the entire population from a small sample of that population. That the first presupposition is true for erythrocyte indices has been shown else-

Total variation of two different subjects

\[ TV = z \times 1.41 \times \sqrt{CV_A^2 + CV_I^2 + CV_G^2} \]

- Example
  - Sodium
    - CV_A (%): 1.1
    - CV_I (%): 0.5
    - CV_G (%): 1.3
    - z: 1.96
  - TV (95% probability) = 1.96x1.41x(3.15)\(^{1/2}\) = 4.94 (%)
  - TV (99% probability) = 2.58x1.41x(3.15)\(^{1/2}\) = 6.46 (%)

\[ TL (95%) \]

\[ TL (99%) \]

\[ Mean \]

\[ TL (95%) \]

\[ TL (99%) \]
How many patients’ data are adequate to detect errors?

- In control-based QC procedures, the number of control samples and the frequency of testing can be specified independently by the laboratories.
- However, in patient-based QC procedures, the number of QC results cannot be specified independently.
- Increasing the number of patient results increase the probability of error detection but also increase the number of incorrect test results.
• The differences between patients' data and target value can be determined by considering the overlap of the 95% confidence intervals of patients' data and target value.
• The minimum number of patients' data can be calculated from the Eq. of confidence interval

\[ CI = k \times \frac{SD}{\sqrt{N}} \]
Can patients’ data be used to detect random and systematic errors?

- Patients data can be used to detect systematic error
- For random error we need complex algorithms

Conclusion

- Patients’ data can be used to monitor IQC
- Currently there is no perfect algorithm to be used for all measurands analyzed in laboratory medicine
- Biological variation model can be used effectively to monitor IQC
- The number of samples being analyzed within a given time is the critical point in continuous monitoring of IQC
- Using patients’ data to monitor IQC:
  - Increase patients’ safety
    - Provides early detection of errors and problems can be solved immediately
    - Reduces the number of samples to be repeated due to errors.