Reference versus Consensus Values in Proficiency Testing of Clinical Chemistry:
A Comparison Based on Laboratories’ Results in Palestine

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Background

• One of the basic elements in all Proficiency Testing (PT) schemes is the evaluation of each participant’s performance. This requires criteria for evaluating reported results.
• For assessing quantitative results, the PT provider has to establish two values, which are used for the performance evaluation:
  - Assigned/reference value (RV)
  - Standard deviation for proficiency assessment (SDPA)
• The Center for Quality in Laboratory Medicine (CQML) is the only provider of PT in the West Bank, Palestine.
  - The External Quality Assurance (EQA) Program was developed by the Medical Laboratory Sciences Department at Al-Quds University in 2001.
• The results of participants at the CQML are compared with Consensus Values (CVs) calculated as the Standard Deviations (SDs) from the results reported by the participants in the same PT round based on Algorithm A of ISO 13528.
• Disadvantages:
  - It might be risky to make conclusions based on CVs exclusively given the wide range of equipment and reagents employed in laboratories.
  - The value of CV may vary substantially from PT round to round, making it difficult for a laboratory to use its z score to look for trends that persist over several PT rounds.

Objectives

• Compare CVs obtained from data collected by the CQML for 11 analytes corresponding to clinical chemistry with certified RVs.
• Compare PT results obtained under both criteria (CV and RV).

Methods

Preparation and Validation of samples by CQML:
- Lyophilized human serum sample
- Homogeneity and stability in accordance with ISO 13528

Testing of samples at INSTAND Calibration Laboratory, Germany:
- RVs calculated for each analyte
- CVs calculated based on Algorithm A of ISO 13528
- ALP% values according to BAK guidelines

Distribution of samples and mock info to participating labs:
- Two samples were distributed to labs participating in the CQML (100 & 101)

Sample analysis & Result submission to CQML by participating labs:

Analysis and Evaluation of results by CQML:
- CVs calculated based on Algorithm A of ISO 13528
- ALP% values according to BAK guidelines

Performance evaluation:
- Percentage Deviation (%D) between CVs & RVs calculated for each analyte
- [Consensus mean – reference mean] x (100/reference value)
- % of labs that met ALP% criteria compared using CVs & RVs

Results

- Figures 2, 3 & 4 summarize the results of laboratories’ performances based on the choice of PT approach:
  - There was very good compliance between reference and consensus values.
  - The deviation between CVs and RVs for the evaluated analytes ranged from -0.56% for Calcium to -14.3% for Aspartate Aminotransferase (GOT).
  - The percentage of laboratories that met the allowable limits of performance (ALP%) ranged between 69.3% - 100% when CVs were used for comparison, whereas the range was 59.6% - 89.3% when using RVs.

Conclusions & Recommendations

- The deviation between CV and RV could vary depending on the analytes under investigation.
- The analysis of a large dataset of PT in clinical chemistry based on RVs showed that most laboratories had suitable performance. The percentage of satisfactory performance was 88% for several analytes.
- The main criteria for CV is having an agreement between the participants with a precision that is fit for the intended use. However, higher standard deviations indicate that this agreement is missing. Therefore, we cannot determine which results are really close to the “true” value.
- Most standard deviations were fit for the intended use since their values were not high. However, Lab Performance should be performed according to method groups for high SD since method groups give lower values compared to combining all methods.

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