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 ad **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** determined
- **11 clinical chemistry analytes**

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 **Rili-BAEK guidelines**

→ **Performance evaluation**
- **Percentage Deviation (%Δ)** 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

CQML: Center for Quality in Laboratory Medicine
RV: Reference Value
CV Consensus Value
ALP%: allowable limits of performance

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 69.3-91.7% when CVs were used for comparison, whereas the range was 59.6-89.5% when using RVs.

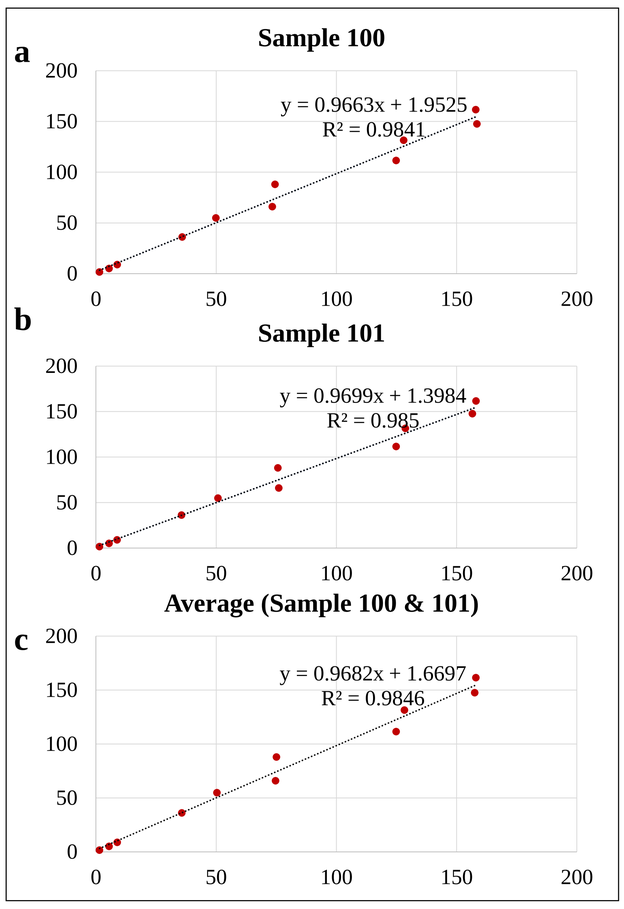

Figure 2: Compliance between CV and RV for 11 clinical chemistry analytes based on the analysis of two samples (100 & 101)

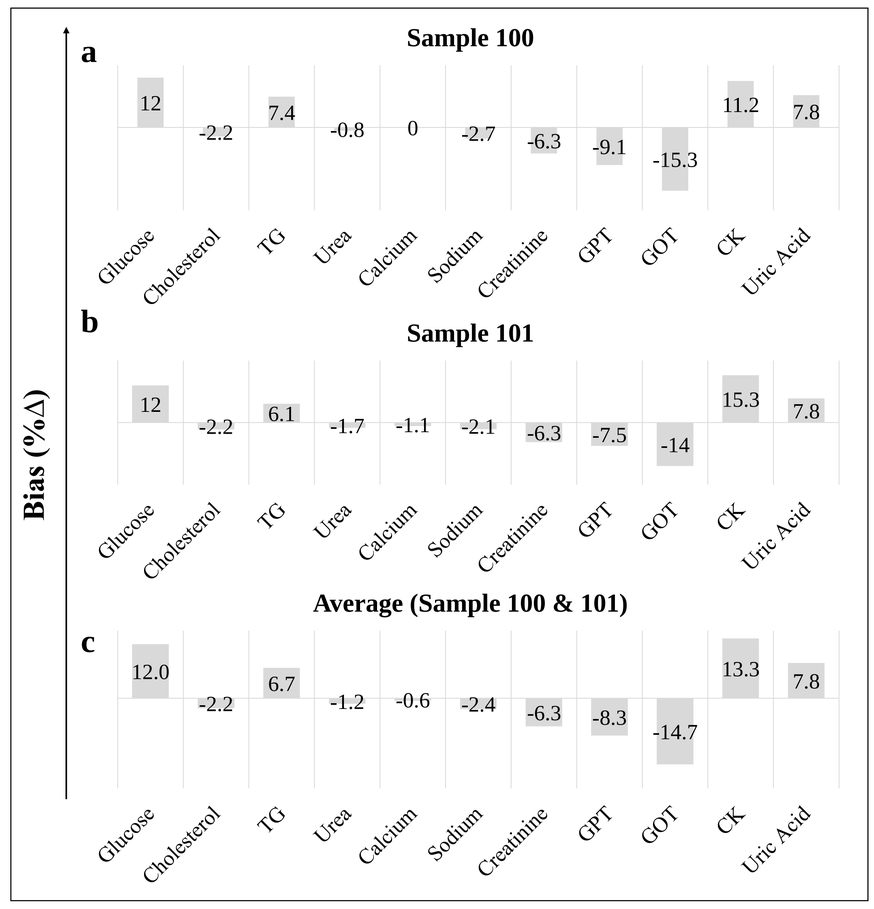

Figure 3: % Deviation between CVs and RVs based on the analysis of two samples (100 & 101)

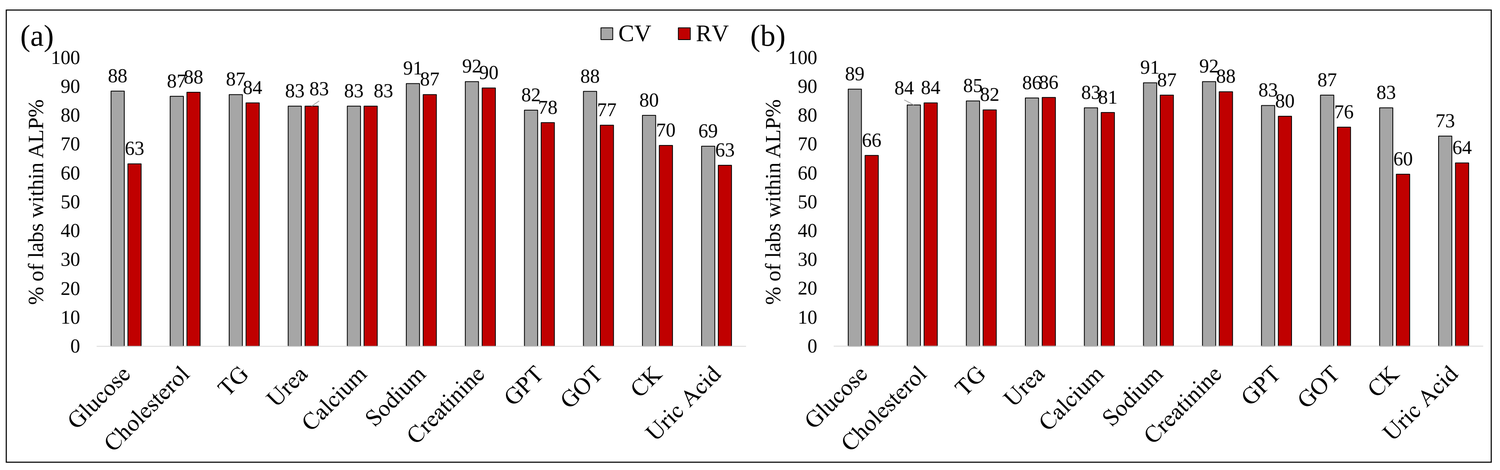

Figure 4: Comparison between % of laboratories that met the allowable limits of performance (ALP%) when consensus mean for samples (a) 100 (b) 101 and target value were used

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 that most laboratories had suitable performance. The percentage of satisfactory performance was >80% 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 can not 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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