Presenting the standards of the ISO 15197 on accuracy and precision of glucometer-strips systems

Author: O.O.Moronwiyan
Supervisor: R.Chlup
Dept. of Physiology, Faculty of Medicine, Palacký University Olomouc, IInd Dept. of Medicine, Teaching Hospital Olomouc

Background & Aims

The IS0 15197 standard (first issued 2003 and updated 2013) specifies requirements for in vitro capillary blood glucose monitoring systems (BGMS). Accuracy and precision of every Glucometer-strips systems (GSS) is essential. Recent studies have laid the groundwork for evaluations of BGMS against these standards.

Aims: To highlight the requirements of ISO 15197 along with recent “hot topics” for accuracy and precision of GSS.

Conclusions

This review aims to enhance understanding of GSS accuracy and precision from trials by Biayni and Jenna on Galileo, Newton, and Contour plus one GSS, Abdallah's work on impact of glucose load on glycemic response and research by Serdar and Alexia on BMI's impact on plasma glucose using glucometers.

Methods

The following key-papers are referenced:

1. International Organization for Standardization (ISO). ISO 15197 (2013 E): https://www.iso.org/standard/54976.html . Last confirmed 2018. Geneva, ISO
2. Bland JM & Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986, 327: 307-310
3. Parkes JL,et al. A New Consensus Error Grid to Evaluate the Clinical Significance of Inaccuracies in the Measurement of Blood Glucose. Diabetes Care 2000;23:1143-48.
4. Tian T, Aaron RE, Kohn MA, Klonoff DC. The Need for a Modern Error Grid for Clinical Accuracy of Blood Glucose Monitors and Continuous Glucose Monitors. Journal of Diabetes Science and Technology 2024;18(1):3-9. doi:10.1177/19322968231214281

Figure 1 – Preparation for procedure

Results

The accuracy criteria: 95 % of the individual glucose results will fall within ± 0,83mmol/L of the reference at PG < 5.55 mmol/L (100 mg/dL) and within ± 15 % at PG ≥ 5.55 mmol/L (100 mg/dL). Evaluation of the system accuracy will be performed with fresh capillary blood samples (Fig. 2). At least 100 pairs of PG concentrations considering 7 specified regions of values (bins). Laboratory adjustment for low and high glucose concentrations is possible. Other 2 reagents‘ LOTs should be tested.
Precision of the GSS is estimated using the SD of differences among individual cPG measurements. P <0.05 is considered meaningful.

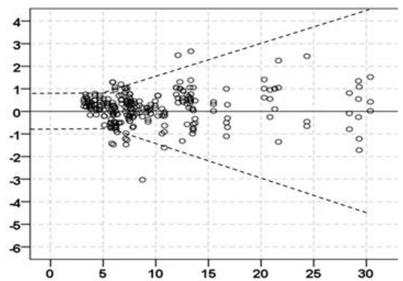

Figure 2 - Assessment of the accuracy of a GSS (example)

Key: Axis x: reference PG values [mmol/l] obtained by means of an accredited method. Axis y: difference between PG value displayed on tested glucometer and the respective value on axis x obtained by the accredited method.

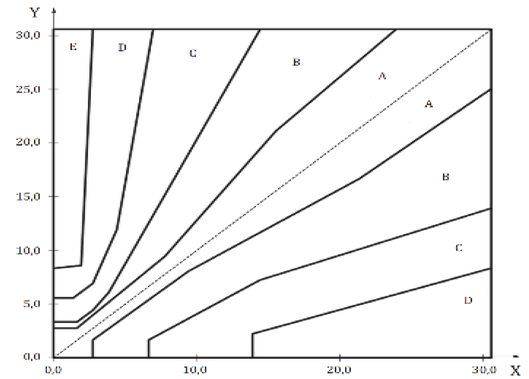

Figure 3 – Consensus Error Grid (mmol/l)

Key: X comparison method, Y meter
The Accuracy criteria: 99% of results lie within zones A and B of the consensus error grid (CEG) for type 1 diabetes.
Zone A and B – little to no effect on clinical outcome.
Zone C-E – increased risk of adverse outcome.

Acknowledgment

I express my gratitude to the Faculty of Medicine and Dentistry and Teaching Hospital Olomouc