Performance of ten systems for self-monitoring of blood glucose by trained healthcare professionals and in the hands of the users

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Background Accurate and reproducible blood glucose results are important for adequate therapeutic decision for persons with diabetes. The aim of this study was to assess the accuracy of ten systems for self-monitoring of blood glucose (SMBG) under optimal conditions achieved by biomedical laboratory scientists (BLS) and by persons with diabetes against the minimum accuracy requirements specified in ISO 15197:2013, and in the new Food and Drug Administration (FDA) draft guidance for SMBG systems for over-the-counter use.

Methods Data from ten SMBG system evaluations performed by Scandinavian evaluation of laboratory equipment for primary health care (SKUP) was used. About 90 persons with diabetes participated in each evaluation. All measurements on each SMBG system were compared with a glucose hexokinase method (the comparison method). Standard reference material from National Institute of Standards & Technology was used to secure traceability of the comparison method. The imprecision of the SMBG systems was calculated using duplicate capillary sample results.

Results Nine of the ten SMBG systems fulfilled the requirements for accuracy specified in ISO 15197:2013 and in the FDA Draft guidance for SMBG systems when BLS performed the measurements. Furthermore, six SMBG systems fulfilled the requirements for accuracy specified in ISO 15197:2013 and in the FDA Draft guidance for SMBG systems when persons with diabetes performed the measurements.
Conclusions The results indicates that there has been an improvement of SMBG systems the last 10-16 years since earlier studies have shown that many SMBG systems did not meet the analytical requirements for accuracy as stated in ISO 15197:2003 and 15197:2013.