Journal of Diabetes Science and Technology
Volume 7, Issue 4, July 2013

MEETING PROCEEDINGS

Do Currently Available Blood Glucose Monitors Meet Regulatory Standards? 1-Day Public Meeting in Arlington, Virginia

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Abstract

Blood glucose monitors (BGMs) are approved by regulatory agencies based on their performance during strict testing conducted by their manufacturers. However, after approval, there is uncertainty whether BGMs maintain the accuracy levels that were achieved in the initial data. The availability of inaccurate BGM systems pose a public health problem because their readings serve as a basis for treatment decisions that can be incorrect. Several articles have concluded that BGMs in the marketplace may not consistently provide accurate results in accordance with the regulatory standards that led to approval. To address this growing concern, Diabetes Technology Society organized and conducted a 1-day public meeting on May 21, 2013, in Arlington, VA, presided by its president, David Klonoff, M.D., FACP, Fellow AIMBE, to determine whether BGMs on the market meet regulatory standards. The meeting consisted of four sessions in which Food and Drug Administration diabetes experts as well as leading academic clinicians and clinical chemists participated: (1) How is BGM performance determined? (2) Do approved BGMs perform according to International Organization for Standardization standards? (3) How do approved BGMs perform when used by patients and health care professionals? (4) What could be the consequence of poor BGM performance?

J Diabetes Sci Technol 2013;7(4):1071–1083

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Abbreviations: (BGM) blood glucose monitor, (CE) Communauté Européenne, (CLSI) Clinical and Laboratory Standards Institute, (FDA) Food and Drug Administration, (ICU) intensive care unit, (ISO) International Organization for Standardization, (MDR) medical device report, (MGC) moderate glycemic control, (OTC) over the counter, (POC) point of care, (SMBG) self-monitoring of blood glucose, (TE) total error, (TGC) tight glycemic control

Keywords: accuracy, Arlington, FDA, glucose, meeting, monitor, performance, SMBG

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