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If SMBG Accuracy Is Critical to Patient Safety, Why Are Inaccurate Meters Still on the Market?

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Abstract

In this issue of *Journal of Diabetes Science and Technology*, Christiansen and colleagues report results from two studies, laboratory and clinical, that assessed the accuracy of a new blood glucose monitoring system, the Contour®Next ONE (Ascensia Diabetes Care, Parsippany, NJ, USA). The new system comprises a blood glucose meter that can link (via Bluetooth®) to the Contour™ Diabetes app, which operates on a smartphone or tablet. Results from both studies showed that the system exceeded the accuracy standards defined by the International Organization for Standardization (ISO) 15197:2013. It is worrisome, however, that many FDA-cleared (and marketed) blood glucose monitoring systems do not meet ISO accuracy criteria. Significant improvements in regulatory oversight and enforcement are needed.

Keywords

accuracy, blood glucose monitoring, SMBG, type 1 diabetes, type 2 diabetes, FDA

Use of self-monitoring of blood glucose (SMBG) within the parameters of a structured testing regimen has been shown to improve clinical outcomes among individuals with diabetes.[1-3] Because consequential therapy decisions are often based on SMBG data, it is critical that test results are consistently accurate. In this issue of *Journal of Diabetes Science and Technology*, Christiansen and colleagues report results from two studies that assessed the accuracy and usability of a new SMBG system, the Contour®Next ONE (Ascensia Diabetes Care, Parsippany, NJ, USA).

In the first study, system accuracy was evaluated in the laboratory, testing fingertip capillary blood samples from 100 subjects in duplicate, using 3 test strip lots. Glucose results obtained from the SMBG system were compared with YSI reference results and assessed per ISO 15197:2013 Section 6 criteria, which specify that ≥95% of SMBG results must be ±15 mg/dl (±0.8 mmol/L) of the reference result for samples with blood glucose concentrations <100 mg/dL (<5.6 mmol/L) and ±15% for samples with blood glucose concentrations ≥100 mg/dL (≥5.6 mmol/L).[4]

The evaluation showed that 100% of results with the system fulfilled the accuracy requirement, and 98.3% of results met an even tighter standard: ±10 mg/dL (0.6 mmol/L) of YSI values <100 (<5.6 mmol/L) and 10% of values ≥100 mg/dL (≥5.6 mmol/L). Importantly, all results were within Zone A of the Parkes consensus error grid,[5] which supports the safety and clinical efficacy of the system.

Investigators also assessed both system performance and ease of use in a clinical study, which enrolled 376 subjects with and without diabetes. Among the 332 subjects who completed the study, 116 with type 1 diabetes, 215 with type 2 diabetes and one did not know their diabetes type. Analysis of self-obtained capillary fingertip results from subjects with diabetes showed that 99.4% of results met ISO 15197:2013 Section 8 accuracy criteria, and, similar to the laboratory study findings, 97.6% (321/329) of results were within the tighter "±10/10%" performance level. Similar results were seen when samples were obtained and tested by clinic staff. Subject responses to an ease-of-use questionnaire revealed that most subjects felt positively about the usability of the system and importance of obtaining accurate test results.

However, there are two concerns that should be considered. First, the evaluated test strips were provided by the manufacturer, which raises the question of whether the test strips were exposed to typical shipping and handling conditions that could affect performance. Second, it appears that although 376 subjects were initially enrolled in the study, none of the nondiabetes subjects completed the study; the ISO criteria (Section 8) requires that approximately 10% of the study population be made up with subjects who do not have diabetes and, thus, naïve to SMBG devices.

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Nevertheless, the study credibly demonstrated that the Contour Next ONE system provides consistently accurate blood glucose test results to users in their daily diabetes self-management. These findings are not surprising. Ascensia Diabetes Care, along with other established manufacturers, such as Abbott Diabetes Care, LifeScan, and Roche Diabetes Care, have a long history of producing accurate, high-quality SMBG systems. Unfortunately, many less-established companies cannot make that claim.

In a recent review, Klonoff and Prahalad reported that a significant proportion SMBG devices cleared by the US Food and Drug Administration (FDA) do not perform at the level for which they were cleared or according to international accuracy standards.[6] In that review of 11 studies that presented data about the clinical performance of SMBG systems, it was found that only 15 of 31 (48.3%) of SMBG systems met the ISO 15197 2013 criteria in all of studies in which they were evaluated.[6] These findings concur with several earlier studies that revealed significant inaccuracy and lot-to-lot variability in up to 45% of the SMBG systems currently marketed.[7-10] Most of these systems are manufactured offshore and marketed at much lower prices than branded systems.

Most worrisome is that many of these SMBG systems are being offered to Medicare beneficiaries through the Competitive Bidding Program, which has already shown to be both disruptive and harmful.[11] According to a recent Office of the Inspector General (OIG) report, the manufacturers of many systems previously found to inaccurate currently have products that make up 55.4% of the SMBG systems sold to Medicare beneficiaries via mail order.[12] Because, many Medicare mail order suppliers offer only these products, beneficiaries are at increased risk for severe adverse health outcomes.[13,14]

Why these SMBG systems remain on the market is unknown. One could speculate that some companies have simply failed to maintain adequate quality standards in their manufacturing processes over time. Unfortunately, the FDA does not have the resources and/or opportunity to effectively monitor off-shore manufacturers.[15] However, a more insidious explanation is that offshore manufacturers may be falsifying their supporting data when filing for FDA 510(k) clearance. The FDA does not conduct an independent evaluation of the devices and must rely on the performance data generated and submitted by manufacturers. The agency acknowledges that fraudulent system performance data is, in fact, an issue.[15] This concern has also been raised by several recognized diabetes specialists.[16]

It is comforting that the FDA is working to strengthen its postmarket surveillance processes.[17] However, the agency must take immediate and aggressive steps to verify the accuracy of currently available SMBG systems that have previously been found to be inaccurate through independent research, and, when necessary, remove these systems from the market. Until these steps are taken, inaccurate SMBG systems will remain a danger to individuals with diabetes.

Abbreviations

FDA, US Food and Drug Administration; ISO, International Organization for Standardization; SMBG, self-monitoring of blood glucose.

Declaration of Conflicting Interests

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References

1. Polonsky WH, Fisher L, Schikman CH, et al. Structured self-monitoring of blood glucose significantly reduces A1c levels in poorly controlled, noninsulin-treated type 2 diabetes: Results from the structured testing program study. *Diabetes Care*. 2011;34:262-267.
2. Franciosi M, Lucisano G, Pellegrini F, et al. ROSES: role of self-monitoring of blood glucose and intensive education in patients with type 2 diabetes not receiving insulin. A pilot randomized clinical trial. *Diabet Med*. 2011;28:789-796.
3. Kato N, Cui J, Kato M. Structured self-monitoring of blood glucose reduces glycated hemoglobin in insulin-treated diabetes. *J Diabetes Invest*. 2013;4:450.
4. International Organization for Standardization. ISO 15197:2013(e): In vitro diagnostic test systems—requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. Geneva, Switzerland: International Organization for Standardization; 2013.
5. Parkes JL, Slatin SL, Pardo S, Ginsberg BH. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. *Diabetes Care*. 2000;23:1143-1148.
6. Klonoff DC, Prahalad P. Performance of cleared blood glucose monitors. *J Diabetes Sci Technol*. 2015;9:895-910.
7. Brazg RL, Klaff LJ, Parkin CG. Performance variability of seven commonly used self-monitoring of blood glucose systems: clinical considerations for patients and providers. *J Diabetes Sci Technol*. 2013;7:144-152.
8. Baumstark A, Pleus S, Schmid C, Link M, Haug C, Freckmann G. Lot-to-lot variability of test strips and accuracy assessment of systems for self-monitoring of blood glucose according to ISO 15197. *J Diabetes Sci Technol*. 2012;6:1076-1086.
9. Freckmann G, Schmid C, Baumstark A, Pleus S, Link M, Haug C. System accuracy evaluation of 43 blood glucose monitoring systems for self-monitoring of blood glucose according to DIN EN ISO 15197. *J Diabetes Sci Technol*. 2012;6:1060-1075.
10. Freckmann G, Baumstark A, Jendrike N, et al. System accuracy evaluation of 27 blood glucose monitoring systems

according to DIN EN ISO 15197. *Diabetes Technol Ther*. 2010;12:221-231.
11. Puckrein GA, Nunlee-Bland G, Zangeneh F, et al. Impact of CMS competitive bidding program on Medicare beneficiary safety and access to diabetes testing supplies: a retrospective, longitudinal analysis. *Diabetes Care*. 2016;39:563–571.
12. Office of Inspector General. Department of health and human services. HHS OIG data brief. February 2017. oei-04-16-00471. Medicare market shares of mail order diabetes test strips from April to June 2016. Available at: https://OIG.HHS.Gov/oei/reports/oei-04-16-00470.Pdf.
13. Hospital admission guidelines for diabetes mellitus. *Diabetes Care*. 1990;13:1118-1119.
14. What's new on the home-testing horizon for DM programs? *Health Demand Dis Manag*. 1997;3:70-71.
15. Klonoff DC, Reyes JS. Do currently available blood glucose monitors meet regulatory standards? 1-day public meeting in Arlington, Virginia. *J Diabetes Sci Technol*. 2013;7:1071-1083.
16. Edelman SV, Gavin JR, Hirsch IB, Wolpert HA, Wright Jr EW. Letter to Division of Dockets Management (HFA-305), Food and Drug Administration. March 23, 2014. Available at: https://www.Pharmamedtechbi.Com/~/media/supporting%20documents/the%20gray%20sheet/40/19/drs%20%20comments%20on%20fda%20glucose%20monitor%20guidance%20328.Pdf.
17. US Food and Drug Administration. CDRH reports. National evaluation system for health technology. September 20, 2016. Available at: http://www.Fda.Gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm301912.Htm.