

We Need Tighter Regulatory Standards for Blood Glucose Monitoring, But They Should Be for Accuracy Disclosure

Barry H. Ginsberg, M.D., Ph.D.

Abstract

Regulatory interest has focused on the accuracy of blood glucose monitoring systems. Currently, almost all systems meet the International Organization for Standardization (ISO) 15197 clinical standard ($\geq 95\%$ of the values within 20% of the reference for values above 75 mg/dl and within 15 mg/dl below that level). Should the systems have to meet one of the extended ISO standards of 15%, 10%, or even 5%? There is a wide variety of people with diabetes doing glucose monitoring, and the majority do not need better accuracy. Indeed, when selecting an insulin dose, the inaccuracy of the glucose reading has little effect compared with the inaccuracy in counting carbohydrates and the variability in insulin absorption. It might be far better to evaluate the accuracy in a standard method and provide the accuracy values on a standard label. Patients and health care providers could then select the monitoring system that best meets their needs.

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Author Affiliation: Diabetes Technology Consultants, Wyckoff, New Jersey

Abbreviations: (BGM) blood glucose monitoring, (FDA) U.S. Food and Drug Administration, (ISO) International Organization for Standardization, (MAE) mean absolute error

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Corresponding Author: Barry H. Ginsberg, M.D., Ph.D., Diabetes Technology Consultants, 501 Lydia Lane, Wyckoff, NJ 07481-1712; email address diabetes_consultants@yahoo.com