

Clinical Implications and Economic Impact of Accuracy Differences among Commercially Available Blood Glucose Monitoring Systems

Erwin S. Budiman, Ph.D., Navendu Samant, Ph.D., and Ansgar Resch, M.D., M.P.H., M.B.A.

Abstract

Background:

Despite accuracy standards, there are performance differences among commercially available blood glucose monitoring (BGM) systems. The objective of this analysis was to assess the potential clinical and economic impact of accuracy differences of various BGM systems using a modeling approach.

Methods:

We simulated additional risk of hypoglycemia due to blood glucose (BG) measurement errors of five different BGM systems based on results of a real-world accuracy study, while retaining other sources of glycemic variability. Using data from published literature, we estimated an annual additional number of required medical interventions as a result of hypoglycemia. We based our calculations on patients with type 1 diabetes mellitus (T1DM) and T2DM requiring multiple daily injections (MDIs) of insulin in a U.S. health care system. We estimated additional costs attributable to treatment of severe hypoglycemic episodes resulting from BG measurement errors.

Results:

Results from our model predict an annual difference of approximately 296,000 severe hypoglycemic episodes from BG measurement errors for T1DM (105,000 for T2DM MDI) patients for the estimated U.S. population of 958,800 T1DM and 1,353,600 T2DM MDI patients, using the least accurate BGM system versus patients using the most accurate system in a U.S. health care system. This resulted in additional direct costs of approximately \$339 million for T1DM and approximately \$121 million for T2DM MDI patients per year.

Conclusion:

Our analysis shows that error patterns over the operating range of BGM meter may lead to relevant clinical and economic outcome differences that may not be reflected in a common accuracy metric or standard.

Further research is necessary to validate the findings of this model-based approach.

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Author Affiliation: Abbott Diabetes Care Inc., Alameda, California

Abbreviations: (BG) blood glucose, (BGM) blood glucose monitoring, (CGM) continuous glucose monitoring, (CI) confidence interval, (ISF) insulin sensitivity factor, (ISO) International Organization for Standardization, (MDI) multiple daily injections, (T1DM) type 1 diabetes mellitus, (T2DM) type 2 diabetes mellitus

Keywords: accuracy, blood glucose monitoring system, clinical impact, economic impact, hypoglycemia, multiple daily injections

Corresponding Author: Erwin S. Budiman, Ph.D., Abbott Diabetes Care Inc., 1360 South Loop Rd., Alameda, CA 94502; email address erwin.budiman@abbott.com