Why the Accuracy of Your Patient's Blood Glucose Meter Matters — More Than You Might Think

KEY POINTS:

- By (1) detecting actual hypoglycemic events so they can be treated accurately and in a timely manner, and (2) helping to prevent hypoglycemia by delivering accurate blood glucose readings that provide the basis for patients to calculate and administer the appropriate insulin dose, blood glucose monitoring systems (BGMS) play a key role in reducing the impact of hypoglycemia.[1]

- Accuracy of BGMS counts: In patients with Type 1 diabetes, a study shows when the margin of error of BGMS increases 2-fold, there is more than a 10-fold increase in the risk of missing hypoglycemic events.[2]

- Despite accuracy standards for strip-based BGMS, important performance differences exist among commercially available BGMS currently and previously approved by the FDA.[1]

Self-monitoring of blood glucose by persons with diabetes, especially those who are on insulin therapy, is an important tool for helping patients to manage their disease and maintain optimal control of blood glucose.[1] For example, the results obtained from a blood glucose monitoring system (BGMS) help guide patients' insulin dosing. Measuring preprandial glycemia influences the prandial insulin dose, which in turn affects postprandial glycemic excursions.[1] Therefore, the accuracy (how close the average of a series of values is to an average of the reference values) and precision (consistency of readings) of patients' BGMS can minimize errors in insulin dosing.[1,3] Accurate dosing not only affects clinical outcomes but also potentially impacts economic outcomes, such as direct and indirect health care costs.[1,4,5]

Hypoglycemia, which is one of the most common and most severe complications of insulin therapy, contributes to considerable morbidity and mortality in persons with diabetes.[6,7] Hypoglycemia limits successful metabolic control of the disease and may prevent both patients and their health care providers from initiating appropriate insulin therapy and achieving optimal glycemic control as early as possible in the disease progression.[8]

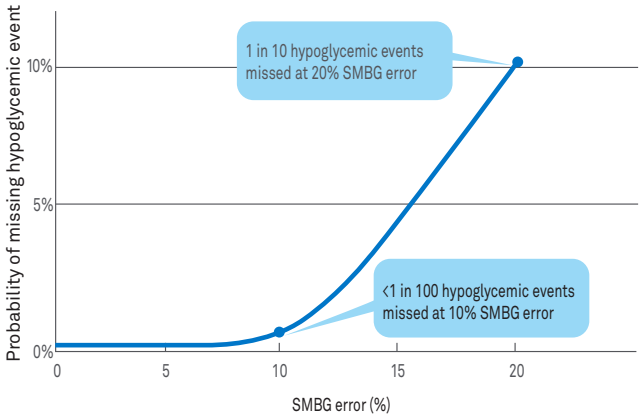
The average person with Type 1 diabetes experiences approximately 2 episodes of symptomatic hypoglycemia each week—a figure that has remained essentially unchanged for 20 years.[7] More than three quarters of people with Type 2 diabetes have experienced self-treated hypoglycemia, with 36% experiencing an episode within the last month.[8]

In addition to its effects on clinical outcomes in persons with diabetes, hypoglycemia is also associated with substantial economic burdens.[1,4] One study simulating the additional annual risk of hypoglycemia due to BGMS errors showed that use of more accurate BGMS can help prevent nearly 300,000 additional severe hypoglycemic episodes in Type 1 diabetes patients and more than 100,000 severe hypoglycemic episodes in Type 2 diabetes patients, with potential savings for the US health care system of more than $500 million per year.[1]

An analysis of the economic impact of hypoglycemia in a cohort of patients with Type 2 diabetes mellitus from 2003 through 2008 estimated the mean costs for outpatient treatment of a hypoglycemic event at $285 and mean costs for a patient with a hypoglycemia event treated initially in the emergency room and then admitted as an inpatient at more than $10,000.[4]

Health authorities in the United States and in other countries recognize the importance of accuracy for self-monitoring of blood glucose. The American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan (2015) state that "self-monitoring of blood glucose is an important tactic to help patients document hypoglycemia, although it is essential that the glucose meter meet accuracy standards."[9]

Figure 1. The probability for missing a reference hypoglycemic level of 60 mg/dL as a function of the error in self-monitoring of blood glucose (SMBG).[2]



In 2013, the International Organization for Standardization (ISO) tightened accuracy standards for BGMS to require analytical accuracy be within ±15 mg/dL when glucose concentrations are <100 mg/dL, and within ±15% for samples with glucose concentrations ≥100 mg/dL.[10] According to the FDA's 2014 draft guidance accuracy standards for BGMS, 95% of results should be within ±15% and 99% of results within ±20% across the entire glycemic range.[11]

However, even within the boundaries of these standards, considerable differences exist in the performance of commercially available systems, especially in the low glucose range.[1]

These performance differences can potentially have a major impact on the risk for missing detection of hypoglycemic events and thus adequately identifying and treating them. (See Figure 1.) For example, fewer than 1 in 100 hypoglycemic events will be missed via self-monitoring of blood glucose at 10% error level; at 20% error level, the risk increases more than 10-fold, to 1 in 10 hypoglycemic events missed.[2]

Meters that have only a ±20% level of accuracy are still on the market and in patients' homes. Help your patients understand that the accuracy of their blood glucose meter matters, more than they might think.

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