

Analysis

The Evolution of Glucose Meters

JAMES H. NICHOLS, Ph.D., D.A.B.C.C., F.A.C.B.

GLUCOSE METERS HAVE CHANGED significantly since the first models appeared on the market more than 20 years ago. Glucose testing at that time was based on visually read test strips. Testing required the patient to apply blood to the test strip, time the reaction, and then wipe the blood off of the strip for color comparison with a chart printed on the side of the strip container. The first glucose meters automated the timing and reading steps, which were the primary sources of error with the visually read method. Over-timing could result in further color development and overestimate the patient's glucose, while under-timing could result in falsely decreased glucose levels. Errors were also introduced by the ability of different patients and lighting conditions to discriminate color changes, as well as the manner in which the patient wiped blood off the strip. Later models of glucose meters provided for further improvements by eliminating the need to wipe blood altogether.

While these first glucose meters were a significant improvement over the visual test strips, the meters still had severe limitations. There were hematocrit and oxygen effects, interferences from drugs like ascorbate and salicylate, altitude effects, and risk of strip exposure to heat, cold, light, and moisture. The meters required a fairly large drop of blood, which limited their use on newborns, and the devices could only report one result at a time. Patients had to remember to calibrate meters for each lot of strips, and for hospital use there

were controls to analyze, document, and troubleshoot when they failed. Meter advances in the last several years have addressed many of these limitations, and as new meters have been introduced additional features like data management are now available to meet the growing needs of consumers.

The article in this issue of *DT&T* by Kilo et al.¹ emphasizes how important glucose meter features and technology are to patient care. The authors cite an American study that found only 39% of patients taking insulin monitor their blood glucose once a day and 29% do so less than once a month,² while a report from Scotland concluded that daily self-monitoring of blood glucose was rarer still, only about 20%.³ The low compliance with recommendations for frequent monitoring of glucose levels in patients taking insulin are claimed to be related to the inconvenience of glucose monitoring and the complexity of monitoring systems.^{4,5}

The new monitoring system being evaluated by Kilo et al.¹ has features that could improve the device ease-of-use and potentially enhance patient compliance. The test strips are automatically calibrated and require no coding by the patient. The meter needs only 0.6 μL of blood, and results are available in 15 s. Up to 240 results can be stored in memory, and the average from the previous 14 days can be displayed, so patients can assess the success of their insulin management. The meter can even tell when control solution has been applied to the test strip.

Associate Professor of Pathology, Tufts University School of Medicine; and Director, Clinical Chemistry, Baystate Health System, Springfield, Massachusetts.

The authors conducted a well-designed study of meter performance using both patients with diabetes and health care professionals in multiple patient settings. Different lots of strips were examined, and hematocrit and altitude effects were studied. Meter accuracy was also compared between four alternative testing sites—arm, forearm, abdomen, and thigh—which may be more comfortable for monitoring than fingerstick glucoses. Overall, analytical performance of the meter was judged to be excellent based on International Organization for Standardization (ISO) 15197:2003 criteria⁶ for agreement of the meter to three different laboratory methods, and clinical acceptability was judged to be excellent by use of the Parkes error grid. While ISO criteria are based on the percentage of glucose values that correlate within a defined limit against a laboratory method, error grid analysis assigns clinical risk to a glucose comparison, and the Parkes error grid limits provide error limits determined by survey consensus from a panel of clinicians.⁷ Finally, Kilo et al.¹ noted that patients and health care professionals utilizing the device liked many of the available features and found it easy to use.

While the authors thoroughly examined technical performance, clinical outcomes of patients were not examined. The study data fall short of establishing the effect of the device's new features on patient outcome. It is common during method evaluations to claim that a meter is accurate by comparison with a laboratory method using the criteria established by consensus of a professional society or organization. However, comparability of results does not equal comparability of patient outcomes. Glucose meters are clearly a different methodology than laboratory instrumentation, and each has its inherent biases, interferences, and imprecision. We should remember that efforts to estimate clinical acceptability using error grids are just estimates of the effect of bias on patient management. In the real world, clinical outcomes can only be determined by measuring the difference in clinical errors from basing management decisions on a glucose meter versus a laboratory result and the effects of those decisions or errors on changes in long-term hemoglobin A1c levels, development of specific

complications, requirement for emergency room treatment or hospitalization, additional diagnostic procedures, cost of care, or some other patient outcome measure. One assumes that the availability of additional alternate sites for glucose testing will translate to improved patient convenience, less pain, and therefore better compliance with daily testing. Although the authors did not conclude improved care from alternate site testing nor did they measure the relationship of alternate site testing on patient outcome, this conclusion might be assumed. Many glucose meter evaluations have implied that convenience of design improvements and added features play a role in patient outcome. Companies often claim that patients are more likely to actually use devices with greater convenience and technical advances and will therefore receive greater benefits from the availability of high-tech glucose monitoring. Likewise, less altitude or hematocrit interference is assumed to equal fewer falsely high or falsely low results and fewer errors in clinical management or insulin dosage. These assumptions are merely hypotheses until proven through well-designed studies. In summary, as glucose meters continue to evolve and new devices are introduced to the market, clinicians and patients should be concerned with more than the latest technological features and examine if the new features truly lead to a measurable improvement in patient outcome before investing in the technology.

REFERENCES

1. Kilo C Sr, Pinson M, Joynes JO, Joseph H, Monhaut N, Parkes JL, Baum J: Evaluation of a new blood glucose monitoring system with auto-calibration. *Diabetes Technol Ther* 2005;7:283–294.
2. Harris M: Frequency of blood glucose monitoring in relation to glycemic control in patients with type 2 diabetes. *Diabetes Care* 2001;24:979–982.
3. Evans J, Newton R, Ruta D, MacDonald T, Stevenson R, Morris A: Frequency of blood glucose monitoring in relation to glycemic control: Observational study with diabetes database. *BMJ* 1999;319:83–86.
4. Vincze G, Barner JC, Lopez D: Factors associated with adherence to SMBG among persons with diabetes. *Diabetes Educ* 2004;30:112–125.
5. Irvine AA, Saunders JT, Blank MB, Carter WR: Validation of a scale measuring environmental barriers to

- diabetes-regimen adherence. *Diabetes Care* 1990;13:705-711.
6. International Organization for Standardization: In Vitro Diagnostic Test Systems—Requirements for Blood-Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus. International Standard. Report Number ISO 15197:2003(E). Geneva: International Organization for Standardization, 2003.
 7. 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.

Address reprint requests to:

James H. Nichols, Ph.D., D.A.B.C.C., F.A.C.B.

Director, Clinical Chemistry

Baystate Health System

759 Chestnut Street

Springfield, MA 01199

E-mail: james.nichols@bhs.org