Journal of Diabetes Science and Technology
Volume 7, Issue 4, July 2013

ORIGINAL ARTICLE

Penny Wise and Pound Foolish: Will Shortsighted Cost Reduction Measures Compromise Patient Access to Promising Self-Monitoring of Blood Glucose Technology?

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Abstract

In this issue of *Journal of Diabetes Science and Technology*, Grady and coauthors enrolled 101 patients with type 1 and type 2 diabetes to evaluate new technology incorporated into the LifeScan VerioPro and VerioIQ blood glucose meters. The "pattern detection" software provides real-time, onscreen messages that alert users to patterns of high glucose (fasting and premeal) and low glucose as they are detected. The study showed that most participants possess a good understanding of the factors that can cause hyperglycemia; however, their understanding of the causes of hypoglycemia events was not as strong. Nevertheless, more than 70% of participants indicated they preferred to use a blood glucose meter that provides pattern detection capability. Although not designed to assess the impact of the pattern detection tool on clinical outcomes, the study highlights the value of continuous innovation in self-monitoring of blood glucose (SMBG) technology among manufacturers. Unfortunately, many patients may never have access to these systems due to reductions in Medicare reimbursement. Instead, they may be forced to use SMBG systems that are inaccurate and provide inadequate patient support. Stronger regulatory requirements are needed to ensure that all SMBG systems marketed to patients are accurate, reliable, and supported by adequate patient training, and current health care reimbursement policies should be restructured to encourage manufacturers to continue their efforts to develop innovative technology to further improve the utility and usability of their SMBG systems.

J Diabetes Sci Technol 2013;7(4):979–982

Numerous studies have shown that use of structured self-monitoring of blood glucose (SMBG) regimens improves clinical outcomes and quality of life in patients with insulin-treated and non-insulin-treated diabetes.[1–8] Structured SMBG is an approach in which blood glucose data are gathered according to a defined regimen, interpreted, and then utilized to make changes in therapy.[9] Effective utilization of structured SMBG requires that patients and/or their clinicians possess the knowledge to interpret SMBG data and the willingness to use those data to adjust treatment.[9,10]

To facilitate SMBG data interpretation, many manufacturers are incorporating innovative decision support and data management/interpretation software into the SMBG systems they produce. For example, in this issue of *Journal of Diabetes*

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Abbreviations: (AST) alternate site testing, (FDA) Food and Drug Administration, (SMBG) self-monitoring of blood glucose

Keywords: blood glucose monitoring, Food and Drug Administration, Medicare, structured self-monitoring of blood glucose, type 1 diabetes, type 2 diabetes

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Science and Technology, Grady and coauthors[11] evaluated new technology incorporated into the LifeScan VerioPro and VerioIQ blood glucose meters that informs users and clinicians about potentially problematic glucose trends. The "pattern detection" tool provides real-time, onscreen messages that alert users to patterns of high glucose (fasting and premeal) and low glucose as they are detected. It then prompts users to review the test results that caused the pattern message, thus enabling users and their clinicians to make appropriate adjustments in therapy.

In this multicenter, nonrandomized study, participants with type 1 or type 2 diabetes who were managed with multiple daily insulin injections or insulin pump therapy used the meters over a 4-week period, performing at least six blood glucose tests per day—one fasting, two premeal, one bedtime, and two discretionary. Participants were instructed to adjust their insulin regimens based on their test results and record low pattern, high fasting pattern, and high premeal pattern messages in their logbook and document their understanding of why these patterns occurred, using either predefined codes or free text. Low glucose patterns were defined as two readings <70 mg/dl within a 3 h time bracket over a 5-day period; high fasting and high premeal glucose patterns were defined as readings ≥130 mg/dl within a 3 h time bracket over a 5-day period. The investigators found that the average number of high glucose patterns detected per week correlated with higher baseline hemoglobin A1c and fasting plasma glucose levels; whereas, the average number of low glucose patterns correlated strongly with lower baseline hemoglobin A1c and lower fasting plasma glucose.

Although the study was not designed to assess the impact of the pattern detection tool on clinical outcomes, the investigators reported noteworthy insights regarding participants' ability to interpret the pattern alert messages. Review of diary data regarding participants' understanding of why the various glucose patterns occurred indicated that most participants possess a relatively good understanding of the factors that can cause hyperglycemia; however, their understanding of the factors associated with individual hypoglycemic events was not as strong. Another key finding was participants' high level of acceptance of the device—over 70% indicated they preferred to use a blood glucose meter that provides pattern detection capability, whereas less than 10% indicated a preference for using meters without this feature. Moreover, a study by Katz and coauthors[12] demonstrated that use of pattern detection technology was associated with greater clinician accuracy and efficiency in interpreting SMBG data compared with traditional logbooks.

The integrated pattern detection capability evaluated in these studies is but one example of the continuing advancements in SMBG technology. New SMBG systems with integrated insulin bolus advisors[13] and other sophisticated data analysis software[14] have demonstrated significant value in helping patients more safely manage their diabetes. Unfortunately, many patients may never realize these benefits.

Changes in Medicare reimbursement for blood glucose testing supplies, under the expanding Competitive Bidding Program, could potentially force retail pharmacies to carry only basic SMBG systems (which often provide no data download capability) or discontinue their enrollment as Medicare providers. As a result, many Medicare beneficiaries will be forced to purchase their SMBG supplies from mail-order companies, which, not surprisingly, predominantly promote the lower-cost SMBG systems. A survey conducted by the American Association of Diabetes Educators found that mail-order suppliers currently offer only approximately 38% of the SMBG brands that are said to be offered on the www.medicare.gov website.[15] Surveyors concluded that, under the Competitive Bidding Program, beneficiaries now have fewer choices and limited access to the diabetes test strips most commonly selected.

Even more concerning is that many of the "basic" meters offered by mail-order distributors fail to meet the current standards for testing accuracy. Studies have demonstrated that up to 45% of SMBG systems marketed to patients with diabetes do not meet even the minimum accuracy requirements as defined in the DIN EN ISO 15197 standard, showing significant lot-to-lot variability and in independent laboratory evaluations,[16–18] perhaps because current U.S. Food and Drug Administration (FDA) approval criteria for SMBG systems do not require manufacturers to include lot-to-lot testing data in their submission documents.[19] Moreover, many manufacturers of these SMBG products provide little or no medical device reporting of adverse events associated with the use of their systems; a violation of FDA requirements.[20]

Although the inaccuracies observed in many of the SMBG systems evaluated should raise concerns among health care professionals who prescribe SMBG, of equal (or perhaps greater) concern is the manner in which these systems are marketed to patients. Because many of the low-cost SMBG systems are available only through mail-order distribution channels, clinicians are often unaware of these products and/or that their patients are using them. This "disconnect" between clinicians and patients increases the potential for inadequate patient training and support that may result in even greater and more frequent inaccuracies due to user errors, which are a more significant source of inaccuracies than meter-related errors.[21]

Another concern is how these meters are "positioned" to patients. In an effort to encourage SMBG use, many manufacturers overemphasize alternate site testing (AST).[22] Studies have shown that blood glucose test results from AST may not accurately reflect current glycemic status when glucose levels are fluctuating and that AST (particularly monitoring at the forearm) should be limited to times in which ongoing rapid changes in blood glucose can be excluded.[23–25] Although manufacturers are required to include cautionary information regarding AST in their user manuals, these warnings may be missed or misinterpreted by patients. This poses significant dangers to elderly patients (Medicare beneficiaries), who are more susceptible to hypoglycemia than younger patients.[26,27] Although the motive behind promoting AST is to encourage use of SMBG, a study by Knapp and coauthors[28] found that adherence to SMBG regimens was significantly (p = .003) less among patients using AST compared with patients using fingertip testing.

Although attempting to reduce health care costs by reducing reimbursement for SMBG supplies may appear logical, it is clearly penny wise and pound foolish. Perhaps a more constructive approach to reducing health care costs would be to strengthen FDA regulatory requirements to ensure that all SMBG systems marketed to patients are accurate, reliable, and supported by adequate patient training; reductions in SMBG system errors can significantly reduce the incidence of undetected severe hypoglycemia and improve overall glycemic control,[29] which, in turn, can lead to significant cost savings and improved patient quality of life.[30,31] Moreover, current health care reimbursement policies should be restructured to encourage (not discourage) manufacturers to continue to develop and apply new, innovative technology to further improve the utility and usability of their SMBG systems.

Disclosure:

Christopher G. Parkin has received consulting fees from Roche Diagnostics, Dexcom, and Sanofi.

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