JOHNS HOPKINS MEDICINE
eLITERATURE REVIEW™
eDiabetes Review

Jointly Presented by the Johns Hopkins University School of Medicine and the Institute for Johns Hopkins Nursing

Supported by educational grants from Eli Lilly and Company, AstraZeneca, and Novo Nordisk, Inc.

eDiabetes Review
VOLUME 1, ISSUE 5

STRATEGIES AND DEVICES FOR IMPROVING SELF-MONITORING

In this Issue...

Although SMBG is widely recognized as a key component of diabetes management, many clinicians continue to question the usefulness of self-monitored blood glucose readings in long-term control.

In this issue, we review recent publications describing:

- empirical data describing specific HbA1C targets
- the benefits of structured SMBG in the diabetes management plan
- findings from the two-year follow-up of the STeP study on the continued use of an SMBG tool in a primary care setting
- the use of automated decision support tools (DST)
- the new International Organization for Standardization criteria for glucometers

LEARNING OBJECTIVES

After participating in this activity, the participant will demonstrate the ability to:

- Describe the benefits of structured self-monitored blood glucose (SMBG) for the health care provider caring for patients with type 2 diabetes mellitus (T2DM).
- List key benefits of SMBG in the overall health of the patient with T2DM.
- Identify appropriate fasting and postprandial glucose goals for a patient with T2DM

The Johns Hopkins University School of Medicine takes responsibility for the content, quality, and scientific integrity of this CME activity.

PLANNER DISCLOSURES — **Program Begins Below**

As a provider approved by the Accreditation Council for Continuing Medical Education (ACCME), it is the policy of the Johns Hopkins University School of Medicine Office of Continuing Medical Education (OCME) to require signed disclosure of the existence of financial relationships with industry from any individual in a position to control the content of a CME activity sponsored by OCME. Members of the Planning Committee are required to disclose all relationships regardless of their relevance to the content of the activity. Faculty are required to disclose only those relationships that are relevant to their specific presentation. The following relationship has been reported for this activity:

Om P. Ganda, MD, discloses that he has received grant/research funding from Amarin Pharma,Inc., and has served on advisory boards for Amgen and Sanofi.

No other planners have indicated that they have any financial interest or relationships with a commercial entity whose products or services are relevant to the content of their presentations.

IMPORTANT CME/CE INFORMATION

Program Information
CME Info
Accreditation
Credit Designations
Intended Audience
Learning Objectives
Internet CME Policy
Faculty Disclosures
Disclaimer Statement

Length of Activity
1.0 hour Physicians
1.0 contact hour Nurses

Launch Date
July 31, 2014

Expiration Date
July 30, 2016

TO ACCESS THE POST-TEST

Step 1.
Review the CE Information and study the educational content.

Step 2.
Click the post-test link at the end of the newsletter.

Step 3.
Follow the instructions to access a post-test.

GUEST AUTHOR OF THE MONTH

Commentary:

Susan Porter, MSN, CRNP, CDE

Clinical Nurse Practitioner and Certified Diabetes Educator
Johns Hopkins University School of Medicine
Baltimore, Maryland

Guest Faculty Disclosure

Susan Porter, MSN, CRNP, CDE discloses that she has no financial relationships with commercial supporters.

Unlabeled/Unapproved Uses

Susan Porter has indicated that there will be no references to unlabeled/unapproved uses of drugs or products.

Program Directors' Disclosures

IN THIS ISSUE

COMMENTARY

According to estimates from the Centers for Disease Control and Prevention, more than 25 million Americans > 20 years of age have diabetes, and approximately 35% of all US adults have prediabetes.[1] It is well known that uncontrolled diabetes is linked to microvascular and macrovascular disease; however, those risks can be reduced if glycemic control is maintained. Recent advancements in research and development for diabetes management have added new medication classes and medical technology; despite these advances, however, most patients with diabetes are not at their recommended treatment goals.[2]

As Dr. Mathioudakis noted in his eDiabetes Review newsletter issue (Volume 1, Issue 1), clinical inertia has been identified as a key contributor to suboptimal diabetes control. Other major obstacles include the competing clinical demands during time-limited office visits and finding resources to develop and implement efficient workflow protocols into practice.[3] Since the majority of diabetes patients in the US are treated in the fast-paced primary care setting, it is important that clinicians develop strategies to more effectively use all available tools and therapies to improve the management of type 2 diabetes mellitus (T2DM). One such tool is the use of structured self-monitoring of blood glucose (SMBG), providing a systematic approach to glucose monitoring that reveals glycemic patterns.

SMBG is widely recognized and recommended as a core component of diabetes management.[4] Although there is evidence that SMBG improves HbA1c in T2DM, many still question its usefulness in long-term control. The evidence presented in this issue's reviews demonstrate that the use of structured SMBG can improve diabetes management and adherence to lifestyle modifications and encourage clinicians to treat hyperglycemia earlier, more frequently, and more efficiently. Hemoglobin A1c is the gold standard for monitoring glycemic control, but it does not measure the day-to-day and intraday variability in glucose levels. There is evidence that glycemic variability independently increases the risk for endothelial dysfunction, cognitive impairment, vascular complications, and mortality.[5] Glycemic variability can be identified through SMBG, making it an important adjunct to HbA1C in determining glycemic control. SMBG can distinguish among fasting, preprandial and postprandial hyperglycemia; detect glycemic excursions; identify hypoglycemia; and provide immediate feedback to patients and providers about the effects food choices, activity, and medication have on control.[6]

The evidence presented in the literature shows that it is important that providers treating T2DM understand the value of structured SMBG, personalize the approach, and use the data to interact and embed SMBG into each patient's diabetes management plan. The importance of this personalized approach cannot be over-emphasized when discussing glucose targets. The study by Wei et al establishes glucose targets for HbA1c ranges by reviewing empirical data. Their research found that our current recommendation of a fasting glucose goal of 90-130 mg/dl often pushes patients too low and increases the risk of hypoglycemia. The evidence presented in this paper is important for clinicians to review because it questions our current recommendations and gives patients realistic and individualized HbA1c target goals.

Once the glucose targets are established and the SMBG data is collected, it is useful for the clinician to be able to view the information in a way that can help identify trends to better inform therapeutic decision-making. There are numerous glucometers available on the market today and many of the companies provide software to download SMBG data. A member of the office staff can easily be trained to quickly download the information and include it in the patient's chart. This can be very helpful to the clinician during the time-limited office visits and can also serve as a teaching tool for both clinicians and patients. At our Diabetes Center, we ask every patient to bring their glucometer to each visit and download it whenever possible. It is a tool that I find invaluable to the management of my patients.

It is important to note that not all glucometers can download data and not all glucometers are equally accurate, as noted in the article by Brazg et al. While the patient's choice of glucometer is often based on provider recommendation, insurance formulary, or other financial considerations, it is important that providers know the quality of the glucometers their patients are using. Further, if the data cannot be downloaded, the clinician should try to have a plan with patients to present the SMBG data in a way that it can be quickly analyzed for trends.

Once trends are identified, it is important that providers use this information to guide treatment. The use of decision-support tools (DST) was examined by Rodbard et al. That study found that although DST can help clinicians identify glycemic abnormalities and make appropriate therapeutic decisions to address patterns, even with the increased use of DST the appropriate treatment decision was not always carried out. This finding underscores the need for additional development in DST to help guide the busy clinician. It

should also be noted that the DST used in the Rodbard et al study was developed specifically for that study and, to my knowledge, is not available for use in the clinical setting.

As a diabetes nurse practitioner and clinical diabetes educator at the Johns Hopkins Diabetes Center, I see patients with type 2 diabetes daily, ranging from the well-controlled to the patient with highly complex, uncontrolled diabetes. Each patient I see is asked to perform SMBG and provide me the data, usually by downloading the glucometer readings. By analyzing this important information, I can make informed therapeutic decisions to more effectively manage their diabetes. I hope the information I provide in this newsletter will encourage all providers to incorporate SMBG into their clinical management of patients with type 2 diabetes.

References

1. Centers for Disease Control and Prevention: National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. Atlanta, Georgia., U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011.
2. Saydah SH, Fradkin J, Cowie CC. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. *JAMA*. 2004;291(3):335-342.
3. Parchman ML, Pugh JA, Romero RL, Bowers KW. Competing demands or clinical inertia: The case of elevated glycosylated hemoglobin. *Ann Fam Med*. 2007;5(3):196-201.
4. American Diabetes Association. Standards of medical care in diabetes--2013. *Diabetes Care*. 2013;36 Suppl 1:S11-66.
5. Nalysnyk L, Hernandez-Medina M, Krishnarajah G. Glycaemic variability and complications in patients with diabetes mellitus: Evidence from a systematic review of the literature. *Diabetes Obes Metab*. 2010;12(4):288-298.
6. Parkin CG, Davidson JA. Value of self-monitoring blood glucose pattern analysis in improving diabetes outcomes. *J Diabetes Sci Technol*. 2009;3(3):500-508.

back to top

NEW GLUCOSE TARGETS BASED ON EMPIRICAL DATA

Wei N, Zheng H, Nathan DM. Empirically establishing blood glucose targets to achieve HbA1c goals. *Diabetes Care*. 2014;37(4):1048-1051.

View journal abstract View full article

This study by Wei et al questioned the longstanding glucose targets we have been using for decades and discovered that the current recommendations are pushing patients too hard to achieve lower fasting glucose levels than required. The researchers sought to determine the average fasting, postprandial, and bedtime glucose values required to achieve and maintain target HbA1c levels in the outpatient setting. They analyzed blood glucose data from the hemoglobin A1c-Derived Average Glucose (ADAG) study, a multicenter observational study that used continuous glucose monitoring (CGM) and self-monitoring blood glucose (SMBG) testing to determine the relationship between average glucose and HbA1c.[1]

The three-month ADAG study consisted of 507 nonpregnant adults with type 1 and type 2 diabetes between 18 and 70 years old with stable HbA1c values. During the 12-week study period, HbA1c was measured monthly, and continuous glucose monitoring (CGM) was performed at baseline and three times at four-week intervals for at least a 48-hour period. The participants were instructed to perform eight-point SMBG (preprandial, 90 min postprandial, bedtime, and 3 a.m.) while wearing the CGM. Wei and colleagues performed analyses on a total of 30,108 (4,031 fasting, 12,943 before meals, 12,602 90 minutes after a meal, and 4,563 at bedtime) blood glucose values monitored over an average of 11 days per participant during the study. The mean fasting, premeal, postmeal, and bedtime blood

glucose (BG) for each participant was calculated, averaged in groups based on HbA1c (5.5-6.49%, 6.5-6.99%, 7.0-7.49%, 7.5-7.99% and 8.0-8.5%), and compared between type 1 and type 2 patients with diabetes.

As expected, the study found no difference in mean fasting BG between type 1 and type 2 diabetes patients within the same HbA1c group, but patients with type 1 had higher average pre-meal BG. The authors determined that for a patient with type 2 diabetes who had an HbA1c goal of 6.5-6.99%, mean glucose values as detrmined by SMBG were 139 fasting, 137 premeal, 170 post-meal and 151 mg/dl at bedtime. A chart of all suggested glucose targets for HbA1c ranges can be found in the original article.

The importance of glycemic control to ameliorate diabetes complications has been well documented by the Diabetes Control and Complications Trial (DCCT) and UK Prospective Diabetes Study (UKPDS), and there has been much effort to achieve the HbA1c targets that proved effective in these studies. The SMBG targets for the DCCT, which are commonly referred to in clinical practice, are 70-120 mg/dl preprandial and < 180 mg/dl postprandial. Although the origin of these targets is unclear, it appears to be based on expert opinion or extrapolations from regression equations comparing the means of all the daily capillary-measured plasma glucose levels, independent of the distribution during the day, and HbA1c.2 The findings by Wei et al demonstrated that the current SMBG targets are not consistent with the empirical data and are more aggressive with the fasting BG levels, whereas the postprandial BG levels are more in line with the current targets. In addition, the authors were able to quantify the actual postprandial value for patients with type 1 and type 2 diabetes (~ 150 mg/dl) that will result in HbA1c levels < 7%.

The current diabetes guidelines specify that treatment goals should be individualized based on age, comorbidities, and duration of illness.[2,3] Considering the safety concerns surrounding hypoglycemia, especially in high risk patients, the current recommendations should be reevaluated. In light of this study, reasonable blood glucose targets for patients with type 2 diabetes aiming for an A1C between 6.5% and 6.99% might be 130-150 fasting and 160-180 mg/dl postprandial. This study establishes realistic target BG levels, based on empirical data, that the authors hope will be used by professional societies and clinicians to guide individualized patient-centered care.

References

1. Wei N, Zheng H, Nathan DM. Empirically establishing blood glucose targets to achieve HbA1c goals. *Diabetes Care*. 2014;37(4):1048-1051.
2. Nathan DM, Kuenen J, Borg R, et al. Translating the A1C assay into estimated average glucose values. *Diabetes Care*. 2008;31(8):1473-1478.
3. American Diabetes Association. Standards of medical care in diabetes--2013. *Diabetes Care*. 2013;36 Suppl 1:S11-66.

back to top

RECENT STUDIES OF SMBG IN TYPE 2 DIABETES CHALLENGING THE COCHRANE REVIEW

Schnell O, Alawi H, Battelino T, et al. Monitoring of blood glucose in type 2 diabetes: recent studies. *J Diab Sci Technol*. 2013;7(2):478-488.

View journal abstract View full article

SMBG has been recognized as a core component of diabetes management,[1] based on evidence that SMBG improves long-term control in patients with T2DM, helps prevent complications, and increases awareness of hypoglycemia.[2-6] Despite this evidence, some authors have presented conflicting observations, citing that SMBG increases treatment burden for patients and could lead to anxiety and self-blame.[5] In January 2012, a long awaited Cochrane database review on SMBG in patients with non-insulin-requiring T2DM reported a "small" overall effect on glycemic control that was considered to subside after 12 months.[6] This review has been criticized, as many studies, including the widely

recognized STeP study, were excluded from the analysis.[7] The aim of this 2013 review by Schnell et al was to present the results of innovative studies and publications on SMBG in T2DM and to discuss the results in light of the Cochrane review. Schnell's review included six new trials and six trials included in the Cochrane review, which taken together gave a more complete picture on the effects and potentials of SMBG in T2DM.

The key trials included were:

- Structured Testing Program study (STeP)[8]
- St. Carlos study[9]
- Role of Self-Monitoring of Blood Glucose and Intensive Education in Patients with Type 2 Diabetes Not Receiving Insulin[10]
- Retrospective Study Self-Monitoring of Blood Glucose and Outcome in Patients with Type 2 Diabetes-In-Praxi Follow-Up (ROSSO-in-praxi)[11]
- Delivering Early Care in Diabetes Evaluation Study[12]
- Prospective Randomized Trial on Intensive Self-Monitoring of Blood Glucose Management Added Value in Non-Insulin-Treated Type 2 Diabetes Mellitus Patients (PRISMA).[13]

All of the studies showed that structured SMBG led to either improvements in HbA1c, lifestyle modifications, and/or improvement in identifying glycemic abnormalities.[10-15]

Reviews and meta-analyses included were:

- Aberdeen Health Technology Assessment Group[14]
- The Meta-Analysis of Individual Patent Data in Randomized Trials of Self-Monitoring of Blood Glucose in People with Non-Insulin-Treated Type 2 Diabetes[15]

The Aberdeen Health Technology Assessment Group, which included a review of 10 trials, did find a statistically significant reduction in HbA1C of 0.21% in favor of SMBG. The meta-analysis, which included six trials, found a mean improvement of 0.35% in HbA1C at 12 months; although important, this was considered "not convincing for a clinically meaningful effect."[14,15]

Other documents included in Schnell's review were:

- Case-Based Recommendations for Self-Monitoring of Blood Glucose; Personalizing Treatment in Type 2 Diabetes[16,17]

- The Current Role of Self-Monitoring of Blood Glucose in Non-Insulin-Treated Type 2 Diabetes[18]

- Addressing Schemes of Self-Monitoring of Blood Glucose in Type 2 Diabetes: A European Perspective and Expert Recommendation. [19]

The authors also reviewed guidelines by the International Diabetes Federation (IDF) for Self-Monitoring of Blood Glucose in Non-Insulin-Treated Type 2 Diabetes, the IDF Guidelines for the Management of Postmeal Glucose, and the ADA Position Statement 2012: Further Standards of Medical Care in Diabetes. These documents recommend individualized care and support the use of structured SMBG monitoring with education given to patients and providers on how to respond to the results. Further, the IDF and ADA support the use of SMBG use in the patient with T2DM and recommend that it be implemented into the diabetes management plan.[1,20]

The authors' analysis of the studies and reviews listed above found the evidence showed that the use of SMBG demonstrated HbA1C reduction, improvement of glycemic variability, visualization of hypoglycemic episodes, and improvements in lifestyle and medication adherence. The key finding is that SMBG must be structured and personalized, and both patients and clinicians should incorporate SMBG into diabetes management

plans. The authors felt that further studies on SMBG were needed in glucose meters accuracy, development of software-based approaches to visualize glucose values, and the use of telemedicine approaches.

References

1. American Diabetes Association. Standards of medical care in diabetes-2013. *Diabetes Care*. 2013;36(Suppl. 1):S11-S66.
2. Allemann S, Houriet C, Diem P, Stettle C. Self-monitoring of blood glucose in non-insulin treated patients with type 2 diabetes: a systematic review and meta-analysis. *Curr Med Res Opin*. 2009;25(12):2903-13.
3. Kovatchev BP, Otto E, Cox D, Gonder-Frederick L, Clarke W. Evaluation of a new measure of blood glucose variability in diabetes. *Diabetes Care*. 2006;29(11):2433-8.
4. Schnell O, Alawi H, Battelino T, Ceriello A, Diem P, Felton A, Grzeszczak W, Harno K, Kempler P, Satman I, Verges B. Consensus statement on self-monitoring of blood glucose in Diabetes: a European perspective. *Br J Gen Pract*. 2004 Mar;54(500):183-8.
5. Peel E, Parry O, Douglas M, Lawton J. Blood glucose self-monitoring in non-insulin treated type 2 diabetes: a qualitative study of patients' perspectives. *Br J Gen Pract*. 2004;54(500):183-8n.
6. Malanda UL, Welschen LM, Riphag II, Dekker JM, Nijpels G, Bot SD. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. *Cochrane Database Syst Rev*. 2012;1:CD005060.
7. Schnell O, Alawi H, Battelino T, et al. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin: letter to the editor. *Cochrane Database Syst Rev*. 2012;1:CD005060.
8. Polanski WH, Fisher L, Schikman CH, et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: Results from the structured testing program study. *Diabetes Care*. 2011;34(2):262-267.
9. Duran A, Martin P, Runkle I, et al. Benefits of self-monitoring blood glucose in the management of new-onset type 2 diabetes mellitus: the St Carlos Study, a prospective randomized clinic-based interventional study with parallel groups. *J Diabetes*. 2010;2(3):203-11
10. Franciosi M, Lucisano G, Pellegrini F, et al; ROSES Study Group. ROSES: role of self-monitoring of blood glucose and intensive education in patients with type 2 diabetes not receiving insulin. A pilot randomized clinical trial. *Diabet Med*. 2011:28(7):789-96.
11. Kempf K, Kruse J, Martin S. ROSSO-in-praxi follow-up: long term effects of self-monitoring of blood glucose on weight, hemoglobin a1c, and quality of life in patients with type 2 diabetes mellitus. *Diabetes Technol Ther*. 2012;14(1):59-64.
12. Rodbard HW, Schnell O, Unger J, et al. Use of an automated decision support tool optimizes clinicians' ability to interpret and appropriately respond to structured self-monitoring of blood glucose data. *Diabetes Care*. 2012;35(4):693-698.
13. Scavini M, Bosi E, Ceriello A, et al. Prospective, randomized trial on intensive SMBG management added value in non-insulin-treated T2DM patients (PRISMA): a study to determine the effects of a structured SMBG intervention. *Acta Diabetol*. 2011. Epub ahead of print.
14. Clar C, Barnard K, Cummins E, Royle P, Waugh N: Aberdeen Health Technology Assessment Group. Self-monitoring of blood glucose in type 2 diabetes: systematic review. *Health Technol Assess*. 2010;14(12):1-140.
15. Farmer AJ, Perera R, Ward A, et al. Meta-analysis of individual patient data in randomized trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes. *BMJ*.2012;344:e486
16. Schnell O, Alawi H, Battelino T, et al. A consensus of clinical cases on self-monitoring of blood glucose: a European perspective. Diab Metab Heart. 2010;19(5):3-25
17. Ceriello A, Gallo M, Armentano V, Perriello G, Gentile S, De Micheli A; Associazione Medici Diabetologi. Personalizing treatment in type 2 diabetes: a self-monitoring of blood glucose inclusive innovative approach. *Diabetes Technol Ther*. 2012;14(4):373-8
18. Klonoff DC, Blonde L, Cembrowski G, et al. Coalition for Clinical Research-Self-Monitoring of Blood Glucose Scientific Board. Consensus report: the current role of self-monitoring of blood glucose in non-insulin-treated type 2 diabetes. *J Diabetes Sci Technol*. 2011;5(6):1529-48.
19. Schnell O, Alawi H, Battelino T,et al. Addressing schemes of self-monitoring of blood glucose in type 2 diabetes: a European perspective and expert recommendation. *Diabetes Technol Ther*. 2011;13(9):959-65.
20. International Diabetes Federation: IDF guideline on self-monitoring of blood glucose in non-insulin treated type 2 diabetes.

back to top

USE OF STEP STUDY SMBG TOOLS 2 YEARS LATER (STEP PLUS)

Friedman K, Noyes J, Parkin CG. 2-year follow-up to STeP trial shows sustainability of structured self-monitoring of blood glucose utilization: Results from the STeP practice logistics and usability survey (STeP PLUS). *Diabetes Technol Ther*. 2013;15(4):344-347.

View journal abstract View full article

The Structured Testing Program study (STeP) was one of the largest studies to show that the use of structured SMBG positively affects both clinician and patient behaviors and improves clinical outcomes in patients with diabetes.[1] This 12-month, prospective, cluster-randomized, multicenter trial evaluated the use of structured SMBG using the Accu-Chek 360° View tool in 483 insulin-naïve patients with poorly controlled type 2 diabetes from 34 US primary care practices. The Accu-Chek 360° View tool enabled patients to record a seven-point SMBG profile (fasting, preprandial/two hours postprandial at each meal, bedtime) on three consecutive days, document meal size and energy levels, and comment on their SMBG experiences. The STeP study found that patients who used structured SMBG experienced significantly greater improvement in glycemic control and self-efficacy in managing their disease and had less depression and diabetes-related distress.[2] Not only was this study's outcomes impactful, it was also conducted in the primary care setting where the majority of patients with diabetes in the United States are managed.

Two years after completion of the initial STeP study, in Step PLUS, Freidman and colleagues examined whether structured SMBG continued to be beneficial in a real-world clinical setting by conducting a survey of the clinicians participating in the study to assess their attitudes towards the use of Accu-Chek 360° View tool.

Fifteen of the original 21 physicians who participated in the experimental arm of the STeP trial completed an online questionnaire and phone interview to provide further insight into their use of and attitudes toward the tool. Thirteen (86.6%) of the physicians indicated they were currently using the tool in their practice for patients with type 1 and type 2 diabetes and identified the most common clinical situation for use of the tool was that patients could benefit from assistance in problem-solving. The patients typically used the tool as a continuing component of self-management every three or six months and after a medication change in patients with newly diagnosed diabetes, and in those new to fixed insulin or basal-bolus insulin therapy. All users confirmed that the tool allowed them to make more effective medication changes and facilitate discussions with patients about the impact of exercise and meals on glucose control; the majority also reported that it allowed them to make medication decisions more quickly and frequently. Equally if not more important, the majority agreed that the tool enabled them to build more collaborative relationships with their patients, engage patients in their diabetes management, and improve overall diabetes management and outcomes. The main challenges identified were finding the time to train staff and patients to use the tool, convincing patients to perform SMBG at the frequency required, and the cost of test strips for patients without insurance.

The interpretation of trends of SMBG to help guide treatment is crucial in the management of type 2 diabetes. Although this survey had the limitations of small sample size and use of self-reported data (which may not accurately reflect actual attitudes and behaviors), the results from this survey and phone interview suggest that the use of structured SMBG is beneficial and feasible in primary care.

References

1. Polonsky WH, Fisher L, Schikman CH, et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: Results from the structured testing program study. *Diabetes Care*. 2011;34(2):262-267.
2. Fisher L, Polonsky WH, Parkin CG, Jelsovsky Z, Petersen B, Wagner RS. The impact of structured blood glucose testing on attitudes toward self-management among poorly controlled, insulin-naive patients with type 2 diabetes. *Diabetes Res Clin Pract*. 2012;96(2):149-155.

back to top

DECISION SUPPORT TOOLS FOR TYPE 2 DIABETES MANAGEMENT

Rodbard HW, Schnell O, Unger J, et al. Use of an automated decision support tool optimizes clinicians' ability to interpret and appropriately respond to structured self-monitoring of blood glucose data. *Diabetes Care*. 2012;35(4):693-698.

View journal abstract View full article

Recent studies have demonstrated that more timely therapeutic changes are initiated when structured SMBG is combined with comprehensive clinical education on interpretation and use.[1] This finding is significant in light of the information Dr. Mathioudakis presented in his eDiabetes Review newsletter (Vol 1; Issue 1) on clinical inertia, particularly that it often takes the average clinician six years to initiate insulin in a patient with uncontrolled type 2 diabetes. In this study, Rodbard and colleagues developed an automated decision support tool that analyzes SMBG data from the Accu-Chek 360° View blood glucose data collection tool (Roche Diagnostics, Indianapolis, Indiana) and generates a printed report that identifies the primary glycemic abnormality and recommends appropriate therapeutic options. The purpose of the study was to assess the impact of the use of decision support tool (DST) reports on the clinician's ability to correctly interpret structured SMBG data and make appropriate therapeutic decisions.

This was a two-month, multicenter, prospective, randomized study involving 288 clinicians (39.6% family practice physicians, 37.9% general internal medicine physicians, and 22.6% nurse practitioners) who were randomized into four groups (each group n = 72):

a) **STG:** structured SMBG alone, with a data collection tool used enabled patients to record and plot a seven-point SMBG profile for three consecutive days and document meal sizes and energy levels;

b) **DST:** structured SMBG with a decision support tool that graphed and tabulated the SMBG results to provide an automated analysis of results by identifying glycemic patterns;

c) **DVD**: structured SMBG with an educational 28-minute DVD that provided information about SMBG pattern management, with content based on the training clinicians received in the STeP study; d) DST+DVD: structured SMBG with DST and the educational DVD.

Each clinician analyzed 30 patient cases involving type 2 diabetes and was asked to identify the primary abnormality and select the most appropriate therapy.

A total of 222 (77%) clinicians completed all 30 cases (n = 61 STG; n = 50 DST; n = 53 DVD; and n = 58 DST+DVD). In all cases, significantly more DST (49%), DVD (51%), and DST+DVD (55%) clinicians correctly identified the glycemic abnormality and selected the most appropriate therapeutic option compared with STG (33%) clinicians (all $P < .0001$), with no significant difference among DST, DVD, and DST+DVD. Approximately 94% of the clinicians in all groups believed the information provided in the data collection tool was more accurate than data provided in conventional logbooks, and 74% felt it provided more useful information than HbA1c data. Over 90% of the DST and DST+DVD clinicians reported the automated support tool provided clinically useful information and enhanced interpretation of the SMBG data, and > 95% said the DVD helped them more accurately identify glycemic patterns presented in the data collection tool and use this data to adjust patient medications.

SMBG is most useful when glucose data is collected in a structured pattern, accurately interpreted, and when the information provided results in prompt therapeutic actions. Despite the fact that use of structured SMBG was shown to enhance clinicians' ability to correctly identify significant patterns and make therapeutic decisions to address those patterns, many clinicians still did not accurately identify and appropriately treat the primary

glycemic abnormality. The author's findings demonstrate the need for further improvements in clinical diabetes management with structured SMBG interventions that provide actual clinical decision support. Addressing this gap would help address the long-standing problem of "clinical inertia" in the care of patients with type 2 diabetes.

References

1. Polonsky WH, Fisher L, Schikman CH, et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: Results from the structured testing program study. *Diabetes Care*. 2011;34(2):262-267.

back to top

COMPARING GLUCOMETERS AVAILABLE FOR USE BY PATIENTS

Brazg RL, Klaff LJ, Parkin CG. Performance variability of seven commonly used self-monitoring of blood glucose systems: Clinical considerations for patients and providers. *J Diabetes Sci Technol*. 2013;7(1):144-152.

View journal abstract View full article

Many studies have demonstrated the benefit of SMBG, and the ADA has recommended its use in managing patients with T2DM.[1,2] Numerous blood glucose glucometers are available on the market and patients often look to their providers to recommend which one to purchase. It is important that providers make recommendations based on performance standards and understand that all glucometers available are not necessarily equally accurate.

The authors of this study evaluated seven SMBG systems currently on the market in the United States, comparing them against the old International Organization for Standardization ISO criteria (ISO 15197:2003[E]) and the new ISO criteria (ISO 15197:2013) to assess their accuracy in measuring BG levels. The study took place September 2011 through February 2012 and compared seven SMBG systems, consisting of glucometers and test strips. These included (1) Accu-Chek Aviva Plus (Roche Diagnostics, Indianapolis, Indiana); (2) Advocate Redi-Code (TaiDoc Technology Corporations, New Taipei City, Taiwan); (3) Element (Infopia Co. Ltd., Anyang, Republic of Korea); (4) Embrace (Apex Biotechnology Corp., Hsinchu, Taiwan); (5) Prodigy Voice (Diagnostic Devices Inc., Taipei, Taiwan); (6) TRUEbalance (Nipro Diagnostics, Ft. Lauderdale, Florida); and (7) WaveSense Presto (AgaMatrix, Salem, New Hampshire).

The SMBG meters were tested in two groups: group 1: Accu-Chek Avvia Plus, Advocate Redi-Code, Embrace, and TRUEbalance; and group 2: Accu-Chek Aviva Plus, WaveSense Presto, Element, and Prodigy Voice. A total of six glucometers were used per system (12 for Accu-Chek since it was in both groups) and three test strip lots.

- The blood samples of the study patents were collected and distributed in glucose concentration "bins" based on the mean reference BG value of the first reference measurement taken immediately before SMBG measurement and the second reference taken immediately after. These bins were based on the ISO 15197:2003(E) accuracy criteria: 5% of values at < 50 mg/dl, 15% at 50-80 mg/dl, 20% at 81-120 mg/dl, 30% at 121-200 mg/dl, 15% at 201-300 mg/dl, 10% at 301-400 mg/dl, and 5% at > 400 mg/dl. The finger puncture and blood sample testing was obtained by a trained technician who performed the initial reference collection, BG testing with all of the 24 SMBG meter system from group 1 and group 2, and then a final reference collection was obtained. Test strips were randomly selected and rotated every 10 subjects and more frequently when collecting extreme high and low samples.

Accu-Chek Aviva Plus was the only system that met the new (proposed at the time the article was written) ISO accuracy criteria requirement with minimal lot-to-lot variation. A hematocrit effect was seen in the Advocate Redi-Code, Embrace, TRUEbalance, Element, and Prodigy Voice systems, with the bias being greatest at the lower (35%) and upper (55%) range. This hematocrit effect is of great concern among elderly patients with diabetes and chronic kidney disease, in whom accurate detection of hypoglycemia has significant clinical implications.

In addition, this population (likely Medicare beneficiaries) is more likely to be affected by the financial burden of costly test strips. In fact, Medicare beneficiaries are most often directly marketed to by companies whose glucometers were not shown to meet the new accuracy criteria. A limitation of this study is that it did not evaluate some of the other more commonly available glucometers in clinical practice such as Bayer Contour, Freestyle Freedom Lite, and One Touch Verio. This link to the Practice Advisory Blood Glucose Meter Accuracy issued September 16, 2013 by the American Association of Diabetes provides details about more glucometers available for use. (http://www.diabeteseducator.org/export/sites/aade/_resources/pdf/research/Practice_Advisory_BGM_FINAL.pdf)

References

1. American Diabetes Association. Standards of medical care in diabetes--2013. *Diabetes Care*. 2013;36 Suppl 1:S11-66.
2. Polonsky WH, Fisher L, Schikman CH, et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: Results from the structured testing program study. *Diabetes Care*. 2011;34(2):262-267.

back to top

IMPORTANT CME/CE INFORMATION

ACCREDITATION STATEMENTS

Physicians

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the Johns Hopkins University School of Medicine and The Institute for Johns Hopkins Nursing. The Johns Hopkins University School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

Nurses

The Institute for Johns Hopkins Nursing and the American Nursing Credentialing Center do not endorse the use of any commercial products discussed or displayed in conjunction with this educational activity.

CREDIT DESIGNATION STATEMENT

Physicians

eNewsletter: The Johns Hopkins University School of Medicine designates this enduring material for a maximum of 1.0 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Podcast: The Johns Hopkins University School of Medicine designates this enduring material for a maximum of 0.5 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nurses

eNewsletter: This 1 contact hour educational activity is provided by the Institute for Johns Hopkins Nursing. Each newsletter carries a maximum of 1 contact hour or a total of 8 contact hours for the eight newsletters in this program.

Podcast: This 0.5 contact hour educational activity is provided by the Institute for Johns Hopkins Nursing. Each podcast carries a maximum of 0.5 contact hours

STATEMENT OF NEED

- Clinicians do not appropriately intensify therapy as necessary to maintain glycemic control.
- Conflicting data about the safety of incretin agents may unduly deprive patients of treatment benefits.
- Clinicians are not aware of and/or are not implementing strategies to maximize the value of SMBG readings to improve patient outcomes.
- Clinicians do not adequately understand or treat to control CVD risk factors in their patients with T2D.
- Clinicians do not have a sufficiently current knowledge base to effectively consult patients about potential T2D therapeutic advances.
- Clinicians do not adequately counsel and treat their overweight/obese patients with T2D.

INTENDED AUDIENCE

The target audience for this initiative includes: endocrinologists, primary care clinicians, nurse practitioners, physician assistants, Certified Diabetes Educators, and other health care practitioners whose work/practice includes treating patients with T2D.

POLICY ON FACULTY AND PROVIDER DISCLOSURE

As a provider approved by the Accreditation Council for Continuing Medical Education (ACCME), it is the policy of the Johns Hopkins University School of Medicine Office of Continuing Medical Education (OCME) to require signed disclosure of the existence of financial relationships with industry from any individual in a position to control the content of a CME activity sponsored by OCME. Members of the Planning Committee are required to disclose all relationships regardless of their relevance to the content of the activity. Faculty are required to disclose only those relationships that are relevant to their specific presentation. The following relationships have been reported for this activity:

or a total of 3 contact hours for the six podcasts in this program.

SUCCESSFUL COMPLETION
To successfully complete this activity, participants must read the content, and then link to the Johns Hopkins University School of Medicine's website or the Institute for Johns Hopkins Nursing's website to complete the post-test and evaluation. A passing grade of 70% or higher on the post-test/evaluation is required to receive CE credit.

LAUNCH DATE
July 31, 2014; activities expire 2 years from the date of publication.

There are no fees or prerequisites for this activity.

INTERNET CME POLICY
The Office of Continuing Medical Education (CME) at the Johns Hopkins University School of Medicine is committed to protecting the privacy of its members and customers. The Johns Hopkins University SOM CME maintains its Internet site as an information resource and service for physicians, other health professionals, and the public.

Continuing Medical Education at the Johns Hopkins University School of Medicine will keep your personal and credit information confidential when you participate in an Internet-based CME program. Your information will never be given to anyone outside of the Johns Hopkins University School of Medicine's CME program. CME collects only the information necessary to provide you with the services that you request.

DISCLAIMER STATEMENT
The opinions and recommendations expressed by faculty and other experts whose input is included in this program are their own. This enduring material is produced for educational purposes only. Use of the Johns Hopkins University School of Medicine name implies review of educational format design and approach. Please review the complete prescribing information of specific drugs or combination of drugs, including indications, contraindications, warnings, and adverse effects before administering pharmacologic therapy to patients.

STATEMENT OF RESPONSIBILITY
The Johns Hopkins University School of Medicine takes responsibility for the content, quality, and scientific integrity of this CME activity.

Guest Author Disclosures

CONFIDENTIALITY DISCLAIMER FOR CONFERENCE ATTENDEES
I certify that I am attending a Johns Hopkins University School of Medicine CME activity for accredited training and/or educational purposes.

I understand that while I am attending in this capacity, I may be exposed to "protected health information," as that term is defined and used in Hopkins policies and in the federal HIPAA privacy regulations (the Privacy Regulations). Protected health information is information about a person's health or treatment that identifies the person.

I pledge and agree to use and disclose any of this protected health information only for the training and/or educational purposes of my visit and to keep the information confidential.
I understand that I may direct to the Johns Hopkins Privacy Officer any questions I have about my obligations under this Confidentiality Pledge or under any of the Hopkins policies and procedures and applicable laws and regulations related to confidentiality. The contact information is Johns Hopkins Privacy Officer, telephone: 410-735-6509, e-mail: HIPAA@jhmi.edu.

"The Office of Continuing Medical Education at The Johns Hopkins University School of Medicine, as provider of this activity, has relayed information with the CME attendees/participants and certifies that the visitor is attending for training, education and/or observation purposes only."

For CME Questions, please contact the CME Office at (410) 955-2959 or e-mail cmenet@jhmi.edu.

For CME Certificates, please call (410) 502-9634.

Johns Hopkins University School of Medicine
Office of Continuing Medical Education
Turner 20/720 Rutland Avenue
Baltimore, Maryland 21205-2195

Reviewed and Approved by
General Counsel, Johns Hopkins Medicine (4/1/03)
Updated 4/09

HARDWARE & SOFTWARE REQUIREMENTS
Pentium 800 processor or greater, Windows 98/NT/2000/XP/7 or Mac OS 9/X, Microsoft Internet Explorer 5.5 or later, 56K or better modem, Windows Media Player 9.0 or later, 128 MB of RAM, sound card and speakers, Adobe Acrobat Reader, storage, Internet connectivity, and minimum connection speed. Monitor settings: High color at 800 x 600 pixels.

back to top