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Optimizing Outcomes Via Real-Time CGM: The NP/PA's Primary Tool in Improving Intensive Diabetes Management

A CME-Certified dinner symposium to be held in conjunction with the Metabolic & Endocrine Disease Summit West

Wednesday, July 15, 2015 • 5:00 PM
Paris Hotel • Las Vegas, NV

Jointly provided by

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This activity is supported by an independent educational grant provided by **Dexcom**.

Consortium for Glucose Monitoring Education

A unique CME-certified initiative committed to improving outcomes in diabetes management through education about continuous glucose monitoring.

INTENDED AUDIENCE

Nurse Practitioners, Physician Assistants and Certified Diabetes Educators interested in the management of diabetes attending the Metabolic and Endocrine Disease Summit.

STATEMENT OF NEED

Self-monitoring of blood glucose is a core component of a diabetic patient's management but only provides a measurement of blood glucose levels at a specific point in time, without necessarily informing about trends and hyperglycemic or hypoglycemic excursions. Glycosylated hemoglobin (A1C) is an even more limited measure, as it reports a mean of readings over 90 days; therefore, the patient is not alerted about fluctuations in blood glucose at any point in time.

Selection of an appropriate continuous glucose monitoring (CGM) device is important because improvements in accuracy and reliability are ongoing. Real-time (RT) CGM is one cornerstone of optimal glycemic control. Each CGM device varies; relying on different sensing technology and requiring the traditional finger-sticks for confirmation of alerts. The mean absolute relative difference (MARD) between sensor readings and reference glucose levels can vary by as much as 20%, with worrisome discrepancies in the hypoglycemic range. However, new-generation devices have significantly improved MARD measurements. These devices have shorter lag times and greater accuracy.

Many physicians lack the appropriate level of knowledge to employ CGM as part of their practices, highlighting the need for staff training and programs for patient training. Furthermore, economic data support reimbursement benefits of CGM, underscoring recent efforts to expand coverage. Educational programs focused on these knowledge and coverage gaps will enable healthcare professionals to provide improved patient care and continuous coverage to improve healthcare outcomes.

EDUCATIONAL OBJECTIVES

1. Identify methods for optimizing therapy and improving clinical outcomes using personal and professional RT CGM in adult populations
2. Employ applicable management strategies in clinical practice for personal and professional RT CGM in adult populations

ACCREDITATION AND CERTIFICATION

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Dannemiller and CogniMed Inc. Dannemiller is accredited by the ACCME to provide continuing medical education for physicians.

Dannemiller designates this live activity for a maximum of 1.5 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Dannemiller is approved as a provider of nurse practitioner continuing education by the American Association of Nurse Practitioners: AANP Provider Number 090419. This program was planned in accordance with AANP CE Standards and Policies and AANP Commercial Support Standards. It provides 1.5 hours of continuing education.

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This activity is supported by an independent educational grant provided by Dexcom.

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This content and views presented in this educational activity are those of the authors and do not necessarily reflect those of Dannemiller, CogniMed Inc., and Dexcom. This material is prepared based upon a review of multiple sources of information, but it is not exhaustive of the subject matter. Therefore, healthcare professionals and other individuals should review and consider other publications and materials on the subject matter before relying solely upon the information contained within this educational activity.

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Dannemiller Staff

Bernard Abrams, MD, Clinical Content Reviewer, has nothing to disclose.
Jennifer Hodges, Project Manager, has nothing to disclose.
Gordon Ringler, Assistant Director, Medical Education, has nothing to disclose.

CogniMed Inc. Staff

Estelle Perera, Senior Director, Scientific Affairs and Program Design, has nothing to disclose.
Phoebe DeSantis, Program Coordinator, has nothing to disclose.

Chairperson

Susan S. VanBeuge, DNP, APRN, FNP-BC, CNE, FAANP, has nothing to disclose.

Faculty

Susan Owen, RN, MSN, CDE, NP-C, is a speaker for Sanofi.

Traci Sharkey-Wells, MSN, NP-C, CDE, discloses she is a speaker for Dexcom Inc. and her spouse owns stock in Dexcom Inc.

Agenda and Faculty

5:00 PM	Registration and Dinner	
5:15 PM	Welcome and Introduction	**Susan S. VanBeuge, DNP, APRN, FNP-BC, CNE, FAANP**
5:25 PM	*Introduction to CGM and Clinical Study Review*	**Susan S. VanBeuge, DNP, APRN, FNP-BC, CNE, FAANP**
5:35 PM	*CGM and Applied Clinical Use*	**Traci Sharkey-Wells, MSN, NP-C, CDE**
6:10 PM	*Practical Use of Professional and Personal Real-Time CGM: Interpretation and Reimbursement*	**Susan Owen, RN, MSN, CDE, NP-C**
6:40 PM	Q&A and Discussion	**All Faculty**
6:45 PM	Closing Comments and Adjourn	**Susan S. VanBeuge, DNP, APRN, FNP-BC, CNE, FAANP**

Chairperson

Susan S. VanBeuge, DNP, APRN, FNP-BC, CNE, FAANP
University of Nevada
Las Vegas, NV

Faculty

Traci Sharkey-Wells, MSN, NP-C, CDE
Diabetes Management Team
Center for Thyroid Diseases and Endocrinology
Parma Heights, OH

Susan Owen, RN, MSN, CDE, NP-C
Mercy Health Physician Partners
Grand Rapids, MI

Abstract

To provide optimal diabetes care in the clinical practice setting, nurse practitioners and physician assistants are increasingly being enlisted as the first line of defense, to support the management of diabetes with cutting-edge technology. Continuous glucose monitoring (CGM) has begun to revolutionize diabetes care by giving these clinicians—and their patients—valuable insight into daily glycemic profiles. This leads to improved glucose control, including reduced glycemic variability and fewer hypoglycemic reactions. Considering the growing diabetes epidemic, this is particularly important, as Centers for Disease Control and Prevention findings highlight that the second most common cause of emergency department visits and hospitalizations due to adverse drug reactions in the United States is hypoglycemia induced by antidiabetic medications.

CGM refers to the frequent measurement and recording of interstitial glucose concentrations for a prolonged period. Two types are available today. Professional CGM units are owned and used diagnostically by healthcare providers (HCPs) who place them on patients for a week or more. Most require a download of information onto a computer after use and a retrospective review of that data by the HCP since the glucose data is blinded or not visible to the patient in real time. Professional CGM offers detailed glucose control assessment with minimal patient training and setup time and with wider insurance coverage. Personal real-time CGM (RT-CGM) units are owned by patients and display the information in real time, allowing the patients to monitor and quickly respond to changes in their glucose levels. CGM technology has recently evolved further, with a Professional CGM device recently receiving approval for RT-CGM use, thus providing dynamic, comprehensive data collection and simultaneously demonstrating to patients and clinicians the correlation between behavior and glucose concentration and rate and direction of change in glucose.

These continuous readings provided by CGM may assist HCPs with therapy adjustment and treatment decisions. This is particularly important to reduce the risk of hypoglycemia when intensifying regimens and may even improve glucose control without the need for additional medication. While several CGM devices are commercially available, widespread use of CGM has been limited. Perceived concerns regarding accuracy and reliability persist despite a growing body of evidence suggesting this is not true for the newer devices. The perceived inaccuracy stems largely from the inherent lag between interstitial glucose levels (where CGM measures glucose) and blood glucose readings, particularly when glucose levels are rapidly changing. For accurate readings, the CGM sensor must be calibrated with the blood glucose meter when glucose levels are stable and the two measurements are nearly identical. The various devices have distinct features and functional differences, including accuracy and precision, that are important to consider when making clinical decisions.

CGM greatly increases the usefulness of glucose measurements compared with self-monitoring of blood glucose (SMBG). Use of CGM has been shown to significantly improve glycemic control compared with SMBG, and results improve with frequency of monitoring and consistency of use, with best results for patients who use the CGM ≥6 days per week.

A systematic review and meta-analysis of 33 clinical trials found that glycemic control in patients with type 1 diabetes is better with RT-CGM than SMBG, with no difference in frequency of severe hypoglycemia. When compared with SMBG plus use of a personal CGM every other week for patients with poorly controlled type 1 diabetes despite optimized CSII (continuous subcutaneous insulin infusion) or MDII (multiple daily insulin injections), RT-CGM significantly reduced time in hypoglycemia and improved glycemic control measured by glycosylated hemoglobin (A1C) levels. The benefits of RT-CGM were similar with MDII and CSII therapies.

In a crossover study of patients using insulin pump therapy (CSII), adding on RT-CGM was shown to significantly increase the mean number of daily boluses and reduce A1C and duration of hypoglycemic episodes. Reduction in A1C level and time spent in hypoglycemia were also shown in a group of patients receiving CSII or MDII who had established hypoglycemia unawareness; RT-CGM, however, did not restore hypoglycemia awareness.

In 2010, the American Association of Clinical Endocrinologists (AACE) recommended personal CGM for adults with type 1 diabetes who have hypoglycemic unawareness or frequent hypoglycemia, have A1C levels over target or excess glycemic variability, require lowering A1C without increased hypoglycemia, are pregnant or trying to get pregnant, are children or adolescents with type 1 diabetes and A1C ≥7.0%, and for youth with type 1 diabetes and A1C ≥7.0% and who are able to use it on a near-daily basis. Youth who frequently monitor their blood glucose levels and committed families of children younger than 8 years also may be candidates for a personal CGM device if a trial period of 2-4 weeks is successful. Intermittent use of professional CGM may be more appropriate for youth with type 1 diabetes who are undergoing changes to their diabetes regimen or are experiencing nocturnal hypoglycemia/dawn phenomenon, hypoglycemia unawareness, or postprandial hyperglycemia.

The May 2015 issue of *Endocrine Practice* features the AACE and American College of Endocrinology consensus statement on glucose monitoring, based on proceedings of a conference convened to develop evidence-based guidelines for a comprehensive regulatory action plan for insurance providers and glucose monitoring stakeholders. The panel evaluated current clinical research, utility, and access to blood glucose monitoring and CGM. After noting that A1C is one of the most common measures of glucose control, the participants acknowledged that A1C values might be misleading for 15% of the population, in particular, people in certain ethnic groups and patients with sickle cell anemia or severe kidney disease. Essentially the only way to assess longitudinal glucose control in these patient populations is with frequent glucose monitoring or CGM. CGM also may be particularly appropriate for patients at risk for hypoglycemia, and patients demonstrating hypoglycemia unawareness. Additionally, they noted that intermittent use of CGM (usually 1-2 wk) by patients with type 2 diabetes might be more effective than daily fasting glucose in guiding the need for medication adjustment or intensifying therapy. In summary, any patient at risk for hypoglycemia or who could benefit from therapy adjustment should be considered a candidate for CGM.

The cost of and reimbursement for devices used to manage diabetes is an important clinical consideration. There are two Current Procedural Terminology (CPT) codes for CGM: 95250 covers device hookup, calibration, patient education, disconnection, and download of data, which may be performed by any CGM professional; 95251 covers review, interpretation, and reporting of the data, which must be performed by the HCP. To qualify for insurance reimbursement, CGM data must be collected for at least 72 hours and not more often than once a month. The patient need not be present for the data download and analysis, but a written report is mandatory regardless. The CPT codes may be used for either personal or professional CGM. In 2015, a CPT panel will review CGM codes with the consideration that it is necessary to differentiate between real time and retrospective CGM.

“In summary, any patient at risk for hypoglycemia or who could benefit from therapy adjustment should be considered a candidate for CGM.”

Reimbursement challenges have restricted the use of CGM, particularly RT-CGM. Many private insurers now cover both personal and professional CGM, but details vary and HCPs should verify coverage and coding requirements directly with their payers. The Centers for Medicare and Medicaid Services do not currently reimburse for personal RT-CGM, considering it primarily a convenience rather than medically necessary.

Broader coverage of CGM will improve access and increase its usage. More widespread, proper, and consistent use will ultimately assist in reducing overall healthcare costs and optimizing clinical outcomes for individual patients.

Susan S. VanBeuge, DNP, APRN, FNP-BC, CNE, FAANP

Introduction to CGM and Clinical Study Review

Susan S. VanBeuge is an Assistant Professor in Residence at the University of Nevada, Las Vegas School of Nursing. Dr. VanBeuge received undergraduate degrees at both Pacific Lutheran University and University of Utah, a Master's degree from UNLV and her doctorate at the University of Utah, College of Nursing. She currently serves as the Master's coordinator and teaches in both the Family Nurse Practitioner and Doctor of Nursing Practice programs. Dr. VanBeuge maintains a clinical practice in the sub-specialty of endocrinology and speaks nationally on topics related to this field. She treats patients with general endocrinology diagnoses, as well as many patients with pump therapy and continuous glucose monitoring. Dr. VanBeuge has research interests in the areas of interprofessional communication, cancer survivorship, and health promotion. She is a fellow in the American Association of Nurse Practitioners.

Continuous Glucose Monitoring

- What is CGM?
  - A device that continually reads glucose values
  - Readings are done every 5 minutes, approximately 288 times/day!
  - It is not new technology, but is advancing with accuracy to monitor and act on changes in glucose levels

What is the Science?

- Sensor technology developed in the late 1960s
- Self monitoring of blood glucose isn't all that accurate
- Patients who use CGM have decreased frequency and severity of hypoglycemia and reduced overnight hypoglycemia
- Improved and sustained reductions in HbA1C are common in the literature

Who Should Use CGM?

- Patients who want to have better glucose control
- Insulin sensitive
- Unstable glucose
  - Frequent high or low blood sugars
  - Hypoglycemic awareness
- Anyone interested in improving glucose control

Traci Sharkey-Wells, MSN, NP-C, CDE

CGM and Applied Clinical Use

Traci Sharkey-Wells is a certified NP and certified Diabetes Educator, currently working for a private endocrine practice in Cleveland, Ohio. She received her undergraduate degree at Indiana University and master's at Kent State University. She has experience in all aspects of endocrinology, however her primary focus has been training patients on insulin infusion therapy as well as continuous glucose monitors. Ms Sharkey-Wells' practice uses pump therapy in both type 1 and type 2 populations. She also does a great deal of inpatient management and rounds at 4 surrounding hospitals. Her practice is also involved in clinical trials for diabetic nephropathy and she serves as a sub PI.

Using Real-Time CGM Information to Optimize Control

- Check receiver often throughout the day
- Maintain a log of "events" to help determine reasons for glucose excursions
  - Assess trends and respond to directional trend and how quickly the glucose is rising or falling
  - More interaction with receiver results in better control
- Address rapid increases and decreases in glucose with appropriate adjustments
  - Food
  - Timing of insulin administration
  - Correction factor
  - Insulin-carbohydrate ratio

Many Different Patients May Benefit From CGM

- Type 1 and type 2 diabetes
  - Patients not reaching therapeutic goals in A1C and/or glycemic variability
  - Patients who keep glucose values above the target secondary to fear of hypoglycemia
  - When initiating or changing therapy
- Patients with hypoglycemia unawareness
- Preconception
- Hospital/acute care setting
- Athletes
- Type 2 behavior modification

Taking a Stepwise Approach to Addressing Hypoglycemia

- Determine **when** hypoglycemia occurs and possible contributing factors
  - If **overnight**, consider adjustments in basal insulin
  - If **before meals**, consider adjustment of basal insulin
  - If **after meals**, consider adjustment in meal bolus insulin
  - If **after correction**, consider adjustments to insulin correction factor
  - If **after exercise**, consider adjustments in basal insulin, bolus insulin, and/or need for supplemental glucose during exercise

Susan Owen, RN, MSN, CDE, NP-C

Practical Use of Professional and Personal Real-Time CGM: Interpretation and Reimbursement

Susan Owen is a Nurse Practitioner with a specialty in Diabetes at Mercy Health Physician Partners Diabetes and Endo Center in Grand Rapids, MI. She received her BSN at University of Michigan and her MSN from Kent State University in Ohio. Her post master's certificate for Nurse Practitioner is from Grand Valley State University, Grand Rapids. She started her experience in diabetes in Ohio over 30 years ago. She has participated in Diabetes Education, Research and Clinical Practice. Susan has two grown children and currently resides in Grand Rapids, Michigan with her two crazy dogs, Cooper and CJ.

Office Flow-Diagnostic Sensors

- Identify the patient and choose the system
- Scheduling issues
- The team
- Return of equipment
- Download and printing
- Review of data
- Billing

Coding for CGM

- CPT codes 95250 and 95251
- Not product specific – for diagnostic AND personal CGM
- 95250 – Reflects the costs associated with patient training, hookup, calibration, sensor removal and data download
- 95251 – Reflects the provider services of interpretation of data
  - This may be done non face to face
  - Only providers – physician, NP, PA can use this code

What Do I Do With All That Data?

- Identify hypoglycemia first
- Evaluate overnight patterns
- Fix preprandial issues
- Fix postprandial issues
- Address lifestyle behaviors

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- See also: https://www.opencongress.org/bill/hr5644-113/actions_votes
- See also: http://www.dexcom.com/news/597260989-first-and-only-real-time-professional-cgmdexcom-g4-platinum-professional-continuous
- See also: http://www.diabeteswellbeing.com/continuous-glucose-monitors/

Notes

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Role of the Pharmacist and CGM Technology in Intensive Treatment of Diabetes
Sam Ellis, PharmD, BCPS, CDE

Clinical Use of Real-Time CGM in Pediatric Populations
Jen Block, FNP, MSN, BSRN, CDE

Continuous National Coverage of CGM: Pathway to Improved Outcomes, Reimbursement and Reduced Healthcare Cost
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Davida F. Kruger, MSN, APN-BC, BC-ADM

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Kathleen Wyne, MD, PhD, FACE, FNLA

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Optimizing Outcomes Via Real-Time CGM:
The NP/PA's Primary Tool in Improving Intensive Diabetes Management

CME CERTIFICATE REGISTRATION

Please print clearly.

Name _____

Degree(s)

[ ] MD/DO [ ] NP/PA [ ] Pharmacist [ ] PhD [ ] RN/RD

[ ] Other (please specify) _____

Specialty _____

E-mail _____

Street Address _____

City_____ State_____ ZIP_____

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PRETEST To enable us to measure the quantitative and qualitative effectiveness of this CME program, please complete the pretest.

1. Findings of the Centers for Disease Control and Prevention (CDC) show that hypoglycemia from antidiabetic medications is the _____ cause of emergency department visits and hospitalizations due to adverse drug reactions in the United States.

A) Most common
B) Second most common
C) Fifth most common
D) Tenth most common

2. The key benefit(s) of continuous glucose monitoring (CGM) to the patient is/are _____.

A) Providing insight into trending information and finding patterns that otherwise could not be detected by fingerstick alone
B) Providing information about effects of food intake and timing of insulin administration
C) Allowing the patient to proactively adjust treatment to prevent glycemic excursions (eg, severe hypoglycemic events) when used in real time
D) Detecting unrecognized hypoglycemia, especially during sleep
E) All of the above

3. Which of the following statements about CGM are true?

A) Significantly improves glycemic control compared with self-monitoring of blood glucose
B) Glycemic control improves with frequency of monitoring and consistency of CGM use
C) Patients who use CGM ≥6 days per week have the best results
D) Readings are done every 5 minutes, approximately 288 times/day
E) All of the above

4. According to the AACE consensus statement on glucose monitoring, _____ should be considered a candidate for CGM.

A) Any patient with diabetes (type 1 or 2) at risk for hypoglycemia or who could benefit from therapy adjustment
B) Patients with diabetes whose A1C levels are over target, have excess glycemic variability or are pregnant
C) Patients with sickle cell anemia or severe kidney disease
D) All of the above

5. Currently, costs for a hypoglycemia inpatient admission average _____ per event.

A) $564
B) $1564
C) $17,564
D) $30,564

6. Professional real-time CGM provides dynamic and comprehensive data collection to show patients and clinicians _____.

A) The correlation between behavior and glucose activity
B) The effects that specific foods, exercise, stress, and medications have on glucose levels
C) The rate and direction of glucose change
D) The ability to rapidly self-titrate insulin and modify lifestyle and immediately see the results
E) All of the above

POSTTEST

Please complete the postprogram questionnaire upon activity completion.

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EVALUATION

PRESENTATIONS	POOR				EXCELLENT
Introduction to CGM and Clinical Study Review **Susan S. VanBeuge, DNP, APRN, FNP-BC, CNE, FAANP**					
Overall presentation	1	2	3	4	5
Clinical relevance	1	2	3	4	5
Presentation style/visuals	1	2	3	4	5
Practical Use of Professional and Personal Real-Time CGM: Interpretation and Reimbursement **Susan Owen, RN, MSN, CDE, NP-C**					
Overall presentation	1	2	3	4	5
Clinical relevance	1	2	3	4	5
Presentation style/visuals	1	2	3	4	5

	POOR				EXCELLENT
CGM and Applied Clinical Use **Traci Sharkey-Wells, MSN, NP-C, CDE**					
Overall presentation	1	2	3	4	5
Clinical relevance	1	2	3	4	5
Presentation style/visuals	1	2	3	4	5
Q&A and Discussion All Faculty					
Overall presentation	1	2	3	4	5
Clinical relevance	1	2	3	4	5

ACTIVITY	DISAGREE				AGREE
As a result of this activity, I am better able to:					
1. Identify methods for optimizing therapy and improving clinical outcomes using personal and professional real-time CGM in adult populations	1	2	3	4	5
2. Employ applicable management strategies in clinical practice for personal and professional real-time CGM in adult populations	1	2	3	4	5

The activity:	DISAGREE				AGREE
Met my expectations	1	2	3	4	5
Was relevant to my clinical practice	1	2	3	4	5
Was presented without commercial bias	1	2	3	4	5

	DISAGREE				AGREE
Logistics were well-organized	1	2	3	4	5
Environment was conducive to learning	1	2	3	4	5

After participating in this activity, I will change my clinical practice by:

_____

_____

Additional comments:

_____

I hereby certify that I have spent _____ hour(s) in this educational activity.

Signature _____ Date _____