The Next Step in Continuous Glucose Monitoring: 
Making Diabetes Management Decisions 
with Sensor Glucose Information

A CME-certified breakfast symposium held in conjunction with 
the American Diabetes Association’s 76th Scientific Sessions

Saturday, June 11, 2016 • 5:30 AM
Sheraton New Orleans • New Orleans, LA

This activity is supported by an independent educational grant provided by Dexcom.
INTENDED AUDIENCE
Endocrinologists, Primary Care Physicians, Nurse Practitioners, Certified Diabetes Educators and other Health Care Professionals interested in the management of diabetes attending the ADA 2016 Annual Scientific Sessions.

STATEMENT OF NEED
Self-monitoring of blood glucose (SMBG) 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, often missing trends, hyperglycemic or hypoglycemic excursions. HbA1c is even more limited and reports an average reading over 90 days; therefore incapable of alerting the patient of fluctuations in blood glucose at any point in time.

Selection of an appropriate CGM device is important because improvements in accuracy and reliability are ongoing. RT-CGM is one cornerstone of optimal glycemic control. Each varies; relying on different sensing technology and requiring the traditional finger-stick 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. But new generation devices have significantly improved MARD measurements. These devices have shorter lag times and improvements in accuracy. Many physicians are lacking the appropriate level of knowledge to employ CGM as part of their practices. Educational programs focused on these knowledge gaps will enable healthcare professionals to provide improved patient care.

Significant improvements in accuracy of Continuous Glucose Monitoring (CGM) sensors and device algorithms have made CGM-based decisions a near-term possibility. This program will evaluate the potential clinical application and use of CGM in diabetes management decisions and the importance of various aspects of CGM to guide optimal treatment.

EDUCATIONAL OBJECTIVES
At the conclusion of this activity, participants should be better able to:
1. Define the role of CGM in diabetes management treatment decisions for intensive insulin therapy patients
2. Employ novel management strategies in personal and professional RT-CGM
3. Identify patient types, via clinical case reports, that will most benefit from RT-CGM

ACCREDITATION AND CERTIFICATION
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MODERATOR
Claudio Cobelli, PhD is Grant/Research Support for Dexcom and Roche. He is a Novo Nordisk Advisory Board/Speaker’s Bureau/Consultant.

FACULTY
Andrea Facchinetti, PhD has nothing to disclose
Jan Šoupal, MD is a Medtronic, Roche, and Novo Nordisk Advisory Board/Speaker’s Bureau/Consultant.

Davida F. Kruger, MSN, APN-BC, BC-ADM is Grant/Research Support for Dexcom, Novo Nordisk, Lilly, AZ, Medtronic, and Lexicon. She is an Animas, Dexcom, Lilly, Novo Nordisk, Boehringer Ingelheim, Janssen Pharmaceuticals, Abbott, and Sanofi Advisory Board/Speaker’s Bureau/Consultant. She is a Dexcom Stock Shareholder.

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<td>Welcome and Introduction</td>
<td>Claudio Cobelli, PhD</td>
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<td>Sensor Accuracy and Device Calibration Leading to CGM-based Treatment Decisions</td>
<td>Andrea Facchinetti, PhD</td>
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<td>Jan Šoupal, MD</td>
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<td>Clinical Consult Patient Case Studies</td>
<td>Davida F. Kruger, MSN, APN-BC, BC-ADM</td>
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<td>7:25 AM</td>
<td>Q&amp;A - moderated by Dr Cobelli</td>
<td>All Faculty</td>
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**Moderator**
Claudio Cobelli, PhD  
Department of Information Engineering  
University of Padua, Italy

**Faculty**
Andrea Facchinetti, PhD  
Department of Information Engineering  
University of Padua, Italy

Jan Šoupal, MD  
3rd Department of Medicine  
Endocrinology and Metabolism  
First Faculty of Medicine, Charles University and General University Hospital  
Prague, Czech Republic

Davida F. Kruger, MSN, APN-BC, BC-ADM  
Nurse Practitioner  
Henry Ford Health System  
Division of Endocrinology, Diabetes, Bone and Mineral Diseases  
Detroit, Michigan
Polling Questions

Please participate in this real-time poll:

Go to www.cgmEDUCATION.net/poll or scan the code

I use real-time CGM for:

1. type 1 diabetics on MDI of insulin
2. type 2 diabetics on intensive insulin therapy (MDI, CSII)

- Often
- Sometimes
- Rarely
- Never
Welcome and Introduction

Claudio Cobelli, PhD

Claudio Cobelli, PhD, was born in Bressanone (Bolzano) Italy. He is Full Professor of Biomedical Engineering at the University of Padua, Padua, Italy. He is past Chairman of the Graduate Program in Biomedical Engineering (2000-2009) and the PhD Program in Bioengineering (2000-2011) at the University of Padua. His main research activity is modeling, identification and control of physiological systems, especially metabolic systems. His research is supported by NIH, JDRF and the European Community. Dr Cobelli has published 450 papers in internationally peer-reviewed journals, co-authored 8 books and holds 11 patents. He is Associate Editor of the Institute of Electrical and Electronic Engineering (IEEE) Transactions on Biomedical Engineering and Journal of Diabetes Science & Technology. He is on the Editorial Board of Diabetes and Diabetes Technology & Therapeutics. Dr. Cobelli has been Chairman (1999-2004) of Italian Bioengineering Group; Chairman (1990-1996) of IFAC TC on Modeling and Control of Biomedical Systems, and member of the IEEE Award Committee, as well as EMBS AdCom (2008-2009). He has been a member of the Gruppo di Esperti della Valutazione (GEV), Area 09, of the Agenzia Nazionale per la Valutazione del Sistema Universitario e della Ricerca (ANVUR) (2011-2013). Dr Cobelli is currently President of the Organo di Indirizzo of the Azienda Ospedaliera Universita’ di Trieste. He is Fellow of IEEE, Biomedical Engineering Society (BMES), American Institute for Medical Biological Engineering (AIMBE) and European Alliance for Medical and Biological Engineering and Science (EAMBES). In 2010 Dr Cobelli received the Diabetes Technology Artificial Pancreas Research Award.
Andrea Facchinetti, PhD, received a PhD degree in Bioengineering from the University of Padua, Padua, Italy, in 2009. From 2009 to 2014 he was Post-Doctorate Researcher, also at the University of Padua, where he has been serving as Assistant Professor since 2014. His current scientific interests include optimal filtering, Bayesian estimation, deconvolution techniques, neural networks and real-time prediction applied to continuous glucose monitoring (CGM) signals. Dr Facchinetti’s major research achievements are the development of the “smart” CGM sensor concept and the embedding of the “smart” CGM algorithms into CGM devices. He is the author of 40 papers published in international peer-reviewed journals, has contributed to over 100 conferences, and holds 7 US and international patents. Dr Facchinetti has been co-investigator of several European and national research projects on the development of new technologies and therapeutic methods in the diabetes field. He is referee for several international peer-reviewed journals, including the Institute of Electrical and Electronic Engineering (IEEE) Transactions on Biomedical Engineering, IEEE Journal of Bio-medical Health and Informatics, Diabetes Care, Diabetes, and Diabetes Technology & Therapeutics. He also served as guest editor for the special issue “Glucose Sensors: Revolution in Diabetes Management” of Sensors journal. Dr Facchinetti’s expertise focuses on Signal Processing, Model Identification, Diabetes Technology and Continuous Glucose Monitoring.

**Sensor Accuracy and Device Calibration Leading to CGM-based Treatment Decisions**

*Andrea Facchinetti, PhD*

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**Adults: Time in Hypo**

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<th>Method</th>
<th>Median (25th-75th percentile)</th>
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<tr>
<td>SMBG</td>
<td>20 (7-36) min/day</td>
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<tr>
<td>CGM</td>
<td>15* (5-30) min/day</td>
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*Statistically significant reduction*
Conclusions

- Despite CGM accuracy is now <10%, it is difficult to provide evidence on the safety of nonadjunctive CGM use
- Suitable simulator (e.g. the UVA/Padova T1D simulator) can be used to speed up this process (as happened for the artificial pancreas)
- We proved that CGM is not inferior to SMBG when dosing insulin and that, with specific rules accounting for trends and alarms, CGM is even superior to SMBG for dosing insulin
- One limitation is still the need of SMBGs for calibration, which can be overcome with more sophisticated calibration algorithms

Peds: Time in Hypo

Median (25th-75th percentile)

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<tr>
<th></th>
<th>SMBG</th>
<th>CGM</th>
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<tr>
<td>11 (4-21) min/day</td>
<td>9* (3-16) min/day</td>
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*statistically significant reduction
Jan Šoupal, MD, graduated from the First Faculty of Medicine, Charles University, Prague, Czech Republic, in 2009. While a medical student he undertook a research internship in the laboratories of The University of Maryland, USA. Currently, he works as a consultant in internal medicine at 3rd Department of Internal Medicine, 1st Medical Faculty and General Teaching Hospital, Prague. In clinical practice he is focused on diabetes technology with his main interest in Continuous Glucose Monitoring. In his research, he is investigating the effects of glycemic variability on glycemic control and diabetic complications. The results of this research were presented to the American Diabetes Association (ADA) in Philadelphia in 2012, and in 2013 won the Czech Diabetes Association’s award for the best original publication for an author below 40 years of age. Dr Šoupal is also heavily involved in postgraduate education aimed at the treatment of type 1 and type 2 diabetes.

CGM and MDI: A1c Outcomes and Clinical Benefit

Jan Šoupal, MD

Why real-time CGM with MDI could have a place in diabetes care?

Efficacy

Conclusion

- The combination of RT-CGM and MDI improves glycemic control in patients with T1D.
- Real-time CGM with MDI seems to be more effective than insulin pump therapy alone in reducing HbA1c.
- The combination of RT-CGM and MDI can be a suitable alternative to SAP therapy for patients who are not willing to or cannot use insulin pumps.

Why real-time CGM with MDI could have a place in diabetes care?

Efficacy
Patients' needs

Optimal treatment of hyperglycemia

- ↓ HbA1c
- ↓ hypoglycemia
- ↓ postprandial glycemia
- ↓ glycemic variability
- ↑ patient satisfaction

Good diabetes control
Less complications
Davida F. Kruger, MSN, APN-BC, BC-ADM, is a Certified Nurse Practitioner in the Division of Endocrinology and Metabolism of the Henry Ford Medical Center, in Detroit, Michigan. Ms Kruger received a master of science in nursing from Wayne State University, in Michigan, and a bachelor of science in nursing from Boston College, in Massachusetts. She is a board-certified nurse practitioner in both primary care and advanced diabetes management. Ms Kruger is a co-investigator on multiple studies of diabetes interventions and care, including the National Institutes of Health-funded multicenter Epidemiology of Diabetes Interventions and Complications (EDIC) trial and the Action to Control Cardiovascular Risk in Diabetes (ACCORD). Ms Kruger lectures extensively in the United States on optimizing outcomes in diabetes and diabetes management. She has published nearly 50 abstracts, articles, and chapters on diabetes management and contributed to publications for the American Diabetes Association (ADA). Journals containing her work include Journal of the American Academy of Nurse Practitioners, Nurse Practitioner, Diabetes Educator, and Diabetes. She is author of the second edition of “The Diabetes Travel Guide,” published in 2006, past Editor of Diabetes Spectrum, and presently Editor of Clinical Diabetes. She is a member of the ADA, the American Association of Diabetes Educators, the American Academy of Nurse Practitioners, and the American Nurses Association and past board member of the ADA Research Foundation. She is Past President of Health Care and Education for the ADA and Past Chair of the ADA Research Foundation.

**Clinical Consult Patient Case Studies**

Davida F. Kruger, MSN, APN-BC, BC-ADM

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One is Asking a Question: The Other is Answering:

**METER:** Still leaves the question AM I 160 mg/dL going up or down? How fast is my glucose changing?

**SENSOR:** Answers the question I am 160 mg/dL going down, my glucose is going down fast at a rate of 1-2 mg/dL min.

CGMs can provide the answers and a more complete picture to allow you to make the best decision about your diabetes management.
Using CGM Rate of Change (ROC) Information When Correcting for a High BG

Survey respondents reported making large adjustments to correction or meal insulin doses based on the direction and ROC

2.8 units

[Graph showing glucose levels and insulin adjustments]

5.9 units

[Graph showing glucose levels and insulin adjustments]


Being PROACTIVE to Prevent Hypoglycemia

If my glucose was 120 mg/dl, the earliest I usually take immediate action to avoid hypoglycemia if my trend arrow is (Choices):

1. Arrow angled down
2. 1 arrow straight down
3. 2 arrows straight down
4. I don’t respond to the trend arrows at a glucose of 120 mg/dl.

\[ \leq 70\% \]


• 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/
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The Next Step in Continuous Glucose Monitoring: Making Diabetes Management Decisions with Sensor Glucose Information

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

1. The T1D Decision-Making Model indicates that, compared to SMBG, the non-adjunctive use of CGM is
   A) Inferior  C) Superior
   B) Not Inferior  D) None of the above

2. Computer simulations of CGM for type 1 diabetes have shown that
   i. CGM can significantly reduce both the number and duration of events below 50 mg/dL in adults and children
   ii. CGM can reduce the number of events <50 mg/dL in adults but not in children
   iii. CGM can reduce the number and duration of events below 70 gm/dL in adults and children
   iv. CGM can reduce duration of events below 70 mg/dL in children only
   A) i only  D) ii & iv
   B) iv only  E) None of the above
   C) i & iii

3. Dr. Facchinetti’s presentation discussed the following limitation(s) of non-adjunctive use of currently available CGM:
   A) Relatively poor accuracy (>20%)
   B) The continuing need for SMBGs for calibration
   C) With increasing glucose, time in target is no better than with SMBG therapy
   D) None of the above

4. In the STAR 3 Study, HbA1c with insulin pump plus RT-CGM monitoring (SAP therapy) for adults and children was
   A) Significantly higher versus MDI  C) Significantly lower versus MDI
   B) Comparable to MDI  D) Not investigated

5. The SWITCH study showed that
   A) Addition of RT-CGM to established CSII therapy decreases HbA1c
   B) Removal of RT-CGM from CGM/CSII therapy caused loss of the benefit
   C) Both A & B
   D) None of the above

6. Studies have shown that
   A) HbA1c was lower in CGM users regardless of age or type of insulin delivery
   B) Patients using MDI + CGM had greater reductions in HbA1c than those using CSII + CGM
   C) Reductions in glycemic variability and time spent in hypoglycemia were not significantly different between SAP and MDI/RT-CGM therapy groups
   D) All of the above
   E) None of the above
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   E ) None of the above
Continuous Glucose Monitoring (CGM) Spoken Here

Please ask us about Diabetes Management through Continuous Glucose Monitoring

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