



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

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# ***Clinical Application of Real-Time CGM: Professional Use, Pediatrics and the Pathway to the Bionic Pancreas***

**A CME-certified dinner satellite symposium to be held in conjunction  
with the American Diabetes Association's 74th Scientific Sessions**

Saturday, June 14, 2014 • 6:15 PM  
InterContinental • San Francisco, CA

# Agenda and Faculty

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6:15 PM Registration and Dinner

6:30 PM Welcome and Introduction  
*Clinical Application of Real-Time CGM: Professional Use, Pediatrics and the Pathway to the Bionic Pancreas* **Jay S. Skyler, MD, MACP**

6:40 PM *Professional Use of Real-Time CGM* **Davida F. Kruger, MSN, APN-BC, BC-ADM**

7:10 PM *CGM and Pediatrics* **Bruce Buckingham, MD**

7:40 PM *Pathway to the Bionic Pancreas* **Steven J. Russell, MD, PhD**

8:10 PM Clinical Consult Case Studies & Q&A All Faculty

8:45 PM Adjourn

## Moderator

**Jay S. Skyler, MD, MACP**  
 Professor of Medicine,  
 Division of Endocrinology,  
 Diabetes, and Metabolism  
 at the University of Miami  
 Miller School of Medicine  
 Deputy Director for Clinical  
 Research and Academic  
 Programs at the Diabetes  
 Research Institute  
 Miami, Florida

## Faculty

**Bruce Buckingham, MD**  
 Professor of Pediatric  
 Endocrinology  
 Stanford School of Medicine  
 and Stanford Children's  
 Hospital  
 Palo Alto, California

**Davida F. Kruger, MSN,  
 APN-BC, BC-ADM**  
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 Henry Ford Health System  
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**Steven J. Russell, MD, PhD**  
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 Harvard Medical School  
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 Diabetes Research Center  
 Boston, Massachusetts

# Welcome and Introduction

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*Jay S. Skyler, MD, MACP*

**Jay S. Skyler, MD, MACP**, is currently a Professor of Medicine, Pediatrics, & Psychology, in the Division of Endocrinology, Diabetes, & Metabolism, Department of Medicine, University of Miami Miller School of Medicine, Miami, Florida. He is Deputy Director for Clinical Research and Academic Programs at the Diabetes Research Institute, University of Miami, and is Adjunct Professor of Pediatrics at the Barbara Davis Center for Childhood Diabetes, University of Colorado.

Dr. Skyler is a past President of the American Diabetes Association, the International Diabetes Immunotherapy Group, and the Southern Society for Clinical Investigation, and was a Vice-President of the International Diabetes Federation.

Dr. Skyler was founding Editor-in-Chief of ***Diabetes Care***.



Blood glucose data and A1c results do not provide the complete picture for either the patient or the healthcare provider. We have developed and continue to grow an outpatient program for professional continuous glucose monitoring (CGM). To date, we own 35 CGM devices that are loaned to our patients to gather 7 days of real-time CGM data. Over the past 4 years this program has grown in two sites to over 500 professional CGM evaluations annually.

## Why Use Professional CGM in Your Practice?

- Provides insight into trending information/pattern management
- Identifies insulin action (insulin dose effect) and potential need for additional adjustments/medications to control postprandial glucose
- Provides information about timing of food digestion and timing of insulin administration based
- Provides continuous data for overnight basal testing and assessment of nocturnal hypoglycemia
- Find patterns that otherwise could not be detected by finger stick alone
- Find patterns of undetected low BG in patients at treatment goal
- Allows for efficiently and effectively identify areas of clinical challenges and apply appropriate medical management to address that specific clinical issue.
- And so much more.....

## Take-Home Messages For Professional CGM

- Patient selection is key
- Use for both medical management and ownership
- Match products to patient needs
- Education is the essential component for success
- CGM devices are accurate to use today to improve patients' outcomes
- Reimbursement should not be a barrier now that more national payers are covering CGM

This presentation will:

- Discuss the components, logistics and clinical practice of a successful real-time CGM professional program developed at the Henry Ford Health System, Division of Endocrinology
- Outline the stepwise approach on how to identify the clinical issues that CGM downloads and reports identify
- Review case studies to demonstrate how professional CGM reports can lead to effectively optimize the development of a patient care plan



# CGM and Pediatrics

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*Bruce Buckingham, MD*

**Bruce Buckingham, MD**, is Professor of Pediatric Endocrinology at Stanford University and Packard Children's Hospital. Dr. Buckingham's research interests have focused on continuous glucose monitoring in children and "closing-the-loop." These efforts are being funded by the Juvenile Diabetes Research Foundation, National Institutes of Health and the Helmsley Foundation and are currently focused on preventing nocturnal hypoglycemia with a predictive low-glucose suspend system, and full overnight closed-loop. Other closed-loop studies are focused on 24/7 closed-loop in the ambulatory setting and assessing ways to improve insulin infusion sets to prolong their wear.

## The Subcutaneous Space and Sensor Ratings

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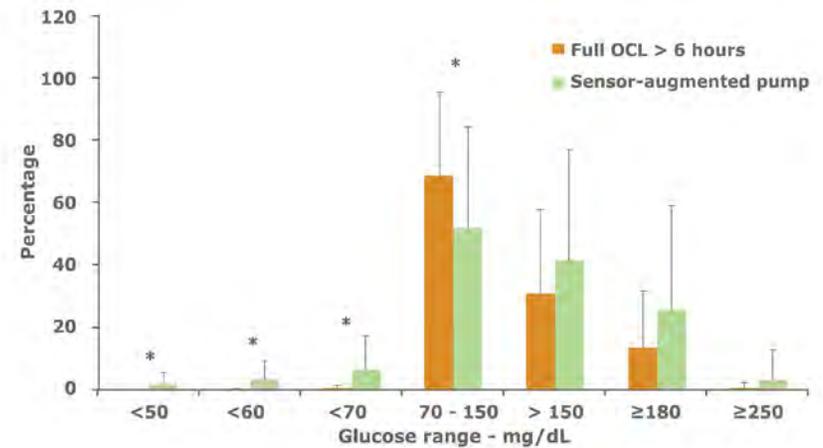
- Patient selection is key
  - There is about a 5-6 minute lag time between blood and the subcutaneous space
  - No significant difference if using buttocks, arms or abdomen – The SQ is the SQ
  - Use of extra adhesives does not effect sensor performance
  - 86% are functioning for 7 Days
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Dr. Buckingham's talk will focus on the use of sensors in pediatric patients, emphasizing that there are no body size or habitus limits, but the size of the sensor and transmitter matters. Continuous glucose monitoring (CGM) is very helpful to patients and parents in real-time and to physicians, especially when the information is integrated with insulin pump data. Adolescents are always a challenging group because, in general, diabetes is not their number 1 priority. We have used CGM in diabetes camp studies and they have functioned very well despite rigorous camp activities which include swimming, capture the flag, climbing walls, etc.

### Remote Monitoring Can Significantly Decrease the Duration of Nocturnal Hypoglycemic Events

	Remote Monitoring	Control Nights
<b>Number of Nights</b>	<b>161</b>	<b>179</b>
<b>&lt;70 mg/dl</b>		
>1 hour	7	33
> 2 hours	0	12
<b>&lt;50 mg/dl</b>		
> 30 minutes	0	9
> 1 hour	0	6

### Full Overnight Closed-Loop Can Significantly Improve the Time in Range and Minimize Hypoglycemia



We have also tested remote monitoring with CGMs at the diabetes camps and found this very helpful in preventing nocturnal hypoglycemia. Remote monitoring is a feature which has been available to families with the Medtronic MySentry and will soon be available to families when the Dexcom "Share" is released. The future is integration of continuous glucose sensors with pumps so that the burden of diabetes management can be decreased with an algorithm helping to regulate insulin delivery to compensate for missed meal-boluses and the inaccuracies of carbohydrate counting (which often plague adolescent diabetes management).



# Pathway to the Bionic Pancreas

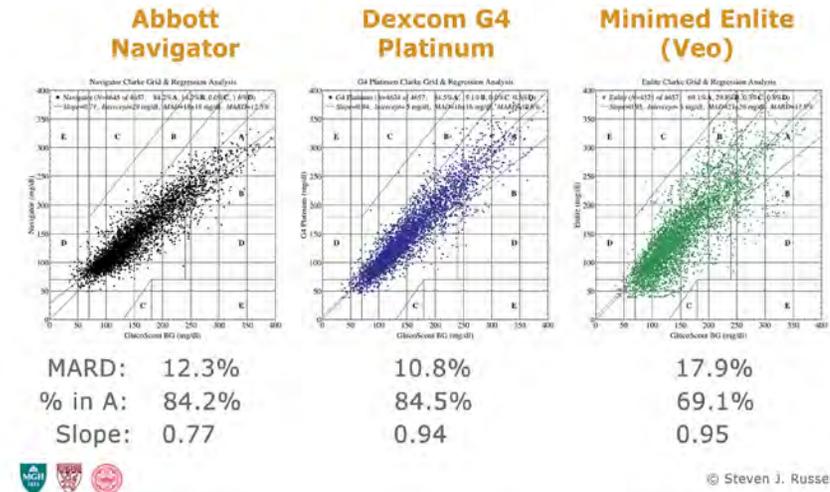
*Steven J. Russell, MD, PhD*

**Steven J. Russell, MD, PhD**, is Assistant Professor of Medicine at Harvard Medical School and an Attending Physician at Massachusetts General Hospital. He completed MD/PhD training at University of Texas Southwestern Medical School and Residency and Fellowship at the Massachusetts General Hospital. He is board certified in Internal Medicine and Endocrinology, Diabetes & Metabolism.

Dr. Russell is the principal clinical investigator of a collaboration between Massachusetts General Hospital and Boston University to develop a wearable bionic pancreas system for automated glycemic management in people with diabetes mellitus. Dr. Russell's other projects include evaluation of continuous glucose monitoring technology, methods for automated management of glucose in hospitalized patients, investigations of methods to improve insulin pharmacokinetics, and development of a device for minimally invasive continuous insulin monitoring.

Dr. Russell's research is supported by the National Institutes of Health, The Leona M. and Harry B. Helmsley Charitable Trust, the Banting Foundation, the American Diabetes Association, and the Juvenile Diabetes Research Foundation.

## Head-to-Head CGM Comparison 3

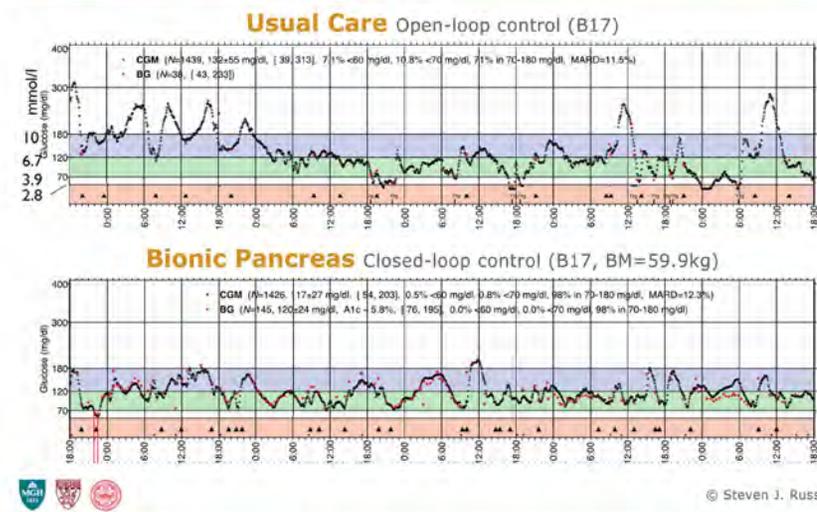


A bionic pancreas delivering insulin and glucagon has achieved excellent, automated blood glucose control in type 1 diabetes in two closely supervised outpatient studies. The system improved mean blood glucose and reduced hypoglycemia in both adults and adolescents. Equally important, it reduces the burden of diabetes management: The amount of input required from the patient wearing the bionic pancreas is limited to twice daily calibrations of a continuous glucose monitor (CGM) along with changing infusion sets and reservoirs. Meals may be announced, but this is not required, and no

“A bionic pancreas delivering insulin and glucagon has achieved an overall excellent automated blood glucose control in type 1 diabetes.”

carbohydrate counting is required when meals are announced. Key elements in the success of the bi-hormonal bionic pancreas have been the availability of an accurate CGM and the development of adaptive algorithms for dosing of insulin and glucagon. Our independent, head-to-head tests have led us to choose the Dexcom G4 Platinum to provide the input to the bionic pancreas. Although the performance of this CGM is already sufficient for successful use in bionic pancreas, further improvements in accuracy, resistance to interfering substances, and a reduction in the dependence on calibrations are eagerly awaited. We have developed and tested adaptive algorithms that require no information about the patient other than body weight for initialization and CGM glucose data; no information about past insulin use is required and the

## Beacon Hill - Five Days Usual Care vs. Bionic Pancreas



system can adapt to changing insulin needs in less than one day. If the CGM glucose stream is interrupted, intermittent glucose measurements can be substituted until the CGM signal can be reestablished. The future of the bi-hormonal bionic pancreas depends on the availability of a more stable glucagon formulation, and we are currently testing such a formulation. More rapid insulin absorption would further improve glycemic control, but is not necessary to achieve dramatic improvements over the current standard of care. The first home use study of the bi-hormonal bionic pancreas is currently underway at Massachusetts General Hospital, with three other sites to follow, and study completion scheduled for early 2015.

## Intended Audience

Endocrinologists, primary care physicians, nurse practitioners, certified diabetes educators, and other healthcare professionals interested in the management of diabetes, attending the ADA 2014 Annual Scientific Sessions.

## 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, often missing trends, hyperglycemic or hypoglycemic excursions. HbA1c is even more limited and reports an average reading over 90 days; therefore it is incapable of alerting the patient of 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 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.

## Educational Objectives

At the conclusion of this activity, participants should be better able to:

1. Identify methods for optimization of therapy and improve clinical outcomes using real-time (RT) personal and professional continuous glucose monitoring (CGM) in both adults and pediatrics
2. Employ applicable management strategies in clinical practice for personal and professional RT-CGM in both adults and pediatrics
3. Discuss the progress and clinical studies of the novel approach to the bionic pancreas, and next steps toward developing the bionic pancreas

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**Nancy Vogel**, Production Editor, has nothing to disclose.

### Moderator

**Jay S. Skyler, MD, MACP**, is a board of directors member to Dance Biopharm; Dexcom; and SynAlpha; is a scientific advisory board member of Boehringer-Ingelheim; Halozyme, Inc; Intarcia; Orgenesis; Sano; Valeritas LLC; and Viacyte; received research support from Mesoblast; and Viacyte; is an advisor/consultant to Astra-Zeneca/Bristol-Myers; Elcelyx; Ideal Life; Novo Nordisk; NPS Pharma; and PhaseBio; and is a Shareholder of Dance Biopharm; Dexcom; Ideal Life; SynAlpha; and Tandem Diabetes Care.

### Faculty

**Bruce Buckingham, MD**, is a consultant to Medtronic; Novo Nordisk; and Sano; and is an investigator for Dexcom and Medtronic.

**David F. Kruger, MSN, APN-BC, BC-ADM**, is on the advisory boards of Abbott; Boehringer-Ingelheim; Dexcom; Eli Lilly and Company; Halozyme; Janssen; Novo Nordisk; and Sano Aventis; is on the speakers' bureaus of Astra-Zeneca/Bristol-Myers, Janssen; Novo Nordisk; Janssen; and Valeritas; and has received grant/research support from Astra-Zeneca/Bristol-Myers, Eli Lilly and Company; Halozyme; Hemsley Foundation; and Novo Nordisk.

**Steven J. Russell, MD, PhD**, is an investigator for Dexcom.



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