Optimizing Insulin Therapy Through Applied CGM

Learning Objectives
- Coach patients on optimal use of CGM on a day-to-day, real-time basis
- Generate and interpret data reports in an efficient and outcomes-driven manner
- Harness the synergy of combined pump/CGM systems

Coaching Patients on Personal (Real-Time) CGM Use

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Disclosure to Participants
Conflict of Interest (COI) and Financial Relationship Disclosures:
Presenter: Ascensia, Dexcom, Insulet, Novo Nordisk
Trainer: Animas, Medtronic, Tandem, Roche, Insulet
Advisory Boards: BD, Convatec, Diasend, InSpark Technologies
Consultant: Byram Healthcare, Dexcom,
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Off-Label Use:
Participants will be notified by speakers to any product used for a purpose other than for which it was approved by the Food and Drug Administration.

Answer This!

In terms of the numbers generated by CGM, patients should:
A. NEVER, EVER use them for dosing purposes
B. Be encouraged to use them as much as possible
C. Be coached on how to use them safely

What do we get in real time?
- Numbers
- Alerts
- Trends

The Numbers
MARD Compared to YSI (lab)
Medtronic Sof-Sensor: 17-18%
Dexcom 7+: 15-16%
Medtronic Enlite: 12-14%
Freestyle Navigator/Libre: 12-13%
Dexcom G5: 9-10%

Can the numbers be trusted?
81% of CGM users openly admit to using CGM glucose values for determining insulin doses.*

* T1D Exchange Research, 2015

- Not during first 1-2 sensor cycles
- Not during the first 12-24 hrs after insertion
- Not in state of rapid rise or fall
- Not if recent calibration off >20%
- Not if acetaminophen is taken in past 4 hrs

*Off-label recommendation

Can the numbers be trusted?
YES.* But...
- Not during first 1-2 sensor cycles
- Not during the first 12-24 hrs after insertion
- Not when recovering from hypoglycemia
- Not in state of rapid rise or fall
- Not if recent calibration off >20%
- Not if acetaminophen is taken in past 4 hrs

*Off-label recommendation
**Alerts**

- **Hi / Low Alert**: Cross high or low threshold
- **Predictive Alert**: Anticipated crossing of high or low threshold (Medtronic only)
- **Rate of Change**: Rapid rise or fall
- **Thresh Suspend**: Shuts off basal insulin up to 2h when low detected (Medtronic only)

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**Types of Alerts**

- Hi / Low Alert: Cross high or low threshold
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**The Value of Alerts:**

Minimizing the duration and magnitude of BG Excursions

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**Timely, consistent response is key!**

1. **Act on the highs**
   - Hydrate
   - Exercise
   - Bolus (less IOB)

2. **Act on the lows**
   - Rapid carbs

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**Use of Threshold Suspend Feature**

- Sensor glucose value with Suspend feature
- Sensor glucose value without Suspend feature
- Insulin infusion stopped (Suspend in action)
- Insulin infusion resumed

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**ASPIRE In-Home Study: Threshold Suspend Results**

The severity and/or duration of nocturnal hypoglycemic events was lower in the Suspend Group (37% less AUC).


37.5% reduction

p<0.001

1547 980 1406 1568

30% reduction

p<0.001

5.0 3.3 5.1 4.7

2.4 1.5 2.5 2.2

32% reduction

p<0.001

Nocturnal Combined Day and Night

Hypoglycemic events were 30% less frequent in the Suspend Group.


No DKA reported in control or suspend groups.
Potential Issues with Threshold Suspend:
- False Positives?
- Unhealthy Reliance?
- Rebound Highs?

Hi/Low Alert:
- must balance benefit vs nuisance
- Low: at least 80 mg/dl
- High: very high (300?), titrate down

Predictive Alert:
- potential for false positives
- set for short time interval

Rate of Change:
- > 3 mg/dl/min fall rate may be useful

Hi/Low Alert:
- must balance benefit vs nuisance
- Low: at least 80 mg/dl
- High: very high (300?), titrate down

Rate of Change:
- > 3 mg/dl/min fall rate may be useful

Potential Hypo Issues:
- 50% of usual carbs
- Med-High G.I. food

Potential Hyper Issues:
- Full or increased carbs
- High G.I. food

Decision-Making Based on Trend Information
Self-Care Choices
- To snack?
- To check again soon?
- To exercise?
- To adjust insulin?

Key Situations
- Owing
- Sports
- Tests
- Bedtime

Hypo Treatment Based on Trend Information
- Predictive Hypo Alert and Hypo Alert & Recovering
- Subtle Treatment
  - Enough to offset 25 mg/dl (1.5 mmol/l)
- Aggressive Treatment
  - Enough to offset 50 mg/dl (3 mmol/l)

Hyper Treatment:
- When the trend graph breaks
  - Break within 2 hours of bolus: Correct!
  - No break within 2 hours of bolus: Do not correct!

Ingredients for Success
- Have the right expectations
- Wear the CGM at least 90% of the time
- Look at the monitor 10-20 times per day
- Do not over-react to the data; take IOB into account
- Adjust your therapy based on trends/patterns
- Calibrate appropriately
- Minimize "nuisance" alarms

CGM Data Analysis: Report Generation
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Program Coordinator
Diabetes Center, Washington University Medical School
Disclosure to Participants
Conflict of Interest (COI) and Financial Relationship Disclosures:

Speaker: Animas, Sanofi
Consultant: Dexcom
I really don’t weigh what’s listed on my driver’s license
I keep a stash of peanut M&M’s under my desk

Why Analyze CGM Data?
Benefits to Clinicians:
• Provides a quick pattern detection
• Identifies areas of strength and weakness
• Pinpoints the effects of lifestyle activities/choices
• Offers insight re: nighttime & postprandial control
• Facilitates progression to new therapies (with patient buy-in)
• Takes the “guesswork” out of patient care

Professional CGM Reports
- INTERMITTENT therapy evaluation
- Perpetual “what” evaluation
- RETROSPECTIVE data

Answer This!
CGM Data Reports are best analyzed:
A. Without outside information
B. Along with causal data (insulin, food, exercise, etc.)
C. By physicians only

Before you analyze, qualify.
• Were sufficient calibrations performed?
• Did the calibrations match the CGM data reasonably well?
• Was the clock/calendar correct?

Medtronic I-Pro: Four Reports
1. Daily Overlay
2. Meal & Nighttime Overlay
3. Daily Summary
4. Pattern Snapshot

We cannot live on glucose data alone!
• Encourage use of event markers
• Merge pump data with CGM data
• Keep notes of pertinent activities
  • Exercise
  • Stress/illness
  • Restaurant meals
  • Travel
  • Menses

MedtronicPortrait
When printed, this one page summary report encompasses:
- Patient demographic & system information
- 60 day snapshot of CGM data
- A CPT code covered by most insurers
Personal Use
CGM Reports:
Don’t take them too personally!

Dexcom Download Logistics
STUDIO
- Downloads up to G4
- Runs on PC, must install software
- Patients can send "patient file" to clinic via email. Clinic can import on their computers

CLARITY
- Creates reports from cloud-based data
- Phone app (for patients)
- Web-based program (for clinics)

Dexcom Clarity Data Reports
- Trend Report
- Overlay Report
- Each line is one day’s data
- Every glucose data point is available in file

Things are moving toward simplicity. (AGP)

Dexcom Clarity: Stats Report
- Frequency, intensity and duration
- Longer bars represent greater glycemic variability
- Outliers are removed (top 25% and bottom 15%)

Medtronic Download Logistics
- Pump downloads using Carelink USB or Contour Next Link meter, plugged into computer
- Program and data are completely web-based
- User-ID protected

Downloading Options
- Medtronic
  - CareLink
  - CareLink Pro
- Dexcom
  - Studio
  - Clarity

Medtronic CareLink
- Sensor Daily Overlay
- Sensor Overlay by Meal
**Action Plan**

**Most Common Event Types preceding Hypoglycemia**

- Nocturnal Hypoglycemia (11PM-2:00 AM)
- Rapid Falling Sensor Rate Of Event Types

### 24-Hour Analysis – Sensor, Insulin, & Settings

<table>
<thead>
<tr>
<th>Date Range</th>
<th>Avg Food Bolus</th>
<th>Avg Carbs</th>
<th>Avg BG</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/20/2014 - 2/2/2014</td>
<td>Avg Food Bolus</td>
<td>Avg Carbs</td>
<td>Avg BG</td>
</tr>
<tr>
<td>Breakfast: 6:00 AM - 10:00 AM (3)</td>
<td>± 20g</td>
<td>2.2U</td>
<td>138mg/dL</td>
</tr>
<tr>
<td>Lunch: 11:00 AM - 3:00 PM (6)</td>
<td>± 121</td>
<td></td>
<td>75g/dL</td>
</tr>
<tr>
<td>Dinner: 4:00 PM - 10:00 PM (21)</td>
<td>± 58mg/dL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Considerations

- **Lean on your patient to take action to avoid hypoglycemia.**
- **Evaluate your patient’s overnight basal rates and consider counseling them on evening boluses.**
- **Recommend counseling your patient on bolus use with meals and/or correcting rapid glucose excursions.**

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**CGM + Pump Reports**

Giving **context** to the data

**t:Connect Logistics**

- Free for users of Tandem pumps
- Requires installation of t:connect uploader software
- Downloads using pump charging cable
- Can generate pdf reports for communication within the clinic
- Clinics can access data directly (and download pump in-office) via patient’s login ID

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**Viewing CGM data in t:connect**

- **tConnect “Dashboard”**
- **Graph Timeout (h:mm)**
- **Alarm**
- **Glucose alert**
- **Sensor**
- **Low Reservoir Warning**
- **Fills**
- **Source: MiniMed 530G - 751**

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**CGM + Pump Reports**

Giving **context** to the data
Each one-hour block shows the highest, average, and lowest readings as well as the mid range.

**Midware**
- DIASEND
  - Meters (most)
  - CGM
  - Pumps

- GLOOKO
  - Meters (most)
  - CGM
  - Pumps

**Diasend Logistics**
- Clinic Typically Pays for Account
- Patients have free access for home downloading
- Clinic ID entered by patient, provides clinic access
- “Uploader” software must be installed and used
- May require converter boxes for office downloading
Diasend Comparison Day-By-Day Report

Glooko Logistics
- Patients typically pays for their own account
- Data downloaded through smart phone
- "Converter" cable required
- Allows generation of pdf reports
- Clinic account allows for patient tracking

Analyzing CGM Data for Improving Patient Outcomes

Glooko Logistics
- Hover over columns to learn more about each patient and view their quick statistics:
  - See which patients are using Glooko remotely
  - See their age and type of diabetes
  - See when and which devices were last synced
  - See their at-risk flags based frequency of high or low glucose readings against a set or customized glucose threshold
- Search for a specific patient
- Tag patients for an easier search

Daily Trends
- View glucose data based on day of week and time of day
- View glucose information color-coded based on 10-90th or 25-75th percentile
- Click on each day of the week to include or not include their statistics in the larger graph
- Hover over each box to learn more information:
  - See 10-90th and 25-75th glucose range
  - See median glucose value per hour
- Set customized date ranges to narrow down data displayed
- Create a PDF summary report to print or share

Set and Site Change
- See glucose percentile based on number of days between set/site changes:
- Use this information to optimize frequency of set/site changes to maintain tighter glucose control
- Learn more about each set/site change, including glucose readings before and after
- Click on a row to be taken to the corresponding Daily Overview
- Set customized date ranges to narrow down data displayed
- Create a PDF summary report to print or share

Interview the patient. What do you want to get out of this?
- Review downloaded reports with the patient
- Avoid focusing on 'outliers'. Applaud the successes!

Ask the right questions
- What time do you take basal insulin?
- How long before the meal do you take meal time insulin?
- What time do you wake?
- What time do you go to sleep?
- If you’re on an insulin pump do you use the bolus calculation?

Disclosure to Participants

Analyzing CGM Data for Improving Patient Outcomes

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Certified Nurse Practitioner
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Population Tracker
- Search for a specific patient
- Tag patients for an easier search
- Learn more about each set/site change, including glucose readings before and after
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Daily Overview
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Conflict of Interest (COI) and Financial Relationship Disclosures:
- Advisory Panel: Janssen Pharmaceuticals, Abbott, Eli Lilly, Novo Nordisk, degradation: Novo, Dexcom, Sollero, Small Awards, Medtronic
- Research Support: Abbott, Janssen Pharmaceuticals, Bristol-Myers Squibb, Novo Nordisk, Eli Lilly
- Research Grants: Bristol-Myers Squibb, Novo Nordisk, Abbott, Calibrations, Diabetes, Dexcom, Medtronic, Gilead, J&J
- Speakers Bureau: Janssen Pharmaceuticals, Bristol-Myers Squibb, Novo Nordisk, Abbott, Calibrations
- Stock: Dexcom

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- Printed on 8/24/2016

Questionnaire
- What is your current diet?
- What is your current physical activity level?
- What are your current social and family relationships?
- What are your current work and school goals?
- What are your current financial resources?
Ask the right questions

- At what number do you feel low blood glucose?
- How do you treat low blood glucose?
- What time of day do you exercise?
- Do you correct high Bg after meals? If yes how do you determine insulin dose?
- Do you snack? If yes what are your “go to” snacks? Do you cover snack?
- Where do you inject insulin/infusion lines (look at sites)?

Lack of Standardization with Modal Day Limits

CGM Data Interpretations

Diabetes and Pregnancy Goals:

- Fasting <90
- 1 hour <130-140
- 2 hour <120
- A1c <6.0 without hypoglycemia

Answer
This!

Which is the best sequence for applying CGM insight:

A. Address the highs before addressing the lows
B. Fix the lows before attempting to fix anything else
C. Fine-tune the basal rates before fine-tuning the basals

Stepwise Approach to Interpreting CGM Reports

1. Fix lows first
   - Overnight
   - Throughout the day
2. Fix overnight hyperglycemia
3. Evaluate/fine-tune basal insulin
4. Fix pre-prandial hyperglycemia
5. Fix post-prandial hyperglycemia
6. Address lifestyle challenges

What do I need to know?

- Patient shared that he likes cookies. A lot.
- Asked to manage qty, cover, and CGM repeated.

What do you see?

What changes would you make?

Diabetes and Pregnancy Goals:

- Fasting <90
- 1 hour <140-130
- 2 hour <120
- A1c <6.0 without hypoglycemia

CGM Automated, Standardized Reporting for Research Analysis and Diabetes Management, ATTD 2013 ADC symposium
What do you think is going on?

Fear of Hypoglycemia???

What do you see?

Is this a Basal or Bolus issue?

What do you fix first?

What do you see?

What do you see?

What do you see?

8/24/2016
What do you see?
What changes are needed?

What do you see?
Switched to newer basal insulin and adjusted Bolus timing.

What do you see?
Is this a basal or a bolus issue?

What do you see?
After adjustments are made:
Evaluating the results.

What do you see?
Where do you start?

What do you see?
What are the potential issues?

Another perspective
What patterns do you detect?

Yes, but when and how often?

Visualizing Glycemic Patterns with AGP

- AGP is a visual report that collapses all glucose readings from a specified date range and presents them as if they occurred in a single 24-hour period, making it easier to visualize glycemic patterns.

... to get a clinically relevant "glycemic snapshot" for a patient, two weeks of CGM may be a justified healthcare resource investment.


Statistical Summary

- Glucose exposure (mean and eA1C)
- Variability (SD & IQR)
- % in target, above and below

Visual Display

- Modal day (14 if possible)
- Smoothing algorithm applied to data to generate 5 glucose curves
  - Median (black line), 25th/75th percentile (solid lines),
  - 10th and 90th percentiles (dotted lines)

 Daily View

- Thumbnail view - each day in the overall profile
- Calendar format
- Work vs. non-work, weekend vs. weekday
- Target range
- "Hover over" tool to see specific glucose values

Ambulatory Glucose Profile (AGP)

Case: Donna – Renal Patient

70 yr. Female

- Type 1.5 (LADA) for 30 years (GAD > 30 nmol/L)
- Dx age 40 as Type 2 - eventually treated with insulin
- Present with fatigue, CKD 4, and frequent hypoglycemia
  - A1C: 6.9%
  - C-peptide: 0.6 ng/mL

- Insulin regimen
  - Insulin glargine: 10 units/day
  - Insulin aspart: pre-meal (AC) sliding scale
  - TDD: 20 units/day

- Logbook BG readings appeared normal
  - AM: ~70-110 mg/dL
  - PM: ~100 mg/dL (before dinner)
Case 2: RW
- Diabetes 35 years
- CVD and CKD
- Hypoglycemia unawareness
- Reports elevated BG that need large bolus of insulin to control
- Pump infusion sites only lasting 1-2 days
- Using syringes away from pump sites for bolus with improvement
- Frustrated

Answer This!
Through CGM data analysis, it is possible to:
A. Fine-tune basal and bolus insulin doses
B. Spot potential issues related to lifestyle choices
C. Evaluate patterns by day-of-the-week

Review: Insights to glean from CGM Report Analysis
1. Stats Summary/Comparison
2. Are bolus amounts appropriate?
   - Meal doses
   - Correction doses
3. How long do boluses last?
4. What is the magnitude of postprandial spikes?
5. Is basal insulin holding BG steady?
6. Are asymptomatic lows occurring?  
Are there rebounds from lows?  
Are lows being over/under treated?  
7. How does exercise affect BG?  
   Immediate  
   Delayed effects  
8. Are ancillary meds doing the job?  

Review: Insights to glean from CGM Report Analysis  
9. How do various lifestyle events affect BG?  
   Hi-fat meals  
   Unusual foods  
   Stress  
   Illness  
   Work/School  
   Sex  
   Alcohol  

Optimizing Insulin Therapy Through Applied CGM  

You don’t have to cover all this in one session!