Integrating Diabetes Technology Into Your Practice: Focus on Professional and Personal Continuous Glucose Monitoring

Davida F. Kruger, MSN, APN-BC, BC-ADM
Certified Nurse Practitioner
Henry Ford Health System
Detroit, MI

Disclosures

Davida Kruger

- Abbott, Eli Lilly, Novo Nordisk, Boehringer Ingelheim, Dexcom, Sanofi Aventis, Takeda

• **Research Support**: 40% of Salary NIH

• **Research Support to HFHS**: Bristol-Myers Squibb, Novo Nordisk, Eli Lilly, Helmsley Charitable Trust, NIH, Abbott, Calibra/land I, Dexcom, IDC, Lexicon, TEVA

• **Speakers Bureau**: Janssen Pharmaceuticals, Bristol-Myers Squibb, Valeritas, BI/Lilly, Novo Nordisk

• **Stock**: Dexcom

State of Current Glucose Monitoring Methods

- **A1c**: Standard of Care, however:
  - Impact of hypoglycemia and hyperglycemia are unknown
  - Unknown glucose variability

- **SMBG**: Provides glucose information for only points in time, however:
  - Hypoglycemia and hyperglycemia are often missed
  - Overnight data is impractical to obtain

- **CGM**: Provides significant amount of glucose data, however:
  - Lower penetration in some areas due to lack of reimbursement, startup cost
  - Provider ambivalence regarding therapeutic adjustments
  - Reports can be difficult to interpret and gain insight

References:
Glycemic Variability

- Pathophysiologic data indicates increased oxidative stress occurs with fluctuating levels.
- Epidemiologic studies suggest correlation between elevated post-meal glucose levels and micro- and macrovascular outcomes.
- The effect of fluctuations of glucose levels, not only the management of chronic hyperglycemia, is hypothesized as a variable though more data is needed to determine it as an independent variable.

Many SMBG Meters --- Too Many SMBG Reports

Measurement Tasks

- Recognize the need
- Assure test strips are current and were stored properly
- Wash hands (for fingerstick test) and dry them
- Remove a test strip from the vial and recap
- Insert test strip
- Lance the fingertip
- Obtain a "good" blood drop
- Properly apply the blood
- Wipe off the blood - clean the site
- Dispose of strip, lancet, wipe
Sources of Error with BGM

- Improper strip storage
- Outdated strips
- Miscoding
- Marked dehydration, Vasoconstriction,
  Hematocrit extremes
  Maltose, galactose, and xylene
  Oxygen extremes
  Hyperuricemia

#1 - Failure to TEST!!!

Potential Clinician Recommendations in Response to Frequent or Severe Hypoglycemia

- Loosen control - establish higher glucose targets
- Increase SMBG frequency
- Change insulin delivery to a pump
- Change SMBG to CGM
Does having a Low or High A1C Protect against Severe Hypoglycemia?

More frequent SMBG is not associated with decreased hypoglycemia

The Cost of Hypoglycemia

- Hypoglycemia impairs the physiological defense to subsequent hypoglycemic episodes
- Insulin-treated patients are prone to impaired awareness of hypoglycemia
  - Estimates suggest hypoglycemia is the cause of 2-10% of deaths of people with type 1 diabetes
  - The cost of admission for one hypoglycemic episode is over $17,000
    - Patients with type 2 DM are especially at risk if treated with insulin or sulfonylureas
• CGM unveils what no meter can. BG monitoring provides a number for a single point in time.
• CGM provides dynamic glucose information by showing where glucose is, where it’s going, and how fast it’s getting there.
• Allows both the HCP and the Patient to make better treatment decisions.

Continuous Glucose Monitoring

• CGM should be viewed as another tool in the management of diabetes.
• CGM provides detailed information on glucose patterns and trends.
• Patients need to be aware of the physiological lag between interstitial and capillary blood glucose. This varies with each system. And has improved with each generation.
• Patients are comfortable with BG meter data they need to adjust to CGM accuracy and difference between devices.
Finger stick Testing Does Not Show the Whole Picture

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

• Professional CGM
• Devices Owned by clinics approved for multiple use when cleaned and used according to the labeling.

• **Dexcom G4**: Real Time Option and Retrospective option.
  7 Days of Data
• **Medtronic Ipro2**: Retrospective Data only
  3 to 5 Days of Data
• **Free Style Libre Pro**: Retrospective Data only
  14 Days of Data

---

**Why Use Professional Real-Time CGM In Your Practice**

- 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
Why Use Professional CGM (cont)

- Find patterns that otherwise could not be detected by finger stick alone
- Find patterns of undetected low BG in patients at treatment goal
- Allows to **efficiently and effectively** identify areas of clinical challenges and apply appropriate medical management to address that specific clinical issue.
- Moves people to personal CGM
- And How did we function before CGM....

So How Do We Do CGM In Detroit?

Our Program (11 years old)

- Last year did more than 1400 Professional CGM: average starts weekly 30 in two sites (can be higher)
- Own 50 CGM dexcom devices, 50 Libre Sensors on hand
- Team: MA’s, RN’s, RD’s, NP’s,
- Dedicated resource of people and space
- Secretarial Support for ordering supplies and personal CGM
- Referrals: Within Division, Within System
- Charging, sign out, down load, returns, cleaning, maintaining supplies and devices
Office Flow

- Same day start VS Scheduled start
- Return to see the NP/or drop off/mail back
- Medical Assistant down loads in exam room
- Each Exam room has ICON and Cord to download or web site
- All supplies placed in box for cleaning and charging
- Mail Back: sensor is downloaded and cut and pasted into record. NP calls patient

Supplies and Starts

- Sign out book for devices in two clinical sites
- Secretarial support for ordering sensors and transmitters
- Starts RNs, MAs, NPs
- Clean: dedicated staff and spot
Our Program continued

- Patient contract
- Electronic medical records: Templates, smart sets and copy paste
- Nurse Practitioner develops care plan and manages follow up
- 7-14 day use of CGM to assess clinical patterns (weekends and weekdays)
- Bill for both the technical training of CGM (95250) and interpretation (95251)
- Patient may return in 7-14 days or mail back/drop off
Contract

• Patients sign contract for lost equipment
• Today few patients loose equipment

Documentation Dexcom

SUPPLIES: Sensor lot number, DEXCOM unit. Patient verbalized understanding of the Dexcom Continuous Monitor Patient Agreement and has signed in agreement. Initiation of Continuous Glucose Sensor (Dexcom)

Inserted Dexcom sensor to ***

INSTRUCTIONS: Pt verbalizes understanding of calibrating in 2 hours by initiating with 2 blood glucose levels and recheck prior to each meal and at bedtime (at the very least, every 12 hours). Patient demonstrates correct use of sensor.

URGENT CONTACT: ***
FOLLOW UP: in 1 week for CGMS interpretation with ***

Documentation Libre Pro

REQUESTED BY: ***
CURRENT A1c: ***
Initiation of Continuous Glucose Monitoring With Free Style Libre Sensor

CURRENT DIABETES THERAPY: ***

SUPPLIES FOR SENSOR START:
Sensor
Alcohol in Sensor box
Skin Tac/Barrier Protection Wipes
IV JARS
Recalibrated Ring: Labeled with Patient Name and MRN
Sign Out Book

Inserted Libre sensor to: ***

INSTRUCTIONS: Pt verbalizes understanding of need to protect and keep sensor in place and if falls off before the two weeks to place sensor in the biohazard bag and bring back to back at scheduled visit.

URGENT CONTACT: ***
Interpreting Data

GM Interpretation: Reviewed each graph with patient and explained findings and patterns detected.

This is used as a prompt in clinic note below CGM data. Actual interpretation is also written.

CGM was mailed to clinic/ Dropped off following has been completed:
1. Sensor was downloaded and data was reviewed
2. Care plan was developed based on interpretation of data
3. Patient was called and data was reviewed over the phone
4. Suggested changes were reviewed with patient
5. Patient has agreed to suggested changes
6. A copy of the CGM download and AVS has been mailed to patient
7. Patient is advised to call with questions after reviewing download

Which Patients Are Candidates?

New to our practice: trying to determine where the patient has been to help develop a management plan moving forward
• Uncontrolled both type 1 and type 2 diabetes
• Hypoglycemia unawareness
• Individuals who have A1c at or below treatment goal and state have no hypoglycemia
• Pregnancy or wants to get pregnant*
• Unsure what to do next
• Unengaged patient with no data
• Almost every patient we see
• Moving patients to professional

* No professional CGM is currently FDA approved for use in pregnancy.

Reports
• Fix lows first
  • Overnight
  • Throughout the day
• Fix overnight hyperglycemia
  • Look to dinner and/or bedtime control
• Fix pre-prandial hyperglycemia
• Fix post-prandial hyperglycemia
• Address lifestyle issues
I Am Not Having Any Low BG !!!!

Still Some Work but Looking Better.

Still Some Work To Go, But Looking Better (Same Patient)
Fear Of Low Blood Glucose

Personal CGM

Personal Use
owns and wears daily

Stand Alone: Dexcom G4, G5, or G6
Integrated: Medtronic: Medtronic sensor
Animas Vibe: Dexcom G4
Tandem Tslim: Dexcom G4/G5
Moving from Professional to Personal use

- Candidates Complete Forms for device
- Secretaries email to Company
- Patient trained in our office or web based
- Patient trained by company reps (medicare) or by NPs as part of scheduled visit
- Apps downloaded on phone if not medicare, set up with invites to upload and send data
- Personal use downloaded each visit and in between as needed

Personal Use: Dexcom

Dexcom G6

- Sensor + Algorithm
  - No Calibrations Required
  - 30 Day Warranty
  - Customizable Alert tones
  - Voted Best CGM for Age 7 and Older
- Applicator
  - Less Painful
  - Rubber Sensor Applicator
  - Tiny Insertion Needle (26Ga)
- Transmitter
  - Communicates via BLE to Contoured Receiver via BLE
  - Communicates to Receiver BLE data to Receiver and Mobile Device
- Receiver
  - No Calibrations Required
  - Communicates to CGMS and CGM Mobile App
  - Communicates to Contour Mobile App

UPDATED Apps:
- New Dexcom G6 App
- NEW Urgent Low Soon Alert
- Firmware upgradable
- Customizable Alerts
G6 Sensor Eliminates the Impact of Acetaminophen on Sensor Performance

- 66 adult type 1 & type 2 subjects
- G6 sensor readings matched with YSI values
- 1 gm acetaminophen (maximum adult dose within a 6 hour time period)

Mean acetaminophen interference effect was ~3mg/dL

Four Steps For Sensor Insertion: Peel – Press – Push – Place

Clinical Study Results
- 100% of all subjects rated the new applicator system as "very easy" or "somewhat easy"
- 84% rated the system as "painless"
- 100% of all subjects rated the instructions for sensor insertion to be "somewhat or very easy"

Dexcom G6: A Factory Calibrated System

100% of Sensor Undergo Performance Evaluation
Each sensor is labeled with a four digit code
Code results in accurate sensor glucose readings

Factory calibration DOES what fingerstick calibrations USED TO DO...
Sensor Application Libre

New Sensor Start

Integrated Insulin Pumps
Guidance for Calibrations vs. Fingersticks with Commercial CGM Systems

<table>
<thead>
<tr>
<th>When to Calibrate?</th>
<th>Dexcom G6</th>
<th>Abbott Libre</th>
<th>Medtronic CGM/ Guardian Connect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only with an outlier sensor reading (no limitations for stable glucose)</td>
<td>Factory calibrated: cannot calibrate</td>
<td>Recommended 4x/day during stable glucose</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>When to Double Check with a Fingerstick for Dosing Decisions?</th>
<th>Dexcom G6</th>
<th>Abbott Libre</th>
<th>Medtronic CGM/ Guardian Connect</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGM does not match:</td>
<td>• symptoms do not match • when there is no CGM number and arrow</td>
<td>When:</td>
<td>• hypoglycemia &lt;70mg/dL • Impending hypoglycemia • Rapidly changing glucose • Symptoms of hyper- or hypoglycemia</td>
</tr>
</tbody>
</table>

**Downloading: Personal CGM**

- All CGM devices are downloaded every visit
- Reimbursement 2-12x annually
- Typically: Medicare and Medicaid 2x annually
- Commercial 2-12x annually
- Patient responsible to determine how many times can get reimbursed
- In between visits patients are encouraged to upload data, send codes, let us know to look !!!!!
CGM Patient Education Personal

- Basic Education regarding device, skin care, insertion, accuracy
- Non-adjunctive use, comfort not doing BG
- Apps, uploads, sharing data
- Using data daily and Big Picture
- Utilizing Arrows

Replace-BG

REPLACE-BG  Alepp0,G et al.

- **Objective**: To determine whether the use of continuous glucose monitoring (CGM) without confirmatory blood glucose monitoring (BGM) in adults with well-controlled type 1 diabetes (T1D)

- **Conclusion**: Use of CGM without regular use of confirmatory BGM is as safe and effective as using CGM with BGM in adults with well controlled T1D at low risk for severe hypoglycemia
Medicare Guidelines

The patient is reminded that they may NOT use their phone either as a primary receiver or, as a secondary device and still be eligible for Therapeutic CGM.

This patient has met the following criteria and it is documented in the medical record:

• Requires therapeutic CGM and has diabetes
• Has been using a home BG monitor four times daily
• Is insulin requiring with 3 or more daily injections or insulin pump
• Treatment requires frequent adjustments of insulin by the patient on the basis of therapeutic CGM testing
• Within 6 months prior to ordering the CGM, the treating practitioner has an in-office visit with the patient to evaluate their diabetes control and determines above criteria have been met
• Every 6 months after initial prescription the patient is seen in the office by the prescribing practitioner to assess adherence to their CGM regimen and diabetes treatment plan.
• Must be obtained through a Durable Medical Supply store not a Pharmacy.

Medicare Guidelines For CGM Use

For CGM products that are used in the home and approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions.

Dexcom G5
Free Style Libre Flash

Who Can Bill For CGM ????

• Initiation which also includes the physical download when returned: RN, MA, NP/PA, MD/DO Pharmacist

• Interpretation: The process of looking at download, determining what it means and documentation : NP/PA, MD/DO (Professional and Personal)
Reimbursement

<table>
<thead>
<tr>
<th>Description</th>
<th>Anthem</th>
<th>Aetna</th>
<th>Cigna</th>
<th>United Healthcare</th>
<th>Medicare</th>
<th>Medicaid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopsy</td>
<td>195.91</td>
<td>186.75</td>
<td>185.03</td>
<td>176.61</td>
<td>145.24</td>
<td>37.32</td>
</tr>
<tr>
<td>CGM</td>
<td>61.66</td>
<td>58.66</td>
<td>58.46</td>
<td>48.27</td>
<td>43.88</td>
<td>17.88</td>
</tr>
</tbody>
</table>

Provided by Stacey Brittain PA-C. Exempla DM and Endocrine Services. Denver, CO; based on her practice reimbursement in 2015.

How do CGM-based decisions enable CGM users to improve glucose control

**Lower A1C**
- Large insulin dose increases for rising glucose
- Respond to high glucose alerts at night decreasing nocturnal hyperglycemia
- More frequent correction between insulin doses
- Lower glucose targets
- Increase timing between insulin dose and meal for rising glucose

**Reduce Hypoglycemia**
- Reduce or eliminate insulin doses for falling glucose
- Respond to low glucose alerts
- Prophylactically eating with carbohydrates to prevent low when glucose is falling
- Decrease timing between insulin dose and meal for falling glucose

Learning from CGM-Based Treatment Decisions

**Lows**
- Too much insulin for a meal or snack?
- Too much insulin to correct a high reading?
- Exercise or Alcohol?
- Inaccurate carbohydrate counting?
- Stack insulin?

**Highs**
- Too little insulin for a meal or snack?
- Too little insulin to correct a high reading?
- Mixed or stress levels change?
- Other medications impacting glucose levels?
- Inaccurate carbohydrate counting?
- Sick?

CGM Is Different:
CGM Provides much More information

- Glucose value
- Trend arrow
- Trend Graph
  - Know where you are by how you got there AND where its going
- Alerts!

What to Do?

My meter always gives me the same answer

220 mg/dL
How do Patients use Real time CGM?

- 222 subjects with T1DM
  - HbA1c: 6.9±0.8 (self reported) – 75% CSII
  - CGM users for >1 year
- Asked 70 scenario based questions
  - Focused on how patients are using CGM data
  - Looked at impact of ROC arrows and patient decision making.

Using CGM Rate of Change (ROC) Information When

- Meal insulin doses based on the direction and ROC

Possible Actions Based on Sensor Glucose Reading’s Trend Arrows

<table>
<thead>
<tr>
<th>Glucose Reading's Trend Arrows</th>
<th>High Glucose Reading</th>
<th>Target Glucose Reading</th>
<th>Low Glucose Reading</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Glucose Reading</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Glucose Reading</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Using CGM Rate of Change (ROC) Information When Correcting for a High BG

- 2.8 units
- 5.9 units


Survey re making large adjustments to correction Meal insulin doses based on the direction and ROC

Possible Actions Based on Sensor Glucose Reading’s Trend Arrows

- Watch and wait
- May adjust insulin to correct a high sensor glucose reading
- Do not stack insulin
- Consider trend graph & recent Alarm/Alert
- May adjust insulin to stay within target
- Do not stack insulin
- Watch and wait
- Make sure you did not over treat for a low
- May adjust insulin to correct a high sensor glucose reading
- Do not stack insulin
- Consider trend graph & recent Alarm/Alert
- May need to eat a snack or fast acting carbohydrate
- Was last insulin dose too high or activity too strenuous?
- Based on last insulin dose and activity, may need to watch and wait
- Consider trend graph & recent Alarm/Alert
- May need to eat a snack or fast acting carbohydrate
What Are Current Recommendations For Adjusting Insulin Based On Real-time CGM Data?

**Variables**
- BS level: i.e. (175 vs 300mg/dl)
- Meal: type, size
- Exercise: type, duration, intensity
- Illness
- Stress
- Medications


How CGM and Trending Information Can Affect Dosing Decisions

<table>
<thead>
<tr>
<th>Percentage Change</th>
<th>Mean Increase/Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0%</td>
<td>111%</td>
</tr>
<tr>
<td>140%</td>
<td>7.2 units</td>
</tr>
<tr>
<td>41%</td>
<td>1.5 units</td>
</tr>
<tr>
<td>48%</td>
<td>3.0 units</td>
</tr>
</tbody>
</table>

Interpretation:

Ambulatory Glucose Profile
Current State of Data Acquisition & Workflow

We need an ECG for Glucose Patterns

AGP is constructed from a modal day plot, which collapses glucose data over several days or weeks, plotted according to time as if the data points occurred over 24 hours.
Ambulatory glucose profile provides key data insights.

- **Introduction to AGP**

  - Trends
    - Hyperglycemia
    - Hypoglycemia
    - Variability

  - **Target Range**
    - 80% of data
    - Median (black line), 25th & 75th Percentile (solid lines), 10th & 90th percentiles (dotted lines)
    - Medical (modal day, 14 if possible)
    - Smoothing algorithm applied to data
    - Mean & SD

  - **Visual Display**
    - Modal day
    - Median glucose
    - Visual algorithm

  - **Daily View**
    - Work vs. non-work
    - Target range
    - "Hover over" tool

  - Statistical Summary
    - Glucose exposure (mean and A1C)
    - Variability (SD & IQR)
    - % in target, above and below

  - **A Standard Report Based on Expert Panel**

*Funded by Helmsley Charitable Trust*
AGP Statistics

AGP Curves

Plot the 10th, 25th, 50th, 75th, and 90th percentile curves based on the

Daily Glucose Profiles
Common Report: Ambulatory Glucose Profile (AGP): An effective way to display glucose data

- Simple but comprehensive - one page (patient and HCP)
- Standardized - same view over and over again
- 3 parts to standard or common report
  - Statistical summary - clinical and research defaults
  - Visualization of typical glucose profile - modal day (14d)
  - Daily view - glucose profile from each day (calendar view)

Interpreting CGM

- Use of AGP to identify glycemic trouble spots
- Applying insights from CGM to improve postprandial glucose control
- Uncovering common pitfalls in CGM use
- Future directions in CGM data analytics

Identifying Glycemic Trouble Spots

Frequent Hyperglycemia

Frequent Hypoglycemia
Identifying Glycemic Trouble Spots

Frequent Hyperglycemia
Frequent Hyperglycemia

No Hypoglycemia
No Hypoglycemia

SAFE TO INCREASE INSULIN DOSE

POTENTIAL RISK FOR HYPOGLYCEMIA IF INSULIN DOSE INCREASED

54 years old
- Duration of diabetes: 18 y
- Frequency of monitoring: 2-4x daily
- BG monitoring device: One Touch, Free Style, Aviva. Whatever she has strips for
- A1c 9.5-10.2%
- Insulin: Glargine and aspart
- Fear of hypoglycemia keeps her blood glucose elevated

Case 1:
- Patient DB
- 54 years old
- Duration of diabetes: 18 y
- Frequency of monitoring: 2-4x daily
- BG monitoring device: One Touch, Free Style, Aviva. Whatever she has strips for
- A1c 9.5-10.2%
- Insulin: Glargine and aspart
- Fear of hypoglycemia keeps her blood glucose elevated
Question – Does Insulin Drive Glucose or Does Glucose Drive Insulin?

CGM Diabetes Management Guidelines

- **General guidelines**
  - Wear the CGM as much as possible
  - Look at your receiver frequently
  - Alerts and alarms should be your friend, not your enemy
  - Share your CGM results
  - Reflect on your past decisions
  - CGM is not perfect, nor is your meter (calibration)

- **Personalized guidelines**
  - Know your glucose targets
  - Have a plan for preventing or responding to low glucose
  - Adjust meal-time insulin dose and timing based on the direction and rate of glucose change
  - Respond to high glucose levels between meals but avoid “stacking” insulin
Summary

- Both professional and personal offers great insights into the management of both type 1 and type 2 diabetes
- A program to offer CGM can be developed in most clinic settings
- Education of the device as well as interpretation of the data is a must for both provider and patient

Summary

- Early warning of high and low glucose levels and/or rapidly changing glucose allows for early intervention
- CGM helps patients with reduced hypoglycemia awareness avoid hypoglycemic episodes
- Data provides a means to identify glycemic patterns, enabling more appropriate medication adjustments
- CGM is particularly helpful in guiding adjustments to address glycemic patterns during non-routine activities, such as exercise or stressful situations
- CGM allows for attainment of improved glycemic control within a short period of time
- Continuous glucose monitoring provided superior data to fingerstick monitoring in regards to frequency and consistency
  - Allows for more aggressive, individualized insulin titration

Questions ?