Continuous Glucose Monitoring: Are we there yet? Current uses and future directions

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Texas AACE August 3rd, 2018
Today’s topics

- Perspective of current use of CGM
- New recently introduced units/technologies
  - Freestyle Libre
  - Dexcom G6
  - Eversense (Senseonics)
- Update on billing and coding
- Expanding clinical scenarios of use
Duality of interest

- Speakers’ Bureau
  - Medtronic
  - Dexcom

- Consulting/Advisory Board
  - Medtronic
  - Insulet
  - Tandem

- Research support
  - Roche Diabetes
Evolution of Glucose Monitoring

First Generation
- Reflectance Meters
- Qualitative results

Second Generation
- Smaller blood volume,
- Less pain, shorter test time,
- Better accuracy/precision,
- Miniaturisation

Third Generation
- Continuous Glucose Monitoring (CGM)
- Invasive & minimally invasive

Fourth Generation
- Non-invasive monitoring

Cost-effective, Comfort, Convenient

Technology Improved A1C

- Lower HbA1c in CGM users regardless of insulin delivery method

![Graph showing the comparison of mean HbA1c levels among different age groups and insulin delivery methods.](chart.png)
27% of Patients Discontinue CGM Use Within 1 Year

- 71% CGM not working / not accurate
- 61% Problems with sensor insertion / adherence
- 58% CGM too expensive / not covered
- 41% Sensor uncomfortable
- 33% Pump user - did not want 2 sites
- 28% CGM too big

n=2,452 adult T1D Exchange participants
Source: T1D Exchange; Why Do Some People with T1D Stop Using a Pump and CGM? 2016
## Table 1—Key metrics for CGM data analysis and reporting

<table>
<thead>
<tr>
<th>CGM metric</th>
<th>Measures</th>
<th>ATTD consensus</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mean glucose</td>
<td>√ (calculated) Clinical diagnosis: event requiring assistance (level 3)</td>
</tr>
<tr>
<td>1</td>
<td>Severe hypoglycemia*</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Percentage of time in hypoglycemic ranges, mg/dL (mmol/L)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Clinically significant/very low/immediate action required</td>
<td>&lt;54 (&lt;3.0) (level 2)</td>
</tr>
<tr>
<td>3</td>
<td>Alert/low/monitor</td>
<td>&lt;70–54 (&lt;3.9–3.0) (level 1)</td>
</tr>
<tr>
<td>3</td>
<td>Percentage of time in target range, mg/dL (mmol/L)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Default</td>
<td>70–180 (3.9–10.0)</td>
</tr>
<tr>
<td>4</td>
<td>Secondary</td>
<td>70–140 (3.9–7.8)</td>
</tr>
<tr>
<td>4</td>
<td>Percentage of time in hyperglycemic ranges, mg/dL (mmol/L)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Alert/elevated/monitor</td>
<td>&gt;180 (&gt;10) (level 1)</td>
</tr>
<tr>
<td>6</td>
<td>Clinically significant/very elevated/Immediate action required</td>
<td>&gt;250 (&gt;13.9) (level 2)</td>
</tr>
<tr>
<td>6</td>
<td>Diabetic ketoacidosis*</td>
<td>Clinical diagnosis: ketones, acidosis, and usually hyperglycemia (level 3)</td>
</tr>
<tr>
<td></td>
<td>Glycemic variability</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Primary glycemic variability</td>
<td>CV</td>
</tr>
<tr>
<td>7</td>
<td>Stable</td>
<td>CV &lt;36%</td>
</tr>
<tr>
<td>7</td>
<td>Unstable</td>
<td>CV ≥36%</td>
</tr>
<tr>
<td>7</td>
<td>Secondary glycemic variability</td>
<td>SD</td>
</tr>
</tbody>
</table>
Hierarchical order of utilization of CGM in clinical practice (Diagnostic and Personal)

- Hypoglycemia (overnight versus daytime)
  - Detection
  - Prevention (Prediction)
  - Avoidance of over correction

- Hyperglycemia: (overnight/fasting versus post-prandial)

- Insulin decision making including integration with Closed loop Systems.

- Data evaluation and interpretation for chronic disease management
  - Estimation of HbA1c
  - Time in Range
  - Estimation of risk of hypoglycemia
Flash Glucose Monitor - Freestyle Libre

- Launched in 11/2017
- ≥ 18 years in US; 4 year-old outside of US
- Approved for insulin dosing
- No calibration needed
- No alarms to users
- Not impacted by Tylenol
- Can store 8 hours of data
- Differences in US version
  - 10-day wear (compared to 14)
  - 12-hour warm-up period (compared to 1)
  - No “share” capability (LibreLinkUp/ LibreLink in Europe)
  - Improved accuracy (MARD 9.7% in US vs 11%)
- Tidepool mobile is web based app to upload data and view trends
Invited Review

Flash forward: a review of flash glucose monitoring

L. Leelarathna¹,² and E. G. Wilmot³

¹Manchester Diabetes Centre, Central Manchester University Hospitals NHS Foundation Trust, Manchester Academic Health Science Centre, ²Division of Diabetes, Endocrinology and Gastroenterology, Faculty of Biology, Medicine and Health, University of Manchester, Manchester and ³Derby Teaching Hospitals NHS Foundation Trust, Royal Derby Hospital, Derby, UK

![Bar graph showing time in hypoglycaemic range (h/day) over different periods: 3.1 to <3.9 mmol/L and <3.1 mmol/L.](image)

Dexcom G6

**Sensor + Algorithm**
- No Calibration Required
- 10 Day Session Duration
- Cannot Restart Sensor Session
- Acetaminophen blocking
- Intended For Use for Ages 2 and Older

**Applicator**
- Less Painful, Simple, Push Button Sensor Applicator
- Tiny Insertion Needle (26Ga)

**Transmitter**
- ~30% Thinner
- Contoured Wearable
- 3 Month Life
- 20 Foot Transmission Range
- Built in BLE for Direct Transmission of CGM data to Receiver and Mobile Device

**Receiver**
- Touchscreen Receiver
- NEW Urgent Low Soon Alert
- Firmware upgradable
- Customizable Alerts (Settings and Sounds)

**Apps**
- Updated Apps:
  - New Dexcom G6 App
  - Fully Customizable Alerts
  - NEW Urgent Low Soon Alert
  - Upgradable Clarity

**Maintaining CGM performance that is safe for diabetes management decisions, with ZERO calibrations**
• iOs and Android compatible for smartphones and smart watches
• System contains:
  • G6 app
  • G6 transmitter
  • G6 receiver
  • G6 sensors (3 pack)
Dexcom G6 Maintains Accuracy Required for Treatment Decisions While Eliminating Calibrations and Extending to 10 Day Wear

**Dexcom System MARD* by Generation**

- **STS 3-Day (2006)**: 26%
- **SEVEN (2007)**: 17%
- **SEVEN Plus (2008)**: 16%
- **G4 PLATINUM (2012)**: 13%
- **G5 Mobile (2015)**: 9%
- **G6 No Cal (Pre-Pivotal)**: 9%

* Mean Absolute Relative Difference (MARD) between CGM readings and blood glucose readings
G6 Sensor Eliminates the Impact of Acetaminophen on Sensor Performance

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

Mean acetaminophen interference effect was ~3 mg/dL

If your glucose alerts and readings from the G6 do not match symptoms or expectations or you’re taking over the recommended maximum dosage amount of 1000mg of acetaminophen every 6 hours, use a blood glucose meter to make diabetes treatment decisions.

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”
Customizable Alerts

- Alert Schedules
  - Allows for a 2\textsuperscript{nd} time frame for alerts
  - i.e., Day Mode and Night Mode

- Discretionary Alert Enhancements
  - Ability to have specific alerts override your phone settings

User decides how they want their phone to alert with this schedule when Silent or Do Not Disturb is turned on

Option for users to decide if they want their phone to alert when Silent or Do Not Disturb are on.
- If always sound ‘on’, phone will alert for every setting turned on as well as the critical system alerts such as urgent low (<55 mg/dL), transmitter failure and sensor failure.
- If always sound is ‘off’ then none of the alerts turned on will give you an audible alert EXCEPT urgent low, transmitter failure and sensor failure.

Users have the ability to customize which alerts they want
- Alerts can be turned on or off
- User chooses the glucose number in which to alert
- User chooses the sound they want the alert to make
Clinically Relevant (Urgent Low Soon)

**Urgent Low Soon Alert:**
- Future alert function
- Provide earlier actionable alert without increasing nuisance factor (93% detection)

![Graph showing glucose levels over time](image)

**Prediction Alerts** = 15 minutes warning

**Threshold alert** = 5 minutes warning

Glucose levels are plotted against time, with thresholds at 55 mg/dL and 80 mg/dL.
## Dexcom G6 Accuracy and Performance

<table>
<thead>
<tr>
<th></th>
<th>G5 2 Cal/Day</th>
<th>G6 No Cal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall MARD</td>
<td>9.0</td>
<td>9.0</td>
</tr>
<tr>
<td>Day 1</td>
<td>10.7</td>
<td>9.3</td>
</tr>
<tr>
<td>Day 2</td>
<td>8.4</td>
<td></td>
</tr>
<tr>
<td>Day 4-5</td>
<td>8.0 (day 4)</td>
<td>9.4</td>
</tr>
<tr>
<td>Day 7</td>
<td>8.5</td>
<td>8.7</td>
</tr>
<tr>
<td>Day 10</td>
<td></td>
<td>9.0</td>
</tr>
<tr>
<td>Hypoglycemia ≤70mg/dL (MAD)</td>
<td>6.8mg/dL</td>
<td>9.4mg/dL</td>
</tr>
</tbody>
</table>
The Eversense CGM System

Sensor
- Fully implanted
- Small size
- Up to 90 days

Smart Transmitter
- On-body vibe alerts
- Removable/Rechargeable
- Gentle adhesive

Mobile App
- Real-time readings every 5 mins
- No extra receiver
- Trends, alerts w/ predictive alerts

The only CGM:
- With fully implantable sensor
- Sensor that lasts up to 90 days
- With on-body vibe alerts
- With a removable transmitter
How the Eversense CGM System Works

Body-worn smart transmitter wirelessly powers subcutaneous sensor

Sensor antenna receives RF energy from smart transmitter to power device

Indicator polymer on surface of sensor fluoresces when glucose is present

Sensor sends raw data back to smart transmitter, which calculates glucose value

Smart transmitter sends sensor glucose value, trend, & alerts to mobile device
Eversense Sensor Insertion

1. Make incision
   ~5 mm Incision
   Upper Arm (Lidocaine)

2. Create pocket with custom tool

3. Insert sensor
   Sensor Inserted with Custom Inserter

4. Close incision
   Steri-Strips™

Office procedure typically takes a few minutes
Eversense Sensor Removal

1. **Make Incision**
   ~5-6 mm incision upper arm (lidocaine)

2. **Remove Sensor**
   Sensor removed with small clamp

3. **Close Incision**
   Steri-Strips™ to close
Indication for Use

- For continually measuring glucose levels in adults (age ≥ 18) with diabetes for up to 90 days

- System is intended to provide:
  - Real-time glucose readings
  - Glucose trend information
  - Alerts for detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia)

- For use as an adjunctive device to complement, not replace, information obtained from standard home blood glucose monitoring devices
The Eversense CGM System

Sensor
- Fully implanted
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The only CGM:
- With fully implantable sensor
- Sensor that lasts up to 90 days
- With on-body vibe alerts
- With a removable transmitter
A Different Kind of Transmitter: Smart

- Powers sensor, calculates and stores glucose readings
- Can be taken off and on without having to replace sensor
- Unique on-body vibe alerts for added safety
- Fresh, gentle-on-skin adhesive changed daily
- Water resistant (IP67 rating) - 1 meter for 30 min
## Sensor Performance Comparison

<table>
<thead>
<tr>
<th>Matched Pairs</th>
<th>15/15% of Reference</th>
<th>20/20% of Reference</th>
<th>30/30% of Reference</th>
<th>40/40% of Reference</th>
<th>MARD (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eversense†</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRECISE II Trial</td>
<td>15,753</td>
<td>87%</td>
<td>94%</td>
<td>99%</td>
<td>100%</td>
</tr>
<tr>
<td>PRECISION Trial</td>
<td>15,170</td>
<td>85%</td>
<td>93%</td>
<td>98%</td>
<td>99%</td>
</tr>
</tbody>
</table>

| Dexcom G5*    |                      |                     |                     |                     |          |
|---------------|                      |                     |                     |                     |          |
| 2,263         | 86%                   | 93%                   | 98%                   | 99%                   | 9.0      |

| Dexcom G6**   |                      |                     |                     |                     |          |
|---------------|                      |                     |                     |                     |          |
| 25,101        | 92%                   |                      |                     |                     | 9.8      |

| Libre*        |                      |                     |                     |                     |          |
|---------------|                      |                     |                     |                     |          |
| 5,772         | 82%                   | 91%                   | 98%                   | 99%                   | 9.7      |

<table>
<thead>
<tr>
<th>Medtronic Enlite 3*</th>
<th>2 Cal / Day</th>
<th>79%</th>
<th>88%</th>
<th>96%</th>
<th>99%</th>
<th>10.6</th>
</tr>
</thead>
</table>

* Summary of Safety and Effectiveness Data (SSED) Medical Device Databases – http://www.fda.gov
**Dexcom G6 User Manual – accessed 6.24.18
†Senseonics Data on File
Update on Coding/Reimbursement

New and Updated Codes for Continuous Glucose Monitoring (CGM) in 2018
Released January 1, 2018
REVISED 7/2/2018

The new CGM CPT being introduced is code 95249.
The description for the code is:
Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording. (This does NOT require the removal of a sensor. This code should only be reported once during the time the patient owns the device.)

Update on Coding/Reimbursement

**Code 95249.**

According to the 2018 CPT book, CPT code 95249 requires the patient to bring the data receiver into the physician or other qualified healthcare professional’s office where the entire initial data collection process is performed.

**Therefore** the correct date of service for CPT code 95249 is the date the CGM recording is printed in the office.

CPT guidelines further indicate CPT code 95249 may not be reported more than once for the duration that the patient owns the data receiver. Obtaining a new sensor and/or transmitter without a change in the receiver may does not warrant reporting 95249 subsequent times. If a separate and significant evaluation and management (E/M) service is performed on the same date, a modifier 25 may be required to be added to the E/M code.

Update on Coding/Reimbursement

The 2018 updated description for CPT code 95250 is:
Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording. (This DOES require the removal of a sensor.)

Often, AACE receives inquiries from members and their staff on the appropriate date of service for CPT code 95250 because the description describes services provided over a span of different dates.

---------therefore the correct date of service for CPT code 95250 is the date that the CGM recording is printed in the office. CPT guidelines indicate code 95250 can only be reported one time per month.
The 2018 updated description for CPT code 95251 is: *Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report.*

The analysis, interpretation and report may be done with data from a physician or other qualified healthcare provider provided CGM device or a patient provided CGM device.

The analysis, interpretation and report is distinct from an evaluation and management service. The CPT description of 95251 does not include an assessment of the patient or indicate a plan of care for the patient. The CPT description for code 95251 indicates an analysis, interpretation and report of a minimum of 72 hours of data collected from a CGM device. An appropriate CGM analysis, interpretation and report should include the following elements:

- Patient’s name, DOB, Medical Record #
- Indication for the device placement
- Name/Type of device placed
- Sensor placement date and Sensor removal date
- Date of printout of data
- Analysis of data:
- Interpretation of data:
- Signature of interpreting physician or other HCP

Update on Coding/Reimbursement

Medicare patients with type 1 and type 2 diabetes on intensive insulin therapy who meet the following criteria may now be able to obtain reimbursement:

- The beneficiary requires a therapeutic CGM. The beneficiary has diabetes mellitus; and,
- The beneficiary has been using a home blood glucose monitor (BGM) and performing frequent (four or more times a day) BGM testing; and,
- The beneficiary is insulin-treated with 3 or more daily injections (MDI) of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,
- The beneficiary's insulin treatment regimen requires frequent adjustments by the beneficiary on the basis of therapeutic CGM testing results.
- Within six (6) months prior to ordering the CGM, the beneficiary had an in-person visit with the treating practitioner to evaluate their diabetes control and determine that the above criteria are met; and,
- Every six (6) months following the initial prescription of the CGM, the beneficiary has an in-person visit with the treating practitioner to assess adherence to their CGM regimen and diabetes treatment plan.

<table>
<thead>
<tr>
<th>CATEGORY III CPT Codes</th>
<th>Official Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0446T</td>
<td>Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training.</td>
</tr>
<tr>
<td>0447T</td>
<td>Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision.</td>
</tr>
<tr>
<td>0448T</td>
<td>Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation.</td>
</tr>
</tbody>
</table>

Sources:
AACE New and Updated Codes for Continuous Glucose Monitoring (CGM) in 2018.
Clinical scenarios

- Pregnancy
- Intra-hospital use
- Detection of hypoglycemia (post bariatric, insulinoma, etc)
<table>
<thead>
<tr>
<th>Author &amp; year</th>
<th>Country &amp; CGM</th>
<th>Number</th>
<th>Gestational age at Randomisation</th>
<th>Intervention</th>
<th>Maternal Outcomes</th>
<th>Fetal Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Murphy et al 2008</td>
<td>UK</td>
<td>71</td>
<td>&lt;8 Weeks</td>
<td>Masked CGM for 7 days every 4-6 weeks</td>
<td>Lower mean A1C between weeks 32 and 36 (5.8 vs 6.4; p=0.007)</td>
<td>Reduced risk of macrosomia (OR 0.36 [95% CI 0.13 to 0.98], p=0.05)</td>
</tr>
<tr>
<td>Secher et al 2013</td>
<td>Denmark</td>
<td>154</td>
<td>&lt;14 weeks</td>
<td>Intermittent real time CGM for 6 days at 8,12,21,27 &amp; 33 weeks</td>
<td>At 33 weeks, A1C in each group was similar (6.1% vs 6.1, p=0.39)</td>
<td>No difference in LGA (45 vs 34%, p=0.19)</td>
</tr>
<tr>
<td>Voormolen et al 2017</td>
<td>Netherlands</td>
<td>304</td>
<td>T I &amp; II DM&lt;16 wks GDM: &lt;30 weeks</td>
<td>Intermittent masked CGM for 5-7 days every 6 weeks</td>
<td>Less pre-eclampsia in the CGM group</td>
<td>No difference in macrosomia between the two groups (RR: 0.99 [95% CI 0.76-1.28])</td>
</tr>
</tbody>
</table>

**CGM-Medtronic minimed**

Yamamoto JM et al. Emerging Technologies for the management of Type I Diabetes in pregnancy. Curr Diab Rep (Jan 2018) 18:4
Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial

Denise S Feig, Lois E Donovan, Rosa Corcoy, Kellie E Murphy, Stephanie A Amiel, Katharine F Hunt, Elizabeth Asztalos, Jon F R Barrett, J Johanna Sanchez, Alberto de Leiva, Moshe Hod, Lois Jovanovic, Erin Keely, Ruth McManus, Eileen K Hutton, Claire L. Meek, Zoe A Stewart, Tim Wysocki, Robert O’Brien, Katrina Ruedy, Craig Kollman, George Tomlinson, Helen R Murphy, on behalf of the CONCEPTT Collaborative Group*

→ involving 31 hospitals in Canada, England, Scotland, Spain, Italy, Ireland, and USA.

Women aged 18–40 years with type 1 diabetes for a minimum of 12 months receiving intensive insulin therapy were recruited.

• Two trials in parallel were run for pregnant participants (≤13 weeks and 6 days’ gestation) and for participants planning pregnancy.

Lancet 2017; 390: 2347–59
Published Online September 15, 2017
http://dx.doi.org/10.1016/S0140-6736(17)32400-5
CONCEPTT STUDY

(2013-2016)
325 women:
215 pregnant & 110 planning pregnancy randomly assigned to:

Case group:
capillary glucose monitoring + CGM:
108 pregnant & 53 planning pregnancy.

Control group:
without CGM
(107 pregnant & 57 planning pregnancy).

Primary outcome:
- change in HbA1c from randomisation to 34 weeks gestation in pregnant women & to 24 weeks or conception in women planning pregnancy.

Secondary outcomes:
Primary glycaemic outcome showing participants’ HbA1c levels according to pregnancy status

<table>
<thead>
<tr>
<th>Participants assessed</th>
<th>CGM</th>
<th>Control</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>45</td>
<td>6.83% (0.67)</td>
<td>6.95% (0.66)</td>
<td>9.5% (0.66)</td>
</tr>
<tr>
<td>38</td>
<td>6.95% (0.67)</td>
<td>6.95% (0.66)</td>
<td>9.5% (0.66)</td>
</tr>
<tr>
<td>45</td>
<td>6.40% (0.53)</td>
<td>6.40% (0.68)</td>
<td>9.5% (0.66)</td>
</tr>
<tr>
<td>89</td>
<td>6.53% (0.57)</td>
<td>6.53% (0.70)</td>
<td>9.5% (0.66)</td>
</tr>
<tr>
<td>34 weeks’ gestation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.35% (0.57)</td>
<td>6.53% (0.70)</td>
<td>9.5% (0.66)</td>
<td></td>
</tr>
<tr>
<td>Change from baseline to 34 weeks</td>
<td>-0.54 (0.62)</td>
<td>-0.35 (0.65)</td>
<td>0.0372</td>
</tr>
<tr>
<td>Achieved HbA1c≤6.5% (48 mmol/mol) at 34 weeks</td>
<td>63/95 (66%)</td>
<td>48/92 (52%)</td>
<td>0.0601</td>
</tr>
</tbody>
</table>
CGM measures from CONCEPTT

Pregnant CGM users spent

More time in target
(68% vs 61%; p=0.0034)

Less time hyperglycemic
(27% vs 32%; p=0.0279)

Less severe hypoglycemic episodes & time spent hypoglycemic
(3% vs 4%; p=0.10).
Clinical Trials using CGM in Non-ICU Settings

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Population</th>
<th>Sample Size</th>
<th># of sites</th>
<th>Type of CGM</th>
<th>Performance Measurement</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rodriguez, 2010</td>
<td>General Wards- ACS</td>
<td>16</td>
<td>1</td>
<td>Guardian</td>
<td>Glycemic control, time to BG &lt;140</td>
<td>Capillary BG</td>
</tr>
<tr>
<td>Burt, 2013</td>
<td>General Ward</td>
<td>26</td>
<td>1</td>
<td>System Gold</td>
<td>Performance Measurement</td>
<td>Comparator</td>
</tr>
<tr>
<td>Schaupp, 2015</td>
<td>General Ward</td>
<td>84</td>
<td>1</td>
<td>iPro</td>
<td>Accuracy</td>
<td>Capillary BG</td>
</tr>
<tr>
<td>Gomez, 2015</td>
<td>General Ward</td>
<td>38</td>
<td>1</td>
<td>iPro-2</td>
<td>Accuracy</td>
<td>Capillary BG</td>
</tr>
<tr>
<td>Gu, 2017</td>
<td>Ward</td>
<td>81</td>
<td>8</td>
<td>Sensor Augmented Pump</td>
<td>Performance Measurement</td>
<td>MDI with Blinded CGM</td>
</tr>
</tbody>
</table>

CGM in Non-ICU Patients with T2D

Hypoglycemia < 2.8 mmol/L

Hyperglycemia >13.9 mmol/L

Schaupp et al.
Diabetes Technology & Therapeutics, 2015
Available data from clinical studies suggest:

- The use of CGM in patients with T2D can provide a more complete picture of the patient’s glycemic status than POC testing.
- CGM provides a better direction of change, magnitude of change and warnings to predict both low and high BG levels compared to POC testing.

Improved accuracy of CGM sensors and reduced need for frequent calibration, or any calibration; are attractive features in the hospital.

Umpierrez & Klonoff. Diabetes Care in press, 2018
CGM Use in the Hospital: Challenges

- New technology, not commonly used by PCPs and hospitalists
- Need for calibration, sensor drift, measurement lag
- Interference (acetaminophen, maltose, ascorbic acid, dopamine, mannitol) with some CGM devices
- Information overload - risk of overtreatment
- Costs
- Lack of strong enough evidence yet to support their widespread use in hospitals
Figure 1. Plasma glucose (PG) and continuous glucose monitoring (CGM) measurements from P0 to P5 for aerobic sessions. Data shown are mean ± standard deviation (SD). PG is denoted by the black solid line and black-shaded area. CGM is denoted by the blue solid line and blue-shaded area. The vertical dashed line indicates the start of aerobic exercise sessions.
Summary

- CGM has moved into the front line for the management of T1 and T2, with many advantages over SMBG
- Not all units/systems “fits everyone needs”
- Medicare coverage is now available for T1&T2
- Insulin decision making/Insulin dosing is now ”on label”
- New technologies now incorporate no calibration and longer sensor life
- Pregnancy, in-hospital use and others scenarios will become the next approved indications