ADVANCED DIABETES TECHNOLOGY

Priscilla Escalona, MD
Assistant Professor
University of South Carolina School of Medicine Greenville
Division of Endocrinology - Prisma Health
Disclosures

• No relationships to disclose
Diabetes Technology

Hardware, devices, and software that people with diabetes use to help manage their condition, from lifestyle to blood glucose levels

Insulin administered by syringe, pen, or pump (continuous subcutaneous insulin infusion)

Blood glucose as assessed by blood glucose monitoring (BGM) or continuous glucose monitoring (CGM)
Overview of Diabetes technology over time

Insulin discovered by Frederick Banting

Backpack insulin & glucagon pump

Intravenous glucose control:
Albisser et al., 1974; Mirouze, Selam et al., 1977; Pfeiffer et al., 1974

Understanding the Metabolic Network:

The Incretin Effect:
GIP, GLP-1 and DPP-4. Nauck et al., 1986.

Subcutaneous Continuous Glucose Monitoring
Minimed CGMS, 1999

First use of s.c. insulin pump
Tamborlane et al., 1979
Pickup et al., 1978.

Quantifying Diabetes:
Glucose variability and Risk Analysis. Kovatchev et al., 1997

1920s

1960s

1970s

1980s

1990s

2000s

Ames Reflectance Meter

The Auto Syringe (Dean Kamen)
ADA Standards of Care: When to solely Using A1C to assess glycemic control

“Clinicians should exercise judgment when using A1C as the sole basis for assessing glycemic control”
ADA Standards of Care:
When to solely Using A1C to assess glycemic control

• A1C does not provide a measure of glycemic variability or hypoglycemia

• For patients prone to glycemic variability, glycemic control is best evaluated by the combination of results from BGM/CGM and A1C
Glycemic Variability

In target range (70-180 mg/dL)  Above Target range (>180 mg/dL)  Below Target range (<70mg/dL)
**Time in Range Goals: International Consensus**

**Type 1 & Type 2 Diabetes**
- Target: 70-180 mg/dL (3.9-10.0 mmol/L)
- <70 mg/dL (3.9 mmol/L)
- <54 mg/dL (3.0 mmol/L)
- >250 mg/dL (13.9 mmol/L)
- >180 mg/dL (10.0 mmol/L)

**Older/High Risk: Type 1 & Type 2 Diabetes**
- Target: 70-180 mg/dL (3.9-10.0 mmol/L)
- <70 mg/dL (3.9 mmol/L)
- <54 mg/dL (3.0 mmol/L)
- >250 mg/dL (13.9 mmol/L)
- >180 mg/dL (10.0 mmol/L)

**Pregnancy: Type 1 Diabetes†**
- Target: 63-140 mg/dL (3.5-7.8 mmol/L)
- <63 mg/dL (3.5 mmol/L)
- <54 mg/dL (3.0 mmol/L)
- >140 mg/dL (7.8 mmol/L)

**Pregnancy: Gestational & Type 2 Diabetes‡**
- Target: 63-140 mg/dL (3.5-7.8 mmol/L)
- <63 mg/dL (3.5 mmol/L)
- <54 mg/dL (3.0 mmol/L)
- >140 mg/dL (7.8 mmol/L)

†Percentages of time in ranges are based on limited evidence. More research is needed.
‡Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed.
Orientation to continuous glucose monitoring
Basics of Continuous Glucose Monitoring (CGM)

- CGM sensor measures glucose in interstitial fluid every 1-15 minutes
- Glucose data is transmitted automatically in a continuous stream to the receiver, reader or smartphone
- The user can scan the receiver to obtain glucose data
- The data is presented as glucose value, trend arrows or trend graph
CGM measurement compartment

The diffusion of glucose from the intravascular to the subcutaneous interstitial fluid compartment leads to a physiologic delay.

Processing of the gained data results in a technological delay.

Time lag between the measurement and display of the result.
Time Lag

When glucose level is stable, the sensor readings and blood glucose readings are similar.

When glucose level is trending up, the sensor readings may be lower than blood glucose readings.

When glucose level is trending down, the sensor readings may be higher than blood glucose readings.

Time Lag: During rapid states of change, SG and BG may differ more than 20%
Continuous Glucose Monitoring Systems

Professional CGM
• Newly diagnosed with diabetes mellitus
• Not using CGM
• May have problematic hypoglycemia, but no access to personal CGM
• Persons with T2D treated with non-insulin therapies as an educational tool
• Persons who would like to learn more about CGM before committing to daily use

FreeStyle Libre Pro

Dexcom G6 Pro
Continuous Glucose Monitoring Systems

**Real-time CGM**
- Measure and store glucose levels continuously and without prompting
- Recommended over intermittently scanned CGM for diabetics with problematic hypoglycemia; predicts alarms

**Intermittently scanned CGM**
- Measure glucose levels continuously but require scanning for storage of glucose values
- Newer versions have real time-optional alarms
- Recommended for patients newly diagnosed with T2D treated with non-hypoglycemic therapies
Current Options for Personal CGM Systems

- Dexcom G6
- Guardian Connect Guardian Sensor 3
- FreeStyle Libre Flash
- Eversense
- Libre 2
Comparison of current CGM systems available

<table>
<thead>
<tr>
<th>CGM group</th>
<th>Dexcom G6®</th>
<th>Eversense®</th>
<th>Freestyle® Libre</th>
<th>Freestyle® Libre 2</th>
<th>Freestyle® Libre 3</th>
<th>Medtronic Guardian 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor life</td>
<td>10 days</td>
<td>180 days</td>
<td>14 days</td>
<td>14 days</td>
<td>14 days</td>
<td>7 days</td>
</tr>
<tr>
<td>Sensor application</td>
<td>Abdomen</td>
<td>Upper arm (implanted)</td>
<td>Back of upper arm</td>
<td>Back of upper arm</td>
<td>Back of upper arm</td>
<td>Abdomen</td>
</tr>
<tr>
<td>Calibration</td>
<td>Factory-calibrated</td>
<td>Yes – 24 hours after insertion 4 calibrations 2-12 hours apart, then twice daily 10-14 hours apart</td>
<td>Factory-calibrated</td>
<td>Factory-calibrated</td>
<td>Factory-calibrated</td>
<td>Yes – minimum of twice daily</td>
</tr>
<tr>
<td>Integrations with Pump</td>
<td>Yes – Tandem t:slim X2 and OmniPod5</td>
<td>No</td>
<td>No, but is compatible with Bigfoot smart pen cap</td>
<td>No</td>
<td>No</td>
<td>Guardian 3: Medtronic 670G/770G Guardian Connect standalone CGM</td>
</tr>
<tr>
<td>Separate Receiver Available</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Not available</td>
<td>No</td>
</tr>
<tr>
<td>Radiograph/MRI Compatible</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>MARD (%)</td>
<td>Mean absolute relative difference</td>
<td>9</td>
<td>8</td>
<td>9.4</td>
<td>9.3</td>
<td>7.9</td>
</tr>
</tbody>
</table>
## Comparison of current CGM systems available

<table>
<thead>
<tr>
<th></th>
<th>Dexcom G6&lt;sup&gt;*&lt;/sup&gt;</th>
<th>Eversense&lt;sup&gt;<em>&lt;/sup&gt; Eversense&lt;sup&gt;</em>&lt;/sup&gt; XL</th>
<th>Freestyle&lt;sup&gt;*&lt;/sup&gt; Libre</th>
<th>Freestyle&lt;sup&gt;*&lt;/sup&gt; Libre 2</th>
<th>Freestyle&lt;sup&gt;*&lt;/sup&gt; Libre 3</th>
<th>Medtronic Guardian 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warm-up time (hours)</td>
<td>2</td>
<td>24</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Audible Alarms/Alerts</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Hypoglycemia predictive alerts</td>
<td>Predictive alerts (vibrates)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trend Arrows</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Share features</td>
<td>Up to 10 people with Dexcom Follow app (Apple, Google)</td>
<td>Up to 5 people with Eversense Now app</td>
<td>Up to 20 people with LibreLinkup app (Apple, Google)</td>
<td>Up to 20 people with LibreLinkup app (Apple, Google)</td>
<td>Up to 20 people with LibreLinkup app (Apple, Google)</td>
<td>Up to 4 people with CareLinkTM Connect web app (Apple, Google)</td>
</tr>
<tr>
<td>Software Compatibility</td>
<td>Dexcom CLARITY Glooko Tidepool</td>
<td>Glooko</td>
<td>LibreView Tidepool (reader only)</td>
<td>LibreView Tidepool (reader only)</td>
<td>LibreView Tidepool (reader only)</td>
<td>Medtronic CareLink</td>
</tr>
<tr>
<td>Interferences</td>
<td>Hydroxyurea – may falsely elevate sensor readings)</td>
<td>Tetracyclines – may falsely lower sensor readings</td>
<td>Vitamin C – may falsely elevate sensor readings</td>
<td>Vitamin C &gt;500mg/day – may falsely elevate sensor readings</td>
<td>Vitamin C &gt;500mg/day – may falsely elevate sensor readings</td>
<td>Tylenol – may falsely elevate sensor readings)</td>
</tr>
</tbody>
</table>

CGM as standard of care: Indications for CGM therapy

American Diabetes Association 2022 (a)
- T1D/T2D on intensive insulin therapy or continuous subcutaneous insulin infusion
- Diabetes management in adults with diabetes on basal insulin

American Association of Clinical Endocrinologist 2021 (b)
- All persons with diabetes treated with intensive insulin therapy
- All individuals with problematic hypoglycemia
- Children/adolescents with T1D
- Pregnant women with T1D and T2D treated with intensive insulin therapy

Endocrine society 2016 (c)
- T1D patients who have A1C levels above target or are well controlled and willing to use these devices
- Intermittent RT-CGM use in adult patients with T2D (not on prandial insulin) who have A1C levels >7%

(a) American Diabetes Association Professional Practice Committee; 7. Diabetes Technology: Standards Of Medical Care In Diabetes — 2022. Diabetes Care 1 January 2022; 45 (Supplement_1): S97–S112
(c) Anne L. Peters Et Al, Diabetes Technology — continuous Subcutaneous Insulin Infusion Therapy And Continuous Glucose Monitoring In Adults: An Endocrine Society Clinical Practice Guideline, The Journal Of Clinical Endocrinology & Metabolism, Volume 101, Issue 11, 1 November 2016, Pages 3922–3937
## Evidence of rtCGM Efficacy
Large Randomized Trials Comparing CGM use with SMBG in patients with T1D or T2D on MDI

<table>
<thead>
<tr>
<th>STUDY</th>
<th>Reduced HbA1C</th>
<th>Reduced hypoglycemia</th>
<th>Reduced Glycemic variability</th>
<th>Improved quality of Life</th>
<th>Improved treatment satisfaction</th>
<th>Reduced Distress due to hypoglycemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOLD/GOLD-3 Studies(^1,2)</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
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<tr>
<td>Poorly controlled Type 1 DM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMPACT(^3)</td>
<td>--</td>
<td>✔️</td>
<td>✔️</td>
<td>--</td>
<td>✔️</td>
<td>†</td>
</tr>
<tr>
<td>Well controlled T1D</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>REPLACE(^4)</td>
<td>--</td>
<td>✔️</td>
<td>✔️</td>
<td>--</td>
<td>✔️</td>
<td>†</td>
</tr>
<tr>
<td>Poorly controlled T2D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIAMOND Studies(^5,7)</td>
<td>✔️</td>
<td>✔️(T1D)</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
<td>†</td>
</tr>
<tr>
<td>Poorly controlled T1D/T2D</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HypoDE(^8)</td>
<td>--</td>
<td>✔️</td>
<td>✔️</td>
<td>†</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Poorly controlled T1D with problematic hypoglycemia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WISDM Study(^9)</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>†</td>
<td>†</td>
<td>†</td>
</tr>
<tr>
<td>Older adults with T1D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobile Study(^10)</td>
<td>✔️</td>
<td>†</td>
<td>†</td>
<td>†</td>
<td>†</td>
<td>†</td>
</tr>
<tr>
<td>Adults with poorly controlled T2D managed in Primary care</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

† Not reported/Not an outcome.

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Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial

Thomas Martens, MD; Roy W. Beck, MD, PhD; Ryan Bailey, MS; Katrina J. Ruedy, MSPH; Peter Calhoun, PhD; Anne L. Peters, MD; Rodica Pop-Busui, MD, PhD; Athena Philis-Tsimikas, MD; Shichun Bao, MD, PhD; Guillermo Umpierrez, MD; Georgia Davis, MD; Davida Kruger, MSN, APN-BC; Anuj Bhargava, MD; Laura Young, MD, PhD; Janet B. McGill, MD; Grazia Aleppo, MD; Quang T. Nguyen, DO; Ian Orozco, MD; William Biggs, MD; K. Jean Lucas, MD; William H. Polonsky, PhD; John B. Buse, MD, PhD; David Price, MD; Richard M. Bergenstal, MD; for the MOBILE Study Group

QUESTION For adults with poorly controlled type 2 diabetes treated with basal insulin without prandial insulin in primary care practices, does continuous glucose monitoring (CGM) improve hemoglobin A1c (HbA1c) levels compared with blood glucose meter (BGM) monitoring?

CONCLUSION This randomized clinical trial found there was a significantly greater decrease in HbA1c level over 8 months with CGM than with BGM monitoring.

POPULATION
- 88 Women
- 87 Men

Adults with type 2 diabetes treated with basal insulin without prandial insulin
Mean age: 57 years

LOCATIONS
- 15 Primary care practices in the US

INTERVENTION
- 175 Patients randomized

116 Continuous glucose monitoring
CGM with BGM testing performed as needed

59 Blood glucose meter monitoring
BGM testing performed when fasting and postprandial 1 to 3 times daily

FINDINGS

<table>
<thead>
<tr>
<th>FINDINGS</th>
<th>Continuous glucose monitoring</th>
<th>Blood glucose meter monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean HbA1c level at 8 months</td>
<td>HbA1c Baseline 9.1%</td>
<td>HbA1c Baseline 9.0%</td>
</tr>
<tr>
<td></td>
<td>8 Months 8.0%</td>
<td>8 Months 8.4%</td>
</tr>
</tbody>
</table>

Risk-adjusted difference was significant, -0.4% (95% CI, -0.8% to -0.1%)

The Effect of Discontinuing Continuous Glucose Monitoring in Adults With Type 2 Diabetes Treated With Basal Insulin

Aleppo G, et al. MOBILE Study Group; The Effect of Discontinuing Continuous Glucose Monitoring in Adults With Type 2 Diabetes Treated With Basal Insulin. Diabetes Care 1 December 2021; 44 (12): 2729–2737. https://doi.org/10.2337/dc21-1304
Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials

Retinopathy

For each 10% less TIR retinopathy progression increased by 64% % (95% CI 51–78) and the microalbuminuria outcome d by 40% (95% CI 25–56)
Figure 2. Prevalence of complications versus percentage of time spent in optimal range

![Graph showing prevalence of diabetes complications versus percentage Time in Range](graph.png)
Patient population: 364 individuals > 18 years with diabetic peripheral neuropathy
Department of Endocrinology and Metabolism, Zhengzhou, China from July 2018 to May 2019
51.92% (189/364) of the participants were diagnosed with painful diabetic neuropathy
TIR is correlated with painful neuropathy independent of A1C glucose variability metrics and risk factors in patients with DM
Time in Range in Relation to All-Cause and Cardiovascular Mortality in Patients With Type 2 Diabetes: A Prospective Cohort Study

Figure 1—Multivariate-adjusted cumulative survival curves of all-cause (A) and cardiovascular (B) mortality by different levels of TIR. Adjusted for age, sex, BMI, diabetes duration, systolic blood pressure, triglyceride, HDL cholesterol, LDL cholesterol, smoking status, history of cancer and CVD, and use of antihypertensive drugs, aspirin, and statins.
Figure Legend:

Patients who spend more TIR are more likely to experience a lower rate of first major adverse cardiac events (MACE)
Age: 65
Sex: female

A1c 8.2%
Regimen: liraglutide 1.8 mg daily metformin 1000 mg twice a day glargine 25 units daily
Dexcom | captůr AGP®

Glucose Statistics

<table>
<thead>
<tr>
<th>Glucose Range</th>
<th>Very Low</th>
<th>Low</th>
<th>In Target Range</th>
<th>High</th>
<th>Very High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg Glucose</td>
<td>186</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mg/dL</td>
<td>0.0%</td>
<td>0.1%</td>
<td>54.7%</td>
<td>45.2%</td>
<td>16.4%</td>
</tr>
</tbody>
</table>

Coefficient of Variation: 33.5%
SD: 62 mg/dL

% Time CGM Active: 96.8%
Data Sufficiency:

Glycemia Glucose Profile

Curves/paint represent glucose frequency distribution by time regardless of date.
Interpretation of CGM Reports
Standardized CGM Metrics for Clinical care
Data sufficiency

- Ideally 14 days of data
- >70% of data from 14 days
- Glucose management indicator CGM-derived estimate of current A1C level
- Measure of glycemic variability (SD/mean) ≤36% considered acceptable
How does GMI Compare With The A1C?

- Glucose Management Indicator (GMI) approximates a patient’s A1c using at least 14 days of data
  - Mathematical algorithm based on between 2800 and 20,160 interstitial glucose values obtained during sensor wear of 10-14 days

- A1c is based on glycation to red blood cells assuming the RBC lifespan is 3 months

- 50% of the total A1C is based upon glycation which occurs within 4 weeks prior to testing.

Limitations to HgbA1c:

- Checked quarterly

- Inaccurate/inconclusive in certain patient populations (ESRD, anemia, hemoglobinopathy, pregnancy, liver disease).

- Over glycation can occur with anemia. Underglycation can occur with rapid RBC turnover such as in patients undergoing dialysis.
TIME IN RANGES METRICS

Two metrics should be used as starting point for assessing glycemis control: %TIR and %TBR

AGP Report
August 21, 2021 - September 3, 2021 (14 Days)

GLUCOSE STATISTICS AND TARGETS

August 21, 2021 - September 3, 2021

% Time CGM is Active
100%

Ranges And Targets For
Type 1 or Type 2 Diabetes

Glucose Ranges
Target Range 70-180 mg/dL
Below 70 mg/dL
Less than 4% (58min)
Below 54 mg/dL
Less than 1% (14min)
Above 180 mg/dL
Less than 25% (1hr 6min)
Above 250 mg/dL
Less than 5% (1hr 12min)

Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

Average Glucose
118 mg/dL

Glucose Management Indicator (GMI)
6.1%

Glucose Variability
31.9%

Time in Ranges

Very High
>250 mg/dL
0% (0min)

High
181 - 250 mg/dL
4% (56min)

Target Range
70 - 180 mg/dL
92% (22h 4min)

Low
54 - 69 mg/dL
4% (68min)

Very Low
<54 mg/dL
0% (0min)

LibreView

TAR LEVEL 2
TAR LEVEL 1
TIME IN RANGE
TBR LEVEL 1
TBR LEVEL 2
**GLUCOSE STATISTICS AND TARGETS**

March 18, 2022 - March 31, 2022 (14 Days)

% Time CGM is Active: 60%

### Time in Ranges

- **Very High**: >250 mg/dL, 0% (0hrs)
- **High**: 181 - 250 mg/dL, 3% (42hrs)
- **Target Range**: 70 - 180 mg/dL, 97% (237 hrs)
- **Low**: 54 - 70 mg/dL, 0% (0hrs)
- **Very Low**: <54 mg/dL, 0% (0hrs)

### Average Glucose: 122 mg/dL

Glucose Management Indicator (GMI): 6.2%

Glucose Variability: 22.3%

Defined as percent coefficient of variation (%CV); target 30%.

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**AMBULATORY GLUCOSE PROFILE (AGP)**

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.

![AGP Graph](image)

**Daily Glucose Profiles**

Each daily profile represents a minimum to maximum period with the data displayed in the upper left corner.
## GLUCOSE STATISTICS AND TARGETS

**February 27, 2022 - March 12, 2022**

<table>
<thead>
<tr>
<th>% Time CGM is Active</th>
<th>100%</th>
</tr>
</thead>
</table>

### Time in Ranges

- **Very High**: >250 mg/dL, 0% (0min)
- **High**: 181 - 250 mg/dL, 1% (14min)
- **Target Range**: 70 - 180 mg/dL, 87% (20h 54min)
- **Low**: 54 - 89 mg/dL, 11% (2h 38min)
- **Very Low**: <54 mg/dL, 1% (14min)

### AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.

![AGP Chart](chart.png)
## Hypoglycemia
- Missing meals
- Stop or decrease Medications
- Consider use of meds which do not increase likelihood of hypoglycemia
- Reduce basal or pre-meal insulin dose
- Modify exercise timing related to insulin dosing
- Reduce or stop alcohol consumption
- Mismatch of prandial insulin dose and carbohydrate meal/intake

## Time in Range < 70 %
- Discuss med adherence
- Add agents
- Discuss carb counting (identification) or meal size as related to prescribed insulin dosing
CGM Qualifying Criteria

CGM: type 1 diabetes or type 2 diabetes on intensive insulin therapy

Diagnosis codes are important

<table>
<thead>
<tr>
<th>Commercial Plans</th>
<th>Medicare¹</th>
<th>Medicaid²</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Plan specific, more flexibility</td>
<td>▪ 3+ injections per day or established on insulin pump for ≥6 mo</td>
<td>▪ Similar to Medicare with a few plan-specific exceptions</td>
</tr>
<tr>
<td>▪ Coverage often through pharmacy vs DME companies</td>
<td>▪ Requires frequent adjustments of insulin based on BG/CGM data</td>
<td>▪ Some plans require either documented hypoglycemia unawareness or evidence of multiple severe low BGs (&lt;50 mg/dL)</td>
</tr>
<tr>
<td></td>
<td>▪ 6-mo provider visits for continued coverage</td>
<td>▪ 30-day log showing &gt;4 finger sticks per day required for most plans</td>
</tr>
</tbody>
</table>


[2] diatribe.org/medicaid-cgm
## CPT Codes for Professional Reimbursement

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>95249</td>
<td>Patient-owned (non-professional) CGM sensor placement, hook-up, calibration, patient training, removal of sensor, and printout of recording</td>
</tr>
<tr>
<td></td>
<td>- Requires minimum of 72 hours of data collection</td>
</tr>
<tr>
<td></td>
<td>- Can only be billed once for the duration the patient owns the device</td>
</tr>
<tr>
<td>95250</td>
<td><strong>Professional</strong> CGM sensor placement, hook-up, calibration, patient training, removal of sensor, and printout of recording</td>
</tr>
<tr>
<td></td>
<td>- Requires minimum of 72 hours of data collection</td>
</tr>
<tr>
<td></td>
<td>- Can be billed once per month</td>
</tr>
<tr>
<td>95251</td>
<td>CGM download and interpretation</td>
</tr>
<tr>
<td></td>
<td>- Patient does not have to be physically in the office</td>
</tr>
<tr>
<td></td>
<td>- Can be billed once a month</td>
</tr>
<tr>
<td></td>
<td>- Requires minimum of 72 hours of data for review</td>
</tr>
<tr>
<td>99091</td>
<td>Download and interpretation of insulin pump data</td>
</tr>
<tr>
<td></td>
<td>- Can be billed once a month</td>
</tr>
<tr>
<td></td>
<td>- CPT codes 95249, 95250, and 95251 cannot be billed in addition to this code</td>
</tr>
</tbody>
</table>

https://www.cms.gov/medicare/physician-fee-schedule/search
Diabetes Technology in the Inpatient Setting
Diabetes Technology in the Inpatient Setting

• Remote inpatient diabetes management is rapidly evolving
• Recent studies have showed accuracy and improved clinical outcomes
• Use of CGM devices have demonstrated increased detection of hyper- and hypoglycemia, and reduced hypoglycemia
• Currently, CGM devices are not approved by the FDA for use in the hospital

Diabetes Technology in the Inpatient Setting

• The continuation of CGM and/or CSII should be considered in hospitalized persons with diabetes (AACE guideline/Grade A; Intermediate Strength of Evidence; BEL 1)

• Noncritically ill hospitalized patients who are at high risk of hypoglycemia, the use of real-time CGM with confirmatory bedside POC blood glucose is suggested (Endocrine Society Clinical Practice Guideline 2022/(2⊕⊕OO))

• Noncritically ill hospitalized patients using insulin pump can continue it rather than changing to SQ basal bolus insulin therapy in hospitals with access to personnel with expertise in insulin pump therapy (Endocrine Society Clinical Practice Guideline 2022/(2⊕⊕OO))
Timeline of CGM in the Inpatient setting

Pre-COVID-19

- 2018: Observational, pilot studies, small RCTs started

COVID-19

- April 2020: No Objection by FDA to use CGM in the hospital
- March 1, 2022: Breakthrough Designation Dexcom Hospital CGM system

Post-COVID-19

- 2021: Real world experience
  - Initial RCT data
- 2022: Jan-2022 ADA SOC insufficient data to support
<table>
<thead>
<tr>
<th>Reference</th>
<th>Population</th>
<th>Study design</th>
<th>CGM used</th>
<th>Study aim</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Singh et al.</td>
<td>T2DM (n = 72) Non-ICU Medicine</td>
<td>RCT Single center</td>
<td>Dexcom G6</td>
<td>RT-CGM/GTS for the prevention of hypoglycemia</td>
<td>RT-CGM/GTS had fewer hypoglycemic events (&lt;70 mg/dL) per patient vs. POC group (0.67 vs. 1.69, P = 0.024).</td>
</tr>
<tr>
<td>Fortmann et al.</td>
<td>T2DM (n = 110) Non-ICU Medicine</td>
<td>RCT Single center</td>
<td>Dexcom G6</td>
<td>RT-CGM for management of acute hyper- and hypoglycemia</td>
<td>RT-CGM reduced percentage of time spent in hyperglycemia &gt; 250 mg/dL vs. UC (27% vs. 33%, P = 0.04)</td>
</tr>
<tr>
<td>Davis et al.</td>
<td>T2DM (n = 209) DM (n = 9) Non-ICU Medicine/Surgery</td>
<td>Pooled analysis of clinical studies Multicenter</td>
<td>Dexcom G6</td>
<td>Accuracy study between CGM and POC</td>
<td>CGM had an overall MARD of 12.8% and median ARD of 10.1%.</td>
</tr>
<tr>
<td>Galindo et al.</td>
<td>T2DM (n = 97) Non-ICU Medicine</td>
<td>Prospective study Multicenter</td>
<td>Abbott FreeStyle Libre Pro</td>
<td>Feasibility and accuracy study between CGM and POC</td>
<td>CGM had an overall MARD of 14.8%.</td>
</tr>
<tr>
<td>Nair et al.</td>
<td>T2DM (n = 10) Non-ICU Surgery</td>
<td>Prospective study Single center</td>
<td>Dexcom G6</td>
<td>Peri-operative accuracy study between CGM and POC</td>
<td>CGM had an overall MARD of 9.4%.</td>
</tr>
<tr>
<td>Tripyla et al.</td>
<td>T2DM (n = 8) T1DM (n = 2) Pancreatic diabetes (n = 5) Prediabetes (n = 5) Non-ICU Surgery</td>
<td>Prospective study Single center</td>
<td>Dexcom G6</td>
<td>Peri-operative accuracy study between CGM and POC</td>
<td>CGM had an overall MARD of 12.7% and median ARD of 9.9%.</td>
</tr>
<tr>
<td>Perez-Guzman et al.</td>
<td>No DM (n = 15) OR and ICU Surgery</td>
<td>Prospective study Single center</td>
<td>Dexcom G6</td>
<td>Peri-operative accuracy study between CGM and POC</td>
<td>CGM had an overall MARD of 12.9% and median ARD of 10.5. - Intermittent signal loss during surgery (electrocautery interference).</td>
</tr>
<tr>
<td>Migdal et al.</td>
<td>T1DM/T2DM (n = 49) Non-ICU Medicine</td>
<td>Pooled analysis of clinical studies Multicenter</td>
<td>Dexcom G6</td>
<td>Accuracy of CGM during radiologic procedures</td>
<td>For diagnostic studies using radiation (X-rays, CT scan, Angiography), CGM had an overall MARD of 13.3% preimaging and 12.7% postimaging.</td>
</tr>
<tr>
<td>Dillmann et al.</td>
<td>T1DM (n = 28) T2DM (n = 25) Non-ICU Medicine</td>
<td>Prospective study Single center</td>
<td>Medtronic Guardian Connect (Enlite)</td>
<td>Feasibility study of glucose telemetry using Guardian Connect</td>
<td>Mean POC of the 167 paired measurements was higher than the mean CGM in those with T2DM and those hospitalized for acute complications, TIR significantly increased between the start of the hospitalization and end of hospitalization, from 75.7% (95% CI 48.5–84.6) to 82.2% (95% CI 63.2–91.8) (P = 0.043), and from 58.3% (95% CI 46.3–69.7) to 66.4% (95% CI 55.6–75.5) (P = 0.031), respectively. - 95% of nurses found GC to be useful while 64% reported that it saved time</td>
</tr>
<tr>
<td>Richard et al.</td>
<td>T1DM (n = 8) T2DM (n = 2) Non-ICU Medicine</td>
<td>Prospective study Single center</td>
<td>Abbot FreeStyle Libre Pro</td>
<td>Feasibility study between CGM and POC in the setting of DKA</td>
<td>Mean POC of the 167 paired measurements was higher than the mean CGM in those with T2DM and those hospitalized for acute complications, TIR significantly increased between the start of the hospitalization and end of hospitalization, from 75.7% (95% CI 48.5–84.6) to 82.2% (95% CI 63.2–91.8) (P = 0.043), and from 58.3% (95% CI 46.3–69.7) to 66.4% (95% CI 55.6–75.5) (P = 0.031), respectively. - 95% of nurses found GC to be useful while 64% reported that it saved time</td>
</tr>
<tr>
<td>Furushima et al.</td>
<td>DM/UnDM (n = 40) ICU Medicine</td>
<td>Prospective study Single center</td>
<td>Abbot FreeStyle Libre Pro</td>
<td>To determine the MAGE using CGM data in septic patients and to assess associations of MAGE with clinical outcomes and oxidative stress</td>
<td>Nonsurvivors had a higher median value of MAGE [68.8 (IQR: 39.7–97.2) mg/dL] compared to survivors [39.3 (IQR: 19.9–53.5) mg/dL], (P = 0.02).</td>
</tr>
<tr>
<td>Abdelhamid et al.</td>
<td>T2DM (n = 31) Non-ICU Medicine</td>
<td>Prospective study Multicenter</td>
<td>Dexcom G4</td>
<td>Detection of hypoglycemia in ICU survivors after ICU discharge</td>
<td>Hypoglycemia in the ICU survivors were predominantly nocturnal (40/51 hr, 78%), asymptomatic (25/29 episodes, 86%), with 5.24% ± 5.50% of total monitoring time spent in hypoglycemia.</td>
</tr>
</tbody>
</table>
Inpatient CGM Studies in non-COVID-19 patients

- Non critical care setting
- Glycemic outcomes with use of real-time-CGM -- 2 single-center RCTs
- Accuracy of Dexcom G6 MARD ranged between 9.4–12.9%
- Use of GTS: Real time-CGM/GTS group had fewer hypoglycemic events
- Accuracy of Freestyle Libre Pro: MARD of 14.8%.
- Despite reduced accuracy compared with the outpatient setting, CGMs have had acceptable safety profiles in the inpatient setting
### Inpatient CGM Studies in COVID-19 patients

<table>
<thead>
<tr>
<th>Reference</th>
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<th>Study Design</th>
<th>CGM Used</th>
<th>Study Aim</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faulds et al.</td>
<td>T1DM (n=2) T2DM (n=16) No DM (n=1) ICU Medicine</td>
<td>Retrospective analysis Single center</td>
<td>Dexcom G6</td>
<td>Feasibility of RT-CGM for insulin infusion titration</td>
<td>CGM had an overall MARD of 13.9 ± 7.8% (median 11.9, IQR 3.3–29.4) on day 1 and 13.5 ± 8.1% (median 10.6, IQR 9.0–15.0) on days 2 through 7. - Use of CGM resulted in 71% reduction in POC use - Negative association found between BMI and MARD (coefficient = -0.291, P = 0.007).</td>
</tr>
<tr>
<td>Chow et al.</td>
<td>DM (n=30) ICU Medicine</td>
<td>Retrospective study Single center</td>
<td>Dexcom G6</td>
<td>Feasibility and accuracy study of RT-CGM and POC</td>
<td>14% reduction in mean glucose during RT-CGM management vs. pre RT-CGM management (235.7 ± 42.1 to 202.7 ± 37.6 mg/dl, P = 0.003). - Use of CGM resulted in 50% reduction in POC use - 63% of nurses reported RT-CGM helped improved clinical care while 49% reported concomitant reduction in PPE use.</td>
</tr>
<tr>
<td>Agarwal et al.</td>
<td>T1DM (n=3) T2DM (n=6) No DM (n=2) ICU Medicine</td>
<td>Prospective study Single center</td>
<td>Dexcom G6</td>
<td>Feasibility and accuracy study between CGM and POC</td>
<td>- CGM had an overall MARD of 12.58% and median ARD of 6.3% - Use of CGM resulted in an estimated 60% reduction in POC use</td>
</tr>
<tr>
<td>Reutrakul et al.</td>
<td>DM (n=9) Non-ICU Medicine</td>
<td>Prospective study Single center</td>
<td>Dexcom G6</td>
<td>Feasibility and accuracy study between CGM and POC</td>
<td>CGM had an overall MARD of 9.77%</td>
</tr>
<tr>
<td>Sadhu et al.</td>
<td>T1DM (n=1) T2DM (n=8) Prediabetes (n=1) Posttransplant DM (n=1) ICU Medicine</td>
<td>Retrospective study Single center</td>
<td>Medtronic Guardian Connect</td>
<td>Feasibility and accuracy study between CGM and POC</td>
<td>Overall MARD was 13.1% for Medtronic and 11.1% for Dexcom (P = 0.13) - Sensor insertion for both systems were easily done however the Medtronic sensor required more steps as calibration was required when compared to Dexcom. Both systems were noted have a tedious initial setup (i.e., creation of individual accounts on manufacturer’s cloud-based platforms)</td>
</tr>
<tr>
<td>Davis GM et al.</td>
<td>T2DM (n=9) ICU Medicine</td>
<td>Prospective study Single center</td>
<td>Dexcom G6</td>
<td>Proof of concept study utilizing hybrid CGM/POC protocol and Glucommander</td>
<td>During protocol use, 75.7% of sensor glucose values &gt; 100mg/dL were within 20% of the reference POC, with a mean number of POC tests per day of 8.2 ± 3.06 (63% reduction in POC use) - Sensor readings were lower during hypoperfusion states (PEA, shock) and with signal loss during cardiac arrest and defibrillator use. - Sensor accuracy was also impacted during therapeutic hypothermia and position changes including pronation or inadvertent sensor compression.</td>
</tr>
</tbody>
</table>
Most studies were observational studies or case reports with a small number of subjects. To date, there are no published RCTs examining CGM devices in COVID-19 patients.
Figure 2: Remote glucose management during the COVID-19 pandemic
Challenges of CGM use in the hospital

- Substance interference (Acetaminophen, ascorbic acid, dopamine, mannitol, heparin and ASA) with some CGM devices
- Limited evidence on the accuracy during periods of arterial hypotension, hypothermia or hypoxia
- Measurement Lag
- Information overload with risk of overtreatment
- Real time data transmission to nursing staff and EMR. Documentation of the sensor placement location and inspection of the site
- Need of imaging studies
- Most medical centers still require finger stick values for dosing insulin as a safety precaution
- Cost
Insulin delivery devices
Subcutaneous basal and bolus injection
Smart Pens

• Ability to program factors to allow for determination of insulin doses
  ◦ Correction doses are possible using a correction factor/insulin sensitivity factor and a target
  ◦ Meal announcements: insulin-to-carbs ratio with discrete carb counting or a more simplified approach using the size of the meals (small, medium, large)

• Prevent stacking of insulin that could increase the risk of hypoglycemia

• Integration with BGM or sensor glucose data

• Dose reminders, temperature tracking, and units remaining are also features that some smart pens afford
Medtronic InPen: Insulin dose calculator + Integrated system + App

THE INPEN™ SMART INSULIN PEN

- Compatible with Novolog®, Humalog®, and Flasp® cartridges (not included)
- Connects to the app via Bluetooth®
- Monitors insulin temperature
- Battery lasts a full year with no need to change
- Delivers half-unit doses

THE INPEN™ APP

- Calculates personalized doses
- Tracks active insulin
- Glucose History
- Syncs with CGMs and blood glucose meters
- Reminds you to dose
- Automatically logs doses given by InPen™
- Creates shareable reports of 7, 14, 30 or 90 days of data

Bigfoot unity diabetes

Packaged with Freestyle Libre and meter. All connected, works as a pen cap, all insulins even concentrated
**AACE Guideline: Recommendations for Insulin Delivery Technologies**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Recommendation</th>
<th>Grade/Strength of Evidence/Best Evidence Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who would benefit from the use of connected pens?</td>
<td>All persons with diabetes treated with intensive insulin management, with ≥3 injections/day and who are not on insulin pump therapy, in whom an assessment of insulin dosing may help the person with diabetes and the clinician optimize the insulin regimen and avoid stacking rapid-acting insulin doses that could lead to hypoglycemia.</td>
<td>C/Intermediate/2</td>
</tr>
<tr>
<td>Who would benefit from the use of an insulin pump without CGM?</td>
<td>Persons with diabetes who are achieving glycemic targets with minimal TBR, who report infrequent episodes of symptomatic hypoglycemia, and who are using SMBG on a regular basis (≥4 times/day for T1D).</td>
<td>B/Intermediate-High/1</td>
</tr>
<tr>
<td>Who would benefit from the use of an insulin pump with CGM?</td>
<td>All persons with diabetes treated with intensive insulin management who prefer not to use automated insulin suspension/dosing systems or have no access to them.</td>
<td>A/High/1</td>
</tr>
<tr>
<td>Who would benefit from the use of more advanced insulin pump technologies: low-glucose suspend (LGS), predictive LGS, and HCL?</td>
<td>LGS strongly recommended for all persons with T1D to reduce severity and duration of hypoglycemia; predictive LGS strongly recommended for all persons with T1D to mitigate hypoglycemia.</td>
<td>A/High/1</td>
</tr>
<tr>
<td></td>
<td>Automated insulin dosing systems strongly recommended for all persons with T1D, since their use has been shown to increase TIR, especially in the overnight period, without causing an increased risk of hypoglycemia. Preferred above other modalities.</td>
<td>A/High/1</td>
</tr>
</tbody>
</table>

Benefits of Pump Therapy

• Changing the infusion set every 3 days
• Finer tuned adjustments of basal insulin delivery
• Smaller increments for basal and bolus insulin dosing
• Preprogrammed bolus calculators
• Insulin on board calculators help prevent stacking of insulin that could increase the risk of hypoglycemia
• Uploading and review of data to help with dose optimization
• Use temporary basal rates physical activity or times of increased insulin needs (illness)
• Provides the foundation for automated insulin delivery
What is the artificial pancreas?
Key developmental milestones towards a truly artificial pancreas

1. Low-glucose suspend
   Cessation of insulin delivery once sensor glucose crosses low threshold

2. Predictive low-glucose suspend
   Cessation of insulin delivery once sensor glucose predicted to cross low threshold

3. Hybrid closed-loop
   Algorithm-driven glucose-responsive insulin delivery with mealtime, user-initiated bolusing

4. Fully automated closed-loop
   Algorithm-driven glucose-responsive insulin delivery without user-initiated mealtime bolus

5. Fully automated multi-hormone closed-loop
   Algorithm-driven glucose-responsive insulin delivery without user-initiated mealtime bolus

Boughton and Hovorka (2021) Diabetologia DOI 10.1007/s00125-021-05391-w
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Degrees of Automation

Hybrid closed-loop
Sensor glucose data fed to an algorithm, adjusts insulin delivery via the pump, requires mealtime bolus input by person with diabetes.

Predictive Low Glucose Suspend
Basal insulin is interrupted once glucose is predicted to crosses low threshold.

Additional insulin delivered

Low Glucose Suspend
Basal insulin is interrupted once glucose crosses low threshold.
What pump to choose?
**MiniMed 670 G system with SmartGuard™ technology**

**Hybrid closed-loop**

Initiation: Insulin must be delivered in manual mode for at least 48 hours (preferably 5-7 days)

**Auto basal (targets 120 mg/dL)**

- Algorithm determines insulin delivery every 5 minutes accounting for current SG value, rate of change, IOB/insulin feedback, other parameters

- Temporary target (150 mg/dL)

**Food bolus**

- Programmed carbohydrate ratio and number of grams

- Determine meal bolus amount

**Correction bolus (target is 150 mg/dL)**

- Sensitivity factor is determined by the algorithm
Limitations to 670 G

- Too many alerts
- Requires a minimum of 3-4 BG checks per day to calibrate the CGM
- Requires carb announcements for all meals
- Many guardrails for safety (min basal, max basal, etc.)
- Target at 120 mg/dL with temporary target of 150

MiniMed 770G System

- Bluetooth-enabled version of MiniMed 670G
Exit Reason Details:

1.4 - High SG Auto Mode Exit
Sensor glucose was high over 1 hour.

2.3 - No Calibration
Sensor was not calibrated (e.g. Calibration not accepted, BG not received, No Calibration occurred, etc.).

5 - BG required for Auto Mode
BG was required to continue in Auto Mode.

6 - Sensor Expired
New sensor needed to be inserted.
**LAUNCHING**

- **MiniMed™ 670G Hybrid Closed-Loop System**
  - Over 135K U.S. patients currently trained on the 670G
  - Ongoing international rollout

- **Guardian™ Connect CGM**
  - Only CGM with IQcast, predicting potential lows, up to 4 hours in advance
  - Strong interest outside traditional sales channels in U.S.

**FY20**

- **Advanced Hybrid Closed-Loop System with Bluetooth (MiniMed™ 780G)**
  - Bluetooth connectivity allowing sharing and software upgrades
  - Auto correction boluses for simplified meal management and hyperglycemia protection
  - Data from 3 feasibility studies indicating time-in-range (TIR) of approximately 90%

- **Non-Adjuvative iCGM Designation**
  - Non-adjunctive sensor to allow dosing and CMS reimbursement

- **Sugar.IQ™ Gen 2**
  - Meal handling + carb counting with Nutrino
  - Extend predictive insights beyond 60 mins

- **Synergy Sensor**
  - 50% smaller than GS3
  - Day 1 calibrations
  - Easy 3 step application

- **Unity Sensor**
  - No calibrations
  - 10-14 days of wear

**BEYOND**

- **Personalized Closed-Loop System (MiniMed™ 890G)**
  - Real-time personalized therapy
  - Advanced adaptation
  - >85% TIR goal

- **Sugar.IQ™ Gen 3**
  - Behavioral feedback
  - Overnight glucose prediction

- **Sugar.IQ™ Gen 4**
  - Meal prediction w/ dosing
  - Advanced glucose prediction

- **Auto Basal and Auto boluses correction features**
- **Adjustable target glucose of as low as 100 mg/dL**
- **Fewer fingersticks with day 1 calibrations only**
- **Extended wear infusion set**

- **Adapts to physiology**
- **Automated meal handling**
- **100% automode capable with TIR goal >85%**
- **Smartphone control**
What is the Control-IQ technology?

• Control-IQ technology is an advanced hybrid closed loop system
• Automatically adjusts insulin delivery every 5 minutes based on 30-minute predicted CGM values, including delivery of automatic correction boluses as needed

Components

- T:slim X2 insulin pump
- Control-IQ embedded algorithm
- Dexcom G6 CGM / No calibration required
Unique Control-IQ algorithm Features

- Automatic basal rate adjustments designed to help keep users in target range
- Automatic corrections boluses
- Automatic pre-population of Dexcom G6 CGM value in bolus calculator
- No calibrations with CGM/Unexpected prompts
- Sleep activity that sets a narrower range of treatment values, designed to help achieve glucose levels of approximately 110-120 mg/dL by the morning
- Exercise activity sets a narrower and higher range of treatment values
- No complicated criteria to staying in closed loop. **CGM data = Control-IQ technology On**
- FDA approved t:connect mobile app to bolus insulin
Dashboard | Wednesday Feb 02, 2022 - Thursday Mar 03, 2022

**Highest Blood Glucose**: 400

**Average Blood Glucose**: 217

**Lowest Blood Glucose**: 60

**Blood Glucose Summary**
- Above Target: 50% (2 times)
- Target Range: 75 - 120 mg/dL
  - 25% (1 time)
- Below Target: < 70 mg/dL
  - 25% (1 time)

**Highest CGM Reading**: 400

**Average CGM Reading**: 127

**Lowest CGM Reading**: 40

**Time in Range**
- Above Target: 13% (> 180 mg/dL)
- Target Range: 70 - 120 mg/dL
  - 82% (29.7 days)
- Below Target: < 70 mg/dL
  - 5%

**Number of Days CGM in Use**: 29.7 days

**Control-Q Technology**
- Time in Use: 28.12 hrs
- Control-Q Set to Off: 0% (6 minutes)
- CGM Tracker: 1% (8 hours, 48 minutes)
- Hump Hunter: 4% (1 hour, 31 minutes)
- Avg. Sleep & Exercise: 7 hours, 11 minutes
- Daily Sleep: 7 hrs, 11 mins
- Weekly Exercise Events: 6 times

**Average Daily Insulin Summary**
- Basal: 45.34 units / day
- Fixed Basal: 0.13 units / day
- Correction Basal: 18.55 units
- Control-Q Auto Basal: 0.50 units

**Average Total Daily Dose**: 45.34 units / day

**Average CGM Readings**: 284.77 times / day

**Avg. Change Frequency**
- Cartridge: Every 9.60 days
- Tubing: Every 3.66 days
- Site/Cannula: Every 13.60 days

**Avg. Fill Amount**
- Cartridge: 150.00 units
- Tubing: 19.55 units
- Site/Cannula: 0.50 units
Omnipod® 5

- Customizable Glucose control
- Glucose targets from 100-150 mg/dL, adjustable by time of day
- Hypoprotect Feature for times of elevated hypoglycemia
- Algorithm adapts based on user’s insulin delivery history
Dual-hormone closed-loop systems

- Insulin*
- Glucagon
- Pramlintide* (amylin analog)

Notes:
- CAD

Image Description:
- A: Diagram of insulin injection site
- B: Diagram of glucagon injection site
- C: Diagram of pramlintide injection site
• Data lock completed for the RCT period of the Insulin-Only Bionic Pancreas Pivotal Trial

• Enrollment started for screening protocol of the Bihormonal Bionic Pancreas Pivotal Trial
Summary

• In the past decade there has been a high-speed evolution in diabetes technologies to improve the quality of life and life expectancy of diabetics

• Continues glucose monitoring is a standard of care

• CGM is a cost-effective technology which can successfully improve patient’s time in range, reduce hypoglycemia risk and reduce glycemic variability

• CGM should be encouraged within the primary care setting where 90% of all diabetes management occurs

• Daily SBGM costs are 4.5 x higher/day than using CGM ($11.60 vs $2.59)\(^1\)

• Technologies provide insight in targeting a rational, safe and comprehensive approach to glycemic management

• Patients using advanced technology have been able to improve their time in range, reduce risk of and time spent within hypoglycemia, improve quality of life

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Summary

- rtCGM appears to be accurate and safe in the hospital settings including patients with reduced eGFR
- Need for more studies for FDA approval to use CGM in the hospital setting
- Smart pens with CGM to be standard of care
- Hybrid Closed Loop systems are improving
- Most systems achieve TIR (>70%)
- Reduce burden for patients
- Progression from Hybrid Closed Loop to fully close loop is undergoing investigation
Thank you