P1752.2 Metabolic Subgroup Meeting

Working Group Sponsored by IEEE Engineering in Medicine & Biology (EMB) Standards Committee

8 March 2022
Teleconference
Agenda

1. Attendance
2. Review of action items
3. Review of tasks
4. Other business
Review of Action Items
Data elements, definitions, units of measure

- Glucose (mg/dL)
- Time in range (%) [TIR] [http://www.agpreport.org/agp/agpreports](http://www.agpreport.org/agp/agpreports)
- Time above range [TAR]
- Time below range [TBR]
- Mean glucose (average)±standard deviation
Ambulatory Glucose Profile CGM

**AGP Report**

**GLUCOSE STATISTICS AND TARGETS**

<table>
<thead>
<tr>
<th>Date Range</th>
<th>Days Active</th>
<th>% Active</th>
</tr>
</thead>
<tbody>
<tr>
<td>26 Feb 2019 - 10 Mar 2019</td>
<td>13</td>
<td>99.9%</td>
</tr>
</tbody>
</table>

**Glucose Ranges**

<table>
<thead>
<tr>
<th>Range</th>
<th>Target</th>
<th>% of Readings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Range 70-180 mg/dL</td>
<td>Greater than 70% (16h 48min)</td>
<td></td>
</tr>
<tr>
<td>Below 70 mg/dL</td>
<td>Less than 4% (58min)</td>
<td></td>
</tr>
<tr>
<td>Below 54 mg/dL</td>
<td>Less than 1% (14min)</td>
<td></td>
</tr>
<tr>
<td>Above 250 mg/dL</td>
<td>Less than 5% (1h 12min)</td>
<td></td>
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</table>

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

**Average Glucose**

173 mg/dL

**Glucose Management Indicator (GMI)**

7.6%

**Glucose Variability**

49.5%

Defined as percent coefficient of variation (%CV); target ≤36%

**TIME IN RANGES**

- **Very High** (>250 mg/dL) ... 20% (4 h 48 min)
- **High** (181-250 mg/dL) ... 23% (5 h 31 min)
- **Target Range** (70-180 mg/dL) ... 47% (11 h 17 min)
- **Low** (54-69 mg/dL) ... 4% (58 min)
- **Very Low** (<54 mg/dL) ... 6% (1 h 26 min)
Ambulatory Glucose Profile Self Monitoring BG
Data elements, definitions, units of measure

• Percentage coefficient of variation for glucose (%CV = [(SD of glucose)/(mean glucose)]

• Glucose Management Indicator (GMI) tells you the approximate A1C level based on the average glucose level from CGM readings for 14 or more days (eA1C → GMI)
  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6196826/

• Number of hypo/hyper events
Additional measures

- Average daily carbs (g)
- Mean amplitude of glycemic excursions (MAGE): the arithmetic mean of differences between consecutive peaks and nadirs of differences greater than one SD of mean glycemia
- Mean of daily differences (MODD: the mean of absolute differences between glucose values at corresponding time points of consecutive days)
Additional measures (metadata)

• Sensor usage (%)
• Calibration

“A number of metrics have been proposed to characterise the accuracy of the CGMs and one, in particular, has emerged as being the most recurrent measure for the sensor accuracy, which is the mean absolute relative difference (MARD). Different studies reported MARD values of 9.5% to 19% for different CGM sensors, which are close to the values reported for glucometers (5.6% and 20.8%).”  
https://www.nature.com/articles/s41598-019-56927-5
Table 6.2
Standardized CGM metrics for clinical care

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>Number of days CGM device is worn (recommend 14 days)</td>
</tr>
<tr>
<td>2.</td>
<td>Percentage of time CGM device is active (recommend 70% of data from 14 days)</td>
</tr>
<tr>
<td>3.</td>
<td>Mean glucose</td>
</tr>
<tr>
<td>4.</td>
<td>Glucose management indicator</td>
</tr>
<tr>
<td>5.</td>
<td>Glycemic variability (%CV) target ≤36%*</td>
</tr>
<tr>
<td>6.</td>
<td>TAR: % of readings and time &gt;250 mg/dL (&gt;13.9 mmol/L)</td>
</tr>
<tr>
<td>7.</td>
<td>TAR: % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)</td>
</tr>
<tr>
<td>8.</td>
<td>TIR: % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)</td>
</tr>
<tr>
<td>9.</td>
<td>TBR: % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)</td>
</tr>
<tr>
<td>10.</td>
<td>TBR: % of readings and time &lt;54 mg/dL (&lt;3.0 mmol/L)</td>
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</tbody>
</table>

CGM, continuous glucose monitoring; CV, coefficient of variation; TAR, time above range; TBR, time below range; TIR, time in range.

* Some studies suggest that lower %CV targets (<33%) provide additional protection against hypoglycemia for those receiving insulin or sulfonylureas. Adapted from Battelino et al. (26).

Glycemic variability indices

<table>
<thead>
<tr>
<th>Continuous glucose monitoring</th>
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<tbody>
<tr>
<td>Mean (average)±standard deviation</td>
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<tr>
<td>J index</td>
</tr>
<tr>
<td>Coefficient of variance</td>
</tr>
<tr>
<td>Low blood glucose index, high blood glucose index</td>
</tr>
<tr>
<td>Average daily risk range</td>
</tr>
<tr>
<td>Mean amplitude of glucose excursion</td>
</tr>
<tr>
<td>Mean of daily differences</td>
</tr>
<tr>
<td>Continuous overall net glycemic action</td>
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Serum

| Glycated albumin |
| 1,5-anhydroglucitol |
| Glycated albumin/glycosylated hemoglobin ratio |
Which measures does Tidepool share with pts/MDs?
Temporal relationships

• Temporal relationship to meal*
• Temporal relationship to sleep*
• Temporal relationship to physical activity
  • e.g., before exercise, after exercise (see related OMH schema)
• Temporal relationship to doses of antihyperglycemic medications
  • May be challenging to implement given the large variety of medications and dosing regimens.

*These elements are present in the Open mHealth blood glucose schema
Example model instances

• [see AGPsample.json file]
Noninvasive Glucose Monitoring


• ‘Noninvasive Glucose Monitoring: In God We Trust—All Others Bring Data’ https://journals.sagepub.com/doi/full/10.1177/19322968211046326
Review of Tasks
Reminder: Use Cases

• Use cases
  1. Continuous Glucose Monitoring for type 1 diabetes
  2. Blood Glucose Monitoring for type 2 diabetes on oral treatment
  3. Continuous Glucose Monitoring for type 2 diabetes on insulin
  4. Continuous Glucose Monitoring for response to food intake in prediabetes/Quantified self/biohacker
Summary of Action Items
Next Meeting
Upcoming Meeting

• Metabolic subgroup:
  • Tuesday, April 5 at 8 am Pacific