P1752.2 Metabolic Subgroup Meeting

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

8 February 2022

Teleconference

Agenda

1. Attendance
2. Review of action items
3. Review of tasks
4. Other business

Review of Action Items

Action Item #1

What does Glucose variability in [DiMe's library of digital endpoints](#) refer to?

- Time in Low Interstitial Glucose (Defined as Below 54 mg/dL [3 mmol/L])
- Time in hypoglycemia (%) (Defined as Below 54 mg/dL [3 mmol/L])
- Time in hyperglycemia (%) (Defined as Above 180 mg/dL [10 mmol/L])
- Change in fasting plasma glucose
- Change in HbA1c
- Change in glucose SD

Action Item #1

- CGM Metrics by daytime only in % of various ranges

- CGM Metrics by nighttime only in % of various ranges

- Glucose Variability over X days, measured with the coefficient of variation and the standard deviation

- Glycemic variability over X days assessed by the Coefficient of Variation

- Number of documented hypoglycemia episodes (< 54 mg/dL [3 mmol/L])

- Change in area under-the-curve of glucose from nighttime to daytime feeds

- Change in mean glucose from baseline (week 0) to week X [over a time period]

Action Item #2

Find definition of list of measures

- Glucose (mg/dL), Glucose peak (postprandial?)
- Mean glucose (average)±standard deviation
- Time in range (%) [TIR]
- Time above range [TAR]: 180 or 250 mg/dL?
- Time below range [TBR]: 54 or 70 mg/dL?
- Metabolic score (%)/ Glycemic index
- Percentage coefficient of variation for glucose (%CV = [(SD of glucose)/(mean glucose)]

Table 6.2

Standardized CGM metrics for clinical care

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

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

| |
|---|
| Continuous glucose monitoring |
| Mean (average)±standard deviation |
| J index |
| Coefficient of variance |
| Low blood glucose index, high blood glucose index |
| Average daily risk range |
| Mean amplitude of glucose excursion |
| Mean of daily differences |
| Continuous overall net glycemic action |
| Serum |
| Glycated albumin |
| 1,5-anhydroglucitol |
| Glycated albumin/glycosylated hemoglobin ratio |

Which measures does Tidepool share with pts/MDs?
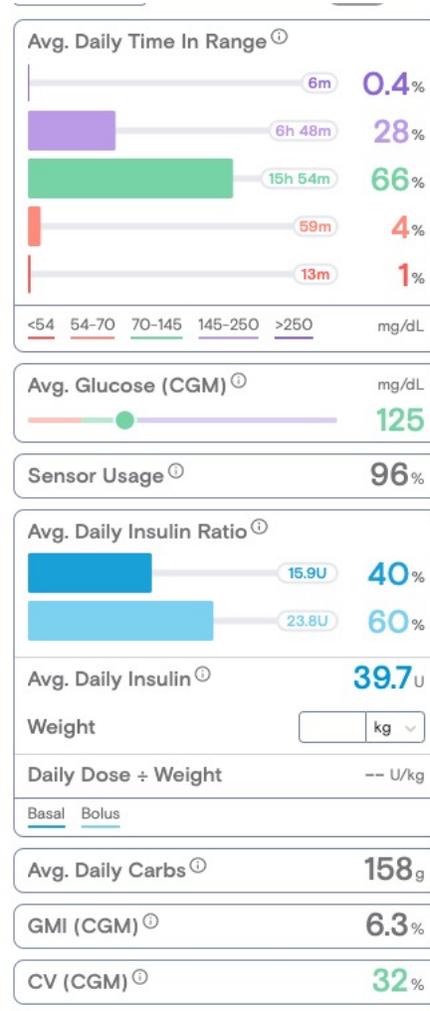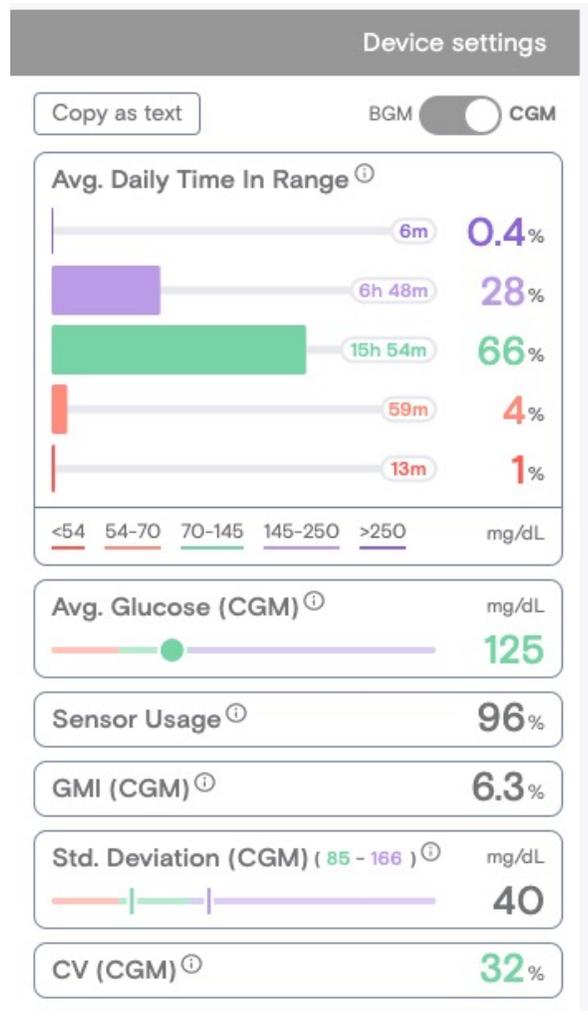
Additional measures

- Sensor usage (%)

- Calibration

- Glucose Management Indicator (GMI) = 3.31 + 0.02392 × [mean glucose in mg/dL]

- 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

- J index = 0.001 × (mean + SD)

BG readings

| Avg per day 1 Total: 11 | Meter | 0 (0%) | Manual | 11 (100%) | Calibrations | 3 |
| | Below 54 mg/dL | 0 (0%) | Above 250 mg/dL | 1 (9%) | | |

Mon	Tue	Wed	Thu	Fri	Sat	Sun
Nov 22	23	24	25	26	27	28
29	30	Dec 1	2	3	4	5
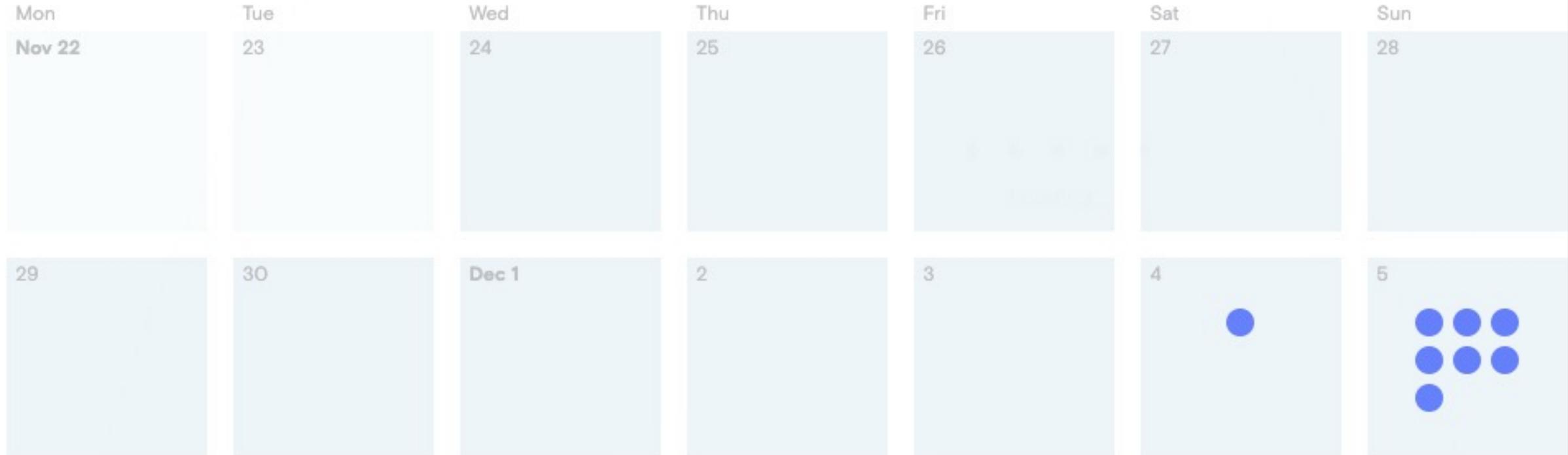
Temporal relationships

- 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

Review of Tasks

Tasks: Continuing Discussion on 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

Upcoming Meeting

- Metabolic subgroup:
  - Tuesday, March 8 at 8 am Pacific