P1752.2 Metabolic Subgroup Meeting

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

15 November 2022

Teleconference

Agenda

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

Review of Tasks

Data elements modeled

- Blood Glucose (mg/dL) / Average blood glucose (OMH schema)

- Time in range (%) [TIR], Time above range [TAR], Time below range [TBR]

- AGP for CGM and SMBG http://www.agpreport.org/agp/agpreports

- Percentage coefficient of variation for glucose (%CV)

- Glucose Management Indicator (GMI)

- Reference ranges (for hypo/hyperglycemia)

List of schemas (shared via email)

- blood-glucose-unit-value
- blood-glucose
- time-in-range
- ambulatory-glucose-profile-cgm
- ambulatory-glucose-profile-smbg
- blood-glucose-variability (coefficient of variation, CV)
- blood-glucose-management-indicator (GMI)
- blood-glucose-ranges

CGM: 2019 Consensus

Table 2

Standardized CGM metrics for clinical care: 2019

1. Number of days CGM worn (recommend 14 days) ([42](#),[43](#))

2. Percentage of time CGM is active (recommend 70% of data from 14 days) ([41](#),[42](#))

3. Mean glucose

4. Glucose management indicator (GMI) ([75](#))

5. Glycemic variability (%CV) target ≤36% ([90](#))[*]

6. Time above range (TAR): % of readings and time >250 mg/dL (>13.9 mmol/L)   Level 2

7. Time above range (TAR): % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)   Level 1

8. Time in range (TIR): % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)   In range

9. Time below range (TBR): % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)   Level 1

10. Time below range (TBR): % of readings and time <54 mg/dL (<3.0 mmol/L)   Level 2

Use of Ambulatory Glucose Profile (AGP) for CGM report

iCoDE project datasets (class 1)

https://www.diabetestechnology.org/icode/

Table 2.1. Composition of iCoDE Core Dataset and iCoDE Expanded Dataset.

Data Class	Data Elements	2019 Consensus	iCoDE Core Dataset	iCoDE Expanded Dataset
Class 1 *Clinical data that is sensed or sensor-derived*	**Calculated metrics**			
	Mean glucose	☑	☑	☑
	Glucose management indicator (GMI)	☑	☑	☑
	Glycemic variability (%CV)	☑	☑	☑
	Time above range, very high (TAR-VH): % of readings and time >250 mg/dL (>13.9 mmol/L)	☑	☑	☑
	Time above range, high (TAR-H): % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)	☑	☑	☑
	Time in range (TIR): % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)	☑	☑	☑
	Time below range, low (TBR-L): % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)	☑	☑	☑
	Time below range, very low (TBR-VL): % of readings and time <54 mg/dL (<3.0 mmol/L)	☑	☑	☑
	Ambulatory Glucose Profile Report	☑	☑	☑
	Individual glucose values		☑	☑

iCoDE project datasets (class 2)

Class 2 *Device- and system-generated data and metadata*	CGM Utilization			
	Number of days CGM worn	☑	☑	☑
	Percentage of time CGM is active	☑	☑	☑
	CGM reporting period start date		☑	☑
	CGM reporting period end data		☑	☑
	Device identification, settings			
	CGM manufacturer and model		☑	☑
	Device identifiers (serial numbers, lot numbers, UDI number)			☑
	CGM settings (sensing mode, configuration)			☑
	Software/firmware version			☑
	Sensor/Transmitter status (total use days, time to replacement)			☑
	Calibrations			☑
	Events, human annotations			☑
	Reference ranges			☑
	Alarms			☑
	Performance data (errors, failures, gaps in data)			☑
	"Insights" - recommendations for care			☑
	User identification			☑

Data elements to model

- Number of hypoglycemia/hyperglycemia events / Timestamps of alarms
- Rate of Increase
- Rate of Decrease

Summary of Action Items

Next Meeting

Upcoming Meeting

- Metabolic subgroup:
  - Tuesday, December 13 at 8 am Pacific