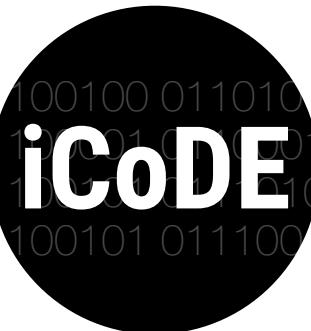


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**Integration of  
Continuous Glucose Monitor  
Data into the  
Electronic Health Record**

# 2022 iCoDE Report: CGM-EHR Integration Standards and Recommendations

*Organized by:*



November 7th, 2022  
Version 1.0

# Authorship Notes

2022 iCoDE Report: CGM-EHR Integration Standards and Recommendations.

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# Foreword

There are so many critical issues in healthcare today: access, cost, equity, safety, outcomes, and quality, to name a few. Data has the potential to drive improvements in all of these areas, but only if we can use it in meaningful ways. The good news is that our data-related barriers tend to be matters of coordination and collaboration, rather than technical. This means that it is possible for a field to advance quickly if we can standardize technical guidance and facilitate collaboration. And this is the goal of iCoDE: to accelerate CGM adoption and use by leveling the playing field for all healthcare organizations who want to leverage their data, and finally provide patients the integrated care experience they deserve. If the process of integration is demystified, simplified, and clearly outlined, then healthcare organization can start focusing on what matters: using the data to deliver better care.

We hope that this first version of the iCoDE CGM-EHR Integration Standards and Recommendation will be helpful to organizations who want to embark on this data journey. It will almost certainly be imperfect or incomplete in some areas, and as technology progresses, this guide will also need to be updated. We hope to provide minor revisions every 6 months, with bigger updates every 1-2 years. Please reach out to us if you think of ways to improve this work, find errors, or want to help us expand our scope.

Finally, we want to express our gratitude to all the people and organizations who made this possible. The Diabetes Technology Society team for believing in this project, helping to organize it, and support it even when it was just an idea. Our partners in industry, academia, government, healthcare, and law who contributed so much of their time and expertise to actually make it happen. The members of the CHLA research team who have been doing this work since our first integration project nearly 5 years ago. The FDA Real Word Evidence Demonstration Project grant that was the nidus and catalyst for all of this work. And of course, the patients who allow us the privilege to care for them and learn from them, and without whom none of this would be possible.

Thank you,



Juan Espinoza, MD, FAAP  
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# Abbreviations

Healthcare and Health IT Terms	
<b>iCoDE</b>	Integration of Continuous Glucose Monitoring Data into the Electronic Health Record Project
<b>WG</b>	Working group
<b>EHR</b>	Electronic health record
<b>HCO</b>	Healthcare organization
<b>IT</b>	Information technology
<b>KPI</b>	Key performance indicator
<b>mHealth</b>	Mobile health
<b>PDF</b>	Portable Document Format
<b>ICU</b>	Intensive Care Unit
<b>CPOE</b>	Computerized provider order entry
<b>MRN</b>	Medical record number
<b>NPI</b>	National Provider Identifier
<b>EMPI</b>	Enterprise Master Patient Index
Diabetes and CGM Terms	
<b>PWD</b>	Person with diabetes
<b>T1D</b>	Type 1 Diabetes
<b>T2D</b>	Type 2 Diabetes
<b>GDM</b>	Gestational Diabetes
<b>SDoH</b>	Social Determinants of Health
<b>PCC</b>	Patient Care Coordination
<b>CGM</b>	Continuous glucose monitor
<b>T1DE</b>	Type 1 Diabetes Exchange
<b>AGP</b>	Ambulatory Glucose Profile
<b>TIR</b>	Time in range
<b>TBR</b>	Time below range
<b>TAR</b>	Time above range
<b>GMI</b>	Glucose management indicator
<b>BG</b>	Blood glucose
<b>CV</b>	Coefficient of variation

<b>GRI</b>	Glycemia Risk Index
<b>MAGE</b>	Mean Amplitude of Glycaemic Excursions
<b>GRADE</b>	Glycemic Risk Assessment Diabetes Equation
<b>Interoperability Terms</b>	
<b>CCD</b>	Continuity of Care Document
<b>CDA</b>	Clinical Document Architecture
<b>C-CDA</b>	Consolidated Clinical Document Architecture
<b>HL7</b>	Health Level Seven
<b>SMART</b>	Substitutable Medical Applications, Reusable Technologies
<b>FHIR</b>	Fast Healthcare Interoperability Resources
<b>SMART on FHIR</b>	Substitutable Medical Applications, Reusable Technologies on Fast Healthcare Interoperability Resources
<b>API</b>	Application programming interface
<b>Data Models and Vocabularies</b>	
<b>CDM</b>	Common data model
<b>DQ</b>	Data quality
<b>OMOP</b>	Observational Medical Outcomes Partnership
<b>I2b2</b>	Informatics for Integrating Biology & the Bedside
<b>PCORNet</b>	Patient-Centered Outcomes Research Network
<b>Sentinel</b>	Sentinel Initiative Common Data Model
<b>USCDI</b>	US Core Data for Interoperability
<b>SNOMED</b>	Systematized Nomenclature of Medicine
<b>SNOMED-CT</b>	Systematized Nomenclature of Medicine—Clinical Terms
<b>LOINC</b>	Logical Observation Identifiers Names and Codes
<b>ICD-10</b>	International Classification of Diseases 10th Revision
<b>RxNORM</b>	RxNorm Normalized Names and Codes
<b>CPT</b>	Current Procedural Terminology
<b>Organizations and Agencies Relevant to Health IT and Standards Development</b>	
<b>OHDSI</b>	Observational Health Data Sciences and Informatics
<b>NCBC</b>	National Center for Biomedical Computing
<b>ISO</b>	International Organization for Standardization
<b>IEEE</b>	Institute of Electrical and Electronics Engineers
<b>IHE</b>	Integrating the Healthcare Enterprise
<b>NIST</b>	National Institute of Standards and Technology Cybersecurity Framework

<b>FDA</b>	Food and Drug Administration
<b>EMA</b>	European Medicines Agency
<b>CLSI</b>	Clinical and Laboratory Standards Institute
<b>NIH</b>	National Institutes of Health
<b>ONC</b>	Office of the National Coordinator for Health Information Technology
<b>BRIDG</b>	Biomedical Research Integrated Domain Group
<b>HITSP</b>	Health Information Technology Standards Panel

## Privacy, Security and Compliance

<b>UDI</b>	Unique Device Identification System
<b>HIPAA</b>	Health Insurance Portability and Accountability Act of 1996
<b>PHI</b>	Protected Health Information
<b>PII</b>	Personal Identifiable Information
<b>BAA</b>	Business Associate Agreements
<b>DUA</b>	Data Use Agreement
<b>HITRUST</b>	Health Information Trust Alliance
<b>SOC2</b>	Service Organization Control 2

*All other terms capitalized herein have the meanings ascribed to them under applicable law.*

# How to Use This Report

This report is intended to be a comprehensive yet practical guide for any organization who would like to implement a CGM-EHR integration. It is written to be generalizable to most healthcare settings, which necessitates writing at a level that omits some details. This report is ideal for clinical champions, administrators, IT leaders, and project managers directly involved in integration efforts. It contains significant technical detail, but is not intended to be a stand-alone technical guide; local expertise and collaboration with third parties (CGM manufacturers, aggregators, integrators) will still be required.

**Part 1** describes the genesis, organization, and process of iCoDE, as well as key concepts and definitions used through the report. Do not skip this part.

**Part 2** contains detailed technical information about data, data structure, data models, ontologies interoperability, account linkage, and cybersecurity.

**Part 3** discusses a number of practical implementation considerations, including clinical workflows, team compositions, patient experience, EHR data displays, and integration project management.

**Part 4** is a template Project Implementation Guide that can be adapted by any HCO ready to move forward with an CGM-EHR integration.

The **Summary of Recommendations** is a list of formal recommendations adopted by the iCoDE steering committee.

The **Appendix** contains references, full membership of iCoDE, acknowledgements, and funding information.

*Figures and tables are called out in **bold blue text**.*

*References to other sections of the report are in **bold red text**.*

# Part 1:

# Introduction

# 1. Introduction

## 1.1. Background

Continuous glucose monitors (CGMs) are an important technology for improving glycemic outcomes in diabetes. The opportunity for patient, caregivers, and clinicians to see real-time glucose concentrations measured automatically and continuously has transformed the practice of diabetes care. There are multiple CGMs currently available with different interfaces. However, there are no data standards or common data management systems among CGM manufacturers. This heterogeneity impacts EHR integration projects, provider workflows, and overall patient care. Standardized core data elements and definitions would facilitate data storage, clear interpretation, and accurate clinical intervention. Data standards and ontologies are critical for ensuring interoperability across information systems and can help drive adoption of novel data. Beyond standardization, these core elements should also be mapped to existing medical ontologies and specified by US Core Data for Interoperability (USCDI), such as Systematized Nomenclature of Medicine—Clinical Terms (SNOMED-CT), Logical Observation Identifiers Names and Codes (LOINC), Consolidated Clinical Document Architecture (C-CDA), and Observational Medical Outcomes Partnership (OMOP). Therefore, the purpose of this project was to bring a panel of manufacturers, clinicians, industry partners, and policy makers to develop a consensus approach to both the technical and operational aspects of CGM-EHR Integration.

## 1.2. Problem Statement

The current lack of continuous glucose monitor (CGM) data integration into the EHR is holding back the use of this technology in health care. This failure to integrate with other healthcare data inside the EHR renders CGM data less available for analysis and therefore less useful in its present form. The current process for implementing integration into a healthcare organization (HCO) or hospital EHR is slow and complex. There is no consensus on how best to address these issues.

## 1.3. Project Goals

The Integration of Continuous Glucose Monitoring Data into the Electronic Health Record (iCoDE) Project is a consortium whose purpose is to facilitate efficient uploading and integration of continuous glucose monitor (CGM) data into the Electronic Health Record (EHR). The two goals of the iCoDE project are to 1) develop technical specifications to integrate CGM data into the EHR and 2) develop workflows and guidelines to facilitate data integration efforts.

## 1.4. Project Organization

### 1.4.1 Participants

iCoDE was conceived of by Juan Espinoza and organized by Juan Espinoza, David Klonoff, and the Diabetes Technology Society in 2021 and 2022. The Project is composed of:

- **Planning Committee:** led by the two project co-chairs, and responsible for all aspects of logistics and content
- **Steering Committee:** Individuals representing industry, healthcare, academia, and regulatory agencies who attended iCoDE Project meetings and provided feedback
- **Working Groups:** a subset of steering committee members who participated in 6 working groups that met regularly in between project meetings to advance the development of various components of the

deliverables. Each working group was led by a working group Chair who was responsible for leading their Working Group and synthesizing their recommendations into this document.

- **Technical Advisory Group:** Individuals with technical expertise who periodically reviewed the recommendations from the Working Groups for feasibility, acceptability, and harmonization with other technical standards
- **Observers:** representatives from key government agencies who were invited to observe the process primarily for awareness and alignment, and to provide informal feedback.

iCoDE Key Personnel are shown in **Table 1.1**. The full membership of iCoDE can be found in **Appendix A.1**.

**Table 1.1.** iCoDE Key Personnel.

Role	Name	Affiliation	Email
iCoDE Co-Chair	Juan Espinoza	Children's Hospital Los Angeles	jespinoza@chla.usc.edu
iCoDE Co-Chair	David Klonoff	Mills-Peninsula Medical Center	dklonoff@diabetestechology.org
Administrative Support	Andrea Yeung	Diabetes Technology Society	yeung@diabetestechology.org
Administrative Support	Jingtong Huang	Diabetes Technology Society	huang@diabetestechology.org
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WG 1 Chair	Juan Espinoza	Children's Hospital Los Angeles	jespinoza@chla.usc.edu
WG 2 Chair	Randi Seigel	Manatt, Phelps & Phillips, LLP	RSeigel@manatt.com
WG 3 Co-Chair	Julian Goldman	Harvard University	jmgoldman@mgh.harvard.edu
WG 3 Co-Chair	Shahid Shah	Netspective	shahid.shah@netspective.com
WG 4 Chair	Sarah Corathers	Cincinnati Children's Hospital	Sarah.Corathers@cchmc.org
WG 5 Chair	Alaina Vidmar	Children's Hospital Los Angeles	avidmar@chla.usc.edu
WG 6 Chair	Maurice Tut	Children's Hospital Los Angeles	mtut@chla.usc.edu
Technical Advisory Group	Shahid Shah	Netspective	shahid.shah@netspective.com

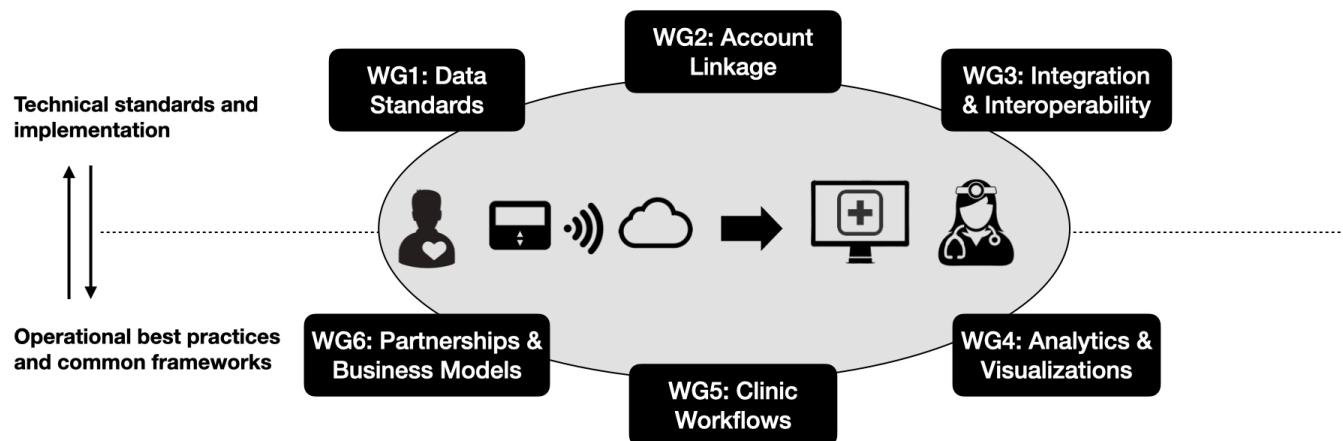
#### 1.4.2. Working Groups

iCoDE created 6 Working Groups in order to work on different aspects of developing CGM standards. Conceptually, the Working Groups tackled either technical aspects that would benefit from more prescriptive standards, and implementation aspects that would benefit from best practices and guidelines (**Figure 1.1**). Steering committee members were invited to join working groups that matched their expertise. Working groups met every 3-4 weeks for one hour each time. Each working group was led by a Chair, who was responsible for ensuring that the working group achieves its stated goal. Each

Working Group Chair met with the iCoDE Co-Chairs prior to their first working group meeting and were provided with a detailed outline of the content to be discussed by the working group; Chairs were then able to expand on the content based on the insights and expertise of the Working Group. The iCoDE Co-Chairs also attended most of the Working Group meetings.

An administrative staff member was responsible for collecting contact information for all working group members, coordinating with the Chair to schedule meetings, teleconferencing support, record the meetings, track deliverables, and follow up on action items. A research staff member attended each workgroup meeting and was responsible for taking detailed notes, synthesizing the discussions and deliverables, and coordinating with other working groups as needed. Chairs were responsible for reviewing and approving the meeting summaries.

**Figure 1.1.** Conceptual organization of iCoDE Working Groups



The six iCoDE Working Groups were:

- **Group 1: Data Standards**
  - **Chair:** Juan Espinoza
  - **Key Topics:** Which values should be reported, in what units, how are they calculated, timestamped, mapping to existing ontologies and data models, device metadata
  - **Goals:**
    - Develop consensus on a core set of structured clinical data elements that should be made available by all manufacturers
    - For each clinical data element, establish standardized metadata (e.g., timestamp, units, provenance)
    - Additional device data elements that should be included (e.g., model, serial number)
    - Map all core data elements to appropriate ontologies (e.g., LOINC, SNOMED) where possible, and begin the process to request new codes or entries as appropriate
    - Review existing data models, and how CGM data may be stored and mapped in those models; propose modifications/extensions of data models as appropriate
- **Group 2: Account Linkage (Entity and Identity Resolution, Patient Identity Matching)**
  - **Chair:** Randi Seigel

- **Key Topics:** Best practices for linking patient CGM data accounts with their EHR records, minimum number of identifiers needed; consent, privacy, security, and legal concerns
- **Goals:**
  - Recommend minimum number and type of identifiers needed to link accounts
  - Recommendations around patient consent/permission to link data to EHR
  - Use of CPOE to establish linkage
  - Data security and encryption at rest and in transit
  - Identify and recommend appropriate existing security standards and practice to safeguard patient data
  - Develop a shared model of CGM manufacturers as covered entities
- Group 3: Integration and interoperability
  - **Chairs:** Shahid Shah and Julian Goldman
  - **Key Topics:** How to define common approaches and best practices for ingesting data into the EHR, storing the data, surfacing the data
  - **Goals:**
    - Recommend standard message exchange framework to support data integration (HL7, SMART on FHIR, etc), and define common message elements and structure
    - Mapping CGM data to EHR tables vs. storing in data warehouse
    - Triggers to push/pull data, like CPOE
- Group 4: Analytics and Visualization
  - **Chair:** Sarah Corathers
  - **Key Topics:** How to best represent that data in the EHR, leveraging data platform functionality, integrating with other clinical data
  - **Goals:**
    - Define the goal of analytics and visualizations - what are the outcomes of interest? What are the KPIs? How do the analytics and visualizations serve those outcomes and KPIs?
    - Approaches to visualization in the EHR (storing PDFs, native graphing capabilities, linking out to web portal directly from the EHR, Embedded web pages, etc)
    - Determine the minimum necessary data to display and visualize, with descriptions of required capabilities
    - Recommendations for EHR display of data, including trends over time, and co-display with other clinical or contextual data
- Group 5: Workflows
  - **Chair:** Alaina Vidmar
  - **Key Topics:** What are best practices after the data has been ingested, for operationalizing new capabilities and onboarding patients
  - **Goals:**
    - Define the goal of workflows - what are the outcomes of interest? What are the KPIs? How do the workflows serve those outcomes and KPIs?
    - Develop checklist and descriptions of all new necessary workflows, including consent, account linkage, data pull/push, new patient experience, existing patient experience
    - Identify best practices and approaches to localize these processes
    - Map of roles and responsibilities in a new clinic workflow roll out
- Group 6: Contracting, Partnership, Project Management, and Business Models
  - **Chair:** Maurice Tut

- **Key Topics:** How to define the roles and responsibilities of each party, what are the appropriate contractual components of an integration project, common Gantt charts for implementation, checklist development, outcomes-driven reimbursement design

- **Goals:**

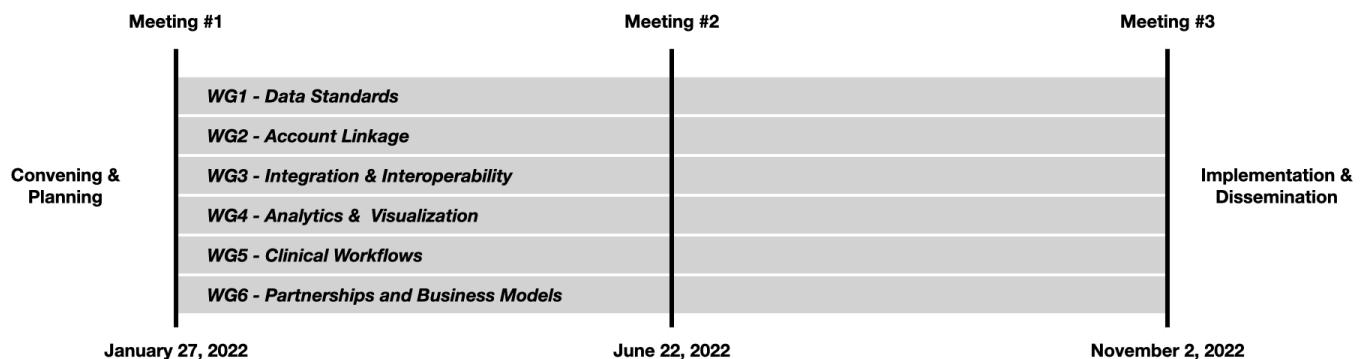
- Checklist of all team members and subject matter experts need to participate in a data integration project, including roles and responsibilities
- Consensus on appropriate contractual elements, such as BAAs, DUA, masters service agreements, etc
- Develop a general project plan that can be used by all teams for adoption and integration

#### 1.4.3. Timeline

The iCoDE Planning Committee began meeting in 2021 to design the overall project, set goals, and engage stakeholders and sponsors. In addition to monthly working group meetings, the entire iCoDE community came together for three larger project meetings (**Figure 1.2**):

- **January 27, 2022 | Project Kick-Off Meeting:** The first, full-day meeting served as an opportunity to convene stakeholders, clearly define the problem and goals, review the anticipated deliverables, and hear perspectives from a number of presenters representing different sectors.
- **June 22, 2022 | Mid-Project Feedback Meeting:** This half-day meeting is an opportunity for each working group to report back on their progress and receive feedback from other members of the steering committee. Project leadership will also provide overall updates on the project status.
- **November 2, 2022 | Project Closing Meeting:** This meeting presented the finalized iCoDE recommendations, results of steering committee voting, and the plan for next steps in dissemination and adoption.

**Figure 1.2.** Summary of the iCoDE Project Timeline.



#### 1.4.4. Dissemination

In addition to meetings, publications were part of our overall communication and dissemination strategy. As of this writing there are three iCoDE publications:

1. Espinoza J, Xu NY, Nguyen KT, Klonoff DC. The Need for Data Standards and Implementation Policies to Integrate CGM Data into the Electronic Health Record. *J Diabetes Sci Technol.* 2021 Nov 20:19322968211058148. <https://doi.org/10.1177/19322968211058148>

2. Xu NY, Nguyen KT, DuBord AY, Klonoff DC, Goldman JM, Shah SN, Spanakis EK, Madlock-Brown C, Sarlati S, Rafiq A, Wirth A, Kerr D, Khanna R, Weinstein S, Espinoza J. The Launch of the iCoDE Standard Project. *J Diabetes Sci Technol.* 2022 Jul;16(4):887-895. <https://doi.org/10.1177/19322968221093662>
3. Yeung AM, Huang J, Klonoff DC, Seigel RE, Goldman JM, Shah SN, Corathers SD, Vidmar AP, Tut M, Espinoza JC. iCoDE June 22, 2022 Steering Committee Meeting Summary Report. *J Diabetes Sci Technol.* 2022 Aug 29:19322968221119146. <https://doi.org/10.1177/19322968221119146>

We anticipate additional publications detailing the iCoDE consensus methodology and discussing future applications and implications of iCoDE.

## 1.5. Recommendations Development Process

The iCoDE Planning Committee created a framework for the overall content and goals of the iCoDE project. Steering committee members provided feedback on this framework during the project kick-off. Their feedback was incorporated, and then the Working Groups received their outlines and assignments. Working Groups met regularly to refine their thought process, research, and recommendations. Working Group Chairs conferred with each other when topics overlapped. Each Working Group Chair presented their work to date at the mid-project feedback meeting to the entire iCoDE community. Feedback was incorporated, and the Working Groups continued to meet until they had a final guidance document. The iCoDE Co-Chairs collected these six final guidance documents, synthesized them into a single report, and derived a series of explicit recommendation statements based on the report. The final report and recommendation statements were sent out to the Working Group Chairs for feedback and edits. Once these were accepted, the finalized report Recommendation statements were sent to the entire Steering Committee for review and voting. Those Recommendation Statements that received at least 80% approval were to be classified as *Strong Recommendations*. Statements that received 60% - 79% approval were to be classified as *Conditional Recommendations*. Statements receiving less than 60% approval were not to be adopted as recommendations. For completeness, the statements not adopted are still included in this report and presented separately.

## 1.6. Key Concepts

To facilitate a shared understanding of the organizations, people, and technologies involved, this report will use the following terms and concepts throughout. They have been selected so as to be broadly generalizable, and as such may vary slightly from other sources, including publications, institutions, and manufacturers.

### *Organizations:*

- **Health Care Organization (HCO):** a hospital, clinic, or health system.
- **CGM Manufacturer:** the company that makes a CGM.
- **Aggregator:** a third party that collects data from multiple CGM manufacturers (and often other devices) and makes it available to HCOs. Some aggregators also have portals for patients and clinicians.
- **Integrator:** a third party that builds interfaces between two systems to allow them to exchange data

### *People:*

- **Clinician:** a catch-all term that refers to any licensed healthcare professional who may interact with CGM data in the course of caring for patients, including physicians, trainees, nurses, nurse practitioners, physician assistants, registered dieticians, diabetes educators, pharmacists, etc.

- **Patient:** the person who uses the CGM as part of their health management. “People with Diabetes (PWD)” is the preferred terminology when specifically addressing diabetes; we chose to use the term “patient” in this document to be more general and relevant to other CGM use cases beyond diabetes.
- **Representative:** A parent, spouse, legal guardian, or other individual who participates in health care decision-making, provides consent, or is otherwise involved in the care of the patient.

#### *CGMs:*

For the purposes of this report, we will use the following definition of a CGM:

*A glucose monitoring device that autonomously generates a glucose value at regular and frequent intervals continuously over the wear period using a sensor. Measurements produced by the device reflect the glucose concentration and have been calibrated to established consensus as currently recognized by international regulatory bodies and agencies, including but not limited to FDA, CLSI, and/or EMA.*

Functionally, a CGM system consists of 4 components:

- **Sensor:** this component interacts with the body to detect glucose levels. Externally worn sensors are disposable and need to be changed frequently by the user, usually on the order of days or weeks. Implantable sensors can last several months, and are changed by a clinician.
- **Transmitter:** this component interacts with the sensor to send data to another device for viewing, storage and interpretation. A physical transmitter also needs to be changed, although less frequently than sensors.
- **Receiver:** this component receives data from the transmitter and makes it available for viewing and storage. The receiver may be a dedicated device or a compatible device, such as a smartphone.
- **Portal (Patient or Clinician):** the receiver can upload data to a cloud-based data platform hosted by the CGM manufacturer that allows the patient to view their data over time and share it with clinicians.

In practice, the sensor, transmitter, and receiver may be combined in different physical configurations, may involve patient-owned devices, or be software only, such as a mobile application. The exact configuration will vary by manufacturer and the technology used. In this report, unless otherwise specified, the term “CGM” will refer to the functional combination of Sensor + Transmitter + Receiver.

#### *Data Systems:*

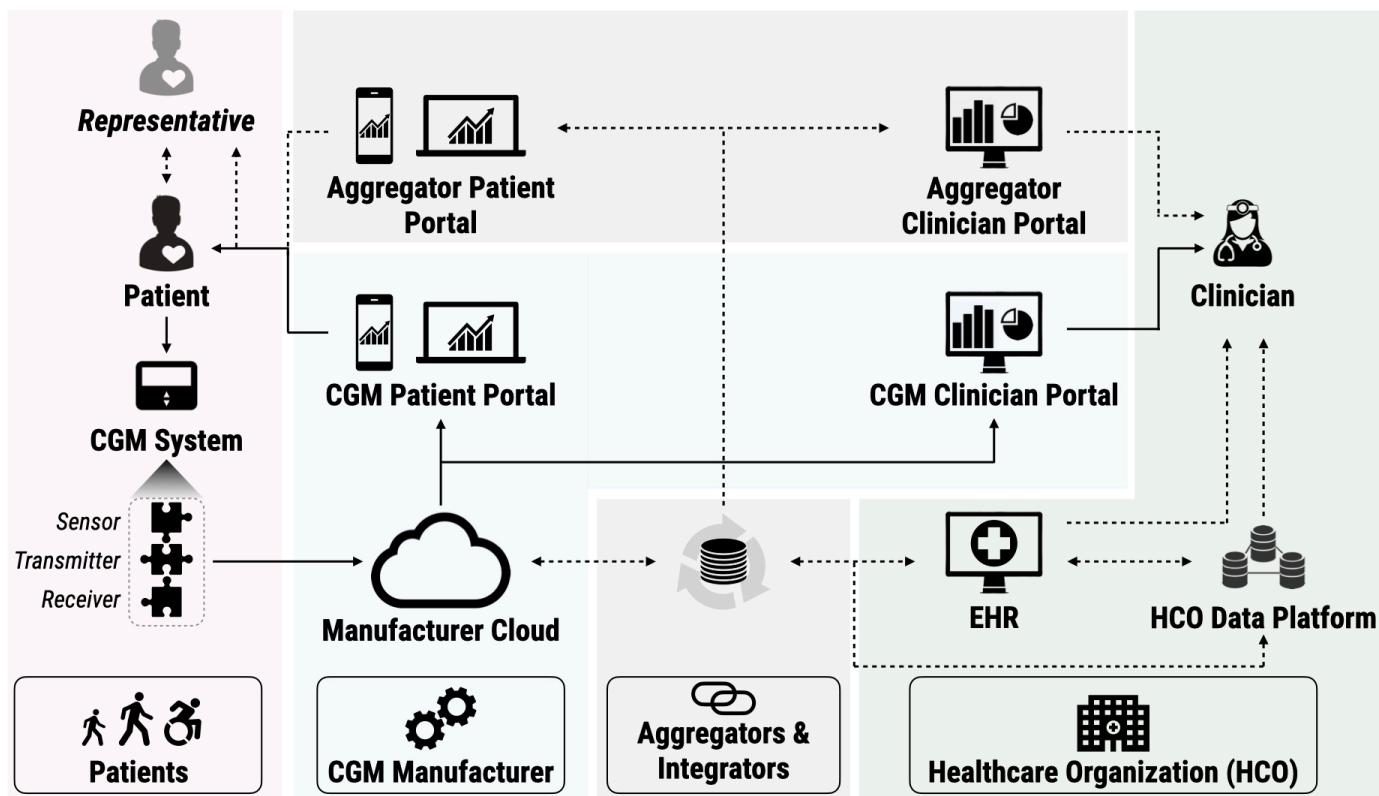
- **Manufacturer Cloud:** this generic term refers to the cloud-based data platform used by each manufacturer to host CGM data. Manufacturer clouds may offer different interfaces, including Patient Portals (to allow patients or representatives to view data), Clinician Portals (to allow clinicians to review patient data, sometimes organized into clinics or panels), and APIs (to allow data systems to connect directly and exchange data).
- **Electronic Health Record (EHR):** a software system owned and maintained by an HCO that contains an electronic version of a patient's medical history, and includes key administrative and clinical data relevant to that person's care, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports.<sup>1</sup>
- **HCO Data Platform:** this generic term refers to a data system that can ingest data from multiple sources, and apply advanced transformation, calculation and visualization. This system can also provide structured data for ingestion into the EHR. Some common terms that would fit under the umbrella of HCO Data Platform include data warehouse, data lake, and middleware platforms.

**Data:**

- **CGM Data:** broadly refers to all data generated by a CGM system, including sensed values, calculated metrics, utilization data and metadata, etc.
- **Clinical Data:** for the purposes of this report, the term clinical data refers to data typically found in the EHR, such as vital signs, diagnoses, laboratory results, etc.
- **Protected Health Information (PHI):** This class of data was created by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and refers to any identifiable health information, in any form (physical, electronic, spoken) that is used, maintained, stored, or transmitted by a HIPAA Covered Entity or Business Associate in relation to the provision of healthcare or payment for healthcare services. There are at least 18 classes of identifiers that are deemed PHI by HIPAA.<sup>2,3</sup>
- **Personally Identifiable Information (PII):** any data or other information that can be used to directly or indirectly identify an individual, including any information that is linked or linkable to that individual.<sup>4</sup>

**Figure 1.3** provides an overview of some of these key concepts and their relationships to one another.

**Figure 1.3.** Key Concepts and relationships in the iCoDE Report. Concepts are grouped into 4 main domains: Patients (in pink), CGM Manufacturers (in blue), Aggregators and Integrators (in grey), and Healthcare Organizations (in green). Solid black lines are connections that are common and exist today. Dotted black lines represent optional or less common, including EHR integration. The Aggregators and Integrators domain has been simplified significantly for the purposes of this figure.



## 1.7. CGM Data Flow (current state, pre-integration)

Generally speaking, as the patient wears the CGM system, the sensor component is generating data that is stored temporarily in the transmitter component, and then eventually transferred to the receiver component. If the receiver is a physical device, it can:

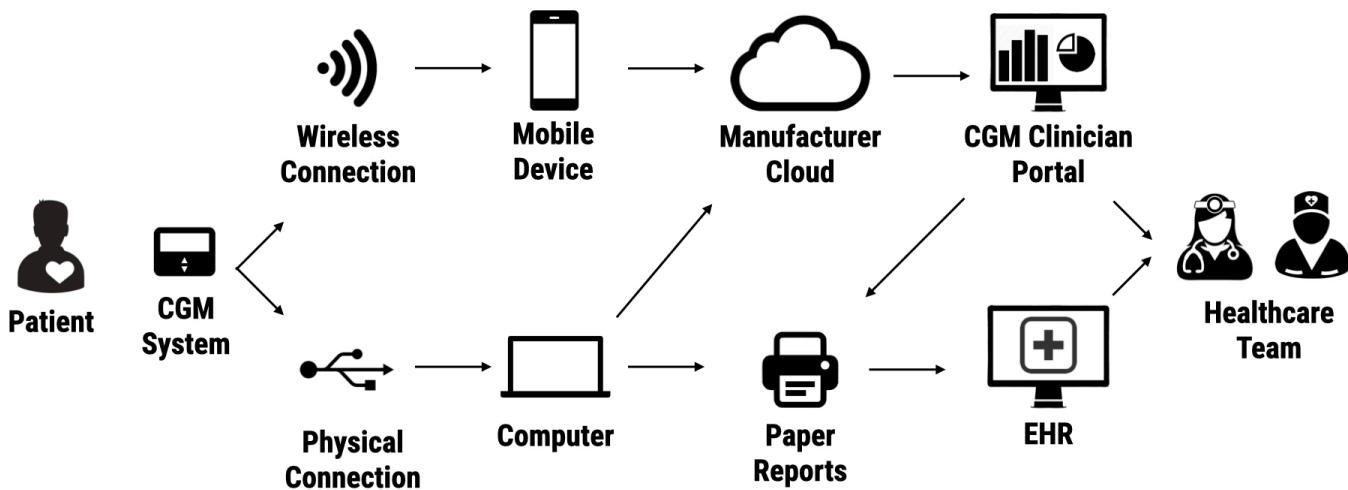
- Perform a wired or wireless transfer of data to a computer, where it can be stored and uploaded to the CGM Patient Portal.
- Wirelessly upload the data directly to the CGM patient portal.

If the receiver is virtual, such as an application on a smart device, the application can upload data to the CGM Patient Portal. If a patient does not have access to a computer or a smart device, then they often bring their receiver to their clinician's office, where the receiver is connected to a computer and the data is uploaded to the manufacturer cloud (either through the patient or clinician portal, depending on the system) or an Aggregator platform. Clinicians can review the CGM data in a few different ways:

- In the CGM Clinician Portal
- In an Aggregator's Clinician Portal
- Asking the patient to log into the CGM patient portal on their personal device and sharing their screen with the clinician
- In printed reports generated from any of the three methods described above

To make the CGM data part of the medical record, paper reports are filed and/or scanned, and some amount of the CGM report data is manually transcribed into the EHR by a member of the healthcare team. This overall data flow can be seen in **Figure 1.4**.

**Figure 1.4.** Mapping CGM data from the patient to the healthcare team.

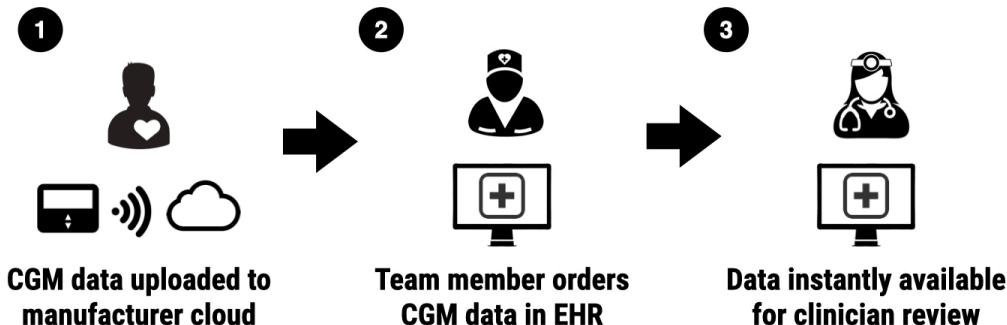


## 1.8. CGM Data Flow (desired state, post-integration)

The ultimate goal of CGM-EHR integration is to make CGM data directly available in the EHR to facilitate clinical decision making, optimize clinical workflows, and minimize clinician disruptions and task-switching.<sup>5</sup> In an ideal state, requesting and reviewing CGM data would be no different than requesting and reviewing other types of clinical data, such as vital signs, laboratory results, or radiology reports: an

order is placed in the EHR for the data, and then the data is available in the EHR alongside other results (**Figure 1.5**).

**Figure 1.5.** CGM-EHR integration simplified data flow.

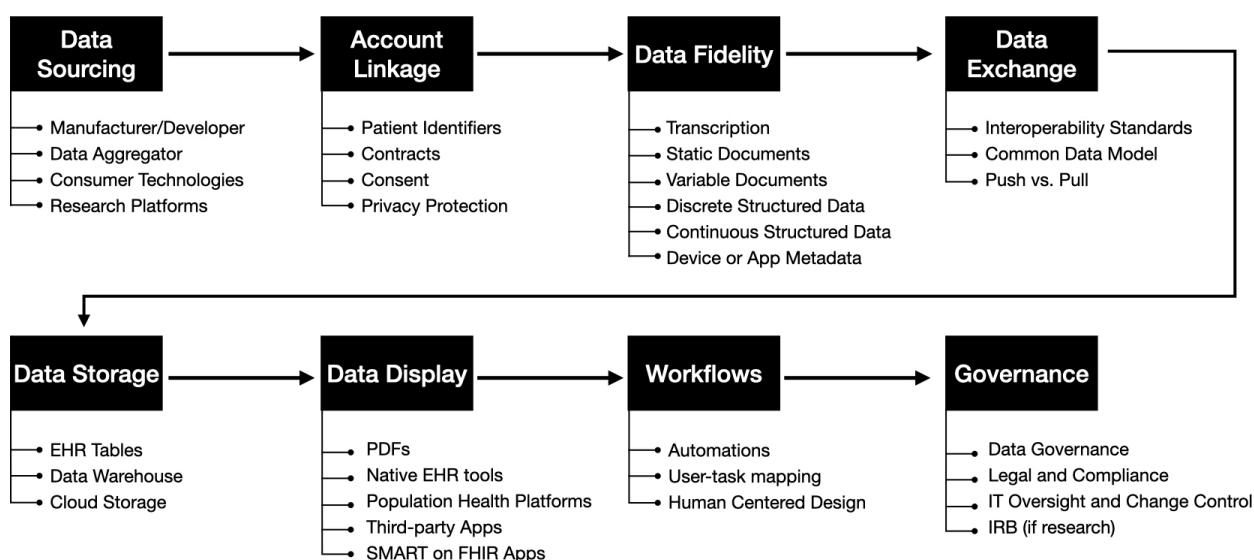


## 1.9. Barriers to CGM-EHR Integration

A number of barriers to integration have been previously identified.<sup>6</sup> These can be broadly categorized as Technical, Operational, Legal and Compliance, and Financial. Technical barriers are those that relate to the data, platforms, and technologies involved. Operational barriers relate to the staffing needs and workflow development. Legal and compliance barriers refers to contracting needs, data sharing, and liability. Finally, financial barriers are related to the cost of creating and maintaining the integration, including software, data subscriptions, and staff. **Figure 1.6** maps many of these critical concepts.

**Figure 1.6.** Critical concepts and barriers in CGM-EHR integration.

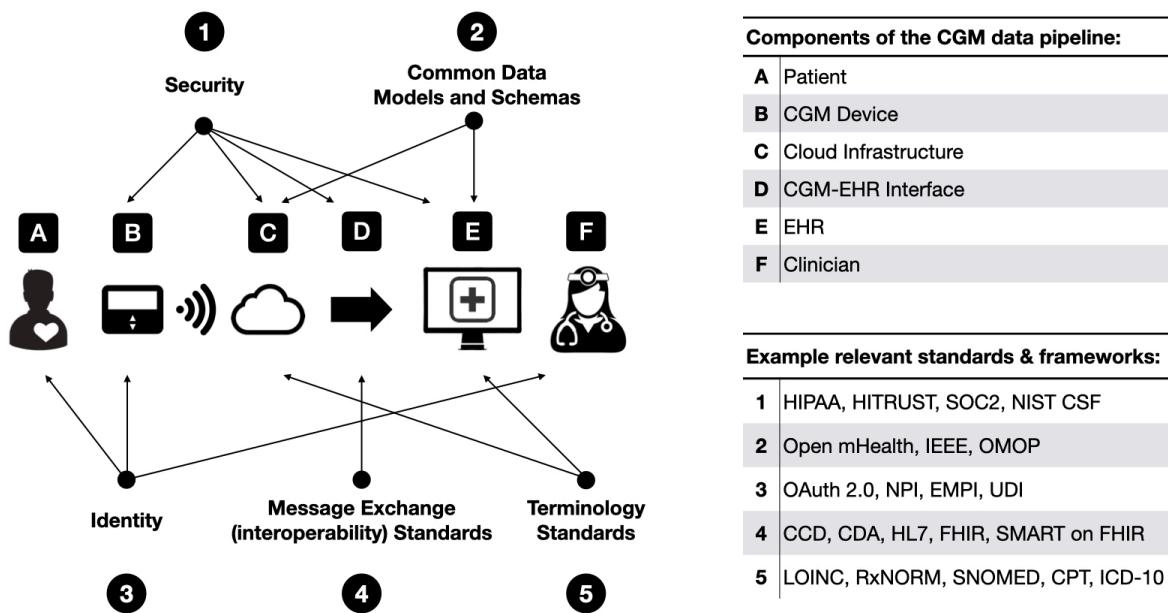
# Technology Integration Barriers



## 1.10. Opportunities to introduce Standards and Best Practices to CGM-EHR Integration

While there is significant complexity to the CGM data pipeline, iCoDE is predicated on the concept that adoption of standards and best practices can simplify the pipeline and make it easier for organizations at various levels of sophistication to develop CGM-EHR integrations (**Figure 1.7**).<sup>7,8</sup> There are a number of existing healthcare data standards. Therefore, to minimize redundancies and confusion, iCoDE endorses a philosophy of “Adopt, Adapt, Create.” This means that, whenever possible, we will adopt an existing standard that meets our needs. If an existing standard is close, then we will adapt it by recommending modifications or extensions. Finally, if an appropriate standard does not exist, then we will recommend the development of a new one.

**Figure 1.7.** CGM data pipeline map with key opportunities to introduce standards and best practices.



## 1.11. Defining clinical use cases of CGMs

As of this writing, all CGMs available in the US are cleared or approved for outpatient use in the management of patients with diabetes. Over the past several years (and accelerated by the COVID-19 global pandemic), there has been growing interest in the use of CGMs to manage hospitalized patients.<sup>9</sup> Although this is not currently approved in the US, this off-label use of regulated devices has been recognized as “an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine” by the United States Supreme Court.<sup>10</sup> We will discuss both outpatient and inpatient use of CGMs in this report, although it is worth noting that the use of the technology is quite different in each of those settings. We adopted a framework of thinking of CGMs as “one device, two modes.”

- **Mode 1:** Retrospective. Intermittent, remote patient monitoring where the most important data is the summary metrics (TIR, TAR, TBR, etc). Individual BG measures are less relevant to the provider although still useful, insofar as they inform visualizations or the ability to troubleshoot with patients.

This is most consistent with current outpatient or ambulatory use of devices in standard clinical care and consistent with the approved FDA use of the devices.

- **Mode 2:** Real-Time. The CGM is used as a continuous physiologic monitor (like a pulse oximeter or heart rate monitor), where the most important data is the individual BG measures to help drive clinical decision-making. The summary metrics are secondary in this mode. This is most consistent with some of the reported inpatient and ICU use cases, and the CGM output can be considered a form of telemetry. This is not the current standard of care or approved/ cleared use by the FDA, but is permissible under “off-label use” considerations.

All use cases leverage the device and its data in one of these two modes (or in combination). The mode depends on the use case and the user. For example, in outpatient ambulatory care, the clinician might be focused on Mode 1, but the patient might be focused on Mode 2 because they are adjusting their diet or behaviors based on the real time data. In inpatient care, the bedside nurse may be interested in Mode 2, but the managing clinician might be interested in Mode 1 for adjusting the overall regimen.

## 1.12. Health Equity in Diabetes-Related Technology

Low-income communities and communities of color experience higher rates of diabetes and related morbidity and mortality.<sup>11</sup> This inequity is in large part driven by access to healthcare, socioeconomic status, racism, and other social determinants of health (SDoH). The growing digital divide has led to the recognition of access to technology as another important determinant of health.<sup>12</sup> The relationship between SDoH, diabetes, and technology access should prompt all key stakeholders (including providers, payors, industry, government agencies, and others) to be mindful of the impact of CGM-EHR integration will have on vulnerable populations and their ability to meaningfully access and receive care.<sup>5</sup>

## 1.13. Patient Data Rights, Autonomy, and Shared Decision Making

The iCoDE participants strongly endorse the principle that individuals retain the right to make decisions about their health data, how it's used, and for what purpose. We in healthcare are stewards of their data, and our responsibility is to ensure that it is safe, and used meaningfully to advance the health of individual patients as well as society through meaningful research. As it applies to CGM-EHR integration, there are a number of important recommendations around patient data:

- CGM manufacturers and Aggregators should allow patients to view which institutions are accessing their data, and provide options to manage that access
- HCOs should notify patients that they are accessing their cloud-based data from CGMs and other connected devices
- HCOs should add CGM and other connected devices to the categories of data managed by Health Information Management departments, and provide patients with options to access, manage and transfer that data as appropriate, particularly during care transitions
- Patients should be able to ask HCOs to “disconnect” from their data sources, particularly during care transitions

Finally, we are strong proponents of shared decision-making. Patient autonomy should be respected and patients should never be penalized for disagreeing with their care team’s recommendations.

# Part 2: Technical Standards & Considerations

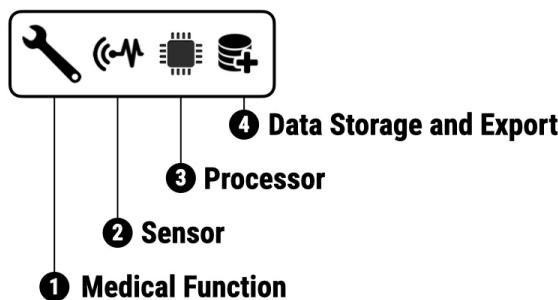


# 2. Technical Standards & Considerations

## 2.1. Data Types

Medical devices that generate data can generally be abstracted to their key components as seen in the schematic in **Figure 2.1**. There is a *Medical Function* component, which is often a physical object that interacts with the human body, such as a valve, a catheter, a needle, etc. There is a *Sensor*, which is typically attached to or incorporated into the medical function component. The sensor's output is sent to a *Processor*, which transforms the output into usable data, and (in some cases) controls aspects of the sensor or medical function component. Finally, a *Data Storage and Export* component enables data to be extracted from the device and used by patients and clinicians. In some devices, the medical function and sensor components may be the same, and in Software as a Medical Device (SaMD), these components may be replaced or augmented by a data input or interface component.

**Figure 2.1.** Abstraction of key components of a medical device that generates data.



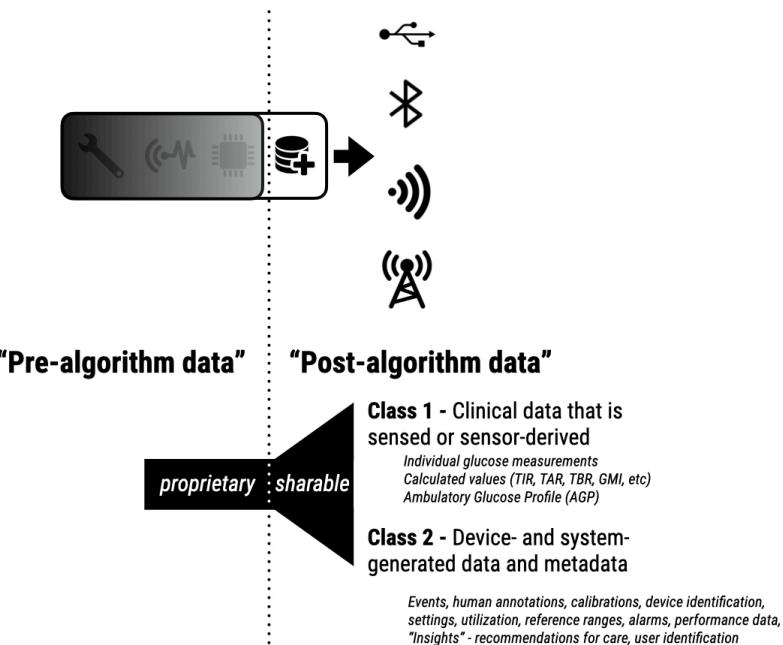
A significant amount of “raw” data is exchanged between components 1, 2, and 3 in **Figure 2.1**. This data and the code that supports it is often proprietary, manufacturer-controlled, regulated, and not intended for sharing. An algorithm transforms the data from the processor as it transitions to component number 4. This data provides the opportunity to share, integrate, and build applications for novel data use. This division of data can be conceptualized as pre-algorithm data and post-algorithm data; iCoDE only deals with post-algorithm data (**Figure 2.2**). Post-algorithm data can be further divided into two classes of data:

- **Clinical data that is sensed or sensor-derived (Class 1):** this is data directly related to the device's function to send glucose levels, and includes:
  - Individual glucose measurements
  - Calculated values (e.g., TIR, TAR, TBR)
  - Ambulatory Glucose Profile (AGP)
- **Device- and system-generated data and metadata (Class 2):** this includes data about the device, device use, and events, including:
  - Device utilization
  - Events, human annotations
  - Calibrations
  - Device identification, settings
  - Reference ranges

- Alarms
- Performance data
- “Insights” - recommendations for care
- User identification

This CGM data classification framework can help simplify and prioritize integration efforts.

**Figure 2.2.** Medical device data classes and data generation with CGM examples.



## 2.2. Minimum Dataset

In order to address the various use cases of all stakeholders, we recommend that CGM manufacturers and Aggregators provide the 11 data elements identified in the 2019 International Consensus Standardized CGM metrics for clinical care<sup>13</sup>:

- Number of days CGM worn (recommend 14 days)
- Percentage of time CGM is active (recommend 70% of data from 14 days)
- Mean glucose
- Glucose management indicator (GMI)
- Glycemic variability (%CV)
- Time above range (TAR): % of readings and time >250 mg/dL (>13.9 mmol/L)
- Time above range (TAR): % 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 (TBR): % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)
- Time below range (TBR): % of readings and time <54 mg/dL (<3.0 mmol/L)
- Ambulatory Glucose Profile (AGP) CGM report

We propose an **iCoDE Core Dataset** and an **iCoDE Expanded Dataset** (**Table 2.1**). The Core Dataset includes all of the elements of the 2019 consensus standard as well as individual glucose values. This generally maps to all the Class I data elements and some Class II data elements. CGM manufacturers are encouraged to make available at least the Core Dataset and to consider including additional elements of Class II to offer the Expanded Dataset.

**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	<b>Calculated metrics</b>			
	Mean glucose	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Glucose management indicator (GMI)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Glycemic variability (%CV)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Time above range, very high (TAR-VH): % of readings and time >250 mg/dL (>13.9 mmol/L)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Time above range, high (TAR-H): % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Time in range (TIR): % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Time below range, low (TBR-L): % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Time below range, very low (TBR-VL): % of readings and time <54 mg/dL (<3.0 mmol/L)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	<b>Ambulatory Glucose Profile Report</b>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Class 2  Device- and system-generated data and metadata	<b>Individual glucose values</b>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	<b>CGM Utilization</b>			
	Number of days CGM worn	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Percentage of time CGM is active	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	CGM reporting period start date		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	CGM reporting period end date		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	<b>Device identification, settings</b>			
	CGM manufacturer and model		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Device identifiers (serial numbers, lot numbers, UDI number)			<input checked="" type="checkbox"/>
	CGM settings (sensing mode, configuration)			<input checked="" type="checkbox"/>
	Software/firmware version			<input checked="" type="checkbox"/>
	Sensor/Transmitter status (total use days, time to replacement)			<input checked="" type="checkbox"/>
	<b>Calibrations</b>			<input checked="" type="checkbox"/>
	<b>Events, human annotations</b>			<input checked="" type="checkbox"/>
	<b>Reference ranges</b>			<input checked="" type="checkbox"/>
	<b>Alarms</b>			<input checked="" type="checkbox"/>
	<b>Performance data (errors, failures, gaps in data)</b>			<input checked="" type="checkbox"/>
	<b>“Insights” - recommendations for care</b>			<input checked="" type="checkbox"/>
	<b>User identification</b>			<input checked="" type="checkbox"/>

## 2.3. Data Schema

In order to enable meaningful description, exchange, sharing, and use of health data and metadata, it is important to adopt a standardized representation through data schemas (templates), which define syntax and semantics of relevant data and metadata elements, including their data types, units of measure (where relevant) and precise definitions. Adoption of a standardized representation will improve the ease and alignment accuracy of aggregating data across multiple mobile health sources (semantic interoperability) and will reduce the costs of using this data for self- and health-care and biomedical discovery.

Specifically, we recommended adopting and contributing to the IEEE P1752 family of standards for mobile health data. In particular, IEEE 1752.1 (published in 2021) describes metadata from mobile and wearable devices. Beside standardizing time stamps to ISO 8601, 1752.1 metadata schemas model data elements to describe data provenance.

In the context of P1752.2, which is currently in development, specific work is underway on metabolic measures, including blood glucose. Schemas under discussion are promising and appear to meet the needs of CGM data. They will be published on the P1752 open-source repository. P1752's precursor is Open mHealth, which developed schemas for a number of quantitative measures, including blood glucose. For future iterations of CGMs explicitly focused on inpatient use, IEEE 11073 is an appropriate data schema that governs general medical device communication standards.

Time stamps are critical for CGM data, and manufacturers should adopt a single date and time format like ISO 8601. All timestamps should include metadata that indicate what the timestamp refers to (e.g., when the data was collected by the device, when it was received by the CGM manufacturer from the device, when it was transmitted, etc.). Given the importance of day/night and sleep/wake patterns in diabetes management, the time zone of the timestamp and the time zone of the patient should either be the same or clearly delineated. There should also be a mechanism to alert HCOs to changes in the data

**Table 2.2.** Useful data schema references and links.

Name	Details	Link
IEEE Standards Association (IEEE SA)	n/a	<a href="https://standards.ieee.org/about/">https://standards.ieee.org/about/</a>
ISO 8601	Data and time formats	<a href="https://www.iso.org/iso-8601-date-and-time-format.html">https://www.iso.org/iso-8601-date-and-time-format.html</a>
IEEE 11073	Health informatics - Medical / health device communication standards	<a href="https://standards.ieee.org/ieee/11073-10207/6032/">https://standards.ieee.org/ieee/11073-10207/6032/</a>
P11073-10425	Standard for Health Informatics — Personal Health Device Communication — Part 10425: Device Specialization — Continuous Glucose Monitor (CGM)	<a href="https://standards.ieee.org/ieee/11073-10425/7248/">https://standards.ieee.org/ieee/11073-10425/7248/</a>
IEEE P1752	Open Mobile Health Data Working Group	<a href="https://sagroups.ieee.org/1752/">https://sagroups.ieee.org/1752/</a>
1752.1-2021	IEEE Standard for Open Mobile Health Data — Representation of Metadata, Sleep, and Physical Activity Measures	<a href="https://ieeexplore.ieee.org/document/9540821">https://ieeexplore.ieee.org/document/9540821</a>
IEEE P1752.2 Metabolic subgroup	Standard for Open Mobile Health Data: Representation of Cardiovascular, Respiratory, and Metabolic Measures	<a href="https://sagroups.ieee.org/1752/metabolic-subgroup/">https://sagroups.ieee.org/1752/metabolic-subgroup/</a>
IEEE 1752 Repository	n/a	<a href="https://opensource.ieee.org/omh/1752">https://opensource.ieee.org/omh/1752</a>
Open mHealth	Precursor to P1752	<a href="https://www.openmhealth.org/">https://www.openmhealth.org/</a>
Open mHealth Repository of schemas	n/a	<a href="https://github.com/openmhealth/schemas">https://github.com/openmhealth/schemas</a>

schema or format that impact timestamps because these are critical for clinical decision making and other derived metrics. **Table 2.2** provides additional information about these data schema.

## 2.4. Terminologies

Given the critical role that standardized terminologies play in interoperability, data sharing, and research frameworks, we recommend that all elements of the iCoDE Core Dataset should have LOINC terms. We used the ATHENA – OHDSI Vocabularies Repository<sup>14</sup> to search for existing terms that could be used. We identified 6 terms that already refer to CGM-specific concepts (**Table 2.3**). A number of other

**Table 2.3.** Existing LOINC codes that can be useful for CGM data.

LOINC Code	Name	Domain	Concept Class	Method	System	Time Aspect
97507-8	Average glucose [Mass/volume] in Interstitial fluid during Reporting Period	Measurement	Lab Test	Calculated	Interstitial Fluid	RptPeriod^mean
97504-5	Percent sensor usage	Observation	Clinical Observation	Calculated	Patient	Reporting Period
97506-0	Glucose management indicator	Measurement	Lab Test	Calculated	Interstitial Fluid	Reporting Period
97505-2	Glucose standard deviation Calculated	Measurement	Lab Test	Calculated	Interstitial Fluid	Reporting Period
97510-2	Glucose measurements in range out of Total glucose measurements during reporting period	Measurement	Lab Test	Calculated	Interstitial Fluid	Reporting Period
99504-3	Glucose [Mass/volume] in Interstitial fluid	Measurement	Lab Test	-	Interstitial Fluid	Point in time (spot)

related terms were also found, but these were not deemed to be specifically useful for labeling CGM data in the EHR.

There are a number of limitations of the LOINC concepts we were able to identify. They are not specifically labeled as CGM-related. They do not indicate the reporting period. Some would argue that CGM data is not canonically “Lab Test” data, since CGMs do not meet the definition or minimum quality standards set out in The Clinical and Laboratory Improvement Amendment of 1988 (CLIA).<sup>15</sup> Because of these limitations, we have developed new LOINC concepts that are being requested (**Table 2.4**).

Of note, the two concepts “CGM Reporting Period Start Date” and “CGM Reporting Period End Date” are critical in order to provide context to the other calculated metrics provided by the device. Data systems will need to be configured to recognize the start date and end date for all other metrics received during a data pull ideally by timestamp of when they were received by the HCO data system. We have also included a term for individual glucose values. This will allow institutions to take the raw CGM data and calculate other metrics, such as Glycemia Risk Index (GRI),<sup>16</sup> Mean Amplitude of Glycaemic Excursions (MAGE), Lability Index, J-Index, Glycemic Risk Assessment Diabetes Equation (GRADE).<sup>17</sup>

**Table 2.4.** iCoDE Core Dataset LOINC concepts requested.

LOINC Code	Name	Domain	Concept Class	Method	System	Time Aspect
pending	CGM Reporting Period Start Date	Observation	Clinical Observation	Calculated	Patient	Reporting Period
pending	CGM Reporting Period End Date	Observation	Clinical Observation	Calculated	Patient	Reporting Period
pending	Number of days CGM worn during reporting period	Observation	Clinical Observation	Calculated	Patient	Reporting Period
pending	Percentage of time CGM worn during reporting period	Observation	Clinical Observation	Calculated	Patient	Reporting Period
pending	CGM Mean Glucose [mass/volume] during reporting period	Measurement	Lab Test	Calculated	Interstitial Fluid	Reporting Period
pending	CGM Glucose Management Indicator during reporting period	Measurement	Lab Test	Calculated	Interstitial Fluid	Reporting Period
pending	CGM Glycemic Variability (%GV) during reporting period	Measurement	Lab Test	Calculated	Interstitial Fluid	Reporting Period
pending	CGM Time above range, very high (TAR-VH), % of readings and time >250 mg/dL (>13.9 mmol/L), during reporting period	Measurement	Lab Test	Calculated	Interstitial Fluid	Reporting Period
pending	CGM Time above range, high (TAR-H), % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L), during reporting period	Measurement	Lab Test	Calculated	Interstitial Fluid	Reporting Period
pending	CGM Time in range (TIR), % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L), during reporting period	Measurement	Lab Test	Calculated	Interstitial Fluid	Reporting Period
pending	CGM Time below range, low (TBR-L), % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L), during reporting period	Measurement	Lab Test	Calculated	Interstitial Fluid	Reporting Period
pending	CGM Time below range, very low (TBR-VL), % of readings and time <54 mg/dL (<3.0 mmol/L), during reporting period	Measurement	Lab Test	Calculated	Interstitial Fluid	Reporting Period
pending	CGM Ambulatory Glucose Profile (AGP) During Reporting Period	Meas Value	Doc Kind	-	Interstitial Fluid	Reporting Period
pending	CGM Glucose [Mass/volume] in Interstitial fluid	Measurement	Lab Test	Measured	Interstitial Fluid	Point in time

## 2.5. Mapping to Common Data Models

Common Data Models (CDMs) play an important role in supporting data exchange, cohort discovery, research networks, and federated learning. If CGM data is to be discoverable in these activities, then it needs to be mapped to these models. Four CDMs have become dominant in healthcare:

- **FDA's Sentinel Initiative**, which is the largest multisite, distributed database in the world dedicated to medical product safety. Sentinel has access to records from 350 million patients, mainly from administrative claims.<sup>18</sup>
- **Patient-Centered Outcomes Research Network (PCORnet)**, a network representing data from approximately 70 million patients, mainly from electronic health records.<sup>19</sup>
- **Informatics for Integrating Biology & the Bedside (i2b2)**, an NIH-funded National Center for Biomedical Computing (NCBC) based at Partners HealthCare System in Boston, Massachusetts. i2b2 supports patient cohort identification at numerous academic medical centers and hospitals serving millions of patients.<sup>20</sup>
- **The Observational Medical Outcomes Partnership (OMOP)**, an observational database of electronic health records set up by Observational Health Data Sciences and Informatics (OHDSI). OHDSI has established an international network of researchers and observational health databases linked by an Office of the National Coordinator for Health Information Technology (ONC) Common Data Model Harmonization 5 central coordinating center, with access to more than 100 different databases, representing more than 500 million patient records from 19 different countries.<sup>21</sup>

None of these CDMs have a table or domain that is specifically intended for devices like CGMs that are worn by patients at home for long periods of time and generate large amounts of data. Until these CDMs' core designs are updated to account for this relatively new type of data, we recommended incorporating CGM data into each CDM as shown in **Table 2.5**.

**Table 2.5.** Recommended CDM location for storing CGM data.

CDM	Table or Domain	Notes
Sentinel	Clinical Data - Lab Result	Can also use Patient Reported Measures Data
PCORnet	OBS_CLIN	Can also use OBS_GEN
i2b2	OBSERVATION_FACT	-
OMOP	OBSERVATION	can include "interstitial Fluid" as the specimen type in the SPECIMEN Table for additional specificity

Alignment with these models should inherently lead to harmonization with the Biomedical Research Integrated Domain Group (BRIDG) Model<sup>21</sup> and ONC IT's overall Common Data Model Harmonization Project.<sup>23</sup> Finally, ONC IT has also created the United States Core Data for Interoperability (USCDI), a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.<sup>24</sup> Currently in version 3, each version has added more information about medical devices, and specifically the FDA Unique Device Identification System (UDI System). It will become important for device identifiers to be included in the data captured by HCOs to comply with these future requirements.

## 2.6. CGM Reference Ranges

The reference ranges for calculated metrics like TIR are based on normative values for patients with type 1 diabetes (T1D). However, an individual patient may be best served by different glucose goals. In other conditions that benefit from CGMs, such as type 2 diabetes (T2D), gestational diabetes (GDM), and obesity, these normative reference ranges are less helpful, or they may have their own reference ranges (now or in the future). Members of the workgroup express that it would be helpful to either be able to fully customize ranges for individual patients, have population- or diagnosis-specific ranges (e.g., T1D, T2D, GDM), or both. For institutions that are able to ingest all of the raw data from the device, transform it, and then load it into the EHR, recalculating calculated metrics based on custom ranges is feasible. However, for those that depend on all of their data coming through a relatively simple, direct integration, they will depend on the data being provided by the manufacturer. There may be regulatory implications for the manufacturers to add disease-specific ranges to their device data reports that may not make this change feasible under current FDA clearances/approvals. A practical middle ground is to create in the data schema a location for ranges and a range category (e.g., T1D) that is currently populated with the accepted normative values and, in the future, can be changed.

## 2.7. Data Quality (DQ)

Patients and clinicians must be able to trust that the data they are using is both valid (does the data reflect the true clinical status) and reliable (is the data always collected in the same way). While CGMs typically include built-in checks to ensure that problems with clinical measurement and data collection are minimized at the point of collection, it is necessary to ensure that the data, once collected by the CGM, is properly transferred to the target EHR system. Failures in this transfer process may lead to incomplete, inaccurate, and/or out-of-date data, which, when utilized in the clinical context, may result in incorrect assumptions about patient status and poor decision-making.

A number of frameworks for assessing and addressing clinical data quality have been proposed, and can be adapted for our purposes. The frameworks developed by Kahn et al<sup>25</sup> and Weiskopf et al<sup>26</sup> are especially relevant to iCoDE. Briefly, these two frameworks define four categories of data quality: (1) Conformance, or adherence to data formats and standards; (2) Completeness; (3) Plausibility, which serves as a proxy for accuracy; and (4) Currency, which speaks to expectations of data “ripeness.” There are many ways in which these data quality constructs can be operationalized in order to measure data quality. We recommend the following assessments as a minimum set to ensure the fidelity of the data transfer process:

- **Conformance**

- Variable Conformance: are the variables in the correct format (i.e. is the date a date?), do they adhere to known data standards (i.e., is the right LOINC code included?)
- Relational Conformance: is the incoming data mapped to the correct patient record (using MRN or some other form of ID)?

- **Completeness**

- For individual glucose values: Are the number of data points collected by the device in a set period of time equal to the number of data points received by the EHR?
- For summary statistics: Were all expected statistics received?

- **Plausibility**

- Atemporal plausibility: Do the values in the EHR match those on the CGM? This can be applied to individual glucose values or to summary statistics, but we would advise prioritizing the summary statistics.

- **Currency**

- Is the delta between time of data collection by the CGM and date of transfer to the EHR minimized?
- Are the most recent individual values and summary statistics from the CGM present in the EHR prior to clinical assessment and decision-making?

In the future, pending the development and implementation of a standalone CGM data platform, a more exhaustive suite of data quality assessment checks would be appropriate. These would include the minimum set of transfer fidelity checks defined above, as well as checks designed to assess the underlying quality of the data, potentially detecting issues with data collection itself. These more advanced checks could incorporate patient-level factors and clinical context to establish patient-specific thresholds and expectations.

Depending on the type of CGM-EHR integration implemented, the approach to DQ will vary. If an HCO opts for a CGM to EHR direct connection, then there are limited opportunities for DQ processes given the relative rigidity of both of these systems, and therefore efforts should focus on completeness of data elements transfer, linkage, etc. Alternatively, if the HCO chooses to use an HCO Data Platform in parallel to, or in series before, the EHR, then full implementation of either of the two DQ frameworks mentioned above is both feasible and recommended, based on available technical and subject matter expertise.

## 2.8. Interoperability

Interoperability is the ability of different information systems, devices and applications (systems) to access, exchange, integrate, and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to 1) provide timely and seamless portability of information and 2) optimize the health of individuals and populations. Health data exchange architectures, application interfaces, and standards enable data to be accessed and shared appropriately and securely across the complete spectrum of care, within all applicable settings and with relevant stakeholders, including the individual.<sup>27</sup>

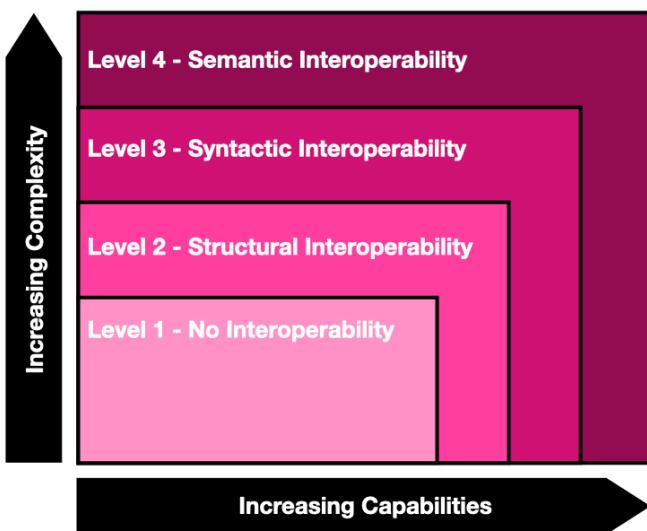
### 2.8.1 Levels of Interoperability

Historically, the level of interoperability has been ranked based on the complexity and functionality of the interoperability between two systems. **Figure 2.3** shows a classic definition of levels of interoperability adapted from Walker et al<sup>28</sup> that includes:

- **Level 1:** No Interoperability. Two systems that do not exchange any data (e.g., phone, fax, mail).
- **Level 2:** Structural Interoperability. Data is machine transportable, but cannot be manipulated (e.g., PDF, image)
- **Level 3:** Syntactic Interoperability. Data is machine organizable, but the two systems must share the same vocabulary and rules (e.g., two PCs exchanging a Word document, email)
- **Level 4:** Semantic Interoperability. Data is machine interpretable. Structured messages with standardized and coded data that enable the system to both “understand” what the data is, and act upon it accordingly (e.g. structured lab results).

More recently, the traditional model is sometimes updated by removing the “No Interoperability” level, and adding “Organizational Interoperability, which refers to the governance, policy, social, and legal considerations that facilitate how organizations, entities, and individuals exchange data.”<sup>27</sup>

**Figure 2.3.** Classic interoperability framework.



In 2022, Espinoza<sup>5</sup> proposed a six-level adapted interoperability framework specifically for CGM data, which has now been expanded to seven levels to account for the role of advanced data platforms (**Table 2.6**).

**Table 2.6.** Adapted interoperability framework for CGM data.

Level	Name	Description
1	Transcription	There is no data exchange between the CGM and the EHR. Clinicians include data in the patient record by transcribing it in notes, copying and pasting screenshots of the clinician portal into their notes, or scanning reports into the EHR. This is the current state for many healthcare institutions.
2	Static Documents	Static documents like PDFs containing predetermined data, such as the Ambulatory Glucose Profile (AGP), are relatively simple for two systems to exchange. At this level, there is no customization, but the EHR can retrieve, store, and display the reports natively, making them part of the medical record.
3	Variable Documents	At this stage, the systems are still exchanging static documents, but the user has the ability to select the contents of those documents. This may include custom date ranges, data elements, or visualizations.
4	Discrete Structured Data	Discrete numerical data can be brought into the EHR and added to existing data tables, where it can be charted, trended, and pulled automatically into notes.
5	Continuous Structured Data	Integrations at this level are accessing the hundreds of data points that CGMs generate each day. This type of integration creates new questions about data storage, but has the potential to provide more granular insights, as well as to generate novel analytics and visualizations
6	Device or App Metadata	In addition to clinical data, CGMs generate metadata about the device, software, and its utilization by the patient. This type of data could be helpful in tracking device serial numbers, understanding patient engagement, and even potentially creating behavioral interventions.
7	Advanced Analytics	Requires the use of a data platform. At this level, machine learning and statistical models can be used to develop risk stratification and predictive models, support population management, and other advanced applications

### 2.8.2. Interoperability Standards

Many standards have been developed over time, often building on each other. While most types of data standards (such as terminologies and CDM, discussed in [section 2.4](#) and [2.5](#), and security standards, discussed in [section 2.12](#)) all contribute to interoperability, standards that govern the format, content, and exchange of messages are especially critical. **Table 2.7** provides links to some of the most important content and transport standards in healthcare interoperability, and Mandel et al<sup>29</sup> provide a comprehensive review of the historical evolution of the HL7-SMART-FHIR family of standards.

**Table 2.7.** Relevant healthcare interoperability standards.

Name	Description	Link
Health Level Seven (HL7) Version 2	A widely implemented messaging standard that allows the exchange of clinical data between systems	<a href="https://www.hl7.org/implement/standards/product_brief.cfm?product_id=185">https://www.hl7.org/implement/standards/product_brief.cfm?product_id=185</a>
Health Level Seven (HL7) Version 3 Clinical Document Architecture (CDA)	An XML-based document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange between healthcare providers and patients	<a href="https://www.hl7.org/implement/standards/product_brief.cfm?product_id=7">https://www.hl7.org/implement/standards/product_brief.cfm?product_id=7</a>
Consolidated CDA (C-CDA)	A health information exchange framework for creating clinical documents that contain both human-readable text and machine-readable XML. It incorporates and harmonizes previous efforts from HL7, Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP)	<a href="https://www.hl7.org/implement/standards/product_brief.cfm?product_id=492">https://www.hl7.org/implement/standards/product_brief.cfm?product_id=492</a>
Fast Healthcare Interoperability Resources (FHIR)	FHIR focuses on healthcare APIs that are simple to implement and manage, where all exchangeable content is defined as "resources"	<a href="https://www.hl7.org/fhir/overview.html">https://www.hl7.org/fhir/overview.html</a>
Substitutable Medical Applications and Reusable Technologies (SMART)	Originally created to transform EHRs into platforms that can support third party applications, and has since evolved into SMART on FHIR as an open and standards-based API	<a href="https://smarthealthit.org/">https://smarthealthit.org/</a>
Direct Standard	Simple, secure, scalable, and standards-based mechanism for participants to send authenticated, encrypted health information to known trusted recipients	<a href="https://directtrust.org/standards/the-direct-standard">https://directtrust.org/standards/the-direct-standard</a>
Digital Imaging and Communications in Medicine (DICOM)	The standard for the communication and management of medical imaging information and related data	<a href="https://www.dicomstandard.org/">https://www.dicomstandard.org/</a>
Integrating the Healthcare Enterprise (IHE)	A series of profiles and specifications sharing information within care settings and across networks related to information access, clinical workflow, privacy & security, administration, and IT infrastructure	<a href="https://www.iheusa.org/implement-ihe">https://www.iheusa.org/implement-ihe</a>

We recommended that, consistent with the current offerings by most CGM Manufacturers and Aggregators, HCOs building CGM-EHR integrations use a FHIR-first strategy for EHR and third-party apps data transfer, with HL7 version 2.x recommended for use cases where FHIR is not possible or appropriate.<sup>30,31</sup>

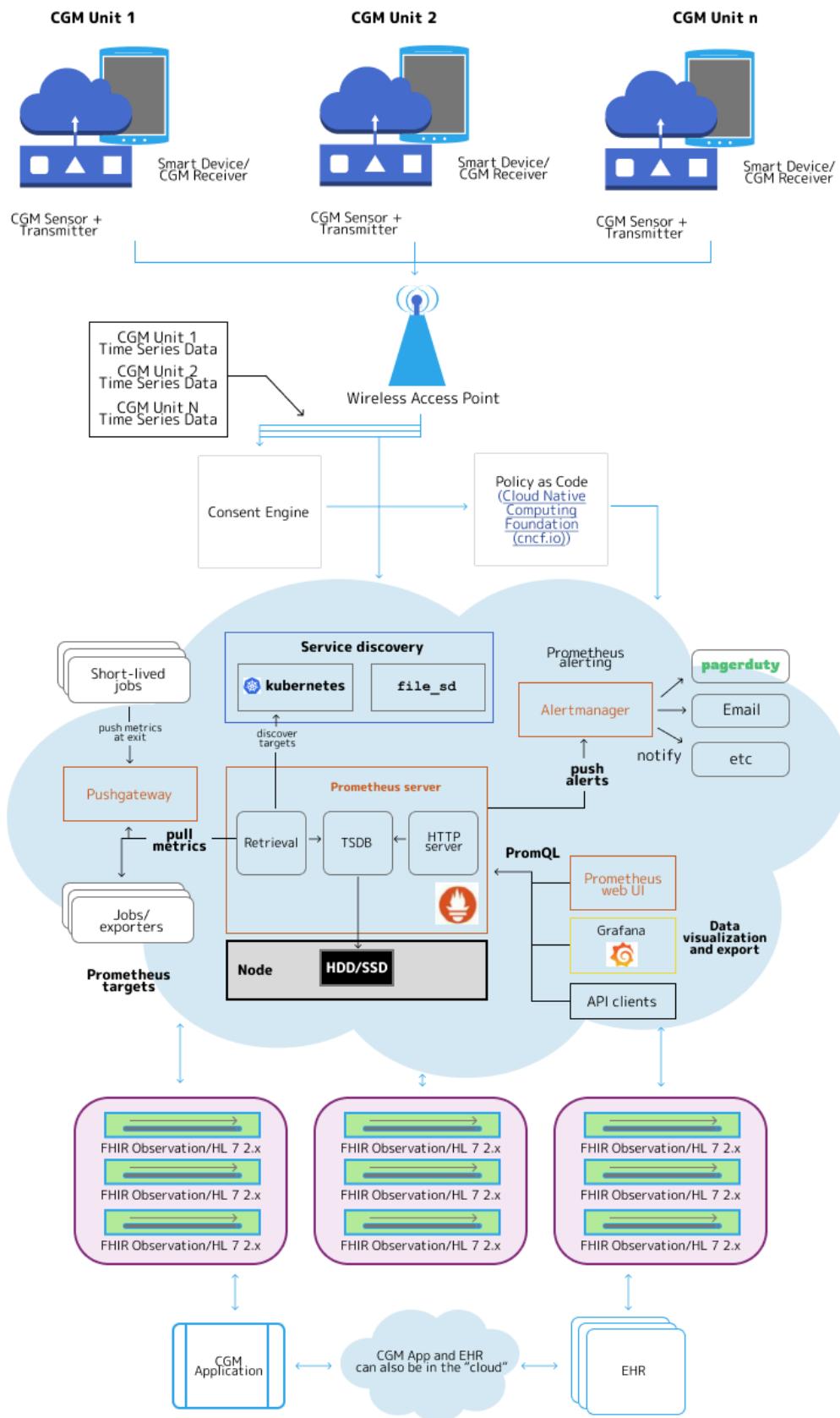
## 2.9. Data Push vs. Pull

Data “push” refers to the source system (e.g., the CGM Cloud) sending out, or “pushing” data at some predetermined time interval. “Pull” refers to the receiving system (e.g., EHR) requesting or “pulling” data from the source system on demand or at predetermined time intervals. For individual patient care, a pull system is more appropriate. The data request is more customizable and timely, and the clinician will be aware of the values being presented. There are some concerns about push methods, including liability for ingesting data into the official medico-legal record that has not been reviewed by the treating physician. There may be a role for data pushes in population health management, but this type of activity may not necessarily or exclusively be conducted in the EHR.

## 2.10. CGM Data Staging and Processing

Assuming that CGM manufacturers will be able to provide at a minimum the **iCoDE Core Dataset**, HCOs may still wish to perform additional transformations or calculations with the CGM data. EHR are systems of record that serve as repositories of medical information and a legal record of the care delivered to patients. In general, they were neither intended nor have the capacity to perform complex computations or advanced data transformation and manipulation. If there is a need to process data, then this should not happen in the EHR, but rather in a separate HCO Data Platform (**section 1.6**) before it reaches the EHR. This approach also provides an opportunity to perform additional data quality checks and align data for patients who may be using multiple devices. The Data Platform can enable advanced analytics, visualizations, and machine learning applications that would be difficult (or impossible) to perform in the EHR. The final output (calculations, novel indices, adjustment of reference ranges, etc.) could then be ported over to the EHR at the discretion of the HCO. Prometheus is an open-source reference architecture that can be adapted or adopted by HCOs looking for a middleware solution (Figure 2.4).<sup>32</sup> The Rising T1DE Alliance Diabetes Data Dock is an example of a diabetes-specific HCO Data Platform implementation.<sup>33</sup>

**Figure 2.4.** CGM-EHR data integration architecture with Prometheus as a reference architecture for middleware.



## **2.11. Connectivity**

There was some concern during inpatient use about access to Wi-Fi to upload data or potential issues with multiple transmitters or receivers in the same room. These issues have likely not been tackled by the manufacturers because CGMs are not currently approved by the FDA for inpatient use. However, once inpatient use becomes standard, CGM manufacturers will almost certainly address these issues by engineering some kind of hospital-based account provisioning and linking, as well as multiple device management. Until then, institutions will need to develop local strategies to address these gaps, although we believe it is unlikely for these issues to create problems.

## **2.12. Security Standards**

The security of the data collected and transmitted by the CGM is of critical importance to CGM manufacturers, clinicians, and patients. Accordingly, the adoption of a clear set of standards adhered to by all parties is important for CGM-EHR integrations. Currently, the most commonly used healthcare privacy and security framework is the Health Insurance Portability and Accountability Act of 1996, as amended, and its implementing regulations (collectively, "HIPAA"). However, HIPAA does not require one security standard nor is it as prescriptive as other security standards. Accordingly, many HIPAA Covered Entities and Business Associates implement other security frameworks, such as NIST or ISO, to demonstrate robust security standards for their stakeholders and potential partners, and for purposes of compliance with HIPAA requirements. For medical devices, manufacturers must comply with FDA pre-market and post-market guidelines that address, among other things, cybersecurity risks. The FDA does not, however, test medical devices to confirm they have met the guidance for cybersecurity.

### *2.12.1. Device Security - IEEE 2621*

Over the past eight years, a team organized by the Diabetes Technology Society has been developing *IEEE 2621 - Medical Device Cybersecurity* as a potential cybersecurity standard for diabetes wireless devices.<sup>34</sup> This standard was developed for connected medical devices, specifically for diabetes devices; its precursor was the Diabetes Technology Society's Standard for Wireless Diabetes Device Security (DTSec).<sup>35</sup> The benefit of this security standard, unlike other standards, including standards used by HIPAA Covered Entities and Business Associates to demonstrate compliance with HIPAA's Security Rule, is that self-attestation of compliance is not necessarily sufficient. Compliance with this standard may require a qualified test lab to review the security architecture and perform penetration testing before determining that a device is compliant with IEEE 2621.

We considered whether IEEE 2621 would interfere with existing security systems already in place for EHRs, and ultimately decided that there was little concern because IEEE 2621 is relevant to the data being transmitted to the EHR but not the EHR itself. Based on these considerations and the desire to adopt an existing standard that contains specificity, we recommend that CGMs comply with IEEE 2621 or a similarly robust industry-leading standard.

## **2.13. Account Linkage**

Account linkage refers to the process of connecting a patient's EHR record with their CGM Cloud record. There are several possible approaches to accomplish this. Key concepts to consider in this process include account privacy, security, ease of use for patients and clinicians, as well as who "owns" the account – the patient or the clinic. For example, Dexcom and Abbott have a patient-centric approach, where the patient is the "owner" of the CGM account and has control of the data; Medtronic has a clinic-centric approach where the data is "owned" locally by the clinic with which the patient is associated.

### *2.13.1. Account Linkage Conceptual Model*

Considering all of these factors, we developed a conceptual model for CGM account linkage:

- An account linkage is essentially a “handshake” between two systems (EHR and CGM Cloud).
- There is informational asymmetry between these two systems; they contain different types and amounts of information about patients.
- The “handshake” can be initiated by the EHR or by the CGM Cloud. The information that can be offered by one party to the other to initiate the linkage is limited by what they already know about the patient. The CGM cloud contains significantly less information than the EHR but is more likely to have accurate contact information like current email and phone number. The EHR has significantly more information than the CGM cloud, but is less likely to have accurate, up-to-date (or any) contact information like email and phone number.
- The data points that they theoretically have in common, like first name, last name, and date of birth may not match, e.g., when users create their CGM cloud accounts, they may choose to enter their name differently than it is represented in their EHR medical record.
- Account linkage can be further complicated in pediatric patients and adults for whom a family member or caregiver plays a significant role in their health management, e.g., the CGM cloud account has the child’s name but the parent’s email address.
- To address these issues of data asymmetry, the handshake must contain either:
  - A sufficient number of data points that allow a patient-matching algorithm to establish a link with a high degree of confidence.
  - An exchange of a unique identifier (like medical record number or an Account ID) submitted by one system to the other. Today, this is typically done through human intermediaries, such as a physician entering the MRN into a software platform, or a patient reading out a user ID to a clinician or staff member, who then enters it into the computerized provider order entry (CPOE) interface to initiate a message exchange.
- There are actual and perceived limitations to the amount and types of PHI/PII that an HCO may share with an outside party like a CGM manufacturer, if the CGM manufacturer is not a Covered Entity or a Business Associate. Even when a CGM manufacturer is a Covered Entity, absent HIPAA-compliant patient Authorization or a Business Associate Agreement, HCOs may be highly unlikely to feel comfortable sharing MRNs with CGM manufacturers.

### *2.13.2. Approaches to Establishing Account Linkage*

Given this conceptual model, we identified four possible approaches to establish account linkage:

1. The CGM Cloud initiates the linkage by offering the information it contains to the EHR and therefore, the HCO does not share any information with the CGM.
2. The EHR can initiate the linkage by sending the CGM cloud the information it contains, supplemented by information obtained from the patient by the provider (i.e., “What email did you use to create your account?”). In this model, the HCO can also request that the patient provide written or verbal consent authorizing the disclosure of the email address and any other information to the CGM manufacturer for purposes of the linkage.
3. The HCO can enter into an agreement with the CGM manufacturer (such as a BAA), have a local version of the CGM software within its firewall, and then internally link CGM and EHR accounts using any identifier they wish, such as MRN.

4. The CGM manufacturer can establish a unique, human readable account ID that is visible on both the webpage and mobile app. The HCO EHR can initiate the linkage by sending the CGM cloud the information it contains along with the unique account ID obtained by the clinician from the patient (e.g., "Can you open your app and read me your user ID?"). In this model, the HCO can also request that the patient sign a HIPAA-compliant Authorization authorizing the disclosure of the email address and any other information to the CGM manufacturer for purposes of the linkage.

Our assessment of each of these four options is as follows:

- **Option 1** will likely result in the lowest success rate for patient matching.
- **Option 2** will perform better but can result in trial and error (e.g., the patient forgets which email address they used to set up their CGM cloud account).
- **Option 3 and 4** will both result in high levels of matching success but require different technical and contractual approaches; if the HCO and CGM have to negotiate a BAA, then this could delay the ability to link the accounts.

We recommend that CGM manufacturers preferentially adopt options 3 or 4 and adopt option 2 as a back-up. Option 1 is not recommended. The CGM manufacturers could develop a HIPAA-compliant Authorization template for this purpose to ease any burden on the HCOs. It should be noted that in some cases, HCOs have recognized CGM manufacturers as Covered Entities, because they also bill health plans using HIPAA transactions. This may be a promising approach to simplify the CGM Manufacturer-HCO data relationship.

#### *2.13.3. Choice of identifiers*

Verifying account linkage requires the exchange of identifiers. CGM device identifiers, such as unique device identifiers (UDIs), lot numbers, or serial numbers are not ideal candidates. Many of the components of the CGM system that bear these numbers are disposable, meaning that their identifiers are not associated with the patient for very long. Some, like lot numbers, are not unique to a device or patient. The CGM Cloud has unique identifiers for patients and is in many ways the ideal identifier to exchange, but this may not be readily accessible under current platform designs.

Patient identifiers are more likely to be useful, but carry all the usual concerns and limitations regarding sharing PHI and PII. Email addresses, in particular, raise concerns because some patients, especially minors, do not have email addresses, some patients change their email address with some frequency, and email addresses alone may not be secure.

#### *2.13.4. Other Account Linkage Considerations*

We discussed whether QR codes could simplify the process of exchanging complex information or long numbers. The CGM Cloud, the EHR, or both, could generate a QR Code that is encoded with the relevant identifiers. The QR code would then be scanned by the other party and verified to establish account linkage. QR codes reduce errors associated with reading out and typing long numerical identifiers, and work very quickly. However, there are some disadvantages to this approach. The data systems may not have the ability to generate QR codes, and using a third party application would mean sharing PII with yet another party. QR codes have not been as widely adopted in the US as in other countries, so there may be a familiarity gap to close. HCOs may not have the right combination of software and hardware to scan and use QR code data in the EHR.

We also considered utilizing a third party for identity management and linkage, such as LexisNexis. However, after group discussion and a presentation by representatives from LexisNexis, it was deemed that a third party solution introduced additional complexity and cost without necessarily addressing some of the key issues of informational asymmetry between the EHR and CGM Cloud, and therefore we do not recommend using third party identity management at this time. We also wanted to minimize alterations or complications to existing workflows for both patients and clinicians.

# Part 3: Clinical Implementation



# 3. Clinical Implementation

## 3.1. Introduction

The materials in this section provide recommendations and guidance for operationalizing CGM-EHR Integrations, with a particular focus on clinical workflows. Each clinical program will need to be tailored to meet the needs and circumstances of the HCO, clinicians, and communities in which they provide care. Given the variability across healthcare settings, there is no simple checklist or solution to clinical workflow design and implementation. Successful clinical integration requires multidisciplinary collaboration; administrative, operational, and IT support; training and education for patients, clinicians, and staff; regular evaluation and iteration.

We have identified four clinical case scenarios in which CGM integration may present within a healthcare system.<sup>36-39</sup> There is a growing body of literature that explores single center experiences with wearable technology integration with an EHR that was reviewed in preparation for the creation of these recommendations.<sup>40</sup> Currently there is no approved regulation from the FDA regarding the use of CGMs within the inpatient setting. However, many clinicians elect to utilize these devices off-label and thus we have included separate inpatient consideration in **Section 3.9**. Furthermore, we acknowledge that there are multiple manufacturers of these devices and thus our workflows are not specific to one manufacturer but can be utilized across a variety of vendors. Purchasing decisions, product selection, and acquisition will be unique within each hospital system and conducted according to standard procedures within that system. Finally, there is significant overlap between the clinical implementation needs for CGM devices alone and automated insulin delivery systems. This report will only focus on CGM integration; however, the report could be useful for future standards related to automated insulin delivery systems.

## 3.2. Roles and Responsibilities

We identified various roles and responsibilities required for successful integration of this process into clinical practice. These tasks vary by clinical setting (primary care vs. subspecialty care) and are based on available resources (**Table 3.1**). There is an expanding literature around which team members, training, and responsibilities are required, including a recent publication by Patil et al<sup>41</sup> describing core professional competencies for diabetes technology use among care team members and support staff.

## 3.3. Encounter types

We identified five use cases that an individual utilizing a CGM may experience:

1. Outpatient in-person encounter
2. Outpatient virtual encounter
3. Outpatient asynchronous data review (not associated with a clinical encounter)
4. Inpatient admission
5. Population/panel management

These workflows may look very different depending on what type of clinician is delivering care. In this report, we provide a high-level, general infrastructure for how to frame the individual's experience. We did not account for alternative patient encounters, such as home visits, outpatient surgery encounters, or diabetes camp experiences, which may require workflow modification.

**Table 3.1.** Roles and responsibilities related to clinical implementation of CGM-EHR integrations.

Domain	Details
<b>Team Composition</b>	MD/DO/NP, RN, CDCES, Medical Assistant, Medical Technician, Front Desk, Pharmacist, Technical Support
<b>Administrative and Programmatic Tasks</b>	<p><b>Outpatient champion identified for:</b>            1) patient education, 2) staff education, 3) technical support (in-person), 4) virtual support, 5) triaging urgent request for data review</p> <p><b>Inpatient champion identified for:</b>            1) patient education, 2) staff education, 3) technical support, 4) data management and monitoring, 5) treatment action, 6) changing sensors</p> <p>Staff On-boarding and Training</p> <p>Equipment identified: Hardware (multiple devices for use, private room), Software (CGM Manufacturers, Aggregators, Integrators), Wi-Fi</p>
<b>Patient Experience Components</b>	<p><b>New User:</b></p> <ul style="list-style-type: none"> <li>- Authorization</li> <li>- New device training</li> <li>- Account setup and linkage</li> <li>- Education for uploading data prior to clinic</li> </ul> <p><b>Pre-Clinic:</b></p> <ul style="list-style-type: none"> <li>- Log of patients on CGM</li> <li>- Contact patient to upload data</li> </ul> <p><b>Clinic:</b></p> <ul style="list-style-type: none"> <li>- Real-time download of devices</li> <li>- Request data to EHR (data pull)</li> <li>- Add data sharing instructions to after-visit summary</li> </ul> <p><b>Post-Clinic:</b></p> <ul style="list-style-type: none"> <li>- Monitoring data in the interim between visits</li> <li>- Notify clinician that new data is available to review</li> </ul>

## 3.4. Outpatient Encounters

### 3.4.1. Patient Experience

We identified multiple points in the patient onboarding process in which additional education beyond standard device education will be required for successful integration. The ability of clinics to utilize CGM integration relies on the patient being able to consistently and accurately share their data. We propose the following outline for CGM education to ensure data sharing is highlighted and reinforced throughout their clinical time.

- First, at the initial new-device onboarding session, the patient should be provided with data-sharing documentation and education from the manufacturer.
- Next, the patient should be provided with a checklist that outlines the data-sharing process with an emphasis that uploading data occurs prior to each clinical encounter, for glucose review by a clinician, and upon admission to the hospital.

- Clinics should assign defined technical support personnel daily, with universal contact information that can be shared with patients so that they know how to contact technical support to upload their data when instructed to do so.
- The data-sharing checklist should be included in every after-visit summary or other written or mailed documentation sent to the family about diabetes management.

The patient's experience begins with device onboarding. Each clinic should continue with onboarding education per the manufacturer recommendation and clinical protocols. The data-sharing instructions should be highlighted, as well as the expected cadence of uploads required for clinical visits. The patient should upload their data 24-48 hours prior to the visit. If they are unable to do that, then clinical support staff should be made available in advance or day of the clinic visit to assist with data uploads. This will require assigned clinical staff members, necessary equipment, and space made available after the check-in process is completed. Once data is confirmed to be uploaded, the patient will be prepared for the clinical visit per standard practice (i.e., vital sign collection, medication reconciliation, allergy review, etc.).

During the visit, the clinician will access CGM data via the EHR, which includes standard metrics and summary downloads. Treatment and medication dosing decisions will be made per standard practice and discussed and agreed upon with the patient during the visit. Upon check-out, the patient will receive and review written and verbal instructions for data uploads prior to the next clinical encounter using teach-back techniques. The patient will also learn how to contact the team and request data review in the interim should an acute situation arise.

Between scheduled visits, if a patient requires assistance with glucose management, then they can contact the assigned clinical staff, upload their CGM data, and await response from the clinical team with information for a scheduled visit to review and discuss data.

### *3.4.2. Clinical Staff Experience*

The specific implementation of these processes will be dependent on the staffing and organization at each HCO. We recommend that a team member be assigned as the CGM integration champion to act as a liaison between clinical staff and people with diabetes. Multiple team members can be trained in the same policies and procedures to assist patients based on their specific roles and competencies to provide backup coverage each clinic day. The needs of these team members may vary slightly whether they are supporting an in-person or virtual workflow.

The clinical staff experience begins at check-in when the front desk staff verifies whether the individual with the CGM has uploaded their CGM data prior to the visit or not. If not, then they need to refer the patient to the location and support team available in the clinic to assist with the upload. Once the upload is completed (either prior to visit by individual or immediately post check-in) the front desk staff will ensure that the CGM is registered in the EHR and the accounts are synchronized for real-time integration. Upon check-out, the clinical staff will review with the patient the instructions for data uploading prior to future scheduled clinical visits and how to utilize this feature should an interim data review be required.

Outside of scheduled clinical visits, there should be an assigned team member to support individuals who need interim assistance with new glucose trends. This would include instructing them on data uploads, troubleshooting device barriers or internet connection concerns, and then creating a workflow in which once the data is uploaded, the team members alert the clinician to review the data and contact the PWD to discuss and make recommendations. This could take the form of an urgently

scheduled virtual or in-person visit or a phone encounter depending on clinical practice at that site. Given the incorporation of hybrid clinical delivery of diabetes care, with combination in-person and virtual encounters, the team members supporting the CGM integration process will need to provide coverage for both components, and potentially a second individual will need to be assigned for virtual support depending on clinical volume. Finally, we recommend a technology support champion be trained and assigned in case advanced technical concerns arise either for the patient or the clinical team executing the CGM integration process, so as to prevent delays in the clinical workflow and process measures. Successful execution of this type of workflow will require in-depth education for team members regarding CGM products, and instruction for using data uploaders, CGM Patient Portals, CGM Clinician Portals, and Aggregator Clinician Portals. Significant time will be needed to explain how this component of the visit will align with other visit requirements and affect staffing, space, and length of the encounter for all personnel involved. An initial intensive training session is recommended with regularly scheduled updates to review process implementation, clinical flow, and device updates. Furthermore, as described in more detail below, additional equipment may be required to ensure team members have an adequate number of computer monitors to review data in addition to private clinical space to provide education and support on uploading device data.

### *3.4.3. Clinician Experience*

Clinician experiences will likely vary between primary care and subspecialty settings. Clinicians should be trained on the CGM-EHR integration, which metrics to evaluate, how to review documents, and the proper use of relevant billing codes, including remote patient monitoring and CGM data review (**Figure 3.1**). The clinician will now have access to CGM data in the EHR to review both for scheduled and urgent visits. The clinician will require adequate devices to view all relevant data in the clinic room and pre- and post-clinical encounters for documentation purposes.

**Figure 3.1.** Common outpatient billing codes relevant to CGM-EHR integration.

Modality	Codes	Reimbursement	Frequency	Technical Requirements
 In-person visit	9920X 9921X 9924X	Variable compensation	Per Insurance	Baseline
 Telehealth visit	same as above + modifier	Same as above*	Per Insurance*	Telehealth Platform
 Virtual Check-in	G2012 G2010	~\$15	2-4 times per month	Phone, Email, Patient Portal
 Remote Patient Monitoring	99091 99453 99454 99457	~\$60	once a month	Devices, Data Platform
 Chronic Care Management	99490 99487 99489 G0506	~\$45	once a month	None

Discrete tasks and overall workflow for outpatient encounters are summarized in **Table 3.2** (in-person encounters) and **Table 3.3** (virtual encounters).

**Table 3.2.** Outpatient in-person workflows for clinics that implement CGM-EHR integrations.

		Task by Role		
Events and Time Points	Time Estimate	Patient	Clinical Staff	Clinician
Pre-Clinic	5 min	-Reviews checklist -Uploads data -Arrives 30 minutes before scheduled visit -Access support staff assists with uploads	-Reminder is sent to patient to upload data up to 48 hours prior to visit -A number is provided to call tech-support for questions or barriers to uploading data	
Check-In	5 min	-Arrives for appointment -Checks in at front desk	-Checks in patient -Registers in EHR -Verifies if data has been uploaded -Directs to tech support staff or personal device kiosk if data isn't uploaded	
Data Upload	5 min	-Uploads data prior to visit - no further action -Uploads data during check in -Meets with tech support	-Patient devices synced -Assigned to the patient's account.	
Data Request	10 min	-Patient is processed for visit	-Place data pull request in EHR	
Clinical Encounter	45 min	-Visit with clinician		-Access summary report from EHR and review
Check Out	5 min	-Schedules follow up	-Review upload instruction -Print after-visit summary	
Equipment and Space		-Clinic room -Kiosk -Mobile van -Personal device -Clinic device	-Two devices to access web-based upload site and EHR -Private clinic space for data/device support to not delay check in for other individuals -Need two people assigned to each role per day (point person and back up)	-Two screens (one with EHR and one with link to trend data)

### 3.5. Population and Panel Management

We have focused on the most common use cases that occur in clinical practice; however, CGM-EHR integration can also support population health management applications. For instance, clinics could utilize CGM-EHR integration to support population management in which the individual's data is pulled at pre-defined periods to evaluate those with consistently out of range glucose levels, especially hypoglycemia, for which immediate clinical action could be taken (a call made to the patient, earlier clinic visits scheduled, home visit, etc.). The algorithms, thresholds, and targets for CGM data would likely be determined by each HCO, though there is a growing body of literature sharing different machine learning applications for diabetes population health management. In addition, this data could be used for quality improvement and assessment initiatives. Important components to consider include privacy considerations, the requirement of consent from the patient, and compliance with all the applicable policies and regulations for this type of data application. **Table 3.4** proposes a possible workflow for this type population and panel management use cases.

**Table 3.3.** Outpatient virtual and asynchronous workflows for clinics that implement CGM-EHR integrations.

Task by Role				
Events and Time Points	Time Estimate	Patient	Clinical Staff	Clinician
Pre-Clinic	5 min	Uploads data prior to visit Open hours with tech-support person are available each day	Scheduled Telehealth Visit: Reminder sent to patient to upload data - number provided to call for questions or barriers to uploading data Urgent request by patient for data review: - contacts patient, triages request, if appropriate, then schedules TH visit and procedures with workflow. If not appropriate for TH visits, then instructs to call on-call clinicians or go to ER Asynchronous data review: - no action, done by clinician	
Check-In	5 min	Day of visit receives notification to upload data Logs onto virtual visit once invitation received	Scheduled Telehealth Visit: Sends person with diabetes virtual invitation for TH visit Verifies data has been uploaded	
Data Upload	5 min	1. Uploads data prior to visit - no further action needed 2. Uploads data during check in with clinical staff	Devices synced and assigned to the individual's account. -Requires two devices to access web-based upload site and EHR -need point person assigned to TH visit (in addition to point person and back up for in person clinic). Virtual care point person can also triage urgent request (need to consider level of training to triage appropriately for urgent situations).	
Data Request	10 min		Place data pull request in EHR	
Clinical Encounter	45 min	Visit with clinician		-Access summary report from EHR and review
Check Out	5 min	Schedule follow up	Review upload instruction, email after visit summary	
Equipment and Space	Personal device		-Two devices to access web-based upload site and EHR - Point person	-three screens (one with EHR, one with patient visit, and one with link to trend data)

**Table 3.4.** Population and panel management workflows with CGM-EHR Integration.

Task by Role				
Events and Time Points	Time Estimate	Patient	Clinical Staff	Clinician
Pre-Review	5 min	Consents to participate Uploads data at prespecified times	Obtain consent for monitoring	
Data Upload	5 min	If regular data upload has taken place, then uploads data at request of clinic	Reviews dashboard, contact patient if: - data missing - data grossly abnormal - algorithm flags patient for further evaluation	
Data Request	5 min		<i>if needed, then place order, though it may be better to automate data pulls for population health management applications</i>	
Data Review	30 min			Review data dashboards with diabetes team, identify patients that may benefit from changes to their care plan
Patient Contact	15 min	Discuss care plan with Clinician or Clinical Staff	Contact patient if needed to discuss care plan	Contact patient if needed to discuss care plan
Equipment and Space	Personal device		-Two devices to access web-based upload site and EHR - Point person	- Two screens (one with HCO Data Platform, one with EHR or CGM Provider Portal as needed)

## 3.6. Space and Equipment Requirements

Clinical teams should evaluate their existing equipment and determine what accommodations are required for successful integration. Possible additional items include:

- **Outpatient:**

- An area in the waiting room to upload data if not done at home
- Two screens to pull up the EHR and web-based link for check in staff
- Possibly an extra clinic room to perform manual uploads if required

- **Inpatient:**

- A monitor to review data at the bedside
- Back-up CGM supplies to keep on hand for established and new patients
- Two to three device screens for the treatment team to view EHR and web-based trends simultaneously
- Smartphones or tablets to receive device data (patient-owned or hospital-owned)

## 3.7. Analytics and Visualization of CGM data in the EHR

We evaluated features of analytics and visualization for integration of CGM data into the EHR. The workgroup considered the ambulatory use case as a priority, with recognition of distinct aspects for inpatient hospital setting considerations in the future. Intermittent data capture of summary metrics or snapshots, as defined in Mode 1 ([Section 1.11](#)), is adequate for the majority of outpatient care needs (similar to EKG). The inpatient hospital setting requires more continuous real-time access to glucose measurements, defined as Mode 2 ([Section 1.11](#)), similar to telemetry.

Based upon existing international consensus guidelines, we accepted the ambulatory glucose profile (AGP) and related standardized CGM metrics as the existing standard for content for integration into the EHR. We recommend using AGP metrics for 14 days as a default standard because this best reflects current clinical practice. A helpful feature is the option to view different time intervals including 30 or 90 days. The audience for integrated CGM data in the EHR could include patients, diabetes specialists, primary care providers, and other allied health providers. Therefore, the workgroup sought to describe essential features as well as desired features for those who may seek additional detail.

### 3.7.1. Minimum Necessary Features

The purpose of integrated CGM data includes individual clinical care, population management, quality improvement outcomes and benchmarking, billing, and reimbursement. The minimum necessary features address each of these purposes. Location of CGM data elements in EHR could present as laboratory data, other results, or flowsheet information for discrete elements. [Figure 3.2](#) shows an example of CGM values displayed as laboratory results in an EHR. Visual elements could be a PDF (portable document format) document stored as a result or in a media tab. The minimum necessary features include:

- **Data Elements:** The minimum necessary data for the EHR is described in the iCoDE Core Dataset
- **Reference Ranges:** Established reference ranges should be included for metrics with a visible alert for out-of-range values (e.g. color-code in a flowsheet row or exclamation point or caret symbol in a result view). [Table 3.5](#) summarizes the current consensus targets for percent of CGM readings in various glycemic ranges for different conditions.<sup>13</sup>
- **Clinician Alerts:** We did not reach consensus on criteria for a critical value that could warrant alerting a clinician, but organizations could determine an institutional standard (for example, % time < 54 mg/dL more than 5% represents a 5-fold increase from established target for general populations of type

1 and type 2 diabetes). For CGM metrics that do not have established targets, organizations may opt to adopt an institutional standard (for example GMI goal < 7%; < 8% being acceptable).

- **Graphs and other Visuals:** The visual AGP report should be available in the EHR (**Figure 3.3**). Visual representations of glucose statistics and targets are helpful, but they should not take the place of discrete data fields. Time in Ranges color-coded “stacked view” is a valued visual tool and should be included if possible. We recommended keeping any color coding consistent with the colors used in the standard ambulatory glucose profile. Daily glucose profile views are useful to be included as part of a complete AGP Report.

**Figure 3.2.** Example screenshot of CGM data displayed in an EHR. Flowsheet screenshot provided courtesy of International Diabetes Center, HealthPartners Institute from Richard Bergenstal, presentation at ADA 2022, Scientific Sessions

Laboratory Results			
Component	Latest Ref Rng & Units	6/7/2021	5/19/2021
# Days Sensor worn - 14d	Greater than 10 days	14	12
% Data Collected - 14d	Greater than 70%	76	70
% Time above range (>250 mg/dL) - 14d	Less than 5%	15 (H)	5 (H)
% Time above range (>180 mg/dL) - 14d	Less than 25%	23	26 (H)
% Time in Range (70-180 mg/dL) - 14d	Greater than 70%	55 (L)	65 (L)
% Time below range (<70 mg/dL) - 14d	Less than 4%	4	3
% Time below range (<54 mg/dL) - 14d	Less than 1%	3 (H)	1
Glucose Management Indicator (GMI %) - 14d	Goal <7%; <8% acceptable	7.2	6.9
Average Glucose (mg/dL) - 14d	Goal <154 mg/dL	164	152
% Glucose Variability - 14d	Less than or equal to 36%	45.9 (H)	37.4 (H)
Date Range 14d		5/24/2021 - 6/7/2021	5/5/2021 - 5/19/2021

**Table 3.5.** Clinical targets for percent of CGM readings in different conditions.

Ranges	Type 1 and Type 2 Diabetes	Older/High-risk Type 1 and Type 2 Diabetes	Pregnancy Type 1 Diabetes
> 250 mg/dL	< 5%	< 10%	
> 180 mg/dL	< 25%	< 50%	
> 140 (pregnancy)			< 25%
Target Range 70-180 mg/dL	>70%	> 50%	
Target Range 63-140 (pregnancy)			> 70%
< 70 mg/dL	< 4%	< 1%	
< 63 mg/dL (pregnancy)			< 4%
< 54 mg/dL	< 1%		< 1%

**Figure 3.3.** Sample Ambulatory Glucose Profile Report. AGP Report image is courtesy of International Diabetes Center, and is available from <http://agpreport.org/>.  
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### Time in Ranges

### Glucose Statistics and Targets

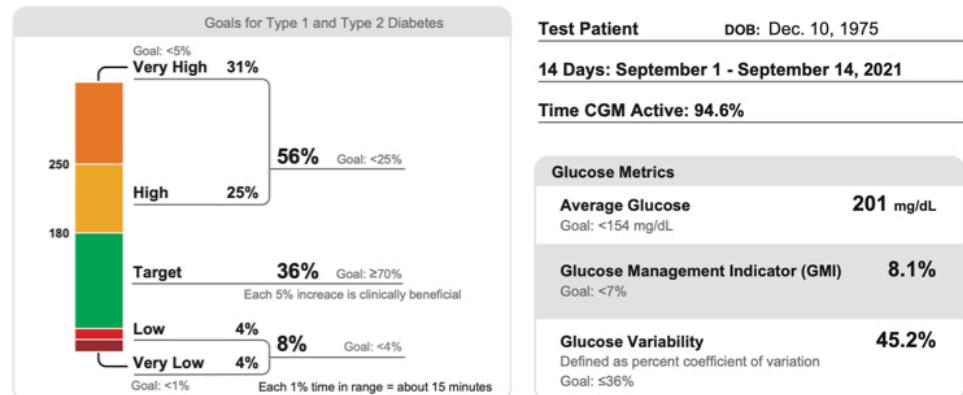
### Ambulatory Glucose Profile (14 days)

### Daily Glucose Profiles

AGP Report image is courtesy of International Diabetes Center, and is available from <http://agpreport.org/>.

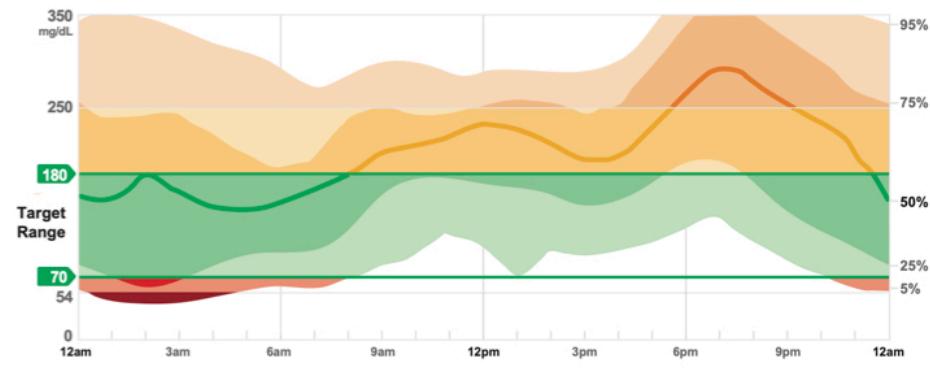
© 2022 International Diabetes Center

#### AGP Report: Continuous Glucose Monitoring



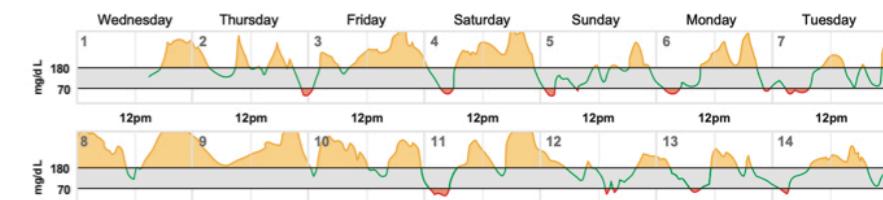
#### Ambulatory Glucose Profile (AGP)

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



#### Daily Glucose Profiles

Each daily profile represents a midnight-to-midnight period.



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captūAGP® v5.0

### *3.6.2. Additional Desired Features*

- Inclusion of target ranges for AGP metrics (see targets above) is helpful to support patient education and empowerment.
- Inclusion of trends over time as a reporting feature.
- Inclusion of visualization of daily views presented in a two-week timeframe. Additional views could layer through an accordion view feature of the EHR to provide additional detail or link to a platform outside of the EHR.
- A link to an external platform/web portal to easily access additional data if a longer or custom date timeframe, or more detailed viewing, is needed. Workgroup 4 suggested that the EHR use an interoperable system for CGM akin to PACS (picture archiving and communication system) for radiology images.
- Attainment of criteria for use in medical documentation and billing (data should flow into the progress note)
- Flexibility to customize to specific populations (pregnancy, older or high-risk populations, different TIR standards, or updated composite measures that emerge).
- An option to review data between visits; if the patient requests a pattern review, then this could come through as a portal message or an alert in the EHR in-basket.

## **3.8. Inpatient Considerations**

Currently, CGMs are not approved/cleared by the FDA for inpatient use. However, three trends are prompting organizations to develop policies to address interest in utilizing CGM devices in hospital settings:

- An increasing number of people wearing these devices
- Advances in accuracy
- Recent experiences with inpatient CGM protocols during the COVID-19 pandemic

For organizations interested in inpatient use, we would call attention to the *2020 Continuous Glucose Monitors and Automated Insulin Dosing Systems in the Hospital Consensus Guideline* by Galindo et al<sup>9</sup> organized by the Diabetes Technology Society. However, given the lack of approval/clearance, we acknowledge that the following recommendations and discussion may not be possible at every institution.

### *3.8.1. Inpatient Use Cases*

We identified three general use cases for CGM during an inpatient stay that could improve both patient satisfaction and outcomes:

- Patients on CGM prior to admission admitted for either a diabetes-related or other acute condition,
- Patients admitted with new onset diabetes requiring initiation of CGM as standard of care for outpatient, chronic diabetes management and preparation for discharge.
- Patients admitted for an acute condition in which CGM could support diagnosis or management of care especially in the setting of hypoglycemia risk.<sup>42,43</sup>

### *3.8.2. Inpatient Barriers*

The major technical barrier for inpatient use of CGM is that, as of the time of writing, CGM data is not available for integration in real-time through any system. For a number of regulatory and compliance reasons, all CGM manufacturers introduce a 1-3 hour delay into their data feeds. For a CGM-EHR

integration, this means that the data that will be available in the EHR will also have a delay, making it less useful as real-time telemetry. Currently, the only way to access real-time, or near real-time data from CGMs is to log on to the CGM cloud (patient or clinician portal) and view the data there. Some institutions have accomplished this by having a mobile device or computer for clinical staff at the bedside to log into the CGM clinician portal and review the most recent CGM glucose readings.

Possible clinical and operational barriers to consider when incorporating CGMs into inpatient management include: (1) team member education, (2) availability of supplies, (3) training on sensor insertions, device pairing with smartphones, setting alarms, enabling companion sharing, site assessments etc., (4) management of alarms and trends, (5) potential interferents utilized as treatment for acute condition, and (6) poor technological infrastructure (e.g., Wi-Fi).

### *3.8.3. Inpatient Policies and Regulations*

There are specific regulatory considerations for inpatient CGM use. Both Center for Medicare and Medicaid Services (CMS) and The Joint Commission have standards and requirements related to the inpatient use of medications or devices prescribed for the home that stipulate the need for written policies, circumstances, orders, and documentation. For example, they require documentation of both an inpatient receiving medications and responding to those medications. Without communication from insulin pumps and CGMs to create documentation in the EHR, it may be difficult to meet these regulatory requirements ([Appendix A.5](#)). Therefore, an essential feature for the inpatient use case is the ability to “pull” a query of a discrete glucose value from the CGM most proximate to an event that could be annotated, for example medication administration, acute symptoms, or mealtime. Documenting CGM glucose values in flowsheets, care notes, or results could be a means of fulfilling regulatory requirements.

Many organizations have provisions for areas of the hospital (specific units) that allow the use of home CGMs. They may require 1) demonstration of competence in using the device by the patient or primary caregiver, 2) consultation by an endocrinologist, and/or 3) documentation of learning competencies for nursing staff as needed. For hospital-supplied CGM devices, additional staff competencies related to CGM insertion, data collection, discontinuation, and cleaning are indicated.

A common feature of existing hospital policy statements for both established wearers using a home supplied CGM or for a new wearer of a hospital issued CGM is designation of data from the CGM as a supplement to standard, point-of-care, intermittent, and capillary blood glucose measurement. In most instances, policy stipulates that a hospital-approved glucose meter will be used to evaluate capillary blood glucose and that clinical decisions will be made using the hospital-approved device. There is emerging clinical practice that a CGM device may be used for insulin dosing within a hybrid protocol requiring intermittent point-of-care validation with a hospital-approved glucose meter if the CGM readings are within pre-specified accuracy limits.

### *3.8.4 Inpatient workflows*

Currently, there are no standard guidelines for educating care teams on managing CGM data, including alarms and trends, nor are there standards on how to interpret and manage CGM data in the inpatient setting. Therefore, each institution would be required to determine specific protocols for appropriate triaging and action regarding glucose trends captured on CGM and the appropriate trained personnel to monitor, report, and act on that data.<sup>44</sup>

Some hospitals may have existing policies on the use of home devices during an inpatient admission. HCOs should consider modifying such policies to incorporate the use of CGM wear for

patients akin to home insulin pump use. If a patient wearing a CGM presented for inpatient admission to an institution that supported home device use, then they should be requested to bring in their own CGM supplies and to self-manage (i.e., change sensors). However, if that is not the case, then hospitals would need access to equipment and personnel to assist with changing sites and working through the hardware component of utilizing a CGM.

For a patient admitted to the hospital with their own CGM, the following protocol template can be adapted and implemented for their CGM during the hospital stay (with additional workflow tasks shown in **Table 3.6**):

- The inpatient staff documents the CGM used, confirms that the patient has CGM supplies, and allows the patient to continue wearing the CGM for the admission.
- The inpatient team can utilize the CGM for treatment determination if accuracy correlates adequately with the point-of-care glucose monitor.
- The clinical team can review the continuous data collected and make dose adjustments as needed according to each institution's policy.
- The inpatient treatment team should be educated on the basics of trend monitoring and management and should be able to utilize the CGM data to support the acute monitoring, treatment, and management of the patient.

**Table 3.6.** Inpatient workflows for CGM-EHR integration

		Task by Role		
Events and Time Points	Time Estimate	Patient	Clinical Staff	Clinician
Admission	5 min	Admitted Requested that CGM supplies be brought from home	Checks in Patient and registers in EHR Data Management/Monitoring: Requires training on alarms and trends and protocols for when action taken	
Data Upload	5 min	Data is uploaded per device/clinical protocols	Devices are synced and assigned to the account Needs access to EHR and web-based account	
Data Request	5 min		Places a request for a data pull in the EHR Alternatively data is pulled continuously	
Monitoring and Decision Making	10 min	Requested to change site when required or change supported by trained clinical staff	Data is continuously available to be reviewed by the inpatient team -Telemetry style -Alarms are reviewed by trained clinical staff and communicated to clinician team	Review summary report in EHR Review real time data in CGM Clinician Portal Determine treatment decisions
Equipment and Space		Personal device, hospital WiFi	-CGM supplies for sensor replacement -Clinical staff is responsible to change sensor if patient is unable -two devices to access web-based upload site and EHR -point person for each component is assigned each shift (CGM hardware, data monitoring/management/ technical concerns) -Location for devices to sit (i.e., telemetry monitoring system)	-two screens (one with EHR and one with CGM Clinician Portal)

### *3.8.5. Inpatient Data and Visualizations*

All of the recommendations for outpatient data analytics and visualization also apply to the inpatient setting. However, unlike the ambulatory setting, in which retrospective summary data is useful for evaluating patterns over time, in the acute care setting, data needs to be available in real-time for clinical decision-making. Concepts like time in range (TIR) may be less relevant in the context of illness with frequent glucose fluctuations, however safety concerns of severe low glucose readings of < 54 mg/dL are significant in either context. In addition, the target ranges established by AGP for ambulatory care often do not necessarily apply in the acute care setting. There may be different levels of targets based on critical illness, pregnancy, or other concurrent medical conditions. We recognize that there is utility for short-term retrospective data in the inpatient setting as beneficial to determine how to adjust an insulin regimen. It will be advantageous to view trends over an 8-hour shift, 24 hours, or an entire hospital stay. Similar to telemetry, it would be useful to access longer trends of monitoring data, with an option to import a snip of a relevant timeframe for documentation of a safety event, like hypoglycemia.

## **3.9. Checklists**

We have developed a number of checklists to help HCOs keep track of important workflow steps for various encounter types. These should be interpreted as general guides, and not considered as complete or exclusive.

### *3.9.1. New Patient Experience Checklist*

- Clinician requests authorization for CGM
- Patient receives device
- Patient account is created in web-based manufacturer system
- Document in EHR: the CGM manufacturer, model, and account information
- Patient is educated to upload data a pre-specified number of days prior to all scheduled clinic visits
- Clinician supplies written instructions for upload
- Staff member reviews devices required (including WiFi and Data Access)
- Staff member reviews all caregivers that may accompany patient to visits and provide training
- Staff member provides instructional video and/or written handout that can be reviewed by patient and caregivers for reference
- Staff member educates patients and caregivers to reach out to on-call hotline and upload data for any interval concerns

### *3.9.2. Established Patient Checklist*

- Patient receives an automated upload request to upload data a pre-specified number of days prior to visit
- Patient brings device to visit, in case manual upload required
- Clinic staff pulls data to EHR
- Clinician reviews data during visit and makes treatment adjustments with patient using shared decision making
- Patient is reminded at checkout to upload data 24-48 hours prior to each visit and receives electronic instruction for upload in after-visit summary
- Staff reviews educational options for data upload
- Patient is provided with written instructions

- Staff provides virtual educational sessions as needed
- Staff provides additional training for caregivers as needed

### *3.7.3. Ad Hoc Patient Checklist*

- Patient calls clinic staff with questions about glucose concentrations
- Patient uploads data
- Clinic staff pulls data into EHR
- Clinician receives notification that there is CGM data to review in the EHR
- Clinician reviews data and discusses with patient/staff as clinically appropriate

### *3.7.4. Patient with Diabetes and Established CGM Inpatient Checklist*

- Patient is admitted
- Inpatient team members (determined by hospital staffing policy) request patient to upload data
- Inpatient staff pulls data from EHR
- Inpatient staff reviews continuous data

### *3.7.5. Patient without established CGM, prescribed CGM by inpatient team Inpatient Checklist*

- Clinician prescribes CGM use for monitoring/treatment
- Inpatient team members (determined by hospital staffing policy) place device on patient
- Inpatient staff pulls data from EHR
- Clinician reviews data as appropriate per local protocols and/or available guidelines

# Part 4: CGM-EHR Data Integration Project Guide



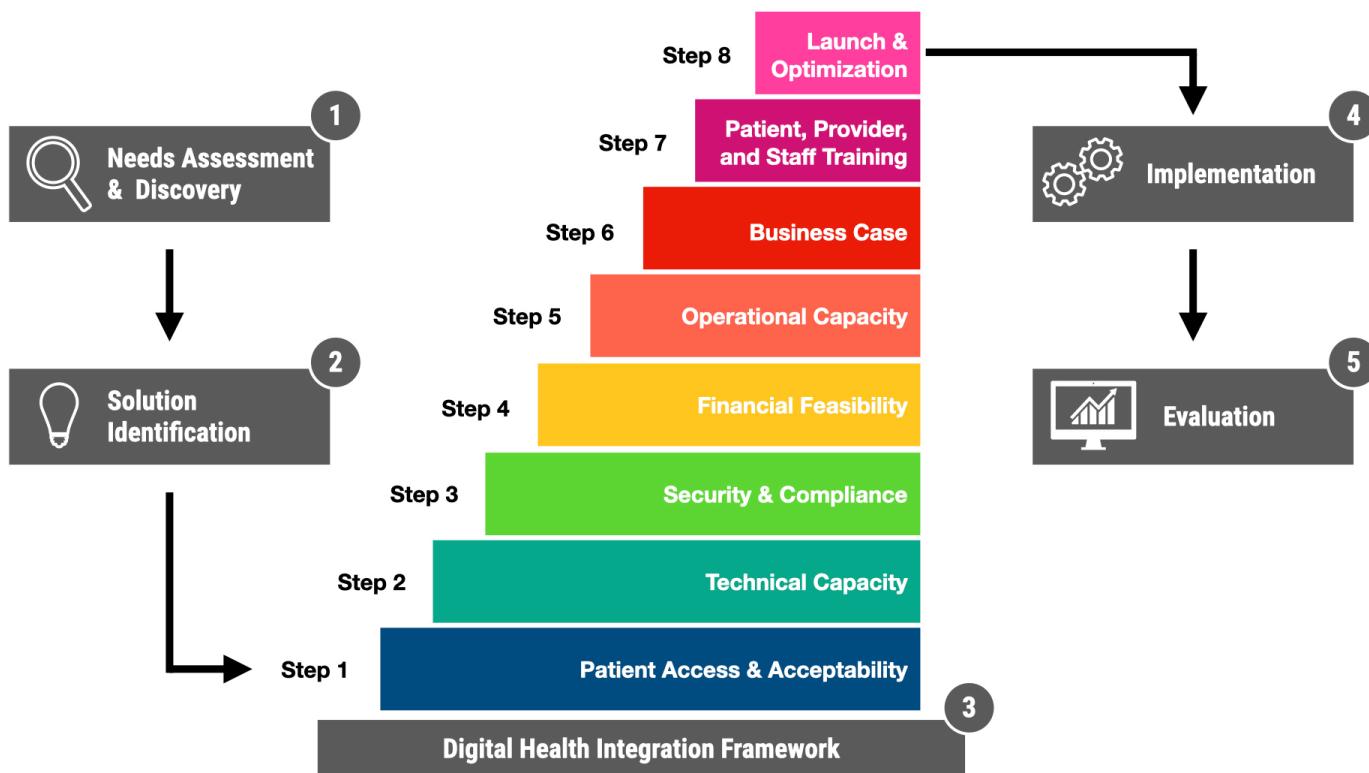
# 4. CGM-EHR Data Integration Project Guide

## 4.1. Introduction

Major aspects of a CGM-EHR data integration program must be described in a cohesive and readable format that is critical for understanding what effort will be needed from a project management perspective. Workgroup 6 primarily focused on creating a comprehensive CGM-EHR Data Integration Project Guide to help guide HCO stakeholders in the initiation and implementation of these types of projects. The creation of the project guide stemmed from a lack of documentation to understand the prerequisites and requirements for a CGM data integration into the EHR. The project guide accomplishes the goal of informing the person of interest by providing a standard framework of best practices and recommendations for the realms of Contracting, Partnership, Project Management, and Business Models. Information was fielded from 1) current HCOs that have implemented or are in the process of implementing an EHR CGM data integration program and 2) CGM manufacturers.

In addition to addressing sections of each project phase (Scoping, Planning, Design, Implementation), the guide also provides a standardized format for a project timeline that can be customized to meet the specific needs of the HCO. We also propose that HCOs use the Diabetes Data and Technology Integration Framework (**Figure 4.1**) to assess their organizational readiness, as well as a project checklist that can be used for self-assessment before attempting to implement a CGM-EHR integration effort.<sup>45</sup>

**Figure 4.1.** Diabetes Data and Technology Integration Framework.



The CGM-EHR Data Integration Project Guide is presented here with certain redactions where it is redundant with other sections of this report. A stand-alone, comprehensive version of the CGM-EHR Data Integration Project Guide is also available from the Diabetes Technology Society:  
<https://www.diabetestechology.org/icode/>

## 4.2. Project Guide

### GOAL

Develop the necessary technical infrastructure so that clinicians can review CGM data within the patient's EHR chart.

### PROJECT SCOPE

This project will allow the following capabilities in the EHR:

- Deliver a summary report as a PDF document to the patient's chart
- Deliver discrete structured data into the results section of the patient's chart
- Optional: Launch a data platform within the EHR to view interactive visualizations for a patient (not included in summary)

### SPECIFIC AIMS

- Establish a scalable process for linking HCO and CGM data platform patient accounts
- Build a data exchange mechanism between HCO and CGM data platform through third party Integration Engine
- Install necessary components at the HCO to view and store data requests and reports

### REFERENCE MATERIALS

- Responsibilities for Execution of clinical Workflows (**Table 3.1, Section 3.2**)
- Clinical Workflow diagrams (**Tables 3.2 and 3.3, Section 3.4**)
- Sample EHR Flowsheet Glucose Statistics (**Figure 3.2, Section 3.7**)
- Sample AGP Report (**Figure 3.3, Section 3.7**)

### DISCRETE DATA/GLUCOSE METRICS AVAILABLE

- We recommend aiming to include all elements of the **iCoDE Core Dataset** available to you in your integration project (**Table 2.1, Section 2.2**)
- CGM manufacturers are also being encouraged to consider expanding and including additional elements of Class II data (**Section 2.1, 2.2**)
- With access to individual glucose readings, an HCO may choose to calculate additional CGM metrics that are not part of the AGP (e.g., GRI, MAGE, GRADE).

### GLUCOSE METRICS SPECIFICATIONS

- HCOs will need to configure time intervals when requesting glucose metrics data. If no specific date interval is configured in the Integration Request process, then the default of 14 days is used.
- If multiple date intervals are requested and approved, the HCO may include a dropdown field in the order to allow a clinician to select a specific interval, or provide date fields to choose a custom date interval.

- Only one order may be placed at a time for glucose metrics. If multiple intervals are approved, then they must still be ordered individually.

## ACCOUNT LINKAGE

- To establish a connection between a CGM Data Platform, Patient account, and your EHR system, an account linkage must occur using data in the EHR and the data platform.
- This patient query or enrollment order must contain the First Name, Last Name, DOB, email address, or other patient identifiers. It is recommended to use a medical record number and/or a unique identifier to increase the success rate of account linkages.
- Data used to identify a patient is dependent on HCO and/or vendor recommendations (see **Section 2.13** for detailed iCoDE recommendations on account linkage)

## PATIENT/REPRESENTATIVE INVITATION TO CREATE DATA PLATFORM ACCOUNT

**Figure 4.2** is an example of a patient/representative email invitation that is used to create a patient account in the CGM data platform and to receive approval to share CGM data with the HCO.

**Figure 4.2.** Diabetes Data and Technology Integration Framework.

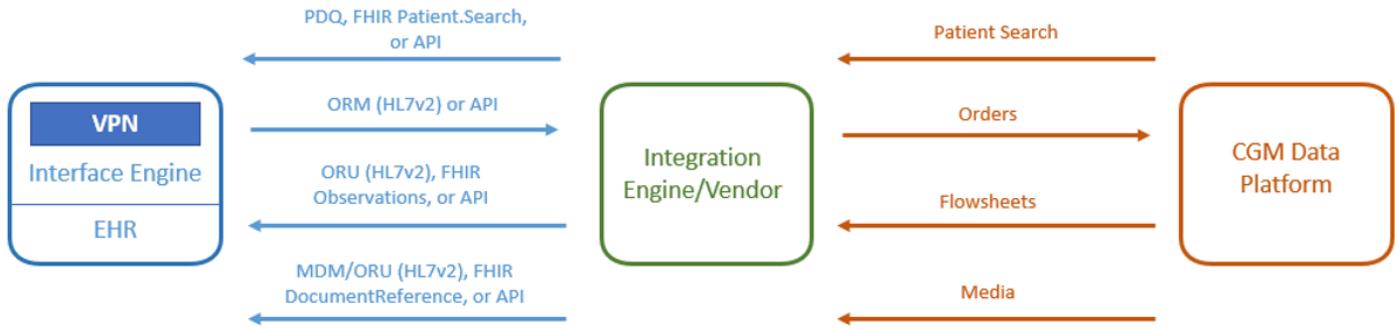
<p><b>CGM Data Platform (CGM Vendor/Platform Name)</b></p> <p>You have an Invitation from (Healthcare Organization Name)</p> <p>(Patient First and Last Name),</p> <p>Your healthcare clinician at (HCO Name) has invited for you to share your diabetes care information, so that you and your healthcare clinician can easily stay connected on your progress.</p> <p>To share your information, you will first need to create a <a href="#">CGM Data Platform</a> account.</p> <p>Signing up is free and only takes a couple minutes to set up.</p> <p>To ensure you are sharing your information with the correct healthcare clinician, please review the healthcare organization information below.</p> <p>If you have any questions about sharing your data with your healthcare clinician, please contact the healthcare organization at the number below. You should decline the invitation request if you do not recognize the healthcare clinician /organization or do not wish to share your data with your healthcare team.</p> <p>(Healthcare Organization name) is located at (Address), (City), (State), (Postal Code). Their office phone number is (HCO/Endocrinology Front Desk Phone Number).</p> <p>By accepting this Invitation, you acknowledge that you are requesting that we are able to share your personal data and reports with your healthcare clinician, who use <a href="#">CGM Data Platform</a> and are professional users at their practice. For more information, please refer to our <a href="#">Privacy Notice</a>.</p> <p>You may click on the button below to accept this invitation and begin the account setup process.</p> <p style="text-align: center;"><a href="#" style="background-color: #0070C0; color: white; padding: 5px 20px; border-radius: 5px;">Accept Invitation</a></p> <p>Have any questions? <a href="#">Learn more at CGM Data Platform</a></p>	<p><b>CGM Data Platform (CGM Vendor/Platform Name)</b></p> <p>You have an Invitation from (Healthcare Org Name) for (Minor First and Last Name)</p> <p>(Parent or Legal Guardian Name),</p> <p>Your healthcare clinician at (HCO Name) has invited for (Minor First and Last Name) to share their diabetes care information, so that your healthcare clinician can easily stay connected on their progress.</p> <p>To share their information, you will first need to create a <a href="#">CGM Data Platform</a> account.</p> <p>Signing up is free and only takes a couple minutes to set up.</p> <p>To ensure you are sharing their information with the correct healthcare clinician, please review the healthcare organization information below.</p> <p>If you have any questions about sharing their data with your healthcare clinician, please contact the healthcare organization at the number below. You should decline the invitation request if you do not recognize the healthcare clinician /organization or do not wish to share their data with your healthcare team.</p> <p>(Healthcare Organization name) is located at (Address), (City), (State), (Postal Code). Their office phone number is (HCO/Endocrinology Front Desk Phone Number).</p> <p>By accepting this Invitation, you acknowledge that you are requesting that we are able to share their personal data and reports with your healthcare clinician, who use <a href="#">CGM Data Platform</a> and are professional users at their practice. For more information, please refer to our <a href="#">Privacy Notice</a>.</p> <p>You may click on the button below to accept this invitation and begin the account setup process.</p> <p style="text-align: center;"><a href="#" style="background-color: #0070C0; color: white; padding: 5px 20px; border-radius: 5px;">Accept Invitation</a></p> <p>Have any questions? <a href="#">Learn more at CGM Data Platform</a></p>
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## DATA EXCHANGE

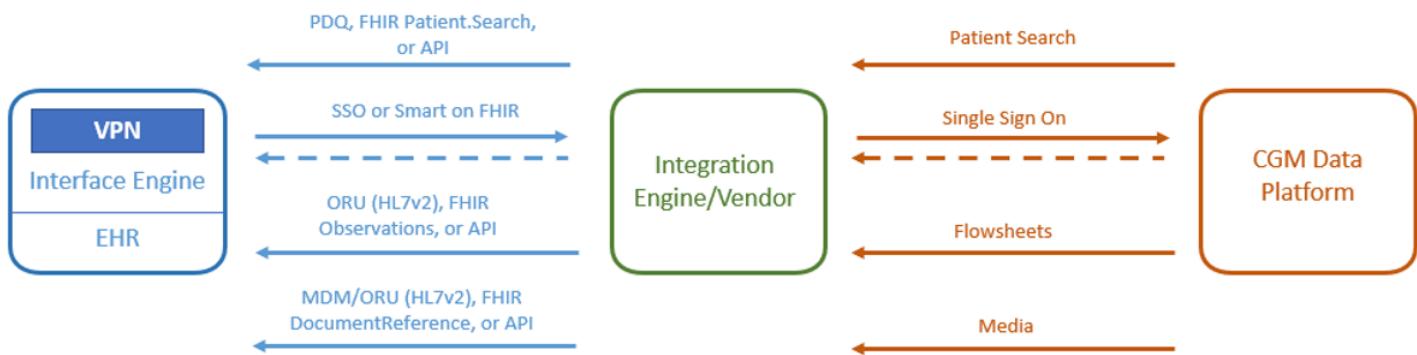
The HCO, Data Platform vendor (either CGM Manufacturer or Aggregator), and third-party integration engine (if required) will need to collaborate on developing the necessary technical infrastructure to facilitate data exchange. The Data Platform vendor and third-party integration engine should meet or exceed all of the HCO's security and technical specifications/requirements.

## HIGH LEVEL DATA INTEGRATION DIAGRAMS

**Figure 4.3.** Data orders/API calls



**Figure 4.4.** Data orders leveraging single sign-on (SSO)



## INFORMATION TECHNOLOGY INSTALLATION

Depending on the HCO, the IT development will fall within two IT depts: clinical information systems (CIS) (Interoperability, Clinical Informatics, and Application Development) and Database Administrators (DBA) / Integrations.

- DBA/Integration will be responsible for handling the data connection between the HCO and third-party Integration Engine.
- CIS will be responsible for developing the order generating interface (CPOE), setting up the FHIR API and/or SMART on FHIR Application, as well as the viewing and storing of the PDF report(s) and Glucose metrics in the EHR.
  - CIS will also work with the CGM Data Platform vendor to define the account linkage process.
  - For IT installs involving FHIR, SMART on FHIR, or Direct/Web API for SAML/OAuth, Application Development will be required to develop connections.

The third-party Integration Engine and CGM Data Platform vendor will both make resources available during development, testing, validation, and go-live support phases.

## **TYPES OF INTEGRATIONS**

iCoDE recommends using a FHIR-first strategy for EHR and third-party apps data transfer, with HL7 version 2.x recommended for use cases where FHIR is not possible or appropriate.

- FHIR API

- HL7 FHIR includes specifications for an Application Programming Interface, or API, based on established web standards and modern information exchange that has been extended to create a full interoperability solution for health care

- SMART on FHIR

- Using FHIR standards for the structure of data, SMART defines how a third-party application should interact with the EHR

- HL7v2 Integration

- An HL7 interface is a data feed that allows the transmission of medical and administrative events in the healthcare setting to different systems

- Direct or Web API

- API integration is the connection between two or more applications, via their APIs, that lets those systems exchange data
  - This type of connection can be used for SAML/OAuth for authentication to the Data platform or to pull other CGM data not made available in other integration types

Other types of integration options may be available and should be discussed between the HCO and CGM data vendor.

## **TECHNICAL REQUIREMENTS - DATA CONNECTION AND MESSAGING**

- VPN and/or TLS connection between Integration Engine and the EHR
  - Active outbound ORM HL7v2 feed or corresponding web service
  - Active inbound MDM HL7v2 feed or corresponding web service

## SAMPLE HL7 ORDERS/MESSAGES

## **Enrollment Order:**

MSH|^~\&| INTEGRATION ENGINE |IGX|||20210420141006||ORU^R01|7071044672|T|2.3|||||||  
PID|1||100017512^^^|Steel^Blue^|19960301||||^~~~~||  
^NET^Internet^newyu.bryce+test+perfect+60@gmail.com|||||10000111391|||||||||||||||  
ORC|RE|1006278593|||||20210420||ETPHYS^^||||||||||||| OBR|1||1006278593|  
737CONNECTION^CGM - DATA SHARING AGREEMENT^||00010101||||||^~~|ETPHYS^^|||||||  
F|~~~~~||||||||||| OBX|1|TX|002^^|Connected|||||F||||~~~~~|||||||

## **Glucose Metrics Request Order:**

MSH|^~\&|INTEGRATION ENGINE|IGX|||20210420141044||ORU^R01|7071128699|T|2.3|||||||  
PID|1||100017512^^^|Steel^Blue^||19960301||||^~~~~~|||||||  
10000111391||||||||||||||| ORC|RE|1006278595|||||||20210420|||  
ETPHYS^^||||||||||||||| OBR|1||1006278595|73730METRICS^CGM - 30 DAYS RESULTS  
REPORT^|||00010101||||||^~~|ETPHYS^^|||||||F||^~~~~~||||||||||||||||||| OBX|1|||  
NM|DW30^Days Worn^||26||Greater than 10 days|||F||| ^~~~~~||||||| OBX|2|NM|  
PERCAP30^Percent Captured^||85||Greater than 70%|||F||| ^~~~~~||||||| OBX|3|NM|

NOS30^Number of Scans^||1|||||F||||^~~~~~||||| OBX|4|NM|TIRATHR30^Time in Target  
 (Above Threshold)^||0||Less than 5%||||F||||^~~~~~||||| OBX|5|NM|TIRABTAR30^Time in  
 Target (Above Target)^||0||Less than 25%||||F||||^~~~~~||||| OBX|6|NM|TIR30^Time in  
 Target^||100||Greater than 70%||||F||||^~~~~~||||| OBX|7|NM|TIRBTAR30^Time in Target  
 Range (Below Target)^||0||Less than 4%||||F||||^~~~~~||||| OBX|8|NM|TIRBTHR30^Time in  
 Target Range (Below Threshold)^||0||Less than 1%||||F||||^~~~~~||||| OBX|9|NM|  
 GMI30^Glucose Management Indicator^||6.0|||||F||||^~~~~~||||| OBX|10|NM|  
 AVG30^Average Glucose^||114|||||F||||^~~~~~||||| OBX|11|NM|COV30^Coefficient of  
 Variance^||30.7||Less than or equal to 36%||||F||||^~~~~~||||| OBX|12|TX|DATERANGE^Date  
 Range^||3/21/2021 - 4/20/2021|||||F||||^~~~~~||||| NTE|1|||

#### **AGP Report Order:**

MSH|^~\&|INTEGRATION ENGINE|IGX|||20210420140706||ORU^R01|7071091231|T|2.3|||||||  
 PID|1||100017514^|||Cavill^Henry^||19830528||||^~~~~~|||||  
 10000111394||||||||||||||| ORC|RE|1006278592|||||||20210420|||  
 ETPHYS^||||||||||||||| OBR|1||1006278592|737REPORT^CGM AGP REPORT^|||  
 00010101|||||||^^^|ETPHYS^|||||||||F||^~~~~~||||||||||||||| OBX|1|ED|001^|||  
 ^PDF^PDF^BASE64^JVBERTi0xLjQKJeLjz9MKNCAwIG9iaiB...

## **4.3. Project Management**

The following sections will focus on providing project focused information to help facilitate CGM data integration projects.

### **PROJECT APPROVALS AND DOCUMENTATION NEEDED**

- *IT Architecture Review*
  - Integration Strategy Guide
  - Data Architecture Documentation
- *Data Governance*
  - List of data elements inbound/outbound between the CGM Data Platform vendor and the HCO
- *EHR Change Control*
- *Information Security*
  - CGM Data Platform vendor internal information security assessment/documentation
  - Security standards to which the CGM adheres

### **INFORMATION SECURITY STANDARDS AND CERTIFICATIONS**

When engaging a CGM device vendor, the following standards/certifications are recommended for the vendor/HCO to have in place before implementation of a data integration in order to protect patient data and comply with HIPAA security requirements.

- *Recommended Information Security Standards*
  - Evidence of NIST 800-53 Controls<sup>46</sup>
  - Evidence of NIST Patient Privacy Controls<sup>47</sup>
  - Annual penetration testing and vulnerability scanning audits
  - OWASP/SAN secure coding practices

- Evidence of IEC 62304 SLDC and Quality Controls
- *Potential Information Security Certifications when appropriate*
  - SOC 2 Type II
    - May be required for insurance or by HCO infosec policies
  - HITRUST certification
    - May be required by HCO infosec policies
- *Other specific types of recommended Information Security Standards*
  - NIST SP800-52, SP800-77, SP800-66, SP800-113, SP800-123, SP800-88, SP800-97
  - FIPS140-2
  - ISO27001/27018, ISO/IEC 29100
  - IEEE 2621: Standard for Wireless Diabetes Device Security Assurance: Product Security Evaluation Program, Protection Profile for Connected Diabetes Devices, and Guidance for Mobile Devices
    - CGM vendor specific standard for medical devices

## CONTRACTS AND AGREEMENTS

- *Clinical Operations*
  - Data Subscription Agreement and Quote between HCO and CGM Data Platform vendor
    - Information Security sections/provisions and/or addendum
  - BAA and MSA between HCO and third-party Integration Engine (if not already using third-party Integration Engine)
    - May bypass if internal HCO Integration can convert JSON API requests to HL7 messaging and vice versa
  - BAA between HCO and CGM Data Platform vendor (depends on HCO)
    - May not be required if the CGM Data Platform vendor has obtained a HIPAA Authorization from the applicable patient
  - HCO Supplier/Vendor Onboarding Form – Vendor Onboarding for A/P (payment)
    - Purchase Order/Invoices
- *Research*
  - Data Use Agreement
  - Pilot Agreement

## INTERNAL STAKEHOLDERS

- Clinical/Project Sponsor
- IT Project Manager
- Endocrinology Clinicians
  - Physicians, RNs, Care coordinators, Diabetes educators, other clinical roles
- DBA/Integration Team
- Clinical Interoperability Team (HL7 specialists)
- Clinical Informatics (Clinical Analyst)
- Application Developer/Engineer (Web services)

## EXTERNAL STAKEHOLDERS

- CGM Data Platform Vendor (CGM Manufacturer or Aggregator)
  - Data/Integrations Team
  - Project Manager

- Third-party Integration Engine Team
- EHR Support team (if implementing FHIR or SMART on FHIR App)

## HIGH LEVEL PROJECT TIMELINE

TASKS	TIME ESTIMATE
<b>EHR CGM Data Integration</b>	<b>Est 6 - 11 Months</b>
<b>Initiation</b>	<b>Est 2 - 3 Months</b>
Develop Business Case/High Level Scope	
Initial Project Discussion - Internal IT/Clinical Team	
Vendor Engagement – CGM Data Vendor and Third-Party Integration Engine	
<b>Planning</b>	<b>Est 2 - 4 Months</b>
Business Requirements Assessment	
Clinical Team Touchpoint w/ CGM Data vendor	
Clinical Team to Design new clinical workflow	
IT Review of Integration Strategy Guide	
Integration Strategy/Data Architecture Discussion	
Integration Project Plan/Schedule Discussion	
Internal Resource Planning	
CGM Data Vendor to finalize and provide project documentation	
List of Final Glucose Metrics/Data Requested	
Final Project Plan (Scope, Stakeholders, Timeline)	
Data Subscription Agreement and Quote	
Information Security Documentation	
Request BAA from Third-Party Integration Engine (if not already using a third- party Integration Engine)	
Project Approvals	
Technology Review Committee Submission/Approval	
Submit project effort for IT review	
Architecture Review Board	
Information Security Review	
Data Governance Committee	

TASKS	TIME ESTIMATE
Legal	
Contract Review/Execution	
Create Purchase Order for vendor invoicing	
<b>Execute</b>	<b>Est 2 - 3 Months</b>
Project Kickoff	
Create/Assess Connectivity w/ Third-Party Integration Engine (VPN and configuration mapping) in test domain	
Create HL7 or FHIR API messages for enrollment order and data request orders (PDFs and/or glucose metrics)	
Create CPOE (HL7) orders or SMART on FHIR App in test domain (Enrollment and Glucose Metrics Orders)	
CGM Data Vendor and HCO to develop/configure Web API	
Functional Testing of Test Environment	
EHR to Third-Party Integration Engine	
Third-Party Integration Engine to CGM Data vendor	
EHR to CGM Data vendor – SAML/OAuth/FHIR	
End User Acceptance Testing	
End User Training	
Communicate Change requests to Third-Party Integration Engine and/or CGM Data vendor	
Functional Testing in Production Environment	
Change Control Review Board - Approval to migrate from test to production	
Push build and integration to Production – HCO/Integration Engine/CGM data vendor	
Testing of all data connection and EHR builds	
End user Testing/Troubleshoot of EHR build and new clinical workflow	
Go Live	
Create Project Support Plan	
Create training guides on new EHR workflow	
Schedule/Assign/Disseminate End User Training	
Schedule Soft Go Live	
Go Live/No Go Decision	
Go Live	

TASKS	TIME ESTIMATE
Closing	
<b>Post Go Live Support - HCO/Integration Engine/CGM data vendor</b>	<b>Est 0 - 1 Months</b>
Project Closure Documentation/Signoff	
Improvement of CGM Data Integration	
New Glucose Metrics/data or additional functionality	Ongoing

## PROJECT READINESS SELF ASSESSMENT

- Review the Diabetes Data and Technology Integration Framework (**Figure 4.1**)
- Journal Article Link: <https://www.frontiersin.org/article/10.3389/fcdhc.2022.867284>

## 4.4. Financial Considerations

### REMOTE PATIENT MONITORING (RPM) BILLING CODES

The code list below (**Table 4.1**) provides the current billing codes that may be charged when using a CGM EHR data Integration to remotely monitor patients, along with reference reimbursement rates by Medi-Cal, California's Medicaid program, as of 3/15/2022. In general, CMS guidance is that if a more specific code is available (like CGM billing) then those should be used, but if not covered, then clinicians can use general RPM codes.

**Table 4.1.** Billing codes relevant to CGM data review.

Code	Code Name	Code Description	Medi-Cal Rate	Patient Contact Required?	Billable Frequency	Requires Physician?
99453	REM MNTR PHYSIOL PARAM SETUP	CPT code 99453 covers the time spent for the initial setup. That includes the onboarding of a patient for RPM services by clinical staff — in other words, the initial explanation of how the device works, and setting up a treatment schedule.	\$17.77	YES	Every 30 days	NO
99454	REM MNTR PHYSIOL PARAM DEV	CPT code 99454 covers monthly remote monitoring of the patient. This includes the supply and use of the medical devices used to remotely monitor and collect patient-generated health data (PGHD). This specifically means data transmission, and does not include time spent educating and setting up the use of the device. 99454 must be billed in conjunction with 99453, and requires the transmission of data from a remote device for a minimum of 16 days within a 30-day period.  Requires review of at least 16 days of data.	\$58.92	NO	Every 30 days	NO

**Table 4.1.** Billing codes relevant to CGM data review.

Code	Code Name	Code Description	Medi-Cal Rate	Patient Contact Required?	Billable Frequency	Requires Physician?
99457	REM PHYSIOL MNTR 1ST 20 MIN	Care Management by Clinical Staff: After analyzing and interpreting remotely collected physiologic data, the data is used to develop a treatment plan and then manage the plan until the targeted goals of the treatment plan are attained. CPT codes 99457 & 99458 are designated as care management services and as such can be provided by clinical staff under the general supervision of the physician or NPP.  Interactive Communication: Services are typically provided remotely using communications technologies that allow interactive communication. Interactive communication, involves, a realtime synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission; as well as, time engaged in non-face-to-face care management services during calendar year. The first 20 minutes of interactive communication is reporting using CPT 99457 and each additional 20 minutes is reported using CPT 99458.	\$44.84	YES	Every 30 days	NO
99458	REM PHYSIOL MNTR EA ADDL 20	Same as above	\$44.32	YES	Every 30 days	NO
99091	COLLECT/ REVIEW DATA FROM PT	After the data collection period for CPT codes 99453 and 99454, the physiologic data that are collected and transmitted may be analyzed by a "physician or other qualified health care professional, qualified by education, training, licensure/regulation." This code includes only professional work and does not contain any direct practice expense (PE). The valuation for CPT code 99091 includes a total time of 40 minutes of physician or NPP work, broken down as follows: 5 minutes of preservice work (for example, chart review); 30 minutes of intra-service work (for example, data analysis and interpretation, report based upon the physiologic data, as well as a possible phone call to the patient); and 5 minutes of post-service work (that is, chart documentation).	\$46.15	NO	Every 30 days	NO
95250	CGM setup and training	Ambulatory continuous glucose monitoring 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.	no Medi-Cal, some private payers	YES	Once when device first deployed	NO
95251	CGM interpretation	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report.	no Medi-Cal, some private payers	NO	Every 30 days	NO

## CGM-SPECIFIC BILLING GUIDES

Some CGM manufacturers also create documentation that explains how to bill for CGM-related services:

- Abbott: <https://provider.myfreestyle.com/pdf/ADC-02243v2.pdf>
- Dexcom:<https://provider.dexcom.com/coding>
- Medtronic: <https://professional.medtronicdiabetes.com/docs/CGM-Billing-and-Reimbursement-Guide.pdf>
- Eversense: <https://www.ascensiadiabetes.com/eversense/health-care-professionals/reimbursement/>

## POTENTIAL REVENUE ESTIMATES

- **Table 4.2** shows gross revenue estimates for data review assuming different rates of encounters captured.
- Additional billing is possible for patient interactions or physician review
- The frequency of billing for code 99091 may depend on individual state and insurer policies

Code	Medi-cal rate	# of patients	Times billed/year	100%	10%	25%	50%
99453	\$17.77	750	1	\$13,327.50	\$1,332.75	\$3,331.88	\$6,663.75
99454	\$58.92	750	1	\$44,190.00	\$4,419.00	\$11,047.50	\$22,095.00
99091	\$46.15	750	12	\$415,350.00	\$41,535.00	\$103,837.50	\$207,675.00
<b>TOTAL</b>				<b>\$472,867.50</b>	<b>\$47,286.75</b>	<b>\$118,216.88</b>	<b>\$236,433.75</b>

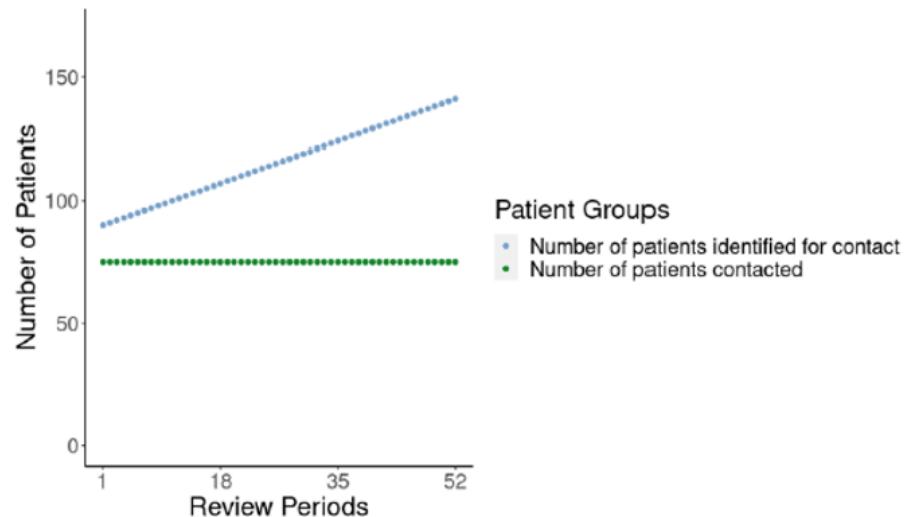
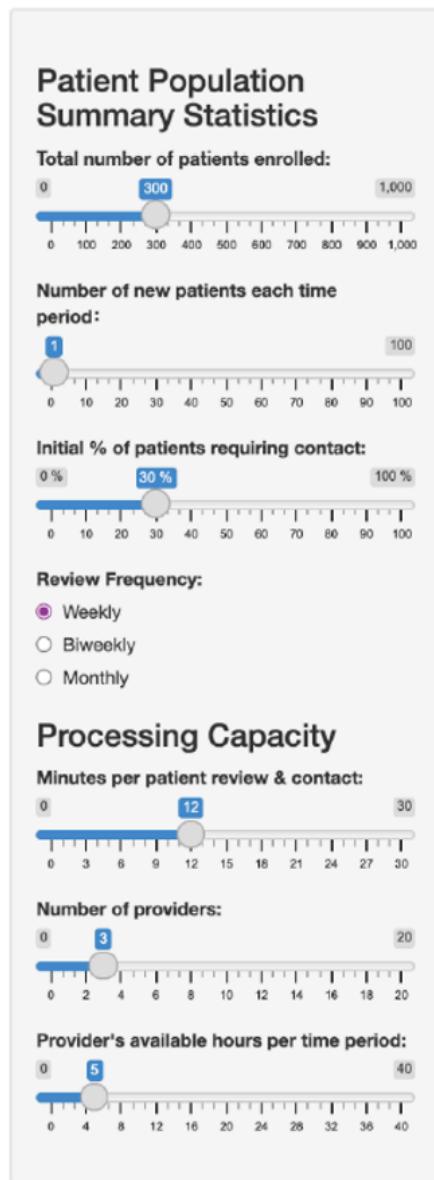
*Gross billing revenue based on percent of encounters captured.*

## REMOTE MONITORING CAPACITY CALCULATOR

The SURF Stanford Medicine Lab (<https://surf.stanford.edu/>), led by Dr. David Scheinker, developed a web-based interactive tool that matches capacity and demand for a remote monitoring T1D clinic with a variety of operational, population, and workforce parameters. The tool contains seven modifiable parameters; generates a table illustrating the match between capacity and demand; displays a timeseries plot of capacity and demand; and calculates three alternative capacity plans that satisfy annual patient demand. It is available online at [www.bit.ly/surf-tide](http://www.bit.ly/surf-tide).

**Figure 4.5.** Example screenshot of the remote monitoring capacity calculator.

## Remote Monitoring Capacity Yearly Projection



Plan	Number of providers	Available hours	Total patient population	Coverage percentage	Matching Demand
Baseline	3	5	300	53	No
Increase # providers	6	5	300	100	Yes
Increase available hours	3	10	300	100	Yes
Decrease total # patients by half	3	5	150	78	No

# Part 5: Summary of Recommendations

# Part 5. Summary of Recommendations

## 5.1 Recommendation Development, Voting, and Adoption

This report provides extensive technical and practical guidance to support the development and implementation of CGM-EHR integrations. We also developed a series of explicit Recommendation Statements to accompany the text and provide guiding principles to all ecosystem stakeholders. Each of the 6 Working Group Chairs created a final summary of their group's thoughts, research, and recommendations. The iCoDE Co-Chairs then synthesized the six summaries into a final report, and derived 54 Recommendation Statements. These Recommendation Statements were then sent to all iCoDE Steering Committee members for feedback and revisions. The feedback was incorporated, and a ballot was sent to all voting members. After the first round of voting, we received additional feedback, and as a result, 13 statements underwent minor revisions (wording, clarifications, examples) and 2 underwent major revisions (change in scope or intent). A revised and final ballot was prepared and sent out to the Steering Committee.

### 5.1.1. Voting Process

Individuals could vote **Yes**, **No**, or **Abstain** on each statement. Since our steering committee included a diverse group of professional backgrounds (e.g, physicians, engineers, nurses, informaticists, attorneys, and patients), The **Abstain** option was included for any person that felt they did not have enough knowledge or expertise to vote on a given statement. Adoption of a recommendation by its approval rate, defined as the total number of **Yes** votes divided by the sum of all **Yes** and **No** votes. **Abstain** votes were not used in the calculation. Statements that received 80% approval or higher were adopted as *Strong Recommendations*. Statements that received between 60% and 79% approval were adopted as *Conditional Recommendations*. Statements that received less than 60% approval were not adopted.

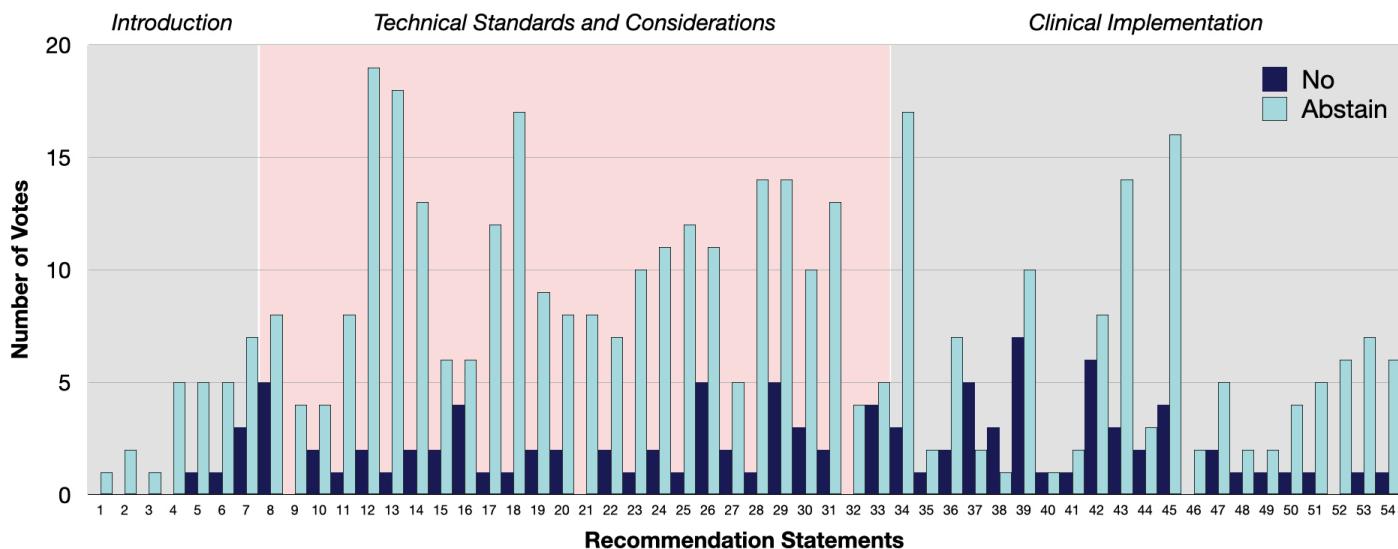
### 5.1.2. Voting Results

We received 90 out of 96 ballots from Steering Committee members eligible to vote (93.8%). All 54 Recommendation Statements were adopted as *Strong Recommendations*. **Table 5.1** shows descriptive statistics of the voting results, and **Figure 5.1** shows the distribution of No and Abstain votes across all recommendations.

**Table 5.1.** Summary of the 90 individual votes on 54 proposed Recommendations received from Steering Committee members.

	Approval Rate	No Votes	Abstain Votes
<b>Average</b>	98%	2	7
<b>Minimum</b>	91%	0	1
<b>Max</b>	100%	7	19
<b>Median</b>	-	2	7
<b>Mode</b>	-	1	2

**Figure 5.1.** Distribution of No and Abstain votes during the Recommendation Statement balloting.



The Recommendation Statements were arranged into 3 groups matching the section of the report from which they were derived:

- Part 1: Introduction
- Part 2: Technical Standards and Considerations
- Part 3: Clinical Implementation

The majority of **Abstain** votes were for the the Technical Standards and Considerations section, which we expected based on the subject matter and the composition of the Steering Committee. In the following sections, each Recommendation Statement is presented alongside its approval rate, **No** votes, and **Abstain** votes.

## 5.2. *Introduction* Recommendation Statements

**Table 5.2.** Recommendation Statements derived from *Part 1: Introduction*

Recommendation Statements (n=7)	Yes	No	Abstain	Approval Rate
HCOs that care for patients with CGMs should pursue CGM-EHR integration as a way to improve patient care, documentation, clinical workflows, and overall quality and outcomes.	89	0	1	100%
All stakeholders who play a role in CGM-EHR integration (HCOs, CGM Manufacturers, payors, government agencies, and others) should be particularly mindful of the impact that social determinants of health and access to technology have on vulnerable populations and their ability to meaningfully access and receive care.	88	0	2	100%

**Table 5.2.** Recommendation Statements derived from *Part 1: Introduction*

<b>Recommendation Statements (n=7)</b>	<b>Yes</b>	<b>No</b>	<b>Abstain</b>	<b>Approval Rate</b>
<b>3</b> Patients retain the right to make decisions about their health data, how it is used, and for what purpose.	89	0	1	100%
<b>4</b> CGM Manufacturers and Aggregators should allow patients to view which institutions are accessing their data, and provide options to manage that access.	85	0	5	100%
<b>5</b> HCOs should notify patients that they are accessing their cloud-based data from CGMs.	84	1	5	99%
<b>6</b> HCOs should add CGM to the categories of data managed by Health Information Management departments, and provide patients with options to access, manage and transfer that data as appropriate, particularly during care transitions.	84	1	5	99%
<b>7</b> Patients should be able to ask HCOs to “disconnect” from their data sources, particularly during care transitions.	80	3	7	96%

### 5.3. Technical Standards and Considerations Recommendation Statements

**Table 5.3.** Recommendation Statements derived from *Part 2: Technical Standards and Considerations*

<b>Recommendation Statements (n=27)</b>	<b>Yes</b>	<b>No</b>	<b>Abstain</b>	<b>Approval Rate</b>
<b>8</b> The iCoDE standards and recommendations only apply to “post-algorithm” data, as defined in section 2.1. “Pre-algorithm” data and code are outside the scope of iCoDE.	77	5	8	94%
<b>9</b> CGM Manufacturers should develop, maintain, and expand the technical infrastructure necessary to make CGM data available for EHR integration.	86	0	4	100%
<b>10</b> CGM Manufacturers and Aggregators should at a minimum be prepared to share the iCoDE Core Dataset, as defined in section 2.2.	84	2	4	98%
<b>11</b> CGM Manufacturers and Aggregators are encouraged to share additional Class 2 data elements as they are developed and made available. Examples of Class 2 data are included in the iCoDE Expanded Dataset, as defined in section 2.2.	81	1	8	99%
<b>12</b> We recommend that CGM Manufacturers and Aggregators adopt the IEEE P1752 family of standards for mobile health data to represent CGM data.	69	2	19	97%

**Table 5.3.** Recommendation Statements derived from *Part 2: Technical Standards and Considerations*

Recommendation Statements (n=27)	Yes	No	Abstain	Approval Rate
<b>13</b> We recommend that CGM manufacturers adopt IEEE 11073 as a data schema for inpatient real-time data.	71	1	18	99%
<b>14</b> We recommend that CGM Manufacturers and Aggregators adopt ISO 8601 to represent time stamps.  Given the importance of day-night cycles in glycemic variability and variations across time zones, We recommend that CGM manufacturers include sufficient time data to both establish the system-standardized time, as well as the relative time for the	75	2	13	97%
<b>15</b> patient. This may be accomplished with two timestamps (for example, a UTC timestamp according to the system; and a user, local, or displayed timestamp) or with a single system timestamp like UTC accompanied by metadata that can guide how to adjust for the users local time zone.	82	2	6	98%
<b>16</b> To enable several data quality and analytics processes, HCOs should track all CGM-provided timestamps (see 15a), as well as timestamps for their own events, including when the data was requested by the the HCO, and whenthe dat was received by the HCO.	80	4	6	95%
<b>17</b> We recommend the creation and adoption of LOINC codes for CGM data as detailed in Table 2.4.	77	1	12	99%
<b>18</b> We recommend that iCoDE manage the process of requesting additional LOINC codes in the future to minimize duplication and confusion.	72	1	17	99%
<b>19</b> CGM data should be mapped to existing common data models as detailed in Table 2.5.	79	2	9	98%
<b>20</b> In order to accommodate the growing number of clinical use cases for CGMs, CGM manufacturers should include in their data model a designation for type of reference range (e.g., T1D, T2D, GDM), as well as the definitions for each tier of the range.	80	2	8	98%
<b>21</b> HCOs that implement CGM-EHR integrations should adopt a data quality evaluation framework that includes the concepts of conformance, completeness, plausibility, and currency.	82	0	8	100%
<b>22</b> We recommend adopting the Adapted Interoperability Framework for CGM Data (Table 2.6) and using it as a way for organizations to assess both their capacity and goals for CGM-EHR integration.	81	2	7	98%

**Table 5.3.** Recommendation Statements derived from *Part 2: Technical Standards and Considerations*

Recommendation Statements (n=27)	Yes	No	Abstain	Approval Rate
<b>23</b> HCOs building CGM-EHR integrations should use a FHIR-first strategy for EHR and third-party apps data transfer, with HL7 version 2.x recommended for use cases where FHIR is not possible or appropriate.	79	1	10	99%
<b>24</b> We recommend a data pull strategy for patient care and clinical applications.	77	2	11	97%
<b>25</b> Data push may be appropriate for population health and panel management applications.	77	1	12	99%
<b>26</b> EHRs are systems of record that were neither intended nor have the capacity to perform complex computations or advanced data transformation and manipulations. HCOs interested in more advanced CGM data applications (not just integration and display) should consider bringing CGM data into a separate data platform, and then pushing data outputs to the EHR as needed.	74	5	11	94%
<b>27</b> As CGM Manufacturers pursue inpatient indications for their devices, they should explore hardware and software solutions to prevent connectivity and safety issues that may arise from multiple CGM systems being in close proximity to each other and trying to connect to receivers and/or the cloud.	83	2	5	98%
<b>28</b> CGMs should comply with IEEE 2621 or a similarly robust industry leading security standard.	75	1	14	99%
<b>29</b> It is reasonable for CGM Manufacturers to be considered covered entities within the context of collecting, sharing, and exchanging patient care data.	71	5	14	93%
<b>30</b> CGM Manufacturers and Data Aggregators should have a unique human readable account ID to facilitate account linkage.	77	3	10	96%
<b>31</b> Account linkage should be initiated on the side of the HCO.	75	2	13	97%
<b>32</b> Account linkage should be performed with the consent of the patient or their representative when appropriate.	86	0	4	100%
<b>33</b> Account linkage should use the minimum number of identifiers to establish patient identity in both systems.	81	4	5	95%

## 5.4. Clinical Implementation Recommendation Statements

**Table 5.4.** Recommendation Statements derived from *Part 3: Clinical Implementation*

Recommendation Statements (n=20)	Yes	No	Abstain	Approval Rate
<b>34</b> A unique CGM account ID is the ideal identifier.	70	3	17	96%
HCOs implementing CGM-EHR integrations may need to designate a multidisciplinary team to support all aspects of				
<b>35</b> integration and workflows. This may include physicians, nurses, CDCEs, medical assistants, medical technicians, front desk, pharmacy, and IT support.	87	1	2	99%
HCOs should establish minimum core professional competencies for team members using diabetes technology in patient care using the competency framework recommended by Patil et al. <sup>40</sup>	81	2	7	98%
<b>36</b>				
<b>37</b> HCOs should make onboarding educational resources available for all patients prescribed a CGM.	83	5	2	94%
<b>38</b> Patient onboarding educational resources created by HCOs should include information about CGM-EHR integration.	86	3	1	97%
<b>39</b> Data upload checklists or guides should be made available to patients with CGM at every visit.	73	7	10	91%
<b>40</b> HCOs should develop standard protocols for data uploads and data pulls into the EHR.	88	1	1	99%
<b>41</b> HCOs should ensure that clinical staff have adequate access to equipment to support in-clinic data uploads when necessary.	87	1	2	99%
<b>42</b> HCOs should ensure that clinicians caring for patients with CGMs have access to adequate screens in order to comfortably access the EHR and data simultaneously. This may include multi-screen, multi-device or large screen setups.	76	6	8	93%
<b>43</b> CGM data should be requested using the CPOE interface of the EHR.	73	3	14	96%
<b>44</b> CGM data should be displayed as results in the EHR. This could be in the laboratory section, or with other monitoring data such as vital signs.	85	2	3	98%
<b>45</b> Continuous, individual CGM glucose readings should not be displayed in tabular format in the EHR. Spot glucose readings may be captured as needed and displayed as discrete values.	70	4	16	95%
<b>46</b> The Observation period (e.g., 14 days, 30 days, 90 days) for CGM metrics should be clearly displayed in the EHR, either as part of the name of the value, or as a distinct structured field.	88	0	2	100%

**Table 5.4.** Recommendation Statements derived from *Part 3: Clinical Implementation*

Recommendation Statements (n=20)	Yes	No	Abstain	Approval Rate
<b>47</b> All components of the iCoDE Core Dataset should be available to be displayed in the EHR.	83	2	5	98%
<b>48</b> The type of CGM (manufacturer, model) being used should be displayed in the EHR.	87	1	2	99%
<b>49</b> The reference ranges used for calculated metrics should be clearly displayed in the EHR.	87	1	2	99%
<b>50</b> If the EHR supports color coding result values, then the HCO should use its existing internal color-coding schema for out of range values for consistency.	85	1	4	99%
<b>51</b> The AGP report that accompanies a given set of CGM metrics should be available in the EHR, either as a PDF or other media file.	84	1	5	99%
<b>52</b> HCOs should establish policies and procedures for continuing to use patient-owned CGMs during inpatient stays.	84	0	6	100%
<b>53</b> HCOs should establish policies and procedures to initiate and connect CGMs during inpatient stays for appropriate patient populations.	82	1	7	99%
<b>54</b> HCOs should ensure access to adequate equipment (e.g., mobile devices, additional screens) to upload and review CGM data during inpatient stays.	83	1	6	99%

## 5.5. List of Recommendation Statements

For easier reading, all statements are presented here again as text without the voting results:

### *Part 1: Introduction (7 Statements)*

1. HCOs that care for patients with CGMs should pursue CGM-EHR integration as a way to improve patient care, documentation, clinical workflows, and overall quality and outcomes.
2. All stakeholders who play a role in CGM-EHR integration (HCOs, CGM Manufacturers, payors, government agencies, and others) should be particularly mindful of the impact that social determinants of health and access to technology have on vulnerable populations and their ability to meaningfully access and receive care.
3. Patients retain the right to make decisions about their health data, how it is used, and for what purpose.
4. CGM Manufacturers and Aggregators should allow patients to view which institutions are accessing their data, and provide options to manage that access.
5. HCOs should notify patients that they are accessing their cloud-based data from CGMs.

6. HCOs should add CGM to the categories of data managed by Health Information Management departments, and provide patients with options to access, manage and transfer that data as appropriate, particularly during care transitions.
7. Patients should be able to ask HCOs to “disconnect” from their data sources, particularly during care transitions.

*Part 2: Technical Standards and Considerations ( 27 Statements)*

8. The iCoDE standards and recommendations only apply to “post-algorithm” data, as defined in section 2.1. “Pre-algorithm” data and code are outside the scope of iCoDE.
9. CGM Manufacturers should develop, maintain, and expand the technical infrastructure necessary to make CGM data available for EHR integration.
10. CGM Manufacturers and Aggregators should at a minimum be prepared to share the iCoDE Core Dataset, as defined in section 2.2.
11. CGM Manufacturers and Aggregators are encouraged to share additional Class 2 data elements as they are developed and made available. Examples of Class 2 data are included in the iCoDE Expanded Dataset, as defined in section 2.2.
12. We recommend that CGM Manufacturers and Aggregators adopt the IEEE P1752 family of standards for mobile health data to represent CGM data.
13. We recommend that CGM manufacturers adopt IEEE 11073 as a data schema for inpatient real-time data.
14. We recommend that CGM Manufacturers and Aggregators adopt ISO 8601 to represent time stamps.
15. Given the importance of day-night cycles in glycemic variability and variations across time zones, We recommend that CGM manufacturers include sufficient time data to both establish the system-standardized time, as well as the relative time for the patient. This may be accomplished with two timestamps (for example, a UTC timestamp according to the system; and a user, local, or displayed timestamp) or with a single system timestamp like UTC accompanied by metadata that can guide how to adjust for the users local time zone)
16. To enable several data quality and analytics processes, HCOs should track all CGM-provided timestamps (see 15), as well as timestamps for their own events, including when the data was requested by the the HCO, and when the dat was received by the HCO.
17. We recommend the creation and adoption of LOINC codes for CGM data as detailed in Table 2.4.
18. We recommend that iCoDE manage the process of requesting additional LOINC codes in the future to minimize duplication and confusion.
19. CGM data should be mapped to existing common data models as detailed in Table 2.5.
20. In order to accommodate the growing number of clinical use cases for CGMs, CGM manufacturers should include in their data model a designation for type of reference range (e.g., T1D, T2D, GDM), as well as the definitions for each tier of the range.
21. HCOs that implement CGM-EHR integrations should adopt a data quality evaluation framework that includes the concepts of conformance, completeness, plausibility, and currency.
22. We recommend adopting the Adapted Interoperability Framework for CGM Data (Table 2.6) and using it as a way for organizations to assess both their capacity and goals for CGM-EHR integration.

23. HCOs building CGM-EHR integrations should use a FHIR-first strategy for EHR and third-party apps data transfer, with HL7 version 2.x recommended for use cases where FHIR is not possible or appropriate.
24. We recommend a data pull strategy for patient care and clinical applications.
25. Data push may be appropriate for population health and panel management applications.
26. EHRs are systems of record that were neither intended nor have the capacity to perform complex computations or advanced data transformation and manipulations. HCOs interested in more advanced CGM data applications (not just integration and display) should consider bringing CGM data into a separate data platform, and then pushing data outputs to the EHR as needed.
27. As CGM Manufacturers pursue inpatient indications for their devices, they should explore hardware and software solutions to prevent connectivity and safety issues that may arise from multiple CGM systems being in close proximity to each other and trying to connect to receivers and/or the cloud.
28. CGMs should comply with IEEE 2621 or a similarly robust industry leading security standard.
29. It is reasonable for CGM Manufacturers to be considered covered entities within the context of collecting, sharing, and exchanging patient care data.
30. CGM Manufacturers and Data Aggregators should have a unique human readable account ID to facilitate account linkage.
31. Account linkage should be initiated on the side of the HCO.
32. Account linkage should be performed with the consent of the patient or their representative when appropriate.
33. Account linkage should use the minimum number of identifiers to establish patient identity in both systems.

### *Part 3: Clinical Implementation*

34. A unique CGM account ID is the ideal identifier.
35. HCOs implementing CGM-EHR integrations may need to designate a multidisciplinary team to support all aspects of integration and workflows. This may include physicians, nurses, CDCES, medical assistants, medical technicians, front desk, pharmacy, and IT support.
36. HCOs should establish minimum core professional competencies for team members using diabetes technology in patient care using the competency framework recommended by Patil et al.<sup>40</sup>
37. HCOs should make onboarding educational resources available for all patients prescribed a CGM.
38. Patient onboarding educational resources created by HCOs should include information about CGM-EHR integration.
39. Data upload checklists or guides should be made available to patients with CGM at every visit.
40. HCOs should develop standard protocols for data uploads and data pulls into the EHR.
41. HCOs should ensure that clinical staff have adequate access to equipment to support in-clinic data uploads when necessary.
42. HCOs should ensure that clinicians caring for patients with CGMs have access to adequate screens in order to comfortably access the EHR and data simultaneously. This may include multi-screen, multi-device or large screen setups.
43. CGM data should be requested using the CPOE interface of the EHR.

44. CGM data should be displayed as results in the EHR. This could be in the laboratory section, or with other monitoring data such as vital signs.
45. Continuous, individual CGM glucose readings should not be displayed in tabular format in the EHR. Spot glucose readings may be captured as needed and displayed as discrete values.
46. The Observation period (e.g., 14 days, 30 days, 90 days) for CGM metrics should be clearly displayed in the EHR, either as part of the name of the value, or as a distinct structured field.
47. All components of the iCoDE Core Dataset should be available to be displayed in the EHR.
48. The type of CGM (manufacturer, model) being used should be displayed in the EHR.
49. The reference ranges used for calculated metrics should be clearly displayed in the EHR.
50. If the EHR supports color coding result values, then the HCO should use its existing internal color-coding schema for out of range values for consistency.
51. The AGP report that accompanies a given set of CGM metrics should be available in the EHR, either as a PDF or other media file.
52. HCOs should establish policies and procedures for continuing to use patient-owned CGMs during inpatient stays.
53. HCOs should establish policies and procedures to initiate and connect CGMs during inpatient stays for appropriate patient populations.
54. HCOs should ensure access to adequate equipment (e.g., mobile devices, additional screens) to upload and review CGM data during inpatient stays.

# Closing Thoughts

The iCoDE standard, developed by Diabetes Technology Society as the convening body, is intended to facilitate CGM data integration into the electronic health record. Hundreds of hours of research, analysis, and discussion by international leaders in CGM data went into this project. Contributions came from experts in manufacturing, data integration, government regulation, medicine (including adult endocrinology, pediatric endocrinology, and primary care), nursing, diabetes education, ontology, informatics, engineering, law, IT, security, and standards development. The project also included patient participation. Through the development of technical standards and clinical implementation processes, an HCO and a CGM manufacturer now have access to a consensus pathway for integration of CGM data into the EHR. The integration will make it easier for patients and clinicians to review, store, and analyze CGM data, leading to better management decisions and improved outcomes. The processes described in iCoDE can also serve as a roadmap for integration of sensor data from other wearable devices besides CGMs in the future. Thus, the iCoDE standard facilitates the collection and use of patient-generated health data, and will ultimately support a precision medicine paradigm for healthcare.



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# Appendices



# A1. References

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# A2. iCode Participants

## iCoDE Leadership and Planning Committee

iCode Role	Name	Title	Affiliation
iCoDE Co-Chair, WG1 Chair	Juan Espinoza	Associate Professor of Pediatrics	Children's Hospital Los Angeles
iCoDE Co-Chair	David Klonoff	Director, Diabetes Research Institute	Mills-Peninsula Medical Center
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Administrative Support	Jingtong Huang	Digital Health Administrator	Diabetes Technology Society
Administrative Support	Nicole Xu	Cybersecurity Administrator	Diabetes Technology Society
Administrative Support	Kevin Nguyen	Bioengineering Administrator	Diabetes Technology Society
Research Support	Payal Shah	Senior Research Associate	Children's Hospital Los Angeles
Research Support	Mahsa Babaei	Postdoctoral Fellow	Children's Hospital Los Angeles
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# A3. Funding Disclosures

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- AI Health
- Ascensia
- Bigfoot Biomedical
- Dexcom
- Diabeloop
- Eli Lilly
- Estenda Solutions, Inc.
- Glytec
- LifeScan
- Medtronic
- Rockley Photonics
- Sanofi
- Teladoc Health
- Terumo
- TransformativeMed
- WellDoc

## A4. Conflicts of Interest

JE was previously a consultant for AI Health. AI Health played no role in the design, execution, analysis, or write up of this work. AI Health did not play a role in the decision to publish this report and had no editorial input.

DCK is a consultant for EOFlow, Fractyl Health, Lifecare, Integrity, Rockley Photonics, and Thirdwayv. AV, MT, SC, RS, AMY, PS, MB, JH, NYX, KTN, JG, SS have nothing relevant to disclose.

*Notes:*

- Conflict of interest statements were only collected for those iCoDE participants who are identified as authors of this report.
- For iCoDE participants and observers affiliated with government agencies, any conflicts are reported and handled per the US Office of Government Ethics (<https://oge.gov/>) and their local agencies policies.

# A5. Policy and Regulation Resources

## CMS regulations relevant for inpatient insulin pump and CGM use

Reference: United States, Centers for Medicare & Medicaid Services, Code of Federal Regulations, 42 CFR § 482.23. 2022

### A-0413 (Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

[§482.23(c)(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.] §482.23(c)(6) (ii) If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to: (A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital. (B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s) and also determine if the patient (or the patient's caregiver/supplier person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s). (C) Identify the specified medication(s) and visually evaluate the medication(s) for integrity. (D) Address the security of the medication(s) for each patient. (E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

### A-0449 (Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.24(c) Standard: Content of Record The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services. Interpretive Guidelines §482.24(c) The medical record must contain information such as notes, documentation, records, reports, recordings, test results, assessments etc. to:  
• Justify admission; • Justify continued hospitalization; • Support the diagnosis; • Describe the patient's progress; • Describe the patient's response to medications; and • Describe the patient's response to services such as interventions, care, treatments, etc. The medical record must contain complete information/documentation regarding evaluations, interventions, care provided, services, care plans, discharge plans, and the patient's response to those activities. Patient medical record information, such as, laboratory reports, test results, consults, assessments, radiology reports, dictated notes, etc. must be promptly filed in the patient's medical record in order to be available to the physician and other care providers to use in making assessments of the patient's condition, to justify continued hospitalization, to support the diagnosis, to describe the patient's progress, and to describe the patient's response to medications, interventions, and services, in planning the patient's care, and in making decisions on the provision of care to the patient.

## The Joint Commission standards relevant for inpatient insulin pump and CGM use

**MM.04.01.01:** Medication orders are clear and accurate.

**Program:** Hospital

**Chapter:** Medication Management

**Introduction:** Medication errors may occur when staff are communicating or transcribing medication orders. Verbal and telephone orders are particularly susceptible to error. The hospital is responsible for reducing the potential for medication errors and the misinterpretation of these medication orders. As part of this process, the hospital determines the required elements of a medication order, the type of medication orders that are deemed acceptable for use, and the actions to take when medication orders are incomplete, illegible, or unclear. Clear understanding and communication between staff and licensed independent practitioners involved in the medication process are essential.

**Rationale:** N/A

### **Elements of Performance:**

1. The hospital follows a written policy that identifies the specific types of medication orders that it deems acceptable for use.
  - Note: There are several different types of medication orders. Medication orders commonly used include the following:
    - As needed (PRN) orders: Orders acted on based on the occurrence of a specific indication or symptom
    - Standing orders: A prewritten medication order and specific instructions from the licensed independent practitioner to administer a medication to a person in clearly defined circumstances
    - Automatic stop orders: Orders that include a date or time to discontinue a medication
    - Titrating orders: Orders in which the dose is either progressively increased or decreased in response to the patient's status
    - Taper orders: Orders in which the dose is decreased by a particular amount with each dosing interval
    - Range orders: Orders in which the dose or dosing interval varies over a prescribed range, depending on the situation or patient's status
    - Signed and held orders: New prewritten (held) medication orders and specific instructions from a licensed independent practitioner to administer medication(s) to a patient in clearly defined circumstances that become active upon the release of the orders on a specific date(s) and time(s)
    - Orders for compounded drugs or drug mixtures not commercially available
    - Orders for medication-related devices (for example, nebulizers, catheters)
    - Orders for investigational medications
    - Orders for herbal products
    - Orders for medications at discharge or transfer
2. The hospital follows a written policy that defines the following:
  - The minimum required elements of a complete medication order, which must include medication name, medication dose, medication route, and medication frequency
  - When indication for use is required on a medication order
  - The precautions for ordering medications with look-alike or sound-alike names
  - Actions to take when medication orders are incomplete, illegible, or unclear

- For medication titration orders, required elements include the medication name, medication route, initial rate of infusion (dose/unit of time), incremental units to which the rate or dose can be increased or decreased, how often the rate or dose can be changed, the maximum rate or dose of infusion, and the objective clinical measure to be used to guide changes
    - Note: Examples of objective clinical measures to be used to guide titration changes include blood pressure, Richmond Agitation–Sedation Scale (RASS), and the Confusion Assessment Method (CAM).
6. The hospital minimizes the use of verbal and telephone medication orders.
  7. The hospital reviews and updates preprinted order sheets, within time frames it identifies or sooner if necessary, based on current evidence and practice.
  8. The hospital prohibits summary (blanket) orders to resume previous medications.
  9. A diagnosis, condition, or indication for use exists for each medication ordered.
    - Note: This information can be anywhere in the medical record and need not be on the order itself. For example, it might be part of the medical history.
  10. The hospital defines, in writing, the circumstances for which weight-based dosing is required for pediatric populations. (See also MM.01.01.01, EP 1)
    - Note: This element of performance is also applicable to sample medications.
  14. The hospital requires an order from a doctor of medicine or osteopathy or, as permitted by law and regulation, a hospital-specific protocol(s) approved by a doctor of medicine or osteopathy to administer influenza and pneumococcal vaccines.
  15. For hospitals that use Joint Commission accreditation for deemed status purposes: Processes for the use of preprinted and electronic standing orders, order sets, and protocols for medication orders include the following:
    - Review and approval of standing orders and protocols by the medical staff and the hospital's nursing and pharmacy leadership
    - Evaluation of established standing orders and protocols for consistency with nationally recognized and evidence-based guidelines
    - Regular review of such standing orders and protocols by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the standing orders and protocols
    - Dating, timing, and authenticating of standing orders and protocols by the ordering practitioner or another practitioner responsible for the patient's care in accordance with professional standards of practice; law and regulation; hospital policies; and medical staff bylaws, rules, and regulations.
  21. For hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home has an electronic prescribing process.

**MM.06.01.03:** Self-administered medications are administered safely and accurately.

Note: The term "self-administered medication(s)" may refer to medications administered by a family member.

**Program:** Hospital

**Chapter:** Medication Management

**Introduction:** N/A

**Rationale:** N/A

**Elements of Performance:**

1. If self-administration of medications is allowed, the hospital follows written processes that guide the safe and accurate self-administration of medications or the administration of medications by a family member (refer to the Glossary for the definition of family). The processes address training, supervision, and documentation. (See also MM.06.01.01, EP 1)
3. The hospital educates patients and families involved in self-administration about the following:
  - Medication name, type, and reason for use
  - How to administer medication, including process, time, frequency, route, and dose
  - Anticipated actions and potential side effects of the medication administered
  - Monitoring the effects of the medication (See also MM.06.01.01, EP 9; PC.02.03.01, EP 10)
7. The hospital determines that the patient or the family member who administers the medication is competent at medication administration before allowing him or her to administer medications.

# A6. Diabetes Technology Competencies

These tables and figures originally appeared in *Patil SP, Albanese-O'Neill A, Yehl K, Seley JJ, Hughes AS. Professional Competencies for Diabetes Technology Use in the Care Setting. The Science of Diabetes Self-Management and Care. 2022;48(5):437-445. doi:10.1177/26350106221120889*. They are reproduced here courtesy of Sage Publishing and the authors.

**Figure 1.** Technology practice levels of competency.

Roles	Licensure, Certification	Specialty Care, Adult and Pediatric (Outpatient and Inpatient settings)	Primary Care, Adult and Pediatric (Outpatient and Inpatient Settings)	Other Settings
<b>Prescriber</b>	MD, DO, PA, NP, PharmD (if applicable, depending on state lic.), medical director of a diabetes specific camp.	Advanced Technology Competencies	Intermediate Technology Competencies	Intermediate Technology Competencies
<b>DCES</b>	DCES who might be CDCES and/or BC-ADM	Advanced Technology Competencies	Intermediate Technology Competencies	Intermediate Technology Competencies
<b>Licensed Non-DCES- Group 1</b>	RN, PharmD, RD, School Nurse, Diabetes Camp Nurse; Camp Healthcare Team; Pediatric Psychologist and CMA in Specialty Setting, Care Coordinator/Case Manager, SNF staff, Long Term Care staff; Exercise Physiologist; Physical Therapist; Occupational Therapist	Intermediate Technology Competencies	Fundamental Technology Competencies	Basic Technology Competencies
<b>Licensed Non-DCES-Group 2</b>	MA/LPN; Social Worker, Psychologist in non-specialty setting, virtual coach, retail pharmacist/tech	Intermediate Technology Competencies	Basic Technology Competencies	Basic Technology Competencies
<b>Non-Licensed Staff</b>	Call center staff, schedulers, patient access coordinators, Diabetes Camp/Camp Counselors, Community Health Worker, group home staff, peer support community	Fundamental Technology Competencies	Basic Technology Competencies	Basic Technology Competencies

**Table 1: DOMAIN 1, STAFF KNOWLEDGE**

<b>BASIC</b>	
<b>1.10</b>	Demonstrate knowledge of glucose meters, CGMs, insulin pumps, and AID systems, including individual components (e.g., pump, infusion set, cartridge, etc.) for patient scheduling and optimizing visits
<b>1.11</b>	Make use of standardized staff education for diabetes technology
<b>FUNDAMENTAL</b>	
<b>1.20</b>	Educate licensed and non-licensed staff to assist all PWD to respond to alarms and alerts
<b>1.21</b>	Educate licensed and non-licensed staff to assist with input of carbohydrate, glucose, and other data into diabetes devices
<b>1.22</b>	Demonstrate awareness of accessibility features of diabetes devices and adaptive devices for people with disabilities
<b>1.23</b>	Demonstrate knowledge of diabetes technology to individualize choices for each PWD
<b>INTERMEDIATE</b>	
<b>1.30</b>	Assess effectiveness of technology based on clinical trial outcomes or real-world evidence
<b>1.31</b>	Demonstrate awareness of current research studies in diabetes technology and direct to clinicaltrials.gov when applicable
<b>1.32</b>	Demonstrate knowledge of basic features and functionality of FDA approved glucose and ketone meters and continuous glucose monitors
<b>1.33</b>	Demonstrate knowledge of accessibility features of diabetes devices and assistive devices and apps for PWD
<b>1.34</b>	Demonstrate knowledge of FDA approved and off-label use of technology to support PWD using glucose and ketone meters and continuous glucose monitors
<b>1.35</b>	Explain device safety including current labeling and recalls related to glucose and ketone meters and continuous glucose monitors
<b>1.36</b>	Create experiential learning opportunities for care team members to wear devices to gain understanding of "on-body" experience
<b>1.37</b>	Inspect the site where PWD is wearing device on the body

Source: Patil SP, Albanese-O'Neill A, Yehl K, Seley JJ, Hughes AS. Professional Competencies for Diabetes Technology Use in the Care Setting. The Science of Diabetes Self-Management and Care. 2022;48(5):437-445. doi:10.1177/26350106221120889.

**Table 2: DOMAIN 2, DEVICE DATA**

<b>BASIC</b>	
<b>2.10</b>	Describe the type of data collected by diabetes devices
<b>FUNDAMENTAL</b>	
<b>2.20</b>	Apply ability to connect device(s) to data sharing platforms or clinic accounts directly or via Apps to upload data
<b>2.21</b>	Compile device data and upload to EHR
<b>2.22</b>	Utilize data sharing platforms

**Source:** Patil SP, Albanese-O'Neill A, Yehl K, Seley JJ, Hughes AS. Professional Competencies for Diabetes Technology Use in the Care Setting. *The Science of Diabetes Self-Management and Care.* 2022;48(5):437-445. doi:10.1177/26350106221120889.

**Table 3: DOMAIN 3, GLYCEMIC TARGETS and DIABETES MANAGEMENT**

<b>BASIC</b>	
<b>3.10</b>	Demonstrate basic knowledge of glycemic targets based on the population and setting
<b>FUNDAMENTAL</b>	
<b>3.20</b>	Identify need to set and change individualized blood glucose meter
<b>3.21</b>	Demonstrate ability to set up and modify settings for blood glucose meters
<b>3.22</b>	Demonstrate ability to follow orders/prescriptions for blood glucose meters
<b>INTERMEDIATE</b>	
<b>3.30</b>	Demonstrate in-depth knowledge of device features and alarms/alerts available with CGM systems and related benefits
<b>3.31</b>	Demonstrate knowledge of CGM consensus guidelines
<b>3.32</b>	Utilize Ambulatory Glucose Profile (AGP) data for pattern management
<b>3.33</b>	Interpret glucose monitoring data (BGM, CGM) to recommend changes to medications and/or behavioral modifications
<b>3.34</b>	Identify need to set and change individualized CGM, and smart pen settings based on needs and preferences of PWD
<b>3.35</b>	Demonstrate ability to set up and modify settings for CGMs, and smart pens and caps
<b>3.36</b>	Identify and incorporate technology in pre-conception counseling (type 1 and type 2)
<b>3.37</b>	Utilize validated written or computerized inpatient insulin protocols that allow for predefined insulin adjustments based on glycemic trends

**Table 3: DOMAIN 3, GLYCEMIC TARGETS and DIABETES MANAGEMENT**

<b>3.38</b>	Discuss the effects of physical activity on glycemia, and possible modifications in the use of technology to optimize glucose levels prior to, during, and after the activity
<b>3.39</b>	Demonstrate ability to complete orders/prescriptions for CGMs, Smart Pens and caps
<b>3.40</b>	Create and implement a process to educate PWD on metrics of AGP and CGM consensus target guidelines
<b>3.40</b>	Demonstrate knowledge of target ranges during pregnancy for patients with diabetes utilizing technology
<b>ADVANCED</b>	
<b>3.41</b>	Identify need to set and change individualized device settings on insulin pumps and automated insulin delivery systems based on needs and preferences of PWD
<b>3.42</b>	Demonstrate ability to set up and change settings in insulin pumps and automated insulin delivery systems
<b>3.43</b>	Demonstrate ability to complete orders/prescriptions for insulin pumps and automated insulin delivery systems
<b>3.44</b>	Demonstrate working knowledge of automated insulin delivery system algorithms and the predicted effect of changes to device settings on glycemic outcomes

Source: Patil SP, Albanese-O'Neill A, Yehl K, Seley JJ, Hughes AS. Professional Competencies for Diabetes Technology Use in the Care Setting. *The Science of Diabetes Self-Management and Care.* 2022;48(5):437-445. doi:10.1177/26350106221120889.

**Table 4: DOMAIN 4, PATIENT EDUCATION, PREPARATION FOR ONBOARDING, AND DURABILITY OF USE**

<b>BASIC</b>	
<b>4.10</b>	Identify resources to support continued use of technology
<b>FUNDAMENTAL</b>	
<b>4.20</b>	Utilize patient education curriculum to support safe, competent, and successful engagement with technology
<b>4.21</b>	Create a process to provide education for the PWD to successfully navigate virtual visits
<b>4.22</b>	Demonstrate use of the electronic health record (EHR) patient portal, if available, and facilitate onboarding the PWD
<b>4.23</b>	Demonstrate awareness of and provide access to non-biased educational materials, including online resources
<b>INTERMEDIATE</b>	
<b>4.30</b>	Demonstrate knowledge of accessibility features of diabetes devices and availability of adaptive devices for people with disabilities
<b>4.31</b>	Demonstrate use of device simulators/apps as a mechanism to prepare for and support device use
<b>4.32</b>	Discuss data sharing options for device data with PWD
<b>4.33</b>	Plan CGM patient education curriculum to support safe, competent, and successful engagement with technology, and associated goals and actions
<b>4.34</b>	Discuss individualized glucose meter, CGM and smart pen settings including alerts, alarms and reminders with PWD
<b>4.35</b>	Identify benefits and limitations of diabetes technologies with special populations including people with disability, older adults, pediatrics, and other groups
<b>ADVANCED</b>	
<b>4.40</b>	Create back up plan for insulin pump device failure
<b>4.41</b>	Plan insulin pump patient education curriculum to support safe, competent, and successful engagement with technology, and associated goals and actions
<b>4.42</b>	Discuss individualized insulin pump settings including automated insulin delivery, alerts, alarms and reminders with PWD

Source: Patil SP, Albanese-O'Neill A, Yehl K, Seley JJ, Hughes AS. Professional Competencies for Diabetes Technology Use in the Care Setting. The Science of Diabetes Self-Management and Care. 2022;48(5):437-445. doi:10.1177/26350106221120889.

# A7. Feedback, Comments, and Updates

The Diabetes Technology Society will maintain and update this document periodically. While this is not intended to be a living document, we intend to make minor revisions every 4-6 months, and major updates every 1-2 years.

The latest information and resources can be found at:

<https://www.diabetestechology.org/icode/>

From this site you will be able to:

- Download the latest version of the iCoDE Report
- Access other iCoDE resources, including LOINC codes, dedicated project implementation guide, and more
- Submit comments, corrections, and feedback
- Suggest future expansions and updates
- Join the iCoDe Consortium
- Connect with individuals who can help support and advise your CGM-EHR Implementation

# 2022 iCoDE Report: CGM-EHR Integration Standards and Recommendations

*Organized by:*



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