Standards and Interoperability

Juan Espinoza, MD

June 28, 2022

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Disclosures

- I receive research funding from FDA, NIDDK, NIMHD, NICHD and NCATS.
- I am a paid consultant for AI Health. AI Health played no role in the design, execution, analysis, or development of this work. AI Health did not play a role in the decision to prepare this presentation and had no editorial input.

Learning Objectives

- Understand the concept of interoperability in healthcare, along with its barriers and facilitators
- Describe the role of standards and the different kinds of health IT standards
- Think critically about standards implementation in Armenia, identify gaps and opportunities

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About Me

- General Pediatrician
- Board Certified Clinical Informaticist
- Co-Director, Clinical Research Informatics Core, SC CTSI
- Director, West Coast Consortium for Technology & Innovation in Pediatrics
- Research focused on patient generated health data, integration and interoperability, health equity, social determinants of health, obesity, and diabetes

Interoperability

Interoperability

"the ability of two or more systems to exchange health information and use the information once it is received."

The Office of the National Coordinator for Health Information Technology (ONC IT)

The Office of the National Coordinator for Health Information Technology

← You are going to see this logo a lot

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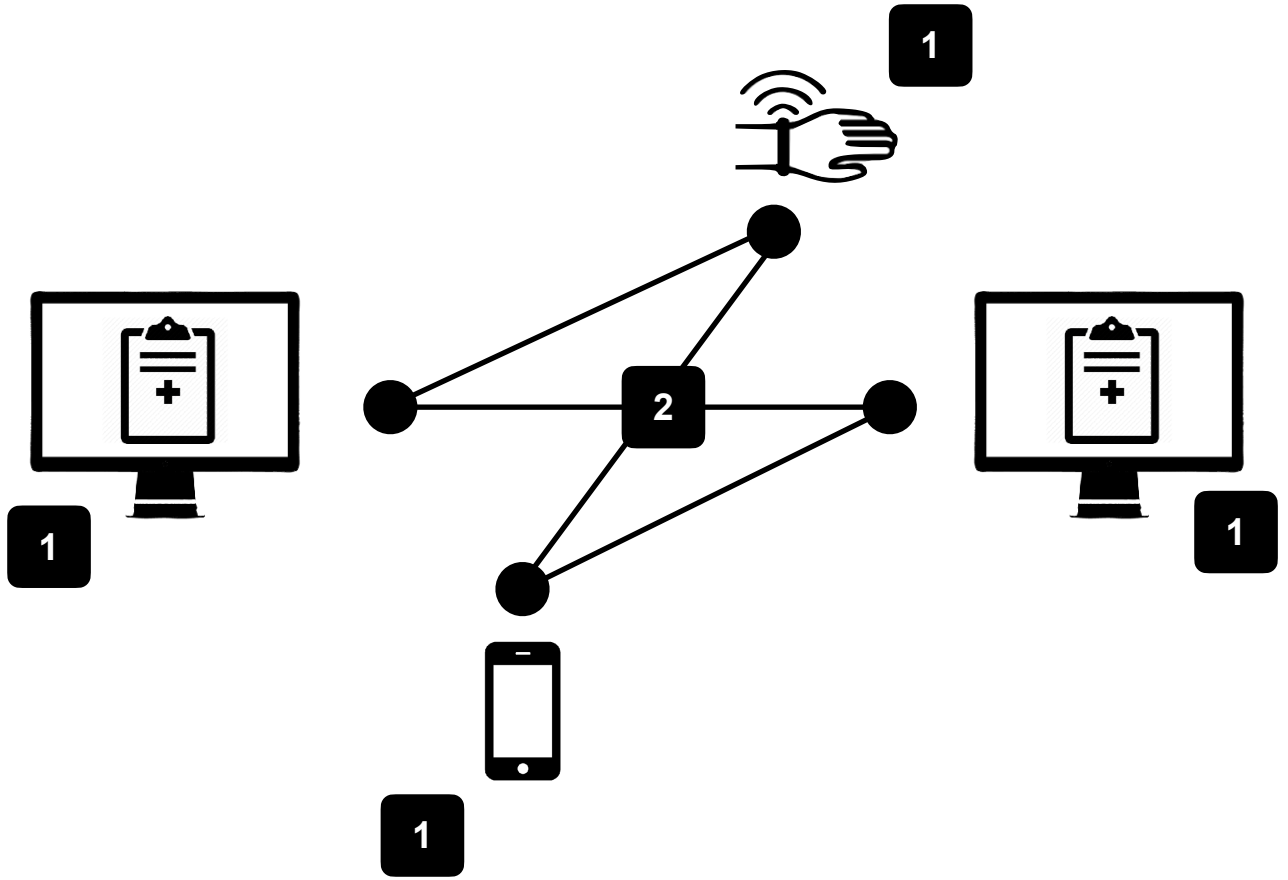
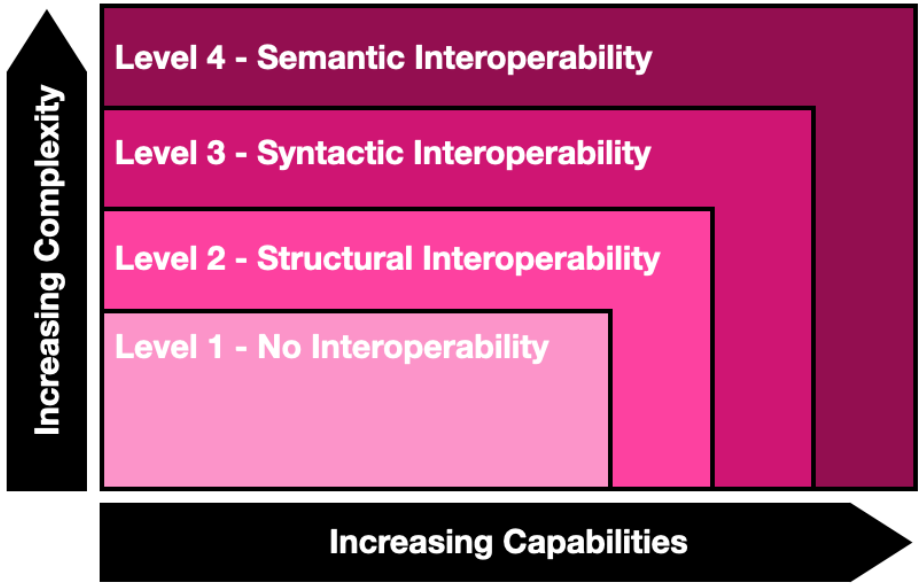
Interoperability requires 2 components:

1. Health information systems, devices and applications
2. Health information exchange services



Levels of Interoperability:

Older Model



Adapted from: Walker J, Pan E, Johnston D, Adler-Milstein J, Bates DW, Middleton B. The value of health care information exchange and interoperability. Health Aff (Millwood). 2005 Jan-Jun;Suppl Web Exclusives:W5-10-W5-18. doi: 10.1377/hlthaff.w5.10. PMID: 15659453.

Newer Model

Foundational (Level 1)	Establishes the inter-connectivity requirements needed for one system or application to securely communicate data to and receive data from another
Structural (Level 2)	Defines the format, syntax and organization of data exchange including at the data field level for interpretation
Semantic (Level 3)	Provides for common underlying models and codification of the data including the use of data elements with standardized definitions from publicly available value sets and coding vocabularies, providing shared understanding and meaning to the user
Organizational (Level 4)	Includes governance, policy, social, legal and organizational considerations to facilitate the secure, seamless and timely communication and use of data both within and between organizations, entities and individuals. These components enable shared consent, trust and integrated end-user processes and workflows

HIMSS

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Standards

Video Time!

Informatics 101: Whats is Interoperability
Vanderbilt School of Nursing
August 28, 2019
https://www.youtube.com/watch?v=LclMadhI7Oo

Standards

What is a standard?

- There's a standard for that!
- ISO, 2004:
  - *A standard document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the optimum degree of order in a given context*

Standards

Why are standards important?

- Promote consistent naming of individuals, events, diagnoses, treatments, etc.
- Allow better use of data for patient care as well as secondary uses, such as quality assurance, research, public health, etc.
- Enhance ability to transfer data among applications, allowing better system integration
- Facilitate interoperability among information systems and users

Standards

Standards throughout history

- Roman chariots
- Railroad tracks
- Telephones
- ASCII text in computers
- Wi-Fi to connect computers, smartphones, tablets, etc. wirelessly to the Internet
- Global financial transactions

Standards

- **Benefits**
  - Interoperability
  - May allow innovation based on common foundation
- **Limitations**
  - Dominance by one segment of industry
  - May stifle innovation
- **May be a mixed bag**
  - Microsoft “standards,” e.g., Windows, Office, etc.
  - Ever hear of Esperanto?
  - “The nice thing about standards is that there are so many of them to choose from.”

Types of Standards

- **Vocabulary/Terminologies**
  - represent discrete concepts unambiguously
- **Identifiers**
  - represent unique individuals
- **Privacy and Security**
  - Protect PII and PHI
- **Content, Exchange and Transport**
  - the format and content of messages between systems

Vocabulary/ Terminologies

Adapted from:

- **Current Procedural Terminology (CPT®):** A code set, maintained by the American Medical Association (AMA), used to bill outpatient and office procedures.
- **Healthcare Common Procedure Coding System:** A set of healthcare procedure codes based on CPT that is used for Medicare reimbursement.
- **ICD-10 and ICD-11:** The International Statistical Classification of Diseases and Related Health Problems (ICD) is a medical classification list by the World Health Organization (WHO). It contains codes for diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases. The 11th revision will replace the ICD-10 in January 2022.
- **Logical Observation Identifiers Names and Codes (LOINC®):** A universal code system for identifying health measurements, observations and documents. These codes represent the “question” for a test or measurement. LOINC codes can be grouped into laboratory and clinical tests, measurements and observations.
- **National Drug Code (NDC):** Maintained by the U.S. Food and Drug Administration, NDC provides a list of all drugs manufactured, prepared, propagated, compounded or processed for commercial distribution.
- **RadLex:** A unified language of radiology terms for standardized indexing and retrieval of radiology information resources, managed by the Radiological Society of North America. It unifies and supplements other lexicons and standards, such as SNOMED-Clinical Terms and DICOM.
- **RxNorm:** A terminology used to normalize names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software. By providing links between these vocabularies, RxNorm can mediate messages between systems not using the same software and vocabulary.
- **Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT)**: A comprehensive clinical health terminology product. It enables the consistent, processable representation of clinical content in electronic health records (EHRs). These codes often represent the “answer” for a test or measurement to the LOINC “question” code.
- **The Unified Code for Units of Measure:** A code system intended to include all units of measures used in international science, engineering and business to facilitate unambiguous electronic communication of quantities together with their units.

Identifiers

- **Enterprise Master Patient Index (EMPI):** A data registry used across a healthcare organization to maintain consistent and accurate data on the patients treated and managed within its departments.
- **Medical Record Number (MRN):** An organization specific code used as a systematic documentation of a patient's history and care during a hospital stay.
- **National Council of State Boards of Nursing ID (NCSBN ID):** A unique identifier automatically generated for each registered nurse and licensed practical/vocational nurse, freely available via the Nursys database and maintained by NCSBN.
- **National Provider ID (NPI):** A unique 10-digit number for a healthcare provider to create a standard identification. These NPIs are included in the free NPI Registry.
- **Object ID (OID):** A globally unique ISO identifier and a preferred scheme for unique identifiers in HL7.

Adapted from:

Privacy and Security

- **In the U.S., the Health Insurance Portability and Accountability Act (HIPAA)** outlines standards that safeguard the privacy and security of protected health information.
- **HIPAA Privacy Rule:** Establishes national standards to protect individuals' medical records and other personal health information. It applies to health plans, healthcare clearinghouses, and healthcare providers that conduct certain healthcare transactions electrically. The rule applies safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures of such information without patient authorization. The rule also gives patients rights over their own health information, including the right to examine and obtain a copy of their records, and to request corrections.
- **HIPAA Security Rule:** Sets national standards for protecting the confidentiality, integrity, and availability of electronically protected health information. Compliance with the Security Rule was required as of April 20, 2005 (April 20, 2006 for small health plans). The rule addresses the technical and non-technical safeguards that "covered entities" must have in place to secure an individual's electronic protected health information. Prior to HIPAA, there were no generally accepted requirements or security standards for protecting health information.
- **In Europe, the General Data Protection Regulation (GDPR)** outlines privacy and security regulations for all processing and storage of data relating to data subjects—or people—in the European Union (EU). This regulation extends to health information and any organization that may process or store data on these subjects, meaning it has extensive reach to many organizations worldwide and related to the sharing of data across organizations.

Adapted from:

HIMSS

Content, Exchange, & Transport

Adapted from:

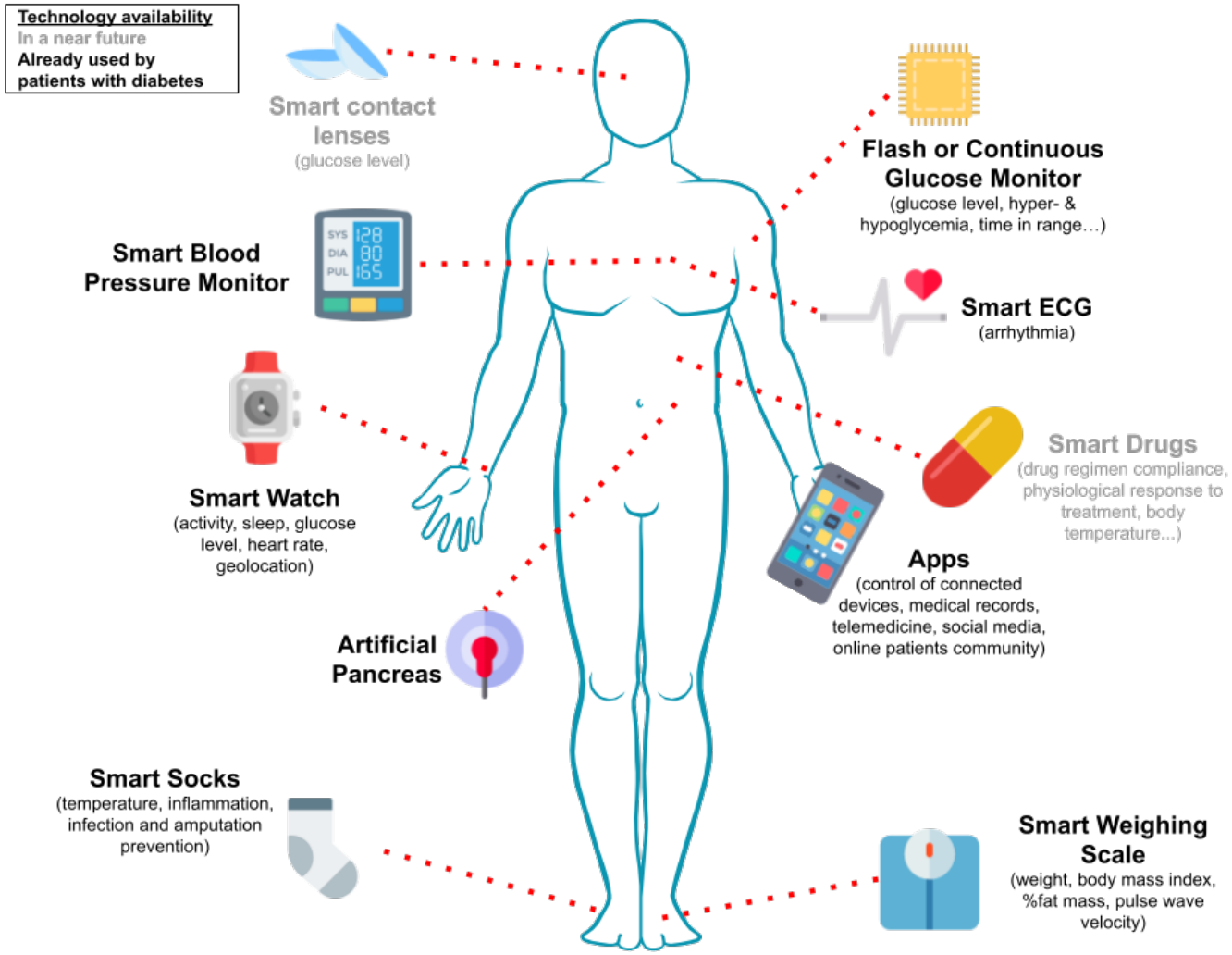
- **Consolidated CDA (C-CDA):** A library of CDA templates, incorporating and harmonizing previous efforts from HL7, IHE, and Health Information Technology Standards Panel (HITSP). It represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination and Continuity of Care Documents, or CCD.
- **HL7's Version 2.x (V2):** A widely implemented messaging standard that allows the exchange of clinical data between systems. It is designed to support a central patient care system as well as a more distributed environment where data resides in departmental systems.
- **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. It defines a clinical document as having the following six characteristics: persistence, stewardship, potential for authentication, context, wholeness and human readability.
- **Digital Imaging and Communications in Medicine (DICOM):** The standard for the communication and management of medical imaging information and related data. DICOM enables the transfer of medical images across systems and facilitates the development and expansion of picture archiving and communication systems.
- **Fast Healthcare Interoperability Resources (FHIR®):** An HL7 standard for exchanging healthcare information electronically. The basic building blocks of FHIR are "resources," which describe exchangeable health data formats and elements. FHIR also provides standardization for application programming interfaces (APIs). FHIR provides a number of benefits and improvements as a modern healthcare standard including facilitating interoperable exchange with legacy standards, lower overhead, shorter learning curve, an ability to transmit only the necessary pieces of information, potential for patient mediated data, and an energized community of supporters and implementers.
- **IHE** provides a number of specifications that can be used in the exchange of health information.
- **Substitutable Medical Applications and Reusable Technologies (SMART):** an open-source, standards-based API that leverages the OAuth 2.0 standard to provide secure, universal access to EHRs. The SMART platform builds on the existing Fast Health Interoperability Resources (hence the name "SMART on FHIR").

Real World Example: iCoDE

Diabetes

A Highly Quantifiable Disease

- BGMs/CGMs
- Insulin Pumps/AIDs
- Smart Insulin Pens
- PROs
- Wearables
- Mobile Applications



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Continuous Glucose Monitors

CLARITY

dexcom
CONTINUOUS GLUCOSE MONITORING

1. CGM uploads data
2. RN logs in to Clarity
3. RN prints report
4. MD reviews report
5. Report scanned into EHR

Workflows

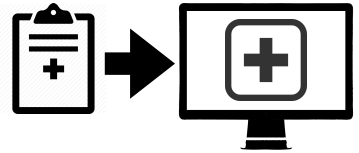
No Workarounds - Just Works

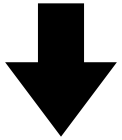
1. 
CGM uploads data

2. 
Staff logs in to platform

3. 
Staff prints report

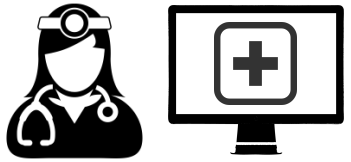
4. 
MD reviews report

5. 
Report scanned into EHR



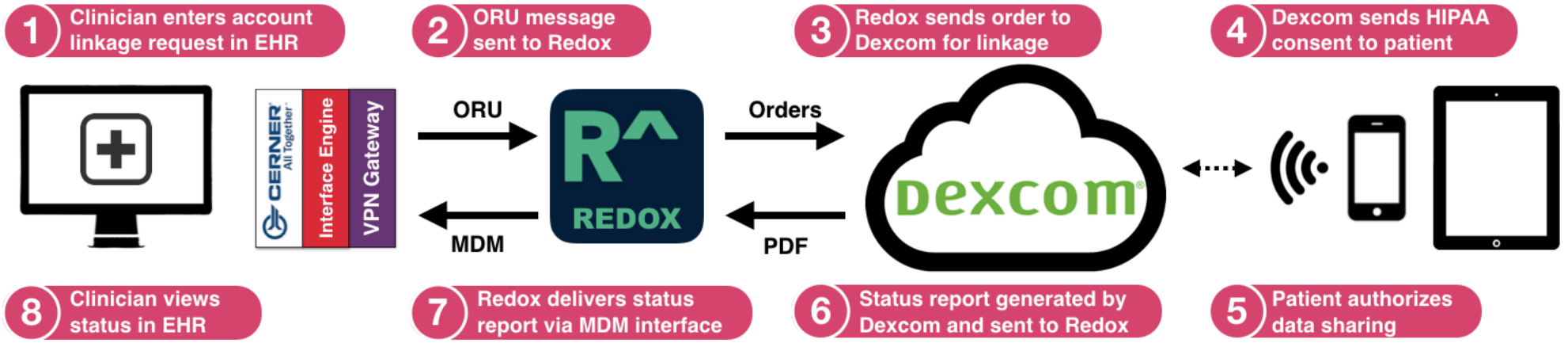
1. 
CGM uploads data

2. 
MD/RN/MA orders CGM data in EHR

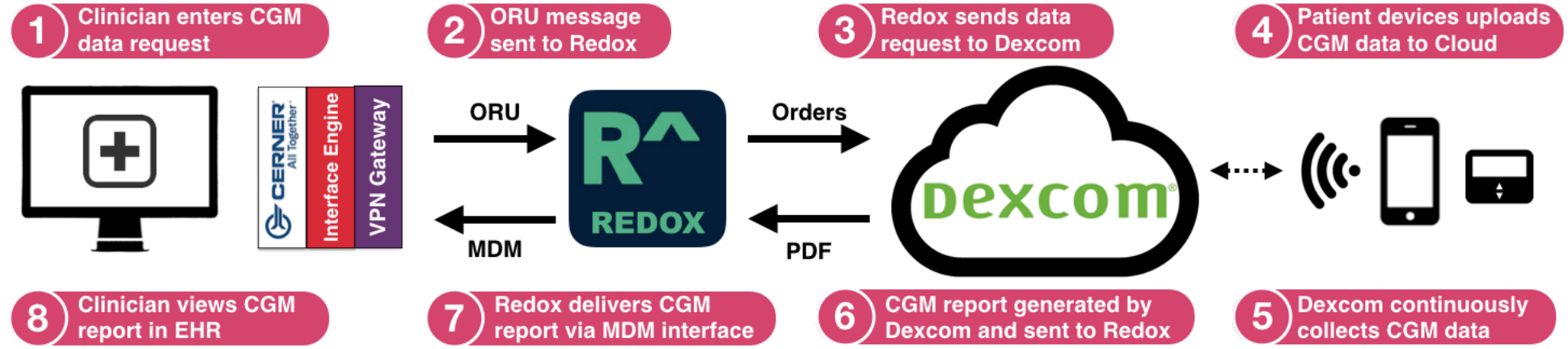
3. 
Data instantly available for Provider review and patient education

Architecture

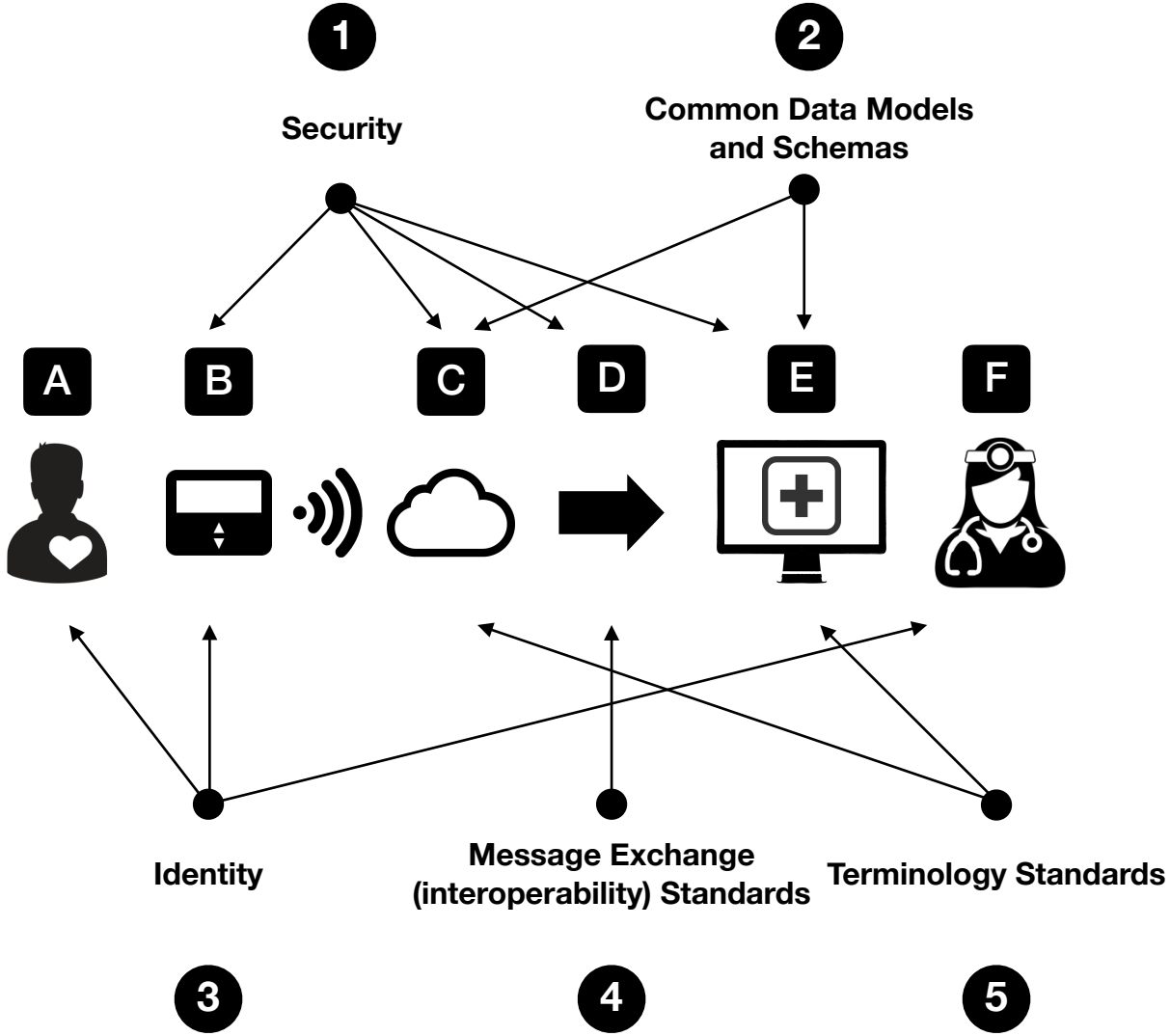
Account Linkage:



Data Request:



Standards & Best Practices



Components of the CGM data pipeline:	
A	Patient
B	CGM Device
C	Cloud Infrastructure
D	CGM-EHR Interface
E	EHR
F	Clinician

Example relevant standards & frameworks:	
1	HIPAA, HITRUST, SOC2, NIST CSF
2	Open mHealth, IEEE, OMOP
3	OAuth 2.0, NPI, EMPI, UDI
4	CCD, CDA, HL7, FHIR, SMART on FHIR
5	LOINC, RxNORM, SNOMED, CPT, ICD-10

Integration of Continuous Glucose Monitor Data into the Electronic Health Record

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Integrating Continuous Glucose Monitor Data Directly into the Electronic Health Record: Proof of Concept

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› J Diabetes Sci Technol. 2021 Jul;15(4):916-960. doi: 10.1177/19322968211016480.

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The Need for Data Standards and Implementation Policies to Integrate CGM Data into the Electronic Health Record

Juan Espinoza, MD, FAAP, Nicole Y. Xu, BA, Kevin T. Nguyen, BA, more... Show all authors

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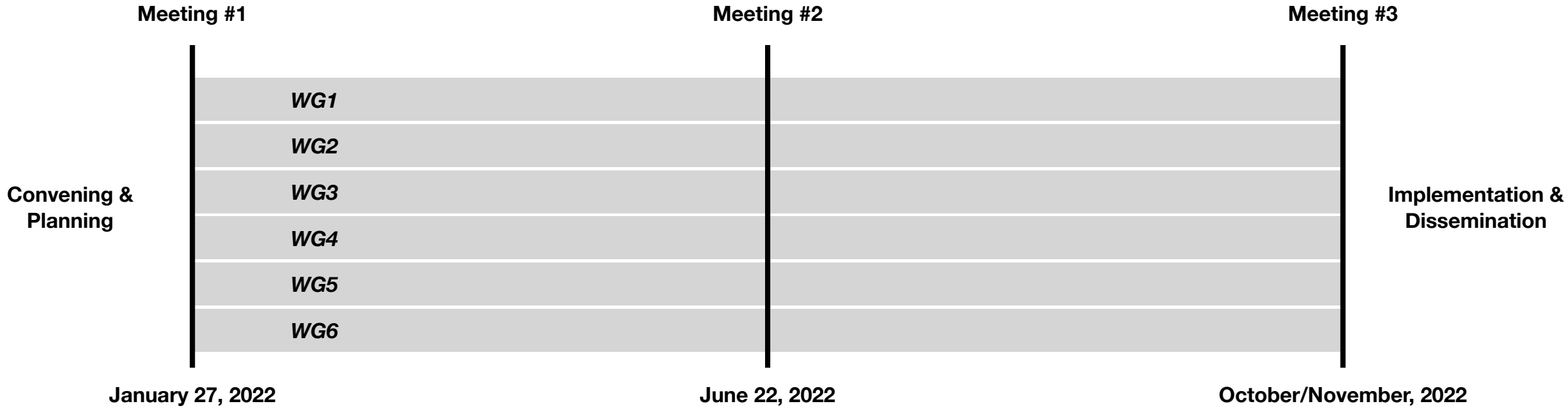
The Launch of the iCoDE Standard Project

Nicole Y Xu [1], Kevin T Nguyen [1], Ashley Y DuBord [2], David C Klonoff [2,3], Julian M Goldman [4], Shahid N Shah [5], Elias K Spanakis [6,7], Charisse Madlock-Brown [8], Siavash Sarlati [2,9], Azhar Rafiq [10], Axel Wirth [11], David Kerr, Raman Khanna [2], Scott Weinstein [12], Juan Espinoza [13]

Integration of Continuous Glucose Monitor Data into the Electronic Health Record



Discussion: Interoperability and Standards in Armenia

Thank You

Please, give me feedback:

https://tinyurl.com/JuanEval

https://airtable.com/shrgBH0ltwKdyyjDW

Contact

Juan Espinoza, MD

Children's Hospital Los Angeles

University of Southern California

jespinoza@chla.usc.edu I @juanespinozamd

Pavetis