The Big Picture of Clinical Decision Support: Bolstering Diverse Decision-Making and Decision-Makers with Standards

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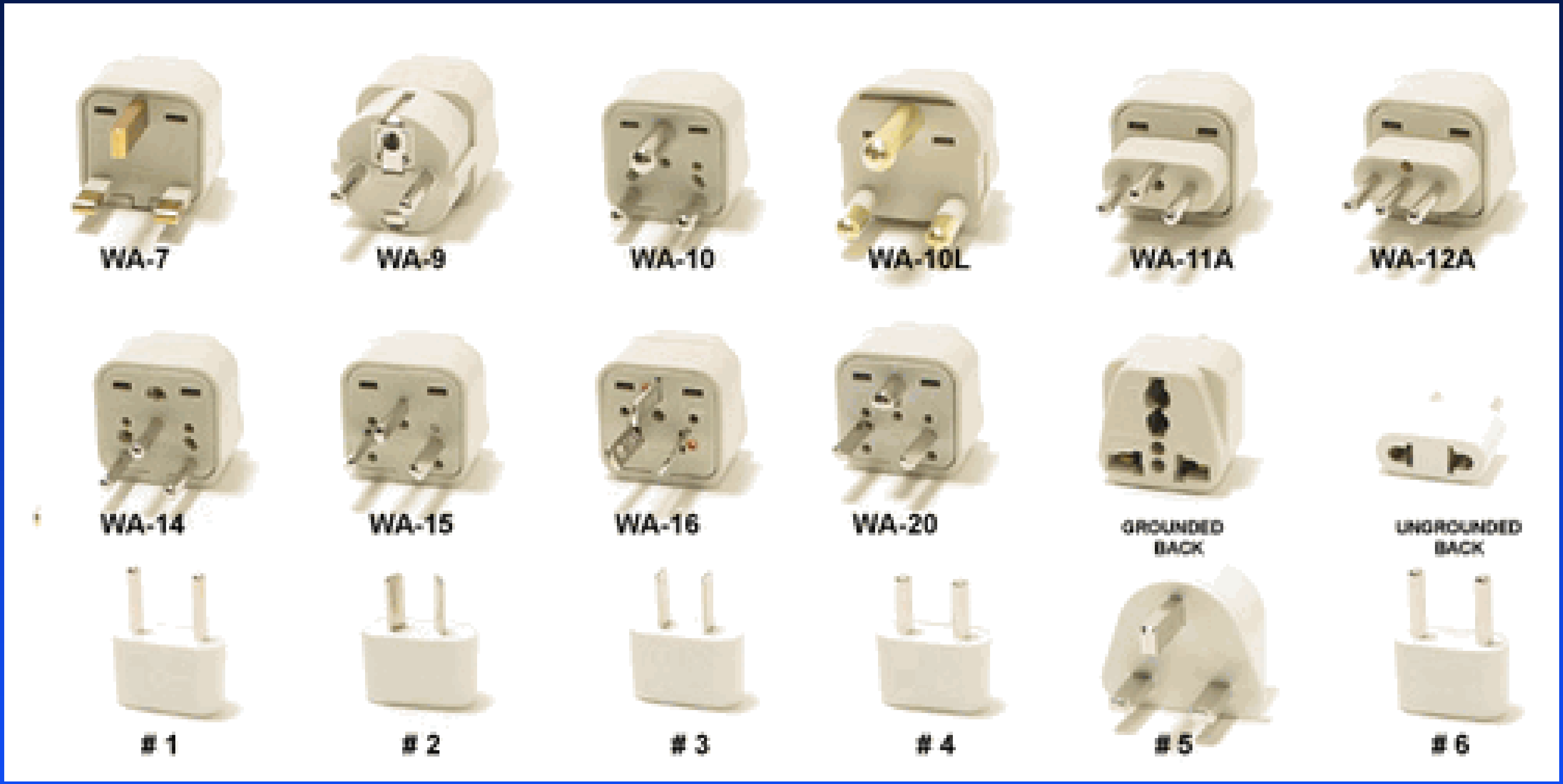
CDS Big Picture: HIT Standards

- **CDS Standards Big Picture: What are they, why do we need them, where do they originate**

- **Current Standards: Purpose, role**
  - **Data Model: FHIR**
  - **Knowledge Sharing: FHIR Clinical Reasoning Arden Syntax, CQL**
  - **Knowledge Access: Infobutton, CDS Hooks**
  - **Framework: SMART on FHIR**

- **Making It Better**
  - **CDSiC: Patient-Centered CDS**
  - **CHAI: Adaptation for AI**

Rationales for Standardization


WA-7
WA-9
WA-10
WA-10L
WA-11A
WA-12A
WA-14
WA-15
WA-16
WA-20
GROUNDED BACK
UNGROUNDED BACK
1
2
3
4
5
6

Standards: Other Domains

- **Aviation METAR**

KSMO 312351Z 22006KT 10SM CLR 23/17 A2979 RMK AO2 SLP086 T02330172 10244 20222 56015

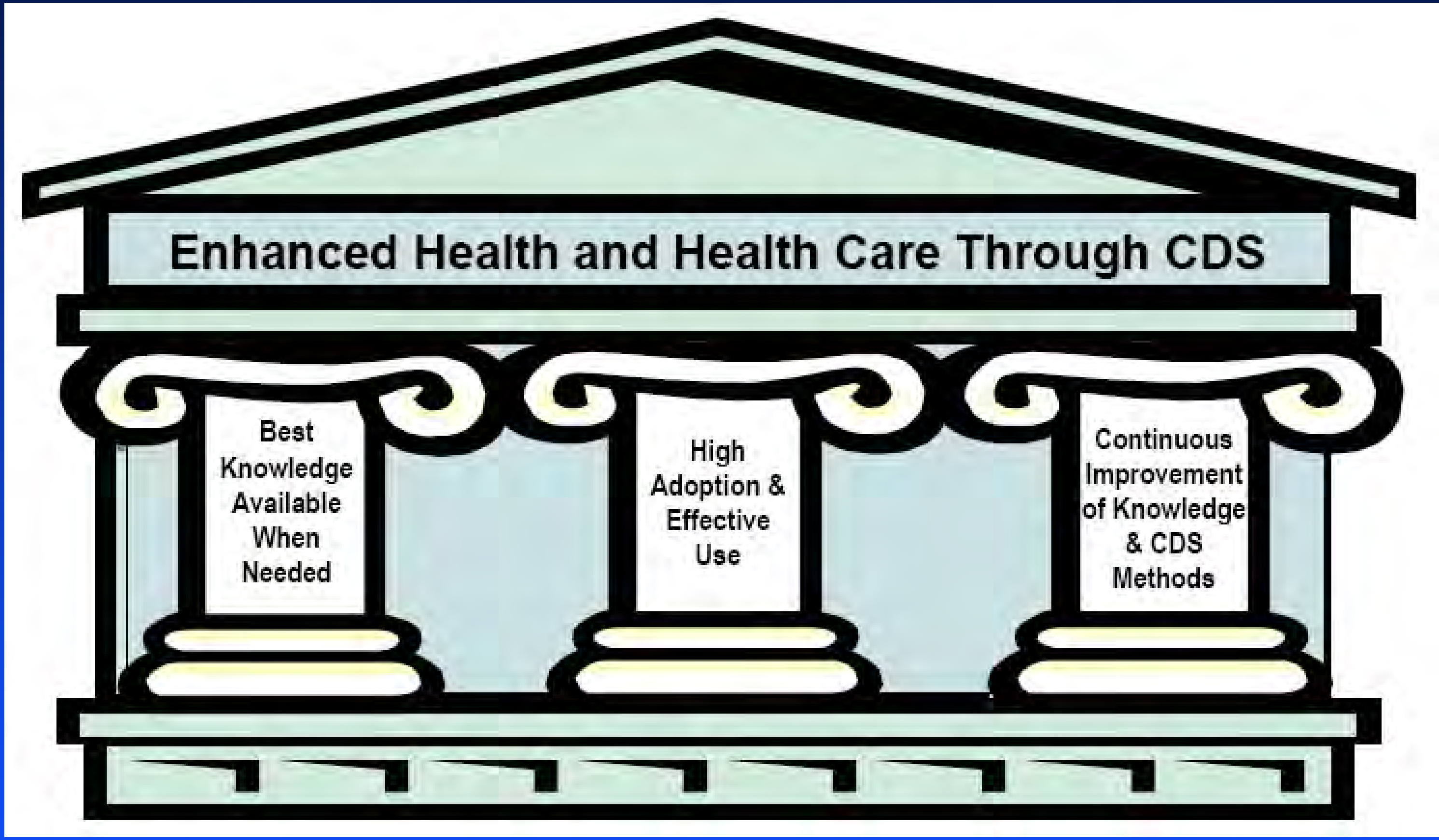
Rationales for Standardization

- **Communication**
  - Understand the transmitted data element
  - Semantic interoperability = Data and knowledge are understood the same at origin and destination
- **Interpretation**
  - Quality improvement: Data analysis & reporting
  - Clinical decision support
- **Computability**
  - Knowledge sharing and reuse
  - Knowledge management: Tools

Rationales for Standardization (continued)

- <u>Conformance / Certification</u>
  - System performance: A CIS that does what it is supposed to do
  - System usability
- <u>Usability</u>
  - Interoperability = Systems can work together without special effort

CDS National Roadmap: Three Pillars



Jenders RA, Morgan M, Barnett GO. Use of open standards to implement health maintenance guidelines in a clinical workstation. Comput Biol Med 1994;24:385-390.

Rationales for Standardization: CDS

Journal of the American Medical Informatics Association Volume 12 Number 4 Jul / Aug 2005 365

Focus on e-Prescribing

AMIA Position Paper ■

Clinical Decision Support in Electronic Prescribing: Recommendations and an Action Plan

Report of the Joint Clinical Decision Support Workgroup

JONATHAN M. TEICH, MD, PHD, JEROME A. OSHEROFF, MD, ERIC A. PIFER, MD, DEAN F. SITTIG, PHD, ROBERT A. JENDERS, MD, MS, THE CDS EXPERT REVIEW PANEL

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Introduction: Rationale for CDS

- <u>Unmet information needs</u>: Approximately 1 question/2 patients, approximately half unanswered (Del Fiol 2018 [systematic review])
- <u>Care of common conditions</u>: Guideline-adherent care in only half of cases
- <u>Precision Medicine</u>: Increasing amounts of (genomic and proteomic) patient-specific data needed to make decisions, particularly for choosing treatment
- <u>Goal</u>: Intelligent assistant that can support decision-makers (clinicians, patients) in making evidence-based choices (diagnosis, treatment) == AI broadly defined
- <u>Tradeoffs</u>: Like anything in clinical medicine
  - Con: Alert fatigue (interruptive, volume, false-positive), costs (acquisition, maintenance), etc

Introduction: Artificial Intelligence

- AI: Academic discipline since the 1950s. (It's not all ChatGPT!)
- Key to Clinical Decision Support from its inception: Focus on reasoning, knowledge representation, planning and natural language processing
  - Important in diagnostic decision support: DXplain, Iliad, QMR, etc
- Relevance of standards
  - Knowledge sharing and reuse to facilitate computer-based reasoning
  - Incorporation of CDS in EHR systems
- AI History: Cycles of boom and bust, lately popular because of deep learning (ANNs) and transformer technology

HL7 Structure: Clinical Decision Support

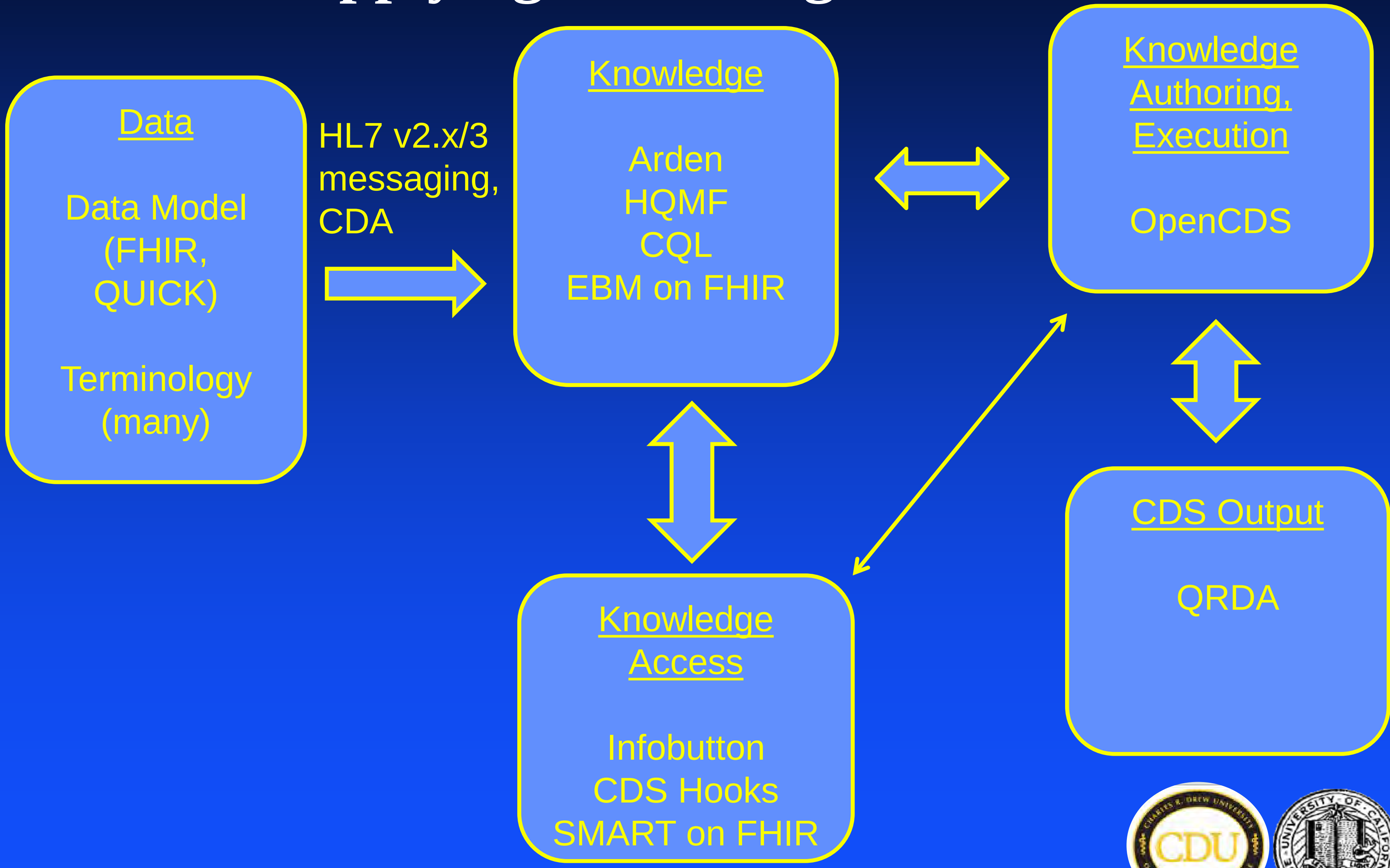
- **Heavily consensus-based, multilayer voting approval process (WGs & membership-wide)**
- **Clinical Decision Support Work Group (Jenders, Kawamoto, Rhodes, Strasberg, Vetter)**
  - **Contribute to data models, inform CDS aspects of other HL7 work, develop overall decision support system model**
- **Arden Syntax WG (Jenders, Haug)**
  - **Smaller committee focused specifically on this particular standard for knowledge sharing**
- **Clinical Quality Information WG**
  - **CDS focused on quality measurement/improvement**

hl7.org, confluence.hl7.org

Other Organizations

- <u>CEN TC 251</u>: Some CDS-specific (knowledge metadata, HIT safety risk classification), but mainly related standards (security, person identifiers, vocabulary maintenance)
- <u>Joint Initiative Council for Global Health Informatics Standardization (JIC)</u>: Coordinate health informatics standards internationally
  - 9 SDOs: CDISC, LOINC, GS1, HL7, IHTSDO, ISO TC215, CEN TC215, IHE, DICOM
- <u>Object Management Group (OMG)</u>: Work with HL7 on business process modeling
- <u>Clinical Decision Support Innovation Collaborative</u> (CDSiC): Work groups promoting use of CDS, including patient-centered CDS
  - https://cdsic.ahrq.gov/cdsic/home-page

CDS "Big Picture": Applying Knowledge to Data



Addressing the CDS Standards Challenge: HL7

- **Knowledge Transfer**
  - Procedural/Executable: Arden Syntax, CQL
  - Declarative: HQMF

- **Knowledge Access**
  - Infobutton, CDS Hooks, SMART on FHIR

- **Infrastructure**
  - Data models: FHIR

Standard Data Models

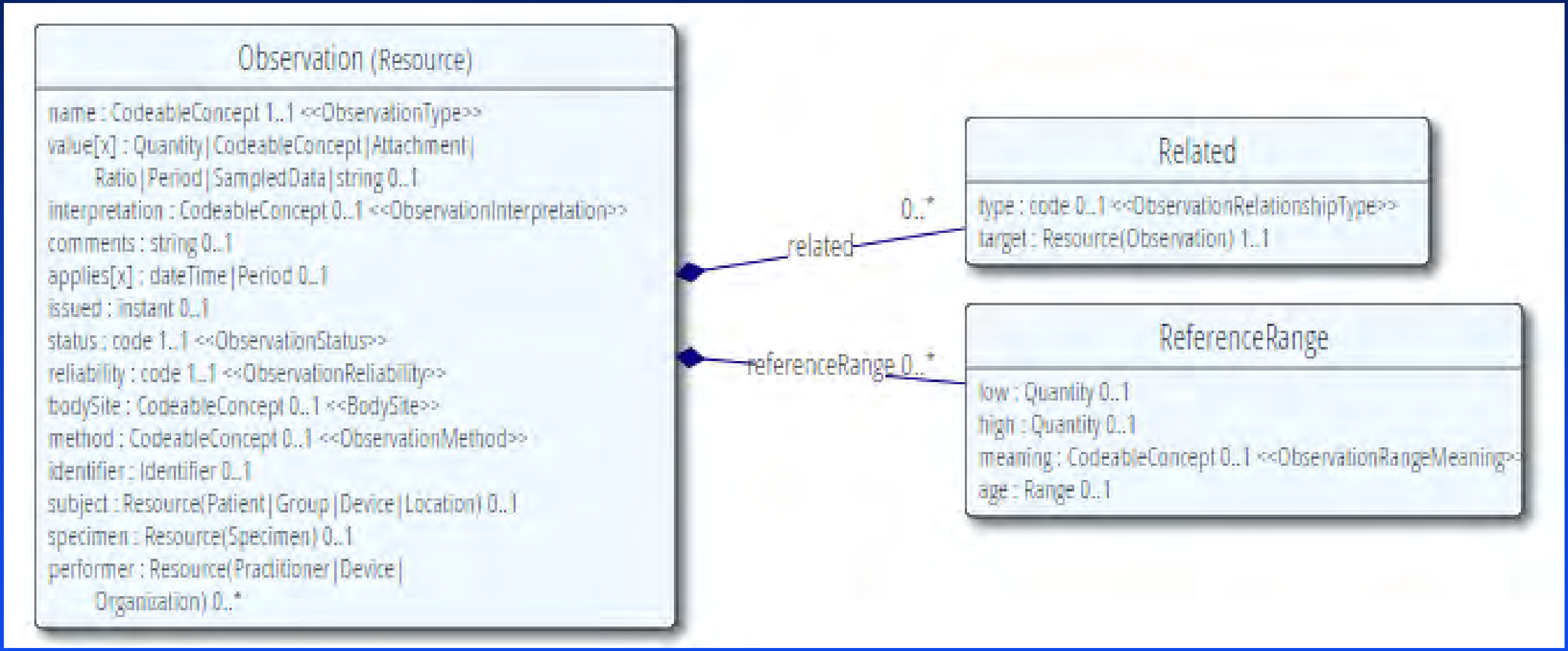
- <u>Candidates</u>
  - FHIR = Fast Health Interoperable Resources
  - RIM = HL7 Reference Information Model
  - CDISC SDTM
  - OMOP CDM
  - i2b2
- <u>Purpose</u>: Promote semantic interoperability
  - Data stored, retrieved, interpreted, displayed and analyzed with the same meaning as when first captured
  - “Big Data” -> Secondary use of clinical data
  - References to data (CDS, research studies, etc) can be shared regardless of vendor or implementation

FHIR®©

- **FHIR = Library of resources**
- **Resource: Primitive XML or JSON object that represents a data element, including terminology bindings**
  - **Object with attributes representing a (more or less) atomic concept**
  - **Patient, provider, blood pressure, etc**
- **Profile: Define how resources are used, nested or inter-related**
- **Value: Standardize structure and references to data**

http://www.hl7.org/fhir/

FHIR®©



Observation (Resource)
name : CodeableConcept 1..1 <<ObservationType>>
value[x] : Quantity | CodeableConcept | Attachment | Ratio | Period | SampledData | string 0..1
interpretation : CodeableConcept 0..1 <<ObservationInterpretation>>
comments : string 0..1
applies[x] : dateTime | Period 0..1
issued : instant 0..1
status : code 1..1 <<ObservationStatus>>
reliability : code 1..1 <<ObservationReliability>>
bodySite : CodeableConcept 0..1 <<BodySite>>
method : CodeableConcept 0..1 <<ObservationMethod>>
identifier : Identifier 0..1
subject : Resource(Patient | Group | Device | Location) 0..1
specimen : Resource(Specimen) 0..1
performer : Resource(Practitioner | Device | Organization) 0..*
related
0..*
Related
type : code 0..1 <<ObservationRelationshipType>>
target : Resource(Observation) 1..1
referenceRange 0..*
ReferenceRange
low : Quantity 0..1
high : Quantity 0..1
meaning : CodeableConcept 0..1 <<ObservationRangeMeaning>>
age : Range 0..1

FHIR Example: Patient

```xml
<Patient xmlns="http://hl7.org/fhir">
  <extension url="http://www.goodhealth.org/consent#trials">
    <valueCode value="renal"/>
  </extension>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml">
      <p>Henry Levin the 7th</p>
      <p>MRN: 123456</p>
    </div>
  </text>
  <identifier>
    <use value="usual"/>
    <label value="MRN"/>
    <system value="http://www.goodhealth.org/identifiers/mrn"/>
    <value value="123456"/>
  </identifier>
  <name>
    <family value="Levin"/>
    <given value="Henry"/>
    <suffix value="The 7th"/>
  </name>
  <gender>
    <text value="Male"/>
  </gender>
  <birthDate value="1932-09-24"/>
  <managingOrganization>
    <reference value="Organization/2"/>
    <display value="Good Health Clinic"/>
  </managingOrganization>
  <active value="true"/>
</Patient>
```

Extension with URL to definition

Human Readable Summary

Standard Data:
- MRN
- Name
- Gender
- Birth Date
- Provider

FHIR Clinical Reasoning Module

- Resources and operations for the representation, distribution and evaluation of clinical knowledge artifacts
- Artifacts (can encode ML classifiers): CDS rules, quality measures, public health indicators, order sets, clinical protocols, evidence summaries
- Describes how expression languages can be used to provide dynamic CDS
- Key resource: PlanDefinition

FHIR PlanDefinition Resource

- Common format for knowledge artifacts: Event/condition/action rules, order sets, protocols

- Components
  - Artifact identity
  - Metadata: Publisher, status
  - Action definitions (actions to be taken)
  - Trigger definitions (which could refer to AI functionality such as classifiers)
  - Expression logic (e.g., CQL library)

Data Model Utility: LADR

- Los Angeles Data Resource: Limited data set managed by UCLA CTSI of operational clinical data from HCOs in Los Angeles County
- Architecture: Federated i2b2 nodes linked via SHRINE
- Data: Lab observations, vital signs, demographics, problem lists, medications
- Purpose: Cohort discovery, hypothesis generation
- Status: Data on 7M patients

https://www.ladr.org/

Mukherjee S, Jenders RA, Delta S. Designing an innovative data architecture for the Los Angeles Data Resource (LADR). Stud Health Technol Inform 2015;216:1055.

Arden Syntax for Medical Logic Modules

- Modular knowledge bases which are independent from one-another
- Share & reuse medical knowledge
- Procedural representation of medical knowledge
- Discrete units of knowledge = Medical Logic Module (MLM)
- Explicit definitions for data elements
- HL7 / ANSI / ISO Standard
- Current version: 2.10 (published 2014), v3 in progress
- Implemented by several vendors

Arden Syntax: Evolving with User Demand

- **Moving away from relatively simple, clinician-friendly expressions to more powerful computability**
- **v2.7: Complex objects**
- **v2.8 (2011): Switch statement, complex list operators**
- **v2.9 (2012): Fuzzy logic**
- **v2.10 (2014): ArdenML = Complete XML version**
- ***v3.0* (2023): Standard data model (FHIR)**

Medical Logic Module

- MLM = an independent unit in a health knowledge base
- MLM: Makes a single health decision
  - maintenance information
  - links to other sources of knowledge/data
  - logic
- MLM = a stream of text stored in an ASCII file in statements called slots
- Purpose: Standard format so that knowledge can be shared

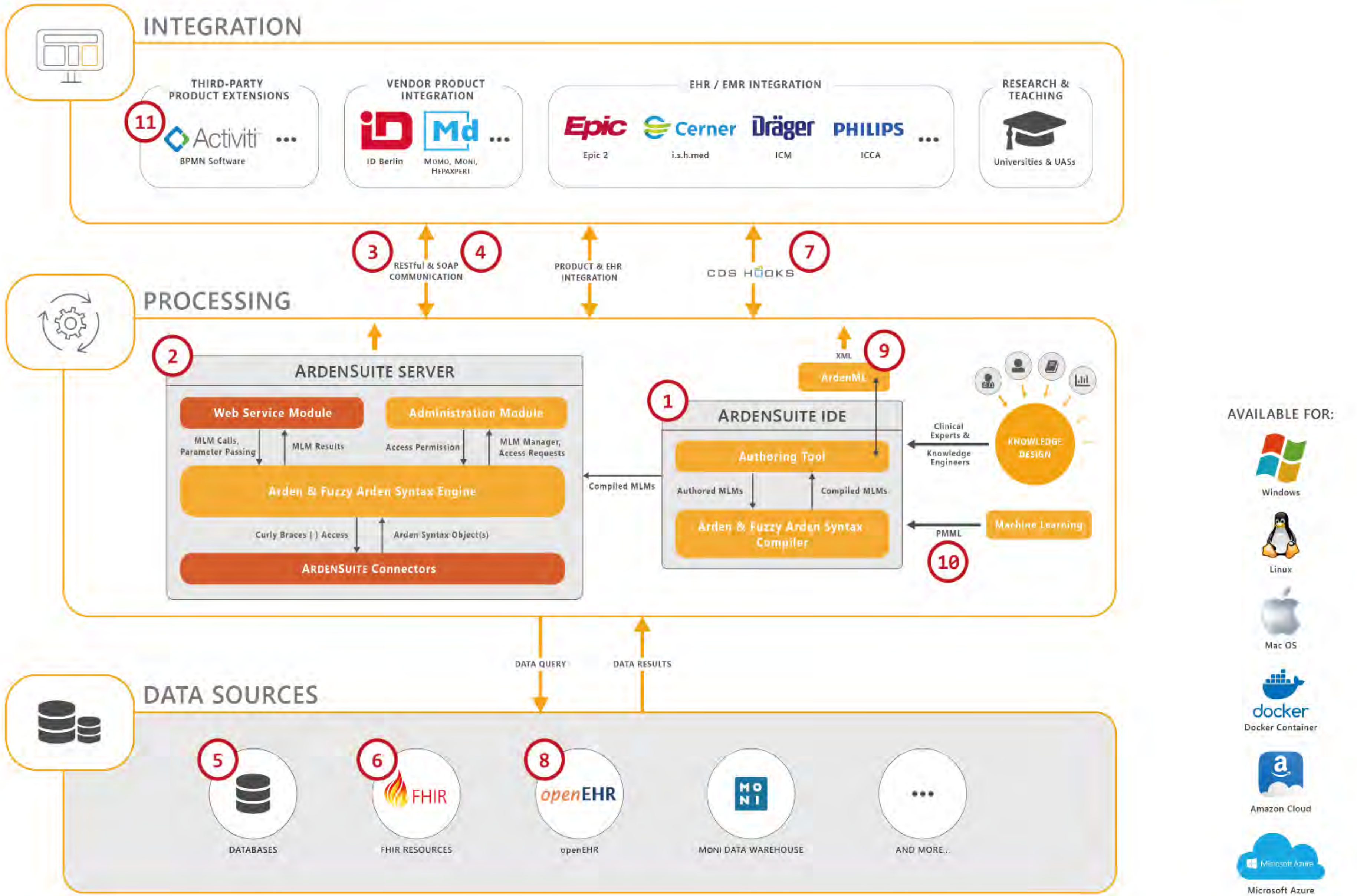
Arden Syntax: Structure

- In Arden Syntax, medical knowledge is hierarchically arranged within medical logic modules (MLMs)
- Each MLM represents sufficient knowledge to make at least one single medical decision
- An MLM is stored in a file that has the file extension “.mlm”
- Each MLM is well organized and structured into **categories** and **slots.**
- Categories must appear in a predefined order.
- Each category contains a category-specific set of **slots,** also in a predefined order.


```
maintenance:
    title:           ;;
    mlmname:         [required];;
    arden:           [required];;
    version:         [required];;
    institution:     [required];;
    author:          ;;
    specialist:      ;;
    date:            [required];;
    validation:      [required];;
library:
    purpose:         ;;
    explanation:     ;;
    keywords:        ;;
    citations:       ;;
    links:           ;;
knowledge:
    type:            data_driven;;
    data:            ;;
    priority:        ;;
    evoke:           ;;
    logic:           ;;
    action:          ;;
    urgency:         ;;
resources:           [optional]
    default:         ;;
    language:        ;;
end:
```

ARDENSUITE Architecture

MEDEXTER Healthcare



Arden Syntax WG: Current Activities

- <u>CDS Big Picture Implementation Guide</u>
  - How to integrate Arden and other standards to implement complete CDS solutions

- <u>Arden Syntax IG</u>: How to use Arden, especially recent added complex features
  - R3 (9/2019): Standard data models, business process modeling
  - R4 (planned 2024): Update for Arden Syntax v3

- <u>Arden v3</u>
  - “curly braces problem”: FHIR = standard data model
  - Being published

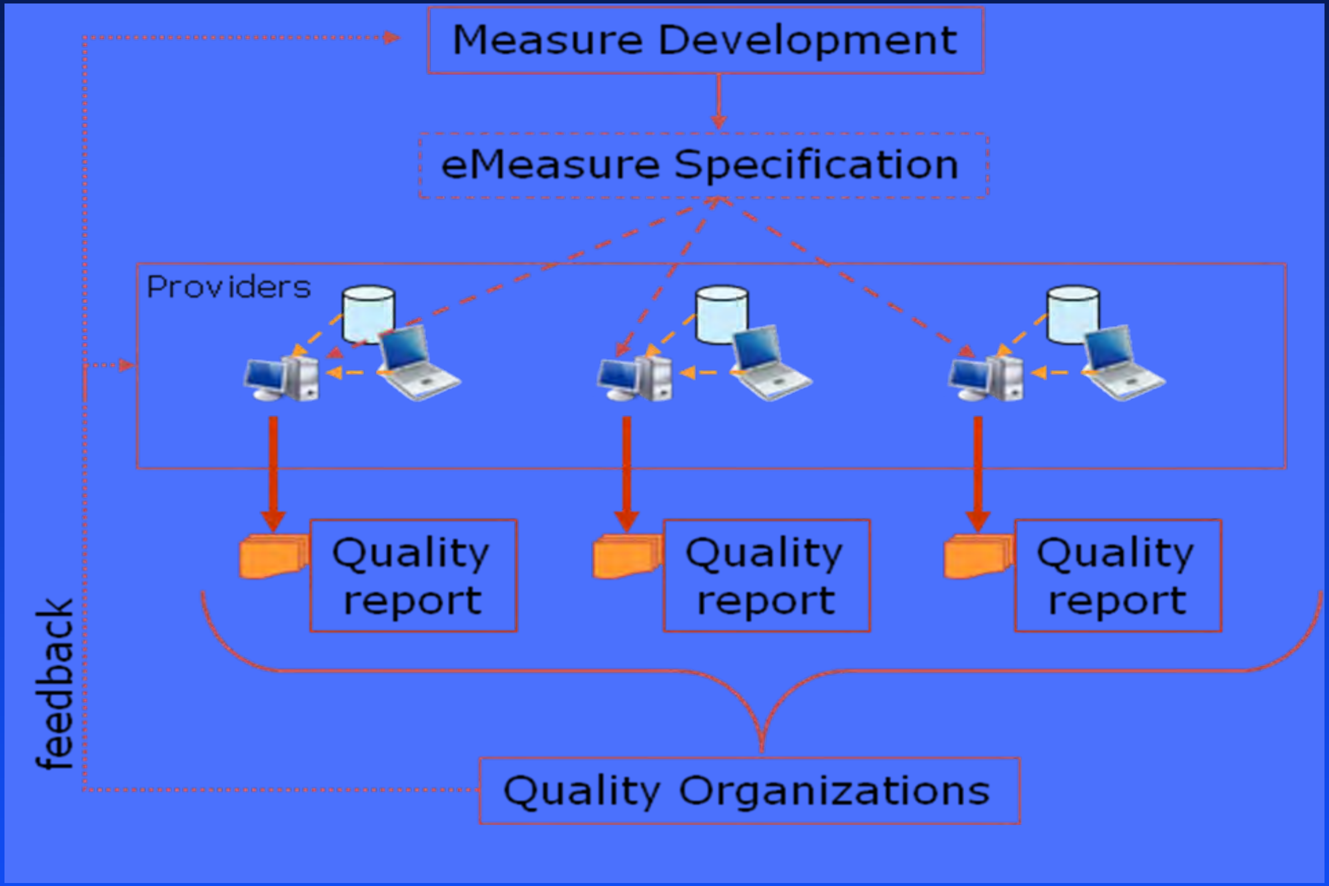
Arden Syntax: Applications

- Guideline implementation
- Interruptive alerts/reminders
- Diagnostic decision support: Many examples
  - Hepatitis test interpretation, antibiotic recommendations, immunization recommendations
- Identifying possible clinical trial subjects
- Surveillance: Cross-population
  - Hospital epidemiology

Clinical Quality Language (CQL)

- Expression language for representation of quality measures and clinical decision support
- Based on Arden Syntax
- Data model is flexible but is aligned with FHIR R4.
- Being aligned with FHIR quality profiles (new project being launched for CQL & FHIR in eCQMs)
- Status: v1.5.2 (Release 1)
- Replaces HQMF
- User-defined functions can link to additional AI processing
- Uses (inter alia): eCQM, knowledge library for FHIR PlanDefinition

CQL (or HQMF): eCQM Representation



Infobutton

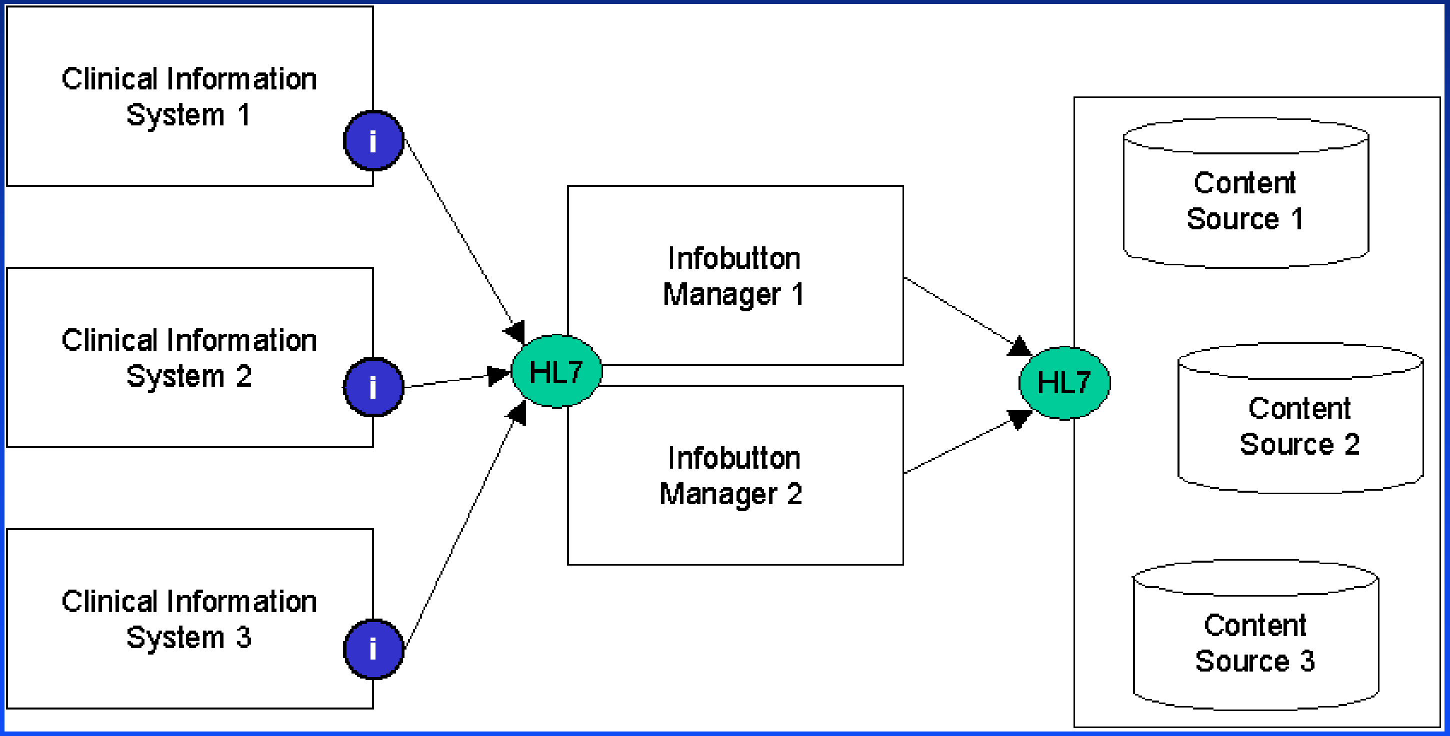
- Infobuttons are context-sensitive links from EHRs to knowledge resources
  - Knowledge access rather than knowledge transfer

- Standard for context-aware knowledge retrieval

- Example: Provides a standard way to express a knowledge request such as *Outpatient treatment of community-acquired pneumonia in a 67-yo male*

Infobutton

- Mediating information seeking between an EHR system user and knowledge sources



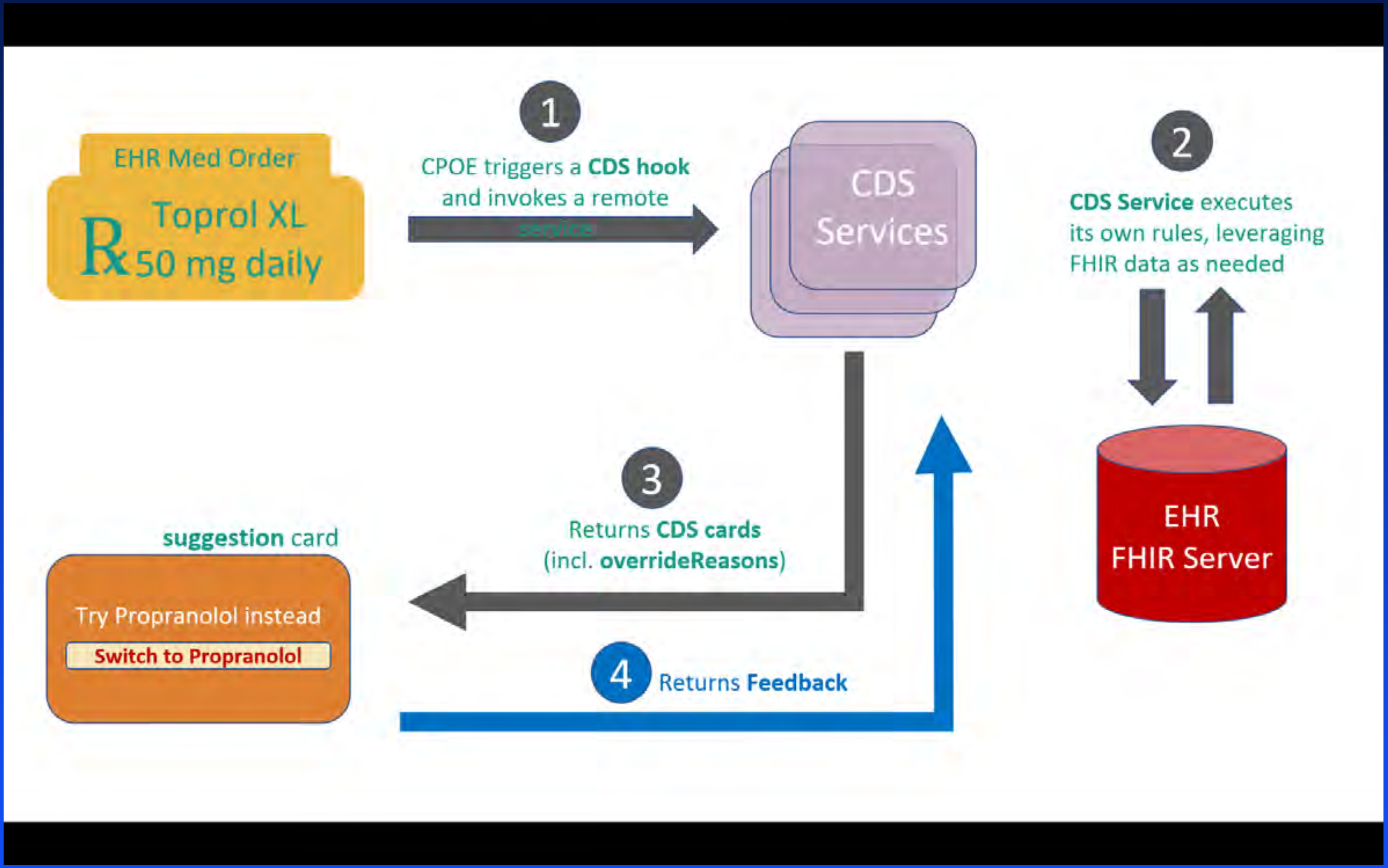
Infobutton Components

- MainSearchCriteria
- Optional components
  - SeverityObservation
  - SubTopic
  - TaskContext
  - Encounter
  - Observation
  - Age
  - Gender
  - InformationRecipient
  - HealthCareProvider

CDS Hooks

- "Hook-based" pattern (API) for invoking CDS within a clinician's workflow
- API supports
  - Synchronous, workflow-triggered (patient-view, order-select, order-sign) CDS returning information and suggestions
  - Launching a user-facing app
- Process
  - Invoked hook notifies registered CDS services with data about the workflow event
  - CDS service returns cards: Information, suggestions, orders

CDS Hooks 2.0

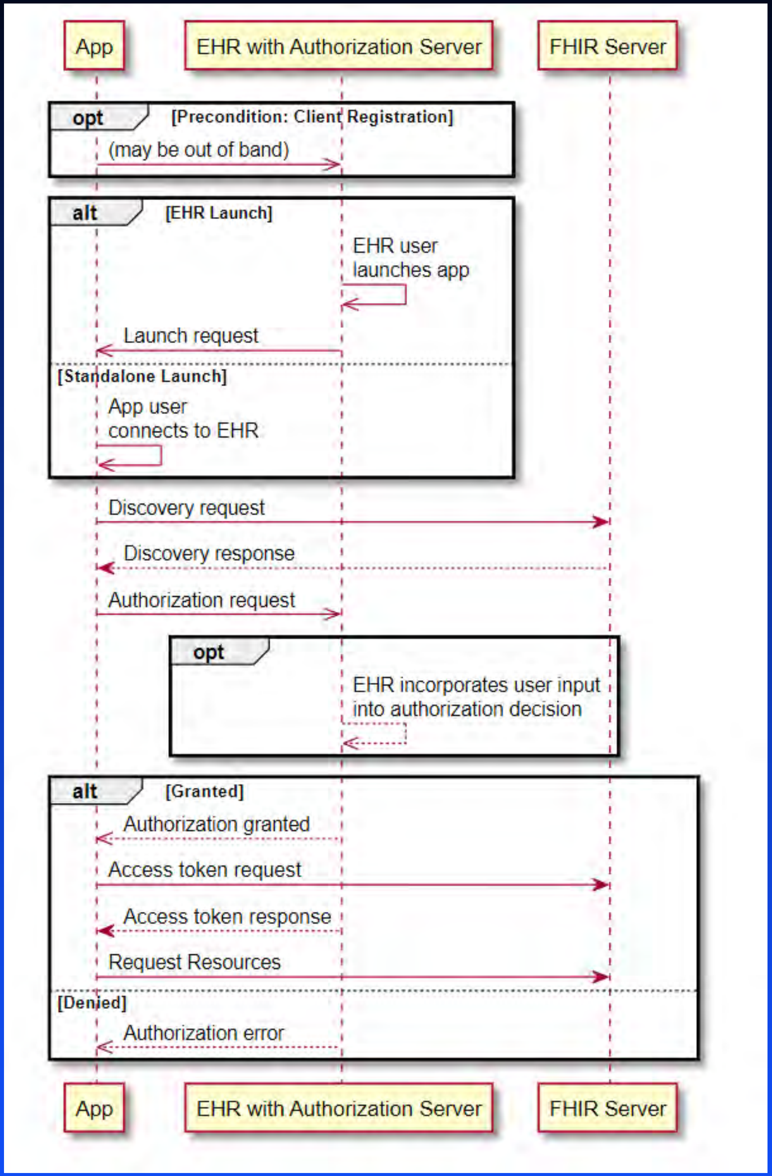


https://cds-hooks.org/

SMART on FHIR

- Allows third parties to develop applications that leverage EHR data
- Standard method to launch external applications from EHRs
- SMART – Substitutable Medical Applications, Reusable Technologies
  - App launch
  - Authentication using OAuth 2.0
  - Apps are granted access only to selected FHIR resources
    - Example: patient/*.rs (permission to read and search any resource for the current patient)
    - Example: patient/Observation.rs (permission to read and search the Observation resource for the current patient)
- FHIR – Data model
- EHR vendors have app marketplaces

SMART on FHIR – Launch Sequence



http://hl7.org/fhir/smart-app-launch/app-launch.html

SMART on FHIR: Examples

- Acute condition management
- Chronic disease management
- Neonatal bilirubin management
- Genomic test ordering and result interpretation
- Opioid prescribing
- Risk prediction
- Medical calculators

Patient-Centered CDS: AHRQ CDSiC

- **5-year project (2022+) centered at U Chicago NORC**
- **Goal: Advancing PC CDS**
  - **Facilitates patients' active involvement in healthcare decision-making with their clinicians**
- **Workgroups**
  - **Measurement and Outcomes**
  - **Implementation, Adoption and Scaling**
  - **Trust and Patient-Centeredness**
  - **Standards and Regulatory Framework**

https://cdsic.ahrq.gov/

PC CDS: Stages of Standards

- Translating guidelines: FHIR, CQL, Arden Syntax
- Managing data provenance: FHIR, USCDI
- Representing Patient-Generated Health Data (PGHD): LOINC and SNOMED are inadequate
- (Workflow) insertion points: FHIR Clinical Reasoning module, CDS Hooks, Infobutton
- Non-Clinical Data: SDOH standards advancing
- Integration of PGHD into EHRs
- CDS-focused APIs
- APIs for bulk data export

CDSiC Initial Products

- Capturing patient preferences for PC CDS
- Taxonomy of override reasons for PC CDS
- Patient preferences for measurement areas

Patient Preferences for PC CDS: Roundtable Findings

- Patient preferences are not collected/used
- Challenges with standardizing patient preferences:
  - Change over time, cost of collecting preferences, challenge of implementing preferences
- <u>High priority preferences</u>
  - Patient engagement
  - Access to information
  - Communication
  - Caregiving
  - Treatment
- <u>Low priority</u>: Disease-specific treatment preferences, potentially sensitive details (mental health)

Patient Preferences for PC CDS

Patient Preference Domain	Examples (*in draft USCDI v5)
Personal Characteristics	• Language*
Communication	• Timing • Mode • Frequency
Engagement	• Degree • Inclusion of others in decisions • Mode
Data	• Clinician access (e.g., coordination, health information exchange)
Healthcare Services	• Type of treatment/intervention * • Receipt of treatment * • Care management
Healthcare Services	• Disease-specific treatment/intervention
Access and Care Experience	• Location for clinical care • Location for health services

PC CDS: Taxonomy for Override Reasons

- <u>Rationale</u>
  - PC CDS = Feedback loop (PDSA, etc)
    - Knowledge-based intervention -> Delivery -> Acceptance or rejection -> Refinement of KB
  - Refinement of CDS interventions requires structured data re uptake & rejection

- <u>Response</u>: Structured taxonomy of override reasons

PC CDS: Taxonomy for Override Reasons

PC CDS does not apply to patient
- Patient does not meet eligibility for recommendation
- Patient has contraindication to recommendation
- Patient has indication/order for planned action
- Recommendation was already performed
- Recommendation previously tried
- Planned action was performed previously
- Recommendation not relevant or a priority in current state of health

PC CDS delivered in suboptimal context
- Could not address recommendation due to limited time
- PC CDS delivered at wrong time in workflow or patient lifeflow
- PC CDS delivered to inappropriate recipient-role
- Could not address recommendation due to need for more information/pending results/pending consult

Recipient disagrees with recommendation because of issues with the evidence
- Recommendation does not align with the latest evidence
- Advice from expert contradicts the recommendation
- Institutional policy/guideline contradicts the recommendation
- Patient does not agree with or trust the recommendation

Recipient has concerns regarding potential health outcomes
- Benefits outweigh risks
- Action taken to mitigate risk of adverse outcome
- Recommendation likely to have adverse health outcomes

Recommendation does not align with patient preferences or values
- Patient fears discomfort from complying with recommendation
- Patient does not want to change behavior or believes the change is unnecessary
- Patient has a cultural or religious reason for not following recommendation
- Patient refuses/declines (no context given)

Recommendation is not convenient or feasible
- Patient has inadequate caregiver/social support
- Treatment or service is not practicably available
- Recommendation cannot be implemented due to technical challenges
- Recommendation is too costly or not covered by insurance
- Patient does not understand the recommendation or know how to perform the recommendation
- Patient has physical, emotional, or psychological barrier to completing recommendation

PC CDS: Measurement

- **Rationale: Need to determine process & clinical outcomes of knowledge-based interventions**
  - **Knowledge maintenance: Key to a learning health system**

- **Response: Environment scan of measurement efforts**

- **Conclusion: More work to be done**

PC CDS: Measurement Inventory

Domain	Count	Sub-domain	Count
Personal Characteristics	0	-	-
Communication	8	-	-
Access and Care Experience	6	Accessibility	2
		IT enabled support tools	2
		Interpersonal/Relational	1
		Provider/System	1
Engagement	20	Information seeking	7
		Decision making	17
		Self-management	3
Data	5	Access	5
		Use of data	3
Healthcare Services	25	Prevention	1
		Receipt of results	4
		Treatment	12
		Advance Care Directives	2
		End-of-life Care	2

PC CDS: Gaps in Measurement

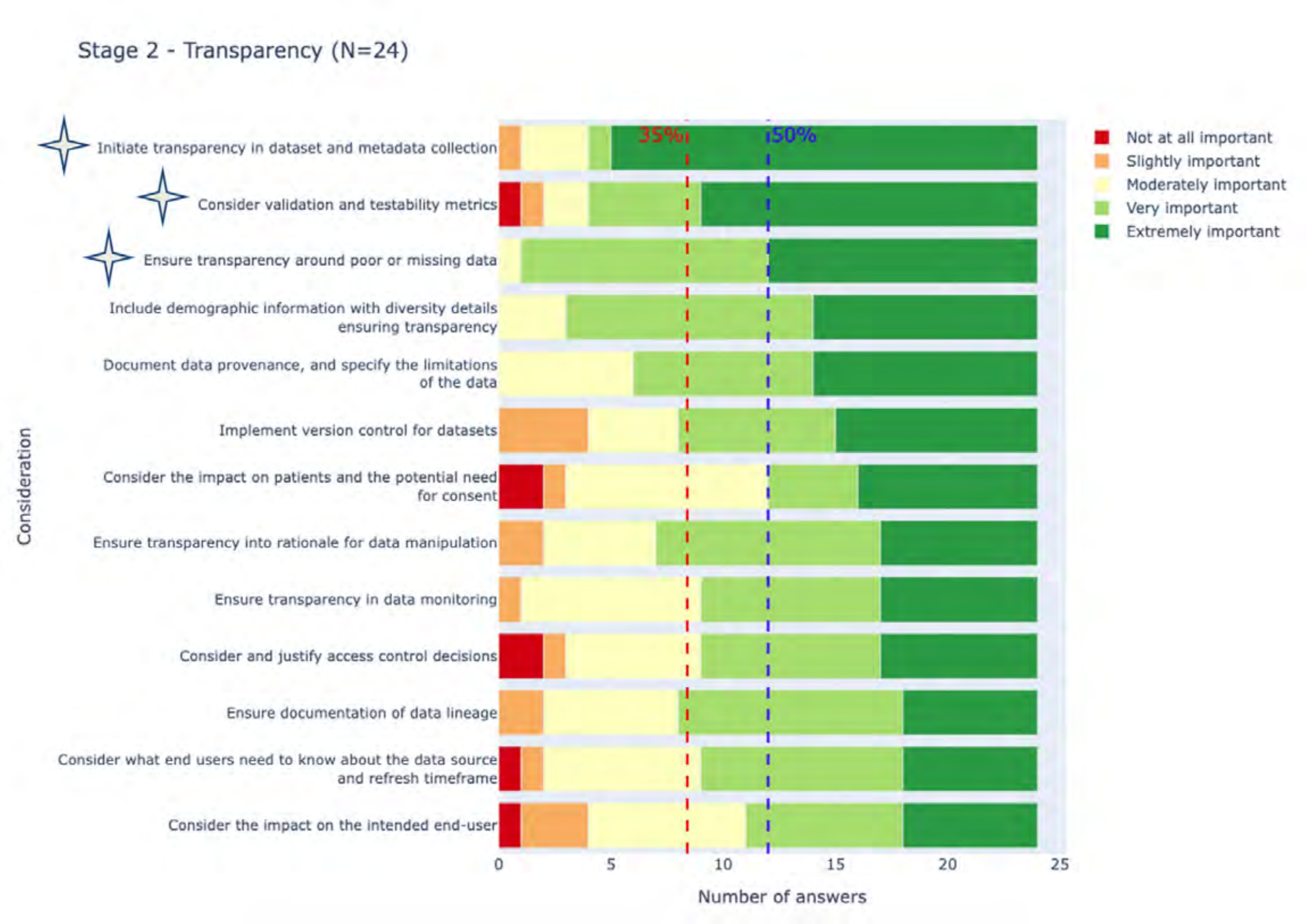
- Conclusion: More work to be done to complete the feedback loop of refining PC CDS
- Gaps
  - Lack of guidance on terminology and measurement frequency
  - Dearth of standardized measurement
  - Limited validated tools
  - Limited data on how patient preferences inform clinical care
  - Elicitation tools may not be fully accessible

CHAI:
Safe and Equitable AI in Health Care

- <u>Thesis</u>: CDS ⊆ AI
  - BMI started as AIM == Artificial Intelligence in Medicine
- <u>Goal</u>: Establish frameworks to facilitate and bound the use of “AI”
- <u>Structure</u>: 5 workgroups
  - Usefulness, Fairness, Safety, Security/Privacy, Transparency
- <u>Products</u>
  - Assurance Standards Guide
  - Assurance Reporting Checklists

https://chai.org/

CHAI: Transparency



CHAI: Assurance Standards Guide

- <u>Purpose</u>
  - Playbook for the development and deployment of AI in health care
  - Actionable guidance on ethics and quality assurance

- <u>Status</u>: Public comment period ended 2024-09-06

- <u>Emphases</u>
  - Governance through SOPs
  - Development of ethical, trustworthy solutions
  - Independent evaluation

CHAI: AI Lifecycle

- **Define Problem and Plan: Stakeholder needs, determine feasibility**
- **Design the AI System: RA, workflow, deployment strategy**
- **Engineer the AI Solution: Develop/validate model, prepare data**
- **Assess: Local validation, risk management plan**
- **Pilot: Small-scale implementation**
- **Deploy and Monitor: Ongoing QA**

CHAI:
Core Principles for Trustworthy Health AI

- Usefulness, Usability & Efficacy: Function, integration with workflow
- Fairness, Equity & Bias Management: Consistency across demographic groups, reduce health disparities
- Safety & Reliability: Primum non nocere, monitor safety
- Transparency, Intelligibility & Accountability: Exposing how it functions, ensure understanding of reasoning
- Security & Privacy: Protect confidentiality, data integrity

CHAI: Assurance Reporting Checklists

- **Purpose**: Guide development of a complete AI solution that adheres to the core principles

- **Uses**
  - Self-reporting
  - Independent evaluators/monitors

- **Function**: Translates best practices in the Assurance Standards Guide into detailed evaluation criteria and yes/no questions

Improving Outcomes with Clinical Decision Support

An Implementer's Guide

Second Edition

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HIMSS

SCOTTSDALE INSTITUTE

AMIA American Medical Informatics Association

AMDIS

shm Society of Hospital Medicine

Summary

- HIT/CDS standardization: Useful, available
- Variety of current standards: Facilitation of knowledge sharing and access
  - Arden Syntax, CQL, FHIR Clinical Reasoning
  - Infobutton, CDS Hooks
  - SMART on FHIR
- Making It Better: Advancing standards, development guidelines
  - CDSiC: Patient-Centered CDS
  - CHAI: Adaptation for AI

Thank You!

- Maria Zebrowski
- Aleece Caron, PhD
- Howard Strasberg, MD, MS, FACMI
- HL7 CDS & Arden Syntax WG Co-Chairs
- HL7, CDSiC, CHAI
- Grants UL1TR000124 (NCATS), U54MD007598 (NIMHD), 1U2CDK129496 (NIDDK), 1U2EMC520970100 (HRSA)

Questions?

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