Patient-Centered Outcomes Research (PCOR) Clinical Decision Support (CDS) Interoperability Standards

AHRQ PCOR CDS Learning Network Webinar

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Disclosures

• In the past year, I have been a consultant or sponsored researcher on clinical decision support for:
  – Office of the National Coordinator for Health IT*
  – McKesson InterQual
  – Hitachi

*via ESAC, SRS, Hausam Consulting, and A+ Government Solutions
Agenda

• Need for standards-based interoperability
• CDS interoperability paradigms
• Current state of standards
• Examples of standards-based CDS
• Proposed next steps
• Discussion
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Gap Between Evidence and Practice

• 15-20 years between research discovery and routine clinical adoption
• Consequences
  – U.S. adults receive recommended care only ~55% of the time
  – Up to 440,000 inpatient deaths/yr due to preventable medical errors
• Findings from patient-centered outcomes research (PCOR) no exception

Clinical Decision Support Promising, but Impact Limited by Lack of Interoperability

• Clinical decision support (CDS) helps ensure evidence-based practice when deployed properly\(^1\)
• Beyond basic medication CDS, however, most clinical care is conducted without effective CDS
• An important reason for the limited availability of effective CDS is the difficulty of sharing CDS and the need for each organization to “build its own”
• Unless standards-based interoperability achieved, societal impact of PCOR-based CDS likely limited

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CDS Interoperability Paradigms

• Standard knowledge artifact: *write once, interpret anywhere*

• Standard patient evaluation service: *write once, use anywhere*

• Standard “apps”: *write once, embed anywhere*
Paradigm 1: Artifact Sharing

- Goal: CDS artifacts can be acquired and deployed by any organization
Paradigm 2: Service-Based Evaluation

- Goal: Allow any organization to obtain CDS guidance through a secure, standard Web service interface

Service Requestor

Service Supplier

Service Request
(patient data + context)

Service Response
(care guidance)
Paradigm 3: App Sharing

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Notable Recent CDS Standardization Efforts

• Health eDecisions (HeD)
  – Public-private partnership sponsored by ONC to develop and validate CDS interoperability standards

• Clinical Quality Framework (CQF)
  – Public-private partnership sponsored by ONC and CMS to develop and validate harmonized standards for CDS and electronic clinical quality measurement (eCQM)
  – Strong emphasis on alignment with HL7 FHIR standard

• SMART on FHIR
  – Traditionally focused on “apps”; expanding to patient evaluation as a service (CDS Hooks)
Foundational Areas for Standardization

• Important for all 3 CDS interoperability paradigms

- Metadata
- Logic Expression Language
- Data Model
Clinical Quality Metadata Conceptual Model

• Based on analysis and harmonization of metadata models in 18 Health Level 7 International (HL7) standards related to clinical quality improvement
• Allows CDS and eCQM standards to express metadata in a consistent manner
• HL7 Informative Specification published Feb 2015
• Reflected in downstream specifications
Clinical Quality Language (CQL)

- Supports both CDS and eCQM
- Builds on prior work in CDS and eCQM standards
- Provides author-friendly view that is transformed to a machine-executable form
  - Expression Logical Model (ELM)
- HL7 Standard for Trial Use (STU)
- Adopted for use in future federal quality measurement programs

Ref 2. [https://ecqi.healthit.gov/cql](https://ecqi.healthit.gov/cql)
using QUICK
valueset "Diabetes": '2.16.840.1.113883.3.464.1003.103.12.1001'
valueset "Sensory Exam of Foot": '2.16.840.1.113883.3.464.1003.103.12.1014'
parameter MeasurementPeriod default interval[Date(2013, 1, 1), Date(2014, 1, 1))
context Patient

define IsAdult:
  AgeAt (start of MeasurementPeriod) >= 18 and AgeAt (start of MeasurementPeriod) < 75

define HasDiabetes: exists
  ([Condition: "Diabetes"] C where C.effectiveTime overlaps MeasurementPeriod)

define InDenominator: IsAdult and HasDiabetes

define InNumerator: exists
  ([Procedure: "Sensory Exam of Foot"] P where P.performanceTime during MeasurementPeriod )
CQL Example for CDS: Diabetes Foot Exam

using QUICK
valueset "Diabetes": '2.16.840.1.113883.3.464.1003.103.12.1001'
valueset "Sensory Exam of Foot": '2.16.840.1.113883.3.464.1003.103.12.1014'
parameter MeasurementPeriod default interval[Date(2013, 1, 1), Date(2014, 1, 1))
context Patient

define IsAdult: Age() >= 18 and Age() < 75

define HasDiabetes: exists ([Condition: "Diabetes"] C where C.effectiveTime overlaps interval [today – 1 years, now])

define IsEligible: IsAdult and HasDiabetes

define NeedsFootExam: not exists ( [Procedure: "Sensory Exam of Foot"] P where P.performanceTime during interval [today – 1 years, now] )
Data Model Levels

• Conceptual model
  – High-level specification

• Logical model
  – Concrete specification based on conceptual model
  – Target of logical expressions

• Physical model(s)
  – Actual implementations based on logical model
  – Used for data exchange in specific technology (e.g., XML, JSON)
Conceptual Model: Quality Improvement Domain Analysis Model (QIDAM)

- Identified common data requirements from Virtual Medical Record (vMR) and Quality Data Model (QDM)
- Expressed in UML
- Published November 2014 as HL7 Informative Specification
Logical Model: Quality Improvement and Clinical Knowledge (QUICK)

- Based on QIDAM
- Expressed in UML
- HL7 Draft Standard Ballot Sept 2014
- Example:

```
+ ageAtOnset :Range [0..1]
+ category :CodeableConcept [0..1]
+ certainty :CodeableConcept [0..1]
+ code :CodeableConcept
+ conditionQualifier :Qualifier [0..*]
+ contributionToDeath :CodeableConcept [0..1]
+ criticality :CodeableConcept [0..1]
+ effectiveTime :Period [0..1]
+ location :BodySite [0..*]
+ severity :CodeableConcept [0..1]
+ status :code
```
Physical Model: Fast Healthcare Interoperability Resources (FHIR) Quality Improvement Core (QICore) Implementation Guide (IG)

- Based on QUICK
- Defined as a set of FHIR “profiles”
- Being made fully compatible with FHIR US Core IG (formerly the Data Access Framework or DAF IG)
- More detailed IGs (e.g., for chemotherapy) being developed in partnership with HL7 Clinical Information Modeling Initiative (CIMI)

This structure is derived from **Condition**

<table>
<thead>
<tr>
<th>Name</th>
<th>Flags</th>
<th>Card.</th>
<th>Type</th>
<th>Description &amp; Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition</td>
<td></td>
<td>0..*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>clinicalStatus</td>
<td>S</td>
<td>0..1</td>
<td>code</td>
<td></td>
</tr>
<tr>
<td>category</td>
<td>S</td>
<td>0..1</td>
<td>CodeableConcept</td>
<td></td>
</tr>
<tr>
<td>severity</td>
<td>S</td>
<td>0..1</td>
<td>CodeableConcept</td>
<td></td>
</tr>
<tr>
<td>code</td>
<td></td>
<td>1..1</td>
<td>CodeableConcept</td>
<td><strong>Binding</strong>: <code>7.org/fhir/daf/ValueSet/daf-problem</code> <em>(preferred)</em></td>
</tr>
<tr>
<td>bodySite</td>
<td>S</td>
<td>0..*</td>
<td>CodeableConcept</td>
<td></td>
</tr>
<tr>
<td>subject</td>
<td>S</td>
<td>1..1</td>
<td>Reference(Profile</td>
<td><strong>Profile qicore-patient)</strong></td>
</tr>
<tr>
<td>context</td>
<td>S</td>
<td>0..1</td>
<td>Reference(Profile</td>
<td><strong>Profile qicore-encounter)</strong></td>
</tr>
<tr>
<td>onset[x]</td>
<td>S</td>
<td>0..1</td>
<td>date</td>
<td>Time, Age, Period, Range, string</td>
</tr>
<tr>
<td>abatement[x]</td>
<td>S</td>
<td>0..1</td>
<td>date</td>
<td>Time, Age, boolean, Period, Range, string</td>
</tr>
<tr>
<td>dateRecorded</td>
<td>S</td>
<td>0..1</td>
<td>date</td>
<td></td>
</tr>
<tr>
<td>asserter</td>
<td></td>
<td>0..1</td>
<td>Reference(Profile</td>
<td><strong>Profile qicore-patient</strong></td>
</tr>
<tr>
<td>stage</td>
<td>S</td>
<td>0..1</td>
<td>BackboneElement</td>
<td></td>
</tr>
<tr>
<td>summary</td>
<td>S</td>
<td>0..1</td>
<td>CodeableConcept</td>
<td></td>
</tr>
<tr>
<td>condition-criticality</td>
<td></td>
<td>0..1</td>
<td>CodeableConcept</td>
<td>Potential impact of the condition</td>
</tr>
<tr>
<td>qicore-bodysite</td>
<td>S</td>
<td>0..*</td>
<td>(Complex)</td>
<td></td>
</tr>
</tbody>
</table>

**URL**: `http://hl7.org/fhir/StructureDefinition/condition-criticality`

**Binding**: QICore Condition Criticality Codes *(example)*

Specific and identified anatomical location

**URL**: `http://hl7.org/fhir/qicore/StructureDefinition/qicore-bodysite`
FHIR Clinical Reasoning Module

Level 1 Basic framework on which the specification is build
- **Foundation**: Base Documentation, XML, JSON, REST API + Search, Data Types, Extensions

Level 2 Supporting Implementation, and binding to external specifications
- **Implementer Support**: Downloads, Common Use Cases, Testing
- **Security & Privacy**: Security, Consent
- **Conformance**: StructureDefinition, CapabilityStatement, Profiling
- **Terminology**: CodeSystem, ValueSet, ConceptMap, Terminology Svc
- **Linked Data**: RDF

Level 3 Linking to real world concepts in the healthcare system
- **Administration**: Patient, Practitioner, Device, Organization, Location, Healthcare Service

Level 4 Record-keeping and Data Exchange for the healthcare process
- **Clinical**: Allergy, Problem, etc.
- **Diagnostics**: Observation, Report, Request, etc.
- **Medications**: Order, Dispense, Administration, Statement, etc.
- **Workflow**: Task, Subscription, etc.
- **Financial**: Claim, EligibilityRequest, etc.

Level 5 Providing the ability to reason about the healthcare process
- **Clinical Reasoning**: Decision Support, Clinical Quality Measures

http://build.fhir.org

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FHIR Clinical Reasoning Module: Shareable CDS Knowledge Artifacts

- [http://build.fhir.org/cqif/cqif-knowledge-artifact-representation.html](http://build.fhir.org/cqif/cqif-knowledge-artifact-representation.html)
- Supports shareable representation of:
  - Event-condition-action rules
  - Order sets
  - Documentation templates
FHIR Clinical Reasoning Module: Decision Support Service

- [http://build.fhir.org/cqif/cqif-cds-on-fhir.html](http://build.fhir.org/cqif/cqif-cds-on-fhir.html)
- SMART on FHIR “CDS Hooks” specification is a functional subset of the FHIR Clinical Reasoning Module’s DSS functionality and in process of harmonization
SMART on FHIR

- Substitutable Medical Apps, Reusable Technologies (SMART)
  - Specification for securely sharing Web-based applications across EHR platforms using OAuth2
- SMART on FHIR refers to use of SMART with FHIR
- Gaining significant vendor support
- Can be combined with CDS interoperability paradigms for sharing knowledge or CDS services

http://smarthealthit.org/smart-on-fhir/
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Example: Standard Knowledge (Documentation Template)
Example: Standard Knowledge (Order Set)

Heart Failure Admission Order Set

**General**
- For patients with advanced heart failure, consider the Heart Failure Score to predict the risk of mortality.

**Nursing Orders**
- Cardiac monitor
- Urinary catheter initiation/management, insert Foley catheter
- Fluid restricted diet

**Medications**
- **Platelet Inhibitors:** Aspirin 81 milligram orally once a day
- **Angiotensin-Converting Enzyme Inhibitors:** Captopril 6.25 milligram orally three times a day, Lisinopril 2.5 milligram orally once a day
- **Vasodilators:** Hydralazine 37.5 milligram orally four times a day, Isosorbide dinitrate 20 milligram orally four times a day
- **Beta-Blockers:** Carvedilol phosphate SR 10 mg multiphase 24 hours
- Metoprolol succinate SR 25 mg 24 hours tab 0.5 tab orally once day

Design Clinicals
Healthcare IT solutions that work
Example: Standard Knowledge (Rule)
End-User Experience

Patient is pregnant and should be assessed for Zika infection risk. Please follow the link below to assess for Zika risk and determine next steps.

Zika infection risk assessment decision support tool

© 2016 Epic Systems Corporation. Used with permission.
Zika Virus Exposure Assessment

Questions:

- Is the patient a resident of, or does the patient travel frequently to, an area with active Zika transmission? See [link](#) for areas with active Zika transmission/exposure risk.
  - Yes
  - No

Submit
Zika Virus Exposure Assessment

Questions:

• Is the patient a resident of, or does the patient travel frequently to, an area with active Zika transmission?  
  See link for areas with active Zika transmission/exposure risk.  
  ○ Yes  
  ○ No

• Is the patient symptomatic for Zika infection?  
  ○ Yes  
  ○ No
Zika Virus Exposure Assessment

Questions:

• Is the patient a resident of, or does the patient travel frequently to, an area with active Zika transmission? See link for areas with active Zika transmission/exposure risk.
  ○ Yes
  ○ No

• Is the patient symptomatic for Zika infection?
  ○ Yes
  ○ No

• How many weeks elapsed between the patient’s potential Zika exposure and symptoms?

Submit
Zika Virus Exposure Assessment

Questions:

- Is the patient a resident of, or does the patient travel frequently to, an area with active Zika transmission? See link for areas with active Zika transmission/exposure risk.
  - Yes
  - No

- Is the patient symptomatic for Zika infection?
  - Yes
  - No

- How many weeks elapsed between the patient’s potential Zika exposure and symptoms?
  - 3 weeks

[Submit button]
Zika Risk-based Management Guidance

Patient is pregnant and symptomatic for Zika infection, with symptom onset 2-11 weeks post-exposure. Recommend:
1) Zika virus IgM testing
2) Dengue virus IgM testing.
3) Supportive care via rest, fluids, antipyretics, and analgesics (avoid aspirin/NSAIDs in case of dengue).

Order Zika IgM Antibody Test
Order Dengue virus IgM Antibody Test
Zika Risk-based Management Guidance

Patient is pregnant and symptomatic for Zika infection, with symptom onset 2-11 weeks post-exposure. Recommend:
1) Zika virus IgM testing
2) Dengue virus IgM testing.
3) supportive care via rest, fluids, antipyretics, and analgesics (avoid aspirin/NSAIDs in case of dengue).

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Order Dengue virus IgM Antibody Test
Zika Risk-based Management Guidance

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Order Zika IgM Antibody Test
Order Dengue virus IgM Antibody Test
Example: SMART on FHIR Bilirubin App with FHIR Clinical Reasoning Decision Support

Consider Exchange Transfusion
Rationale: Patient’s latest bilirubin level of 17.1 mg/dL at 46.57 hrs is above treatment threshold for exchange transfusion (16.98) given gestational age >= 35 wks and < 38 wks with risk factors for exchange transfusion.

Bilirubin Measurements

<table>
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<tr>
<th>Age (Hrs)</th>
<th>Result</th>
<th>Date/Time</th>
<th>Test Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.25</td>
<td>8.1</td>
<td>09/26/16 16:24</td>
<td>Total</td>
</tr>
<tr>
<td>23.38</td>
<td>10.5</td>
<td>09/27/16 03:32</td>
<td>Transcutaneous</td>
</tr>
<tr>
<td>30.68</td>
<td>12.2</td>
<td>09/27/16 10:50</td>
<td>Total</td>
</tr>
<tr>
<td>36.9</td>
<td>14.8</td>
<td>09/27/16 17:03</td>
<td>Total</td>
</tr>
<tr>
<td>46.57</td>
<td>17.1</td>
<td>09/28/16 02:43</td>
<td>Total</td>
</tr>
</tbody>
</table>

Albumin Measurements

<table>
<thead>
<tr>
<th>Age (Hrs)</th>
<th>Result</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>43.85</td>
<td>2.9</td>
<td>09/28/16 00:00</td>
</tr>
</tbody>
</table>

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## Critical Needs and Proposed Next Steps

<table>
<thead>
<tr>
<th>Critical Need</th>
<th>Proposed Next Steps Over Next Year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Identification of CDS integration capabilities already supported by major EHR vendors</strong></td>
<td>- Vendor surveys and interviews</td>
</tr>
<tr>
<td><strong>Rationale:</strong> it is much easier to standardize existing functionality (e.g., via middleware) than to implement new functionality</td>
<td></td>
</tr>
</tbody>
</table>
| **Prioritization of new CDS integration capabilities** not already supported by major EHR vendors (e.g., import/export of static order sets) | - Healthcare provider and knowledge vendor surveys  
- Vendor assessment of effort required to enable support |
| **Piloting and production deployment of interoperable CDS capabilities** | - Use of existing standards for already-funded CDS initiatives, with support from PCOR CDS-LN and ONC CQF initiative  
- Refinement of standards based on implementation experience |
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Thank You!

Kensaku Kawamoto, MD, PhD, MHS, FACMI

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