The Clinical Quality Framework Initiative: Harmonizing CDS and Clinical Quality Measurement Standards to Enable Interoperable Quality Improvement

University of Utah Biomedical Informatics Seminar
April 15, 2014

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Disclosures

• I am, or have been in the past, a consultant on clinical decision support to the following entities:
  – Office of the National Coordinator for Health IT (ONC)
  – Mayo Clinic
  – Partners HealthCare
  – McKesson InterQual
  – RAND Corporation
  – ARUP Laboratories
  – ESAC, Inc.
  – JBS International, Inc.
  – Clinica Software, Inc.
  – Religent, Inc.
  – Inflexxion, Inc.
  – Intelligent Automation, Inc.

• I have no competing interests related to OpenCDS
Agenda

• Background and Problem Definition
• Goal and Scope
• Methodology
• Deliverables
• Pilots
CDS and eCQM: Two Sides of the Same Coin

• Clinical decision support (CDS)
  – Recommends X be done if Y is true
    • E.g., Recommend aspirin due to heart attack

• Electronic clinical quality measurement (eCQM)
  – Measure if X was done if Y is true
    • E.g., Measure if aspirin given after heart attack

• Benefits from coordinated implementation
  – Semantic consistency
  – Implementation efficiency

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The Problem: Divergent Standards

- CDS and eCQM standards were not developed in consideration of each other and used different approaches, in particular with regard to patient data and computable expression logic.

<table>
<thead>
<tr>
<th>Patient Data</th>
<th>Computable Expression Logic</th>
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<tbody>
<tr>
<td><strong>CDS</strong></td>
<td></td>
</tr>
<tr>
<td>- Virtual Medical Record (vMR) (for both physical and logical models)</td>
<td>- CDS Knowledge Artifact Specification (KAS)</td>
</tr>
<tr>
<td><strong>eCQM</strong></td>
<td></td>
</tr>
<tr>
<td>- Quality Reporting Data Architecture (QRDA) (for physical model)</td>
<td>- Health Quality Measure Format (HQMF) (for physical model)</td>
</tr>
<tr>
<td>- Quality Data Model (QDM) (for logical model)</td>
<td>- Quality Data Model (QDM) (for logical model)</td>
</tr>
</tbody>
</table>
Consequences of Divergent Standards

- A CDS rule author cannot easily re-use the work of an eCQM developer or vice versa
- An EHR system that supports both CDS and eCQM will need to map its native data format to 2 data standards and implement computation capabilities for 2 logic expression standards
- Reflected in proposed 2015 EHR certification criteria

Harmonization of the CDS and eCQM standards is required to reduce implementation burdens, promote integration between these two domains, and facilitate care quality improvement.
Clinical Quality Framework (CQF)

• Public-private collaboration sponsored by ONC & CMS, initiated March 2014
• Follow-on to ONC Health eDecisions CDS initiative
• Goals
  – To harmonize standards for CDS and eCQM
  – To refine the standards via pilot implementations
• Scope
  – eCQM: all
  – CDS: rules, order sets, documentation templates
• Standards developed will be available for potential use in federal programs and regulations
Public-Private Partnership

- **ONC and CMS**: Jacob Reider, Kate Goodrich, Julia Skapik, Pavla Frazier, Minet Javellana, Laverne Perlie
- **Initiative Coordination and Support**: Ken Kawamoto, Marc Hadley, Sarah Ryan, Bridget Blake
- **Initiative SMEs**: Aziz Boxwala, Bryn Rhodes, Claude Nanjo, Chris Moesel, Jason Mathews, Lloyd McKenzie, Mark Kramer
- **Community Contributors**: various private and public sector contributors. E.g., McKesson, Epic, Motive Medical Intelligence, Cognitive Medical Systems, Evinance, Wolters Kluwer Health, Zynx Health, National Decision Support Company, HLN Consulting, American College of Radiology, American College of Cardiology, HHS, CDC, universities and healthcare systems, and many others
Use Case 1: Artifact Sharing

- Goal: CDS and eCQM artifacts can be acquired and deployed by any organization.
Use Case 2: Service-Based Evaluation

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

Diagram:
- Service Requestor
- Service Supplier
- Service Request: (patient data + context)
- Service Response: (care guidance or quality measurement)
Focus: Common Foundational Standards

**eCQM Specific Standards**
- HQMF
- QRDA Category-1
- QRDA Category-3
- QDM

**Common Metadata Standard**

**Common Data Model Standards (QUICK* and FHIR** Quality Profiles)**

**Common Expression Logic Standard (CQL)***

**CDS Specific Standards**
- KAS
- DSS
- vMR

* Quality Improvement and Clinical Knowledge
** Fast Healthcare Interoperability Resources
*** Clinical Quality Language

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Clinical Quality Metadata Conceptual Model

- Based on analysis and harmonization of metadata models in 18 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
Clinical Quality Language (CQL)

• Builds on functional requirements defined in:
  – HL7 Harmonization of Health Quality Artifact Reasoning and Expression Logic (Domain Analysis Model)

• Leverages
  – Computability achieved in CDS KAS
  – Human-readable syntax (QDM, Arden heritage)

• Provides author-friendly view that is transformed to a machine-executable form
  – Expression Logical Model (ELM)

• HL7 Draft Standard balloted Jan 2015 (publication imminent)
CQL Example for eCQM: Diabetes Foot Exam

using QUICK
context PATIENT
parameter MeasurementPeriod default interval[Date(2013, 1, 1), Date(2014, 1, 1)]
concept "Diabetes" = ValueSet('2.16.840.1.113883.3.464.1003.103.12.1001')
concept "Sensory Exam of Foot" = ValueSet('2.16.840.1.113883.3.464.1003.103.12.1014')

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

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

let InDenominator = IsAdult and HasDiabetes

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

using QUICK
context PATIENT

concept "Diabetes" = ValueSet('2.16.840.1.113883.3.464.1003.103.12.1001')
concept "Sensory Exam of Foot" = ValueSet('2.16.840.1.113883.3.464.1003.103.12.1014')

let IsAdult = Age() >= 18 and Age() < 75

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

let IsEligible = IsAdult and HasDiabetes

let 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 vMR and 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 Profiles (QICORE)

• Based on QUICK
• Use of FHIR attractive due to available tooling and rapidly growing implementation community
• Original intent: auto-generate from QUICK
  – Prototype implemented, but concerns over resources required for specifying mappings
• Revised approach: manually create based on QUICK
  – Auto-generate “flat” logical model from FHIR profiles
  – Supplemental logical model (UML or OWL) with deterministic mappings (OWL or other) to FHIR profiles (UML or OWL)*
  – Supplemental knowledge (OWL)*

*under investigation
QICORE FHIR Profiles

• Under HL7 ballot, May 2015
• Coordinated with relevant efforts
  – ONC S&I Data Access Framework (DAF)
  – Clinical Information Modeling Initiative (CIMI)
  – Healthcare Services Platform Consortium (HPSC)
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>
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<td>S</td>
<td></td>
<td>patient-qicore-qicore-patient</td>
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<td></td>
<td>encounter-qicore-qicore-encounter</td>
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<tr>
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<td></td>
<td></td>
<td>patient-qicore-qicore-patient, practitioner-qicore-qicore-practitioner</td>
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<td><strong>Binding: QICoreProblemCode</strong> (preferred)</td>
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</tr>
<tr>
<td>detail</td>
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</tbody>
</table>
## Condition

FHIR Implementation: condition-qicore-qicore-condition
FHIR Parent resource: Condition

Detailed information about conditions, problems or diagnoses

Profile of Condition for decision support/quality metrics. Defines the core set of elements and extensions for quality rule and measure authors.

### Field Table

<table>
<thead>
<tr>
<th>Field</th>
<th>Card.</th>
<th>Type and Description</th>
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<td><code>abatement</code></td>
<td>0..1</td>
<td>date</td>
</tr>
<tr>
<td><code>asserter</code></td>
<td>0..1</td>
<td>Patient</td>
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</tr>
<tr>
<td><code>code</code></td>
<td>1..1</td>
<td>CodeableConcept</td>
</tr>
</tbody>
</table>

- **abatement**: The date or estimated date that the condition resolved or went into remission. This is a "remission" or "resolution" - Conditions are never really resolved, but they can abate.

- **asserter**: Person who takes responsibility for asserting the existence of the condition as part of the

- **category**: A category assigned to the condition. E.g. complaint | symptom | finding | diagnosis.

- **clinicalStatus**: The clinical status of the condition.

- **code**: Identification of the condition, problem or diagnosis.
Standards Status

• Metadata
  – Conceptual model published February 2015

• Logical expression
  – CQL publication imminent

• Data model
  – Conceptual model (QIDAM) and logical model (QUICK) balloted
  – Physical model (QICORE FHIR profiles) under ballot

• Downstream standards
  – CQL-based HQMF Implementation Guide under ballot
  – CQL-based CDS KAS currently being prepared
  – Pending: CDS KAS, Decision Support Service (DSS), and HQMF updates to utilize new common data model

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<table>
<thead>
<tr>
<th>Topic</th>
<th>Current Contributors</th>
<th>Point of Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiology: Appropriate Use Criteria in Ischemic Heart Disease Evaluation</td>
<td>• American College of Cardiology</td>
<td>Jimmy Tcheng, <a href="mailto:james.tcheng@duke.edu">james.tcheng@duke.edu</a></td>
</tr>
<tr>
<td></td>
<td>• HHS Office of Population Affairs</td>
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<td>• CDC Divisions of Reproductive Health and STD Prevention</td>
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<td>• Avhana Health</td>
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<td>Chlamydia Screening</td>
<td>• HHS Office of Population Affairs</td>
<td>Johanna Goderre Jones,</td>
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<td>• CDC Divisions of Reproductive Health and STD Prevention</td>
<td><a href="mailto:Johanna.GoderreJones@hhs.gov">Johanna.GoderreJones@hhs.gov</a></td>
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<tr>
<td>Immunization Decision Support</td>
<td>• HLN Consulting, LLC</td>
<td>Daryl Chertcoff, <a href="mailto:daryl@hln.com">daryl@hln.com</a></td>
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<tr>
<td>Ischemic Vascular Disease: Use of Aspirin or Another Antithrombotic</td>
<td>• Motive Medical Intelligence</td>
<td>Julie Scherer, <a href="mailto:jscherer@motivemi.com">jscherer@motivemi.com</a></td>
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<td>• Cognitive Medical Systems</td>
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<td>Oncology Decision Support</td>
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<td>Chad Armstrong, <a href="mailto:chad.armstrong@evinance.com">chad.armstrong@evinance.com</a></td>
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<td>• Elekta Mosaic</td>
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<td>Radiology Appropriateness of Use</td>
<td>• National Decision Support Company</td>
<td>Tom Conti, <a href="mailto:tconti@acrselect.org">tconti@acrselect.org</a></td>
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</table>
Immunization CDS Pilot:
Leveraging existing software to validate CQF standards for Immunization Forecasting

The goal of the Immunization DSS Pilot is to validate how CQF standards can support and evolve immunization forecasting.

This Pilot is leveraging the Immunization Calculation Engine (ICE) – an open-source immunization forecasting software that provides on-demand clinical decision support for immunizations (CDSi). It includes an optional, Web-based authoring tool to manage the business rules.

ICE is:

• Standards-based; utilizes the vMR
• Adapts to changing requirements
• Designed to easily integrate with health information systems
• OpenCDS is the underlying CDS engine platform
• More information about ICE is available at http://www.cdsframework.org

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# Immunization CDS Pilot:
ICE Sample User Interface Currently Based on vMR

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Date</th>
<th>Status</th>
<th>Message</th>
<th>Vaccine Group</th>
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<tr>
<td>Hib</td>
<td>20110228</td>
<td>RECOMMENDED</td>
<td>DUE_NOW</td>
<td>Hib</td>
</tr>
<tr>
<td>Polio</td>
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<td>RECOMMENDED</td>
<td>DUE_NOW</td>
<td>Polio</td>
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<tr>
<td>MMR</td>
<td>20131130</td>
<td>RECOMMENDED</td>
<td>DUE_NOW</td>
<td>MMR</td>
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<tr>
<td>Varicella</td>
<td>20131130</td>
<td>RECOMMENDED</td>
<td>DUE_NOW</td>
<td>Varicella</td>
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<td>Pneumococcal Conjugate</td>
<td>20111130</td>
<td>RECOMMENDED</td>
<td>DUE_NOW</td>
<td>pneumococcal conjugate PCV 13 (133)</td>
</tr>
</tbody>
</table>

- **MMR**
  - Date: 20130103
  - Status: RECOMMENDED
  - Message: DUE_NOW
  - Vaccine Group: MMR
  - Age: 3y 1m 4d
  - Valid: true
  - Vaccine: MMR-Varicella (94)

- **Varicella**
  - Date: 20130103
  - Status: RECOMMENDED
  - Message: DUE_NOW
  - Vaccine Group: Varicella
  - Age: 3y 1m 4d
  - Valid: true
  - Vaccine: MMR (03)
Immunization CDS Pilot: Use of FHIR as Data Exchange Model
Radiology Appropriateness of Use Pilot
EHR Accesses CDS Knowledge at Point of Order

ACR Select presents score of selected exams & any alternates. User refines order based on feedback.

Enter structured reason for exam

Record DSN

Consult AUC
Chlamydia Screening Pilot

Chlamydia Screening Rule in KAS + CQL + QUICK

Avhana Health

Epic

Allscripts

GREENWAY

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Greenway EHR Integration
Allscripts EHR Integration
CDS Recommendations in Greenway

Recommendations

Select orders below before submitting.

Due Now 1  Due Soon 0  Due 6 Months 0

<table>
<thead>
<tr>
<th>ORDER NAME</th>
<th>DUE DATE</th>
<th>LAST DONE</th>
<th>REPORTING</th>
<th>SOURCE</th>
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<td>Chlamydia Screening</td>
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<td>None</td>
<td>Center for Disease Control and Prevention</td>
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</table>

Notes

SUBMIT ORDER (0)
CDS Recommendations in Epic

Stella Avhana is at risk for chlamydia infection by age group, no screening test available in past 1 year
Learn more about these guidelines

- Add to unsigned orders: Chlamydia Screening (Chlamydia Detection by DNA Amplification)
Breast Cancer Treatment Guideline

Radiotherapy after Neo-adjuvant Chemoradiation

No Skin involvement

Radiotherapy (no bolus)

Lymph node: Positive

Sentinel lymph node biopsy: Positive

Radiotherapy to the Breast and/or Chest wall: 40 Gy in 15 fractions or 42.4 Gy in 16 fractions or 50 Gy in 25 fractions

Radiotherapy to the Supraclavicular ± Axilla: 40 Gy in 15 fractions or 42.4 Gy in 16 fractions or 50 Gy in 25 fractions

Lymph node: Negative

Sentinel lymph node biopsy: Negative

Radiotherapy to the Breast and/or Chest wall: 40 Gy in 15 fractions or 42.4 Gy in 16 fractions or 50 Gy in 25 fractions

without Radiotherapy to the Supraclavicular

Lymph node: Unknown

Sentinel lymph node biopsy: Unknown

Radiotherapy to the Breast and/or Chest wall: 40 Gy in 15 fractions or 42.4 Gy in 16 fractions or 50 Gy in 25 fractions

± Radiotherapy to the Supraclavicular: 40 Gy in 15 fractions or 42.4 Gy in 16 fractions or 50 Gy in 25 fractions
Evinance CDS Platform: Tracking Patient Paths

Mary Shortt's Path

- No Carcinoma of the Breast to the Skin:
  - Breast reconstruction
    - Radiotherapy to the Breast: 50.4 Gy in 28 fractions
    - Radiotherapy to the Breast: 40 Gy in 15 fractions or 42.4 Gy in 16 fractions or 50 Gy in 25 fractions

- Carcinoma of the Breast to the Skin:
  - Breast reconstruction
  - Radiotherapy to the Breast: 50.4 Gy in 28 fractions with 0.5 cm bolus

- At least 1:
  - Patient is at most 50 Years
    - Surgical margins: at most 2 mm
    - Boost radiation therapy to the Tumor site: 18 Gy in 8 fractions or 11.25 Gy in 5 fractions or 10 Gy in 5 fractions

- At least 1:
  - Patient is 51 Years to 70 Years
    - Grade 3 out of 3
    - Vascular invasion of tumor present
    - Boost radiation therapy to the Tumor site: 18 Gy in 8 fractions or 11.25 Gy in 5 fractions or 10 Gy in 5 fractions
Ischemic Vascular Disease (IVD) Pilot

- Translation and execution of CQL-QUICK-KAS rule on antithrombotic use in IVD to Drools execution platform
- Pilot lead from Motive Medical Intelligence:
  - Julie Scherer, PhD
- CQL artifact authors from Meliorix, Inc.:
  - Randy Barrows, MD
  - Aziz Boxwala, MD
- CQL-Drools technical implementation team from Cognitive Medical Systems:
  - Neda Alipanah
  - Esteban Aliverti
  - Steven Elliott
  - Claude Nanjo

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Diagrammatic representation of an ECA artifact for NQF 0068, *Ischemic Vascular Disease: Use of Aspirin or another Antithrombotic*
define LastAMI =
  first( [Condition: "Diagnosis, Active: Acute Myocardial Infarction"] C
         where C.statusElement.valueAsString in {'confirmed', 'working'} and ifnull(C.onsetDateTimeType, C.dateAssertedElement) during ACSreviewPeriod
         return tuple { DxText: C.code.textElement.value, DxTime: ifnull(C.onsetDateTimeType, C.dateAssertedElement) }
            sort by DxTime.value desc
  )

define HadAMI = exists LastAMI

define LastIHDprocedure =
  first( ( [Procedure: "Procedure, Performed: Percutaneous Coronary Interventions"]
           union
           [Procedure: "Procedure, Performed: Coronary Artery Bypass Graft"] ) P
         where startOf(P."date") during ACSreviewPeriod
         return tuple { PxText: P.type.text,
                       PxTime: startOf(P."date") }
            sort by PxTime.value desc )

define HadIHDprocedure = exists LastIHDprocedure
Translation and Deployment Process

Objective: validation of isosemantic translation

CQL + QUICK → CQL Reference Implementation → ELM-DRL Translator → DRL

Deployment via Drools AST

ELM AST

Drools Rule Engine

© 2015, Motive Medical Intelligence
OpenCDS and VHA

• OpenCDS
  – Multi-institutional effort led by Univ. of Utah to develop and leverage a standards-based, scalable, and open-source framework for CDS and eCQM
  – Provides a reference implementation of DSS and vMR standards
  – At UUHC, used for eCQM and exploring use for CDS

• VHA
  – Using OpenCDS as core CDS service for VHA’s next-generation EHR system (eHMP)
OpenCDS – Graphical Rule Flow Specification
OpenCDS – Domain Specific Language (DSL)

- DSLs enable knowledge authoring with human-readable rule patterns (~300 defined to date)
- Example:
OpenCDS VHA Pilot of CQF Standards

• Collaboration with Cognitive Medical Systems
• Adapting OpenCDS to leverage and inform further development of CQF standards
• Focal issues/questions
  – What should the CQF logical model be? Is the model auto-generated from FHIR sufficient?
  – How can ontologies be best leveraged?
  – How do we design for the future evolution and extension of the data model?
  – How do we best align with relevant efforts including CIMI, HSPC, and the Federal Health Information Model?
Summary

- CDS and eCQM are closely related, and coordinated implementation is highly desirable
- CQF is harmonizing CDS and eCQM standards, with a particular focus on a common expression language (complete) and data model (in progress)
- Many organizations have been actively piloting the standards to validate and refine the standards
- Resulting standards will be available for potential use in federal programs and regulations
Acknowledgements

• **Financial support**
  – Office of the National Coordinator for Health IT
  – Centers for Medicare & Medicaid Services
  – University of Utah Dept. of Biomedical Informatics
  – University of Utah Information Technology Services
  – University of Utah Office of the CMIO
  – NHGRI K01 HG004645 (PI: K. Kawamoto)

• **CQF contributors**
  – As acknowledged earlier

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