Quality Reporting Document Architecture (QRDA) Initiative Phase I Final Report

Developing a standard for communicating health care quality measurement information



Prepared By:

Liora Alschuler, Alschuler Associates, LLC Chad Bennett, Iowa Foundation for Medical Care Crystal Kallem, American Health Information Management Association Joy Kuhl, Alliance for Pediatric Quality Feliciano Yu, MD, The Children's Hospital of Alabama

December 13, 2007

Table of Contents

ACKNOWLEDGMENTS
Founders:
Primary Benefactor for Phase One:
HL7 Sponsor:
Advisors:
Project Management:
Initiative Team:
EXECUTIVE SUMMARY
Quality Reporting Standardization6
Collaborating With Quality Reporting Initiatives7
Opportunity
ABOUT THE QRDA INITIATIVE
Project Scope9
Key Parallel Efforts10
American Health Information Community (AHIC) Quality Workgroup10
Health Information Technology Standards Panel (HITSP) Population Health Technical Committee 11
The Collaborative for Performance Measure Integration with EHR Systems (The Collaborative)11
National Quality Forum (NQF) Health Information Technology Expert Panel (HITEP)11
Standards Development Organizations
QRDA Phase I Project
DEVELOPMENT OF THE QRDA SAMPLES
Pediatric Inpatient Sample Measures
Reuse of CCD Templates
Clinical Versus Administrative Data17
Validation of QRDA Export19
Adult Outpatient Sample Measures
QRDA DOQ-IT Samples
Flexible Workflow
Limitations of the Phase I Samples22
OUTREACH AND COLLABORATION
Presentation and Discussion of QRDA

Coordination and Collaboration	23
American Health Information Community (AHIC) Quality Workgroup	23
The Collaborative	24
NQF Health Information Technology Expert Panel (HITEP)	24
Integrating the Healthcare Enterprise	24
Health Information Technology Standards Panel	25
Related Efforts	25
Standardizing Assessments and Supporting Health Information Exchange	25
CDA for Common Document Types (CDA4CDT)	
Potential Partners and Pilot Participants	
PHASE I FINDINGS:	27
Standard Clinical Data for Quality Measure Reporting	27
Implications for Registry Management	
Long-term Implications of Clinical Data for Quality Improvement	29
Collaboration Within the Interoperability Landscape	
Timelines for Development and Collaboration	
CONCLUSION	
CALL TO ACTION	
APPENDICES	
Recommended Next Steps	
Specification and Profile Development	
Pilot Deployment and Testing	33
Communication, Education, and Coordination	34
Potential Partners for Future Work	
References	
Contact Information	

Table of Figures

Figure 1: QRDA, automation, and validation of quality measure data collection	9
Figure 2: Display of Joint Commission Pediatric QRDA report in a web browser	14
Figure 3: Partial data mapping of Joint Commission Pediatric CAC-1, CAC-2 to QRDA	15
Figure 4: QRDA XML illustrating the use of CCD templates	17
Figure 5: Joint Commission Pediatric QRDA report: administrative & clinical	18
Figure 6: Schematron rule validating measure compliance	19
Figure 7: QRDA report and update with clinical results	21
Figure 8: Critical path timelines for standards development	31

Acknowledgments

The Quality Reporting Document Architecture initiative team would like to thank the following organizations and individuals for their support:

Founders:

Alliance for Pediatric Quality (AAP, ABP, CHCA & NACHRI) American Health Information Management Association (AHIMA) HL7 Pediatric Data Standards Special Interest Group Iowa Foundation for Medical Care

Primary Benefactor for Phase One:

Alliance for Pediatric Quality

HL7 Sponsor:

HL7 Pediatric Data Standards Special Interest Group

Advisors:

Barry Cannon, RN, Children's Hospital Central California David Classen, MD, First Consulting Group Dexter D'Costa, St. Louis Children's Hospital John Dzivak, Cook Children's Hospital Floyd Eisenberg, MD, Siemens Matt Hall, Child Health Corporation of America Stephen Lawless, MD, Nemours Beki Marshall, American Academy of Pediatrics Michael Miller, MD, Children's Memorial Hospital Rick Moore, National Association of Children's Hospitals and Related Institutions Greg Omlor, MD, Akron Children's Hospital Mitra Rocca, Novartis Pharmaceuticals Corporation Dan Russler, MD, Oracle Corporation Andrew Spooner, MD, Cincinnati Children's Medical Center Bob Underwood, Child Health Corporation of America

Project Management:

Alschuler Associates, LLC

Initiative Team:

Liora Alschuler, Alschuler Associates, LLC Chad Bennett, Iowa Foundation for Medical Care Crystal Kallem, AHIMA Joy Kuhl, Alliance for Pediatric Quality Feliciano Yu, MD, The Children's Hospital of Alabama

Executive Summary

The Quality Reporting Document Architecture (QRDA) initiative results from a private collaboration sponsored by the Alliance for Pediatric Quality (Alliance) – a joint effort of the American Academy of Pediatrics, The American Board of Pediatrics, Child Health Corporation of America, and the National Association of Children's Hospitals and Related Institutions. Its goal is to develop an electronic data standard for exchange of patient-level quality measurement data between health care information systems.

In July 2007, the Alliance funded a short-term effort to explore the technical and logistical challenges and opportunities surrounding standards development for health care quality reporting. This report documents those findings in the context of quality reporting standardization and collaboration with parallel initiatives.

Quality Reporting Standardization

The Phase I QRDA initiative finds that existing standards for clinical data exchange can be used for reporting of current quality measures. In this project, sample measures drawn from the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) and from Doctor's Office Quality – Information Technology (DOQ-IT) map directly to the Health Level Seven (HL7) Clinical Document Architecture (CDA), which is a widely adopted industry standard. This means that when measures are mapped to CDA to create the QRDA, providers can use the same data constructs developed for information exchange to report on quality measures directly out of the electronic medical record (EMR)¹.

Many constructs identified in the initiative's sample measures reuse templates developed for the Continuity of Care Document (CCD), which is proposed as a core component of the interoperability specifications for EMR systems proposed for 2008 EMR certification through the Certification Commission on Healthcare Information Technology (CCHIT). While this approach supports a move to reporting based directly on clinical findings, the underlying

Clinical versus Administrative Data:

The distinction between clinical-findings based reporting (where information is extracted directly from the patient record - an EMR system if one is available) and reporting based on an abstract of that record (typically done for billing or administration), is key to the value of QRDA. Recent work sponsored by the Department of Health and Human Services indicates that clinical data has a much higher value for measurement and improvement than does the current brand of administrative data. [18,19] **Developing and supporting adoption of a clinically-**

based standard for quality reports is a key component in the move toward use of clinical data for quality measurement.

model can also work with administrative data constructs.

¹ This report strives to use the term "electronic medical record" (EMR) in reference to a local or enterprise clinical application and the complementary term for "electronic health record" (EHR) to refer to an extra-enterprise, regional, or distributed longitudinal record or system of systems. Usage of these terms is not consistent in industry, and common usage is preserved here.

Development of automated rules checking at the point of care and point of collection provides immediate feedback on the completeness of submission data sets and can also provide feedback on adherence with related practice guidelines.

The underlying CDA is an open data standard that can be implemented in centralized and distributed systems, irrespective of the underlying application or communications platform or architecture. Interpreting the supplied use cases for distinct implementation workflows, samples were developed supporting incremental or summary reporting and using standard metadata to manage and track both initial data submissions and updates. Thus, initial work indicates that QRDA can support multiple flexible workflows for diverse quality reporting environments, including integration into emerging health information exchanges.

The value to be derived from a move to EMR-compatible, standards-based quality measure reporting is high and supports the mission of the Alliance to lead, shape, and accelerate recognition and adoption of quality improvement.

In addition to increased accuracy, data extracted directly from the EMR will be easier to produce, reducing the reporting burden on providers, fostering greater participation in improvement efforts, and encouraging EMR adoption. Using existing standards makes it easier for vendors to support measure export, especially where the same underlying data constructs (model, vocabulary, data types) support general interoperability requirements.

On the side of the data recipients, the requesters of quality measurement data, a single standard can reduce or eliminate data mapping for import. Looking ahead, utilization of standard clinical constructs opens the door to population-based research, including analysis across a broad range of information resources.

The initial definition of Phase II included an HL7 ballot to establish a QRDA standard and a pilot project to support implementation. This report further refines and defines these Phase II objectives and describes additional actions with high potential to support the goals of the QRDA initiative.

The Phase I effort did not address standards for defining measures for import into electronic health record systems, and a key finding is the need to coordinate the rules for import with the rules for validating measure export.

Collaborating With Quality Reporting Initiatives

With such strong incentive to realize quality measurement from clinical records, it is no surprise that QRDA is not alone in this landscape. The Phase I effort met with and investigated parallel efforts under the Office of the National Coordinator (ONC), professional and quality organizations, and standards development organizations to explore alignment opportunities.

The proposed QRDA supports use case requirements published by ONC and is consistent with requirements defined by the professional societies, quality organizations, and vendors. All indications are that QRDA is a critical component required to meet the data export requirements defined by the National Quality Forum (NQF) Health Information Technology Expert Panel (HITEP), The Collaborative for Performance Measure Integration with EHR Systems (The Collaborative), the Health Information Technology Standards Panel (HITSP), and Integrating the Healthcare Enterprise (IHE). In fact, both HITSP and IHE quality work groups have reviewed the Phase I work on QRDA and have expressed a strong desire to adopt it as an integral part of their 2008 development. Phase I discussions indicate that QRDA supports and complements these efforts.

Opportunity

In a short period of time, the concept of QRDA has been developed and accepted by HL7, IHE, and HITSP as the candidate of choice for standard quality reporting. There is a clear window of opportunity to provide leadership in adoption of a standard for clinical quality reporting that will increase participation and therefore improve care delivery. The national agenda for quality improvement is aggressive and calls for development of data standards within 2008. To meet this challenge, QRDA must become an HL7 Draft Standard for Trial Use (DSTU), tested in pilot implementations and presented to the providers and requesters of quality data through a marketing and communications plan that will support adoption and further implementation of quality improvement measures.

About the QRDA Initiative

Goal: To develop an electronic data standard for exchange of patient-level quality measurement data between health care information systems.

The QRDA initiative is a private collaboration sponsored by the Alliance for Pediatric Quality – a joint effort of the American Academy of Pediatrics, The American Board of Pediatrics, Child Health Corporation of America, and the National Association of Children's Hospitals and Related Institutions. The mission of the Alliance is to promote meaningful improvement in pediatric health through quality measures, data standards, and health information technology.

The American Health Information Management Association (AHIMA) and the Iowa Foundation for Medical Care (IFMC) also contributed valuable insight and resources throughout the project. AHIMA is the premier association for health information management professionals dedicated to the effective management of personal health information needed to deliver quality healthcare to the public. IFMC is a nationally recognized health care value management company with extensive experience defining, implementing, and consulting on national quality measurement programs for the Centers for Medicare and Medicaid (CMS) and the Joint Commission. The combination of background and expertise offered by all project team members facilitated efficient use of resources and alignment with key industry initiatives.

This project stems from the recognition that while health information technology (HIT) contributes to better outcomes and increased efficiency, several barriers prevent widespread adoption. The recent report by the AHIC Quality Workgroup stressed the need to make a transition from a single point in time and site-specific orientation where data is manually abstracted to a longitudinal patient-centric orientation drawn directly from the clinical record.[2]

The QRDA initiative addresses these barriers by developing a standard specification for communicating information on both pediatric and adult quality measurement across a

variety of health care settings. Furthermore, this project supports the requirements of quality reporting by promoting adoption of the specification by providers, vendors, and requesters of quality data in collaboration with existing parallel efforts.

Project Scope

The QRDA defines a data standard for collection of clinical source data documenting compliance with predefined, identified quality measures. QRDA compliant reports will gather data from patients meeting various sets of measure-defined criteria. Data extracted from reports on the initial population becomes part of the numerator and/or denominator, if not eliminated, as the full set of exclusion/inclusion criteria are applied.² [3]

The QRDA focuses on the collection of this source data in interoperable format and its submission to requesters of quality measurement data. It does not address the analysis of aggregate data or the data format for reporting the aggregate results back to health care providers or institutions. QRDA is designed to be used by the requesters/recipients of quality measurement data as the raw material for the analysis and reporting of aggregate data. Thus QRDA sample reports are "patient-level case reports" and are exported from electronic health records or quality-monitoring applications at the point of care.



Figure 1: QRDA, automation, and validation of quality measure data collection

² A similar project for CDA-based public health reporting to the Centers for Disease Control and Prevention National Healthcare Safety Network has also defined aggregate reports. If a QRDA use case is defined for submission of aggregate data, it can be handled in the same manner as for the NHSN.

Figure 1 illustrates the immediate impact of standards for collecting EMR-compatible quality measure data. QRDA will import data from electronic medical records and provide immediate point-of-care, patient-level feedback on compliance with measure data-gathering requirements. For example, if a measure requires evidence of a certain test or observation, absence of that evidence will trigger an error report.

Some source material may remain on paper and will continue to require manual data entry, although initial findings indicate that the capability to collect information required for patient-level reporting is present where EMR systems are in use.[11] While the emphasis is on EMR extraction, the dictation/transcription industry is supporting the same underlying structured data standards. [5] [7]³ This will augment the information available within the EMR and provide the potential for quality reporting from structured document extraction.

QRDA-formatted data can then be sent to registries, institutions aggregating data, and other requesters of quality measure data. In addition to immediate point-of-care feedback on the completeness and validity of the data, QRDA can support local or distributed quality monitoring, practice guidelines, decision support, and health information exchange.

QRDA is an implementation of the Health Level Seven (HL7) Clinical Document Architecture, Release 2.0 (CDA R2) and implemented in Extensible Markup Language (XML) [14]:

"CDA is a document markup standard that specifies the structure and semantics of a clinical document (such as a discharge summary or progress note) for the purpose of exchange... The CDA R2 model is richly expressive, enabling the formal representation of clinical statements (such as observations, medication administrations, and adverse events) such that they can be interpreted and acted upon by a computer. On the other hand, CDA R2 offers a low bar for adoption, providing a mechanism for simply wrapping a non-XML document with the CDA header or for creating a document with a structured header and sections containing only narrative content. The intent is to facilitate widespread adoption, while providing a mechanism for incremental semantic interoperability." [9]

CDA is a key component of the emerging regional and national health information exchanges and is at the core of efforts to standardize the electronic medical record to support broad-based reporting, research, and decision support. [4]

Key Parallel Efforts

Several efforts supporting standardized quality measure collection and reporting are active in parallel with the QRDA project. These include:

American Health Information Community (AHIC) Quality Workgroup

"The American Health Information Community (AHIC) is a federal advisory body, chartered in 2005 to make recommendations to the Secretary of the U.S. Department of

³ The development of these guides was supported by the CDA4CDT project, underwritten by benefactors in the dictation/transcription and document management industries.

Health and Human Services on how to accelerate the development and adoption of health information technology." The AHIC Quality Workgroup promotes the automation of quality measurement data collection, aggregation and reporting and is developing a quality use case to support the identification and definition of interoperability specifications. [2]

Health Information Technology Standards Panel (HITSP) Population Health Technical Committee

HITSP was established in 2005 by the Office of the National Coordinator and given the charge "to identify and harmonize data and technical standards for healthcare."

Eventually, when HITSP has fully identified or defined standards that meet the AHIC use case, and these recommendations are passed to the Secretary of Health and Human Services, they may be integrated into the application certification requirements established by the Certification Commission for Health Information Technology (CCHIT), which then becomes a powerful incentive for adoption among the EMR vendors.

The Collaborative for Performance Measure Integration with EHR Systems (The Collaborative)

The Collaborative is sponsored by the American Medical Association (AMA) and the National Committee on Quality Assurance (NCQA).

In the publication "The Collaborative for Performance Measure Integration with EHR Systems: *A Reference Guide for EHR Vendors*" dated September 27, 2007, it is stated that:

The Collaborative for Performance Measure Integration with EHR Systems ("Collaborative"), co-sponsored by the American Medical Association (AMA) and the National Committee for Quality Assurance (NCQA), is a group of stakeholders in the physician performance measurement and quality improvement arena who have a shared goal to provide industry with workable recommendations for performance measure use. The Collaborative's goals are:

- 1. To create a standardized way of communicating performance measures.
- 2. To establish standards that permit structured, encoded performance measure information to be incorporated into EHR applications while preserving the clinical intent of the performance measure.
- 3. To improve the process of performance measure update and maintenance for EHR vendors." [23]

National Quality Forum (NQF) Health Information Technology Expert Panel (HITEP)

The goal of the HITEP is to identify high-value data from EHR systems for quality measurement. The charge of the group is "To convene an expert panel to develop a set of common data elements and health care workflow changes to enable automation of performance measures through electronic health records (EHRs) and health information exchange." [22]

Standards Development Organizations

Among standards development organizations, key points of contact and harmonization include:

- HL7 Pediatric Data Standards Special Interest Group (PeDSSIG), which would sponsor this project for ballot within HL7
- HL7 Structured Documents Technical Committee (SDTC), which has agreed to cosponsor the ballot with the HL7 Parent Care Technical Committee, parent TC to PeDSSIG
- Integrating the Healthcare Enterprise (IHE) Quality Domain, developing the Patientlevel Export of Quality Data (PEQD) Integration Profile.

The Phase I work on QRDA, described here, looked at these initiatives and their potential relationship to the proposal to build a QRDA, specifically looking for points of overlap, potential conflict, or alignment. Findings are reported in "Collaboration Within the Interoperability Landscape."

QRDA Phase I Project

In August 2007, the QRDA initiative contracted with Alschuler Associates, LLC, to work with project volunteers on a Phase I effort to prototype QRDA as an implementation of CDA R2.

The deliverables from Phase I can be grouped as follows:

Development of QRDA samples:

- 1. Identify data elements for sample measures.
- 2. Develop a minimum of two QRDA samples.

Coordinate with parallel efforts:

- 3. Describe the relationship of QRDA to similar efforts within HL7 and external to HL7 (IHE and others).
- 4. Coordinate with HL7 SDTC on further development.
- 5. Coordinate with IHE through liaison on standards development to support the AHIC Quality Use Case and corresponding HITSP use case requirements and interoperability specifications.

Provide training and education:

- 6. Provide training and education on QRDA for project team and interested stakeholders.
- 7. Deliver executive-level web cast on findings, including options for Phase II.

Deliver Phase I Final Report:

- 8. Describe the potential quantifiable benefit of Phase II work from an IT perspective.
- 9. Assess other organizations as potential collaborators in Phase II.
- 10. Describe options for moving forward including pathways, timelines and partnerships, discussing pros and cons of each option.
- 11. Develop refined project scope and resource requirements for Phase II, including number, role, time commitment and budget for volunteers.

This report describes the QRDA samples developed for deliverables 1-2, the outcome of the coordination efforts in deliverables 3-5 and together with a separate Phase II project proposal and budget, completes deliverables 8 - 11. Training and education per deliverables 6-7 will continue based on the findings described here and a complementary PowerPoint presentation.

Development of the QRDA Samples

The Phase I QRDA initiative addresses reporting of patient-level quality measure performance data for single patients. Sample measures were chosen to represent highpriority areas for pediatric and adult medicine as well as for inpatient and ambulatory settings.

Pediatric Inpatient Sample Measures

The sample was developed to comply with the requirements of the Joint Commission *Specifications Manual for National Hospital Quality Measures – Children's Asthma Care*, version 1.0, for discharges beginning April 2007[20]. In this sample, the subject is a seven-year-old male child seen at an emergency department and then admitted for treatment. He is enrolled for "Use of Relievers for Inpatient Asthma" (CAC-1) and "Use of Systemic Corticosteroids for Inpatient Asthma" (CAC-2).

Note that the style of display here follows that of a clinical record on which the report might be based. The underlying data can also be displayed in a more traditional data-centric format.

Quality Reporting Document Architecture: Phase I Final Report

G QRDA Patient Report: CAC-1 and CAC-2 - Windows Internet Explorer	
	P -
😭 🛠 🌈 QRDA Patient Report: CAC-1 and CAC-2	$Page \star \textcircled{O} Tools \star $
QRDA Patient Report: CAC-1 and CAC-2	
Created On: August 20,2007	
Patient: MRN:	_
Birthdate: September 2,2000 Sex: Male	
PROBLEMLIST	
 Extrinsic Asthma, with Status Asthmaticus Hypoxemia 	
RESULTS	≡
• Pulse Oximetry: 93%O ² saturation at Room Air	
MEDICATIONS	
 Respiratory medication administered by nebulizer Albuterol Inhalant Solution [Accuneb] Oxygen therapy Prednisolone (ORAPRED SOLUTION) 	
ALLERGIES, ADVERSE REACTIONS, ALERTS	
 Contraindication to Relievers (CAC-1):None Contraindication to Systemic Corticosteroids (CAC-2):None 	
ADMISSION SOURCE	
Emergency room	

Figure 2: Display of Joint Commission Pediatric QRDA report in a web browser

Dr. Feliciano (Pele) Yu developed a data set conforming to reporting requirements for inpatient asthma measure and presented them in table format. From there, the mapping to CDA R2 was performed, and a sample QRDA instance was generated.

Data Description	Value/Code Description	Coding System/ Data type	Code	CDA
Template id	Pilot OID	II		<templateid root="2.16.840.1.113883.3.117.1.2.4.3" displayable="Use of relievers for Inpatient Asthma (CAC-1)"/></templateid
				<templateid root="2.16.840.1.113883.3.117.1.2.4.4" displayable="Use of Systemic Corticosteroids for Inpatient Asthma (CAC-2)"/></templateid
Effective Time (visit 1)	timestamp	TS		<effectivetime value="20070820080000-
0400"></effectivetime>
Document id	pilot OID	II	a1	<id extension="s5v1" root="AALLC.nnn"></id>
Document type code	Quality Measure Report/ QRDA	LOINC	QRDA-X	<pre><code code="QRDA-X" codesystem="2.16.840.1.113883.6.1"></code></pre>
Title				<title>QRDA Patient Report: CAC-1 and CAC-2 </title>
ICD-9CM Other	Oxygen therapy	ICD-9CM	93.96	<procedure <br="" classcode="PROC">moodCode="EVN"></procedure>
Procedure Codes	1.			<templateid root="2.16.840.1.113883.10.20.1.29"/></templateid
				Procedure activity template
				<id root="idGoesHere"></id>
				<code <br="" code="93.96">codeSystem="2.16.840.113883.6.103" codeSystemName="ICD-9" displayName="Oxygen therapy"/></code>
				<statuscode code="completed"></statuscode>
				<effectivetime value="20070814"></effectivetime>

Figure 3: Partial data mapping of Joint Commission Pediatric CAC-1, CAC-2 to QRDA

In the table fragment in Figure 3, The Template ID is an optional CDA field used here to represent the measures on which the instance is reporting. Effective Time was defined in the measure sample data and maps directly to a required CDA field. The document

identifier (id) complies with a CDA requirement that each instance have a globally unique identifier.

The document type code is a primary classification field used by document management systems. Here it is given in a format that indicates an appropriate code will be requested from LOINC. Consideration of the proper classification of quality measure reports under QRDA would be a critical component of the development of the draft standard. The document title is a display string that would be printed or displayed on reports. In this case, the title identifies the report as QRDA-, CAC-1-, and CAC-2-compliant.

The ICD-9 code for oxygen therapy is presented as a CDA <procedure> element. The <statusCode> indicates the procedure was completed.

Reuse of CCD Templates

The following figure shows a fragment of the CDA XML encoding underlying the Joint Commission measure report. Note the "templateId" circled. This templateId was defined in the HL7/ASTM Continuity of Care Document (CCD) Implementation Guide and is recognized by CCHIT and HITSP for exchange of clinical information. Its use here indicates that the data meets the conformance criteria defined for the CCD "problem list". Starting in 2008, vendors will be required to import and export this CCD template for CCHIT certification. Utilizing the same structure and semantics for quality reporting will minimize the burden on those developing HIT and those adopting them in the provider sector.

```
    <section>

   <templateId root="2.16.840.1.113883.10.20.1.11" />
   <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
     code="11450-4" displayName="PROBLEM LIST" />
   <title>PROBLEM LIST</title>
 - <text>
   - dist>
       <item>Extrinsic Asthma, with Status Asthmaticus</item>
       <item>Hypoxemia</item>
     </list>
   </text>
 - <entry>
   - <act classCode="ACT" moodCode="EVN">
       <templateId root="2.16.840.1.113883.10.20.1.27" />
      Problem act template -->
       <id root="aib42461-334c-4786-bd05-f641227d0302" />
       <code nullFlavor="NA" />

    <entryRelationship typeCode="SUBJ">

       - <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.1.28" />
          -- Problem observation template
          <id root="ee7e4cf9-62ae-47e4-829b-ea3d5d4307b9" />
          <code code="ASSERTION"
            codeSystem="2.16.840.1.113883.5.4" />
          <statusCode code="completed" />
          <!-- Used the encounter date, but could be any
          desired time -->
          <effectiveTime value="20070814" />
          <value xsi:type="CD" code="493.01"
            codeSystem="2.16.840.113883.6.103"
            codeSystemName="ICD-9" displayName="Extrinsic
            Asthma, with Status Asthmaticus" />
         </observation>
       </entryRelationship>
     </act>
```

Figure 4: QRDA XML illustrating the use of CCD templates

Note the templateId within <procedure> in Figure 4 above. This indicates that the encoding of the oxygen therapy procedure was also in compliance with the encoding of procedures in the CCD.

Clinical Versus Administrative Data

The QRDA uses clinical data for reporting. In this context, clinical data directly extracted from a patient chart or EMR can be considered analogous to primary source data in research. In contrast, most quality measure reports today rely on administrative data, the equivalent of secondary sources abstracted from the clinical report.

An example of each is illustrated in the figure that follows. The measure asks whether respiratory relievers were administered. The clinical data approach answers the question by documenting that albuterol was administered by nebulizer. The administrative data approach poses the question and answers with a Boolean value of "yes."



Figure 5: Joint Commission Pediatric QRDA report: administrative & clinical

From a superficial data-gathering perspective, the two approaches may seem equivalent; however, there are profound implications in the choice where the use of primary clinical data is clearly preferred, both for immediate quality improvement monitoring and for long-term understanding and interoperability. The effect on quality improvement has been studied and documented recently under the auspices of CMS.

The recent study led by Dr. Paul Tang concluded that claims-based measures underestimate populations, allow biased over-reporting of compliance and can misdirect improvement efforts. In contrast, clinical data-based reporting accurately identifies the affected population, gives a better picture of compliance, is less subject to manipulation, and overall is a more accurate tool for managing incentives.[21]

In the long run, semantically interoperable clinical data can support broad-based queries across data sets that would be impossible given the administrative, secondary source data approach. A simple example of the difference is collecting data on the sex of a patient. There is more than one way to ask a question to retrieve this data:

- "Was the patient male?" Yes
- Patient sex: M

In a broad-based query on demographics, it is not always possible to equate the disparate answers ("Yes", "M", "Male") that share the same meaning. With semantically interoperable data, there is a single form of assertion that carries the intended meaning:

<patient><administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"/>

Two CDA-based projects, one under CMS working with the Minimum Data Set and one under CDC working with Healthcare Associated Infection Reports, are defining the use of clinical data for reporting. Initial work on the QRDA indicates that it is a close fit with existing clinical data, so close that the Phase I samples reused existing clinical templates. In a true reporting environment, assertions of the presence of a negative condition ("relievers were not administered") will be defined, still consistent with clinical data structures, to sustain automated and reliable reporting. Pilot implementation with recipients of quality data is needed to ensure smooth transformation and integration into existing data structures. During a transitional period from administrative to clinical data, both forms of the information can be represented within the QRDA.

Validation of QRDA Export

Development of a validating rule set specific to the measures illustrated here was not in scope for Phase I, but the following illustrates how rules are written and applied to measure submissions. Consider, for example, the CAC-1 requirement to monitor administration of respiratory medication for patients with a diagnosis of "Extrinsic Asthma with Status Asthmaticus." In this case, the rule states that:

• when validating CAC-1 known through the templateId:

<templateld root="2.16.840.1.113883.3.117.1.2.4.3" displayable="Use of relievers for Inpatient Asthma (CAC-1)"/>

• if there is a diagnosis of ICD-9 493.01

<value xsi:type="CD" code="493.01" codeSystem="2.16.840.113883.6.103" codeSystemName="ICD-9" displayName="Extrinsic Asthma, with Status Asthmaticus"/>

• then the QRDA instance must contain a code indicating administration of ICD-9 93.94 (Respiratory medication administered by nebulizer)

<value <substanceAdministration> ... <code code="93.94" codeSystem="2.16.840.113883.6.103" codeSystemName="ICD-9" displayName="Respiratory medication administered by nebulizer"/>

The figure that follows shows a sample rule that will validate measure compliance. The rule is written in XML in the Schematron language, used for validation of CDA and CCD compliance and being adopted by CCHIT for certification testing. [13]



Figure 6: Schematron rule validating measure compliance

This approach is consistent with that of other CDA R2 implementations where validating rule sets have been developed, including the CCD and the Healthcare Associated Infection Reports (HAI) Draft Standard for Trial Use (DSTU) developed for the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN).

For HAI, a thorough analysis of submission business rules indicated which parameters could be checked at the point of care and which parameters required data in the NHSN database. The point-of-care rules were written into a validating rule set using the Schematron language, a nonproprietary XML-based syntax that can be run on any XML file. The HAI uses the same approach that CCHIT is taking in validating CCD instances and other CDA document types. (For a live example of how to submit and validate reports, see the "CDA Validator" at http://www.alschulerassociates.com/validator/.)

Adult Outpatient Sample Measures

The adult outpatient samples were developed from the Doctor's Office Quality – Information Technology (DOQ-IT) Use Cases and HL7 Output Implementation Guide for Trial Use Version 1.1 [8]

"This document provides practical examples of the information necessary to submit data for the Ambulatory Care Measures in the DOQ-IT initiative. The data consists primarily of patient observational data collected at a physician's practice."

The QRDA samples used Use Case 1, in which "Patient 1 has been diagnosed and enrolled for all of the Coronary Artery Disease (CAD) and Diabetes (DM) topics in the Ambulatory Care Measure set." The use case provided administrative and clinical data over two visits for a patient with confirmed diagnoses of CAD and diabetes. The DOQ-IT implementation guide provided data in a four-column table listing:

- Data Description
- Value/Code Description
- Coding System
- Code

The QRDA sample was developed by adding data type information to the third column of this table and adding a fourth column with mapping to the CDA R2. The following fragment provides a sample of the table:

The DOQ-IT use case covered two visits. In the first, certain vital signs are reported, but the HbA1c is reported as "Not performed, patient reason." Urine protein is reported as tested, but no value given. In the second visit, several examinations are performed on the feet without results provided, as would be typical of administrative data because admin data only captures the fact that an examination was made, not the findings from the examination. This scenario provided several opportunities to utilize the richness and flexibility of the QRDA concept, so the basic data in the DOQ-IT use case was modified to demonstrate incorporation of clinical results, as well as administrative data, and to show flexible reporting workflow.

Specifically, the scenario was modified to assert that the failure to test HbA1c was due to the patient not fasting and was corrected in a follow-up procedure reported as an update to the initial report. In total, 4 sample QRDA report files were generated to demonstrate that reporting can occur in step with clinical processes, in real-time or near real-time, or can occur at pre-determined intervals, including data across several visits into a single report.

QRDA DOQ-IT Samples

- Sample 1: Single Visit, visit 1 (initial submission)
- Sample 2: Single Visit, visit 1 (update) version 2, adds HbA1c result
- Sample 3: Single Visit, visit 2
- Sample 4: Both visits (HbA1c result available)

🙀 🏘 🌈 QRDA Report for DOQ-IT 👘 🏠 🔹 🗟 🔹 🖶 💌 📴 Page 🗸			
QRDA Report for DOQ-IT Measure 🖗 🏟 🎯 QRDA Report for DOQ-IT 📄 🏠 🔹 👼 🗸			
CAD 1-7 and DM 1-8	Created On: December 17, 2004		
Created On: December 15, 2004			
	Patient: Patient One MRN: XX40404021-		
Patient:Patient OneMRN: XX40404021-AABirthdate:April 15, 1917Sex: Male	Birthdate: April 15, 1917 Sex: Male		
PHYSICAL EXAMINATION	PHYSICAL EXAMINATION		
Eye Exam: Not performed, patient reason	Eye Exam: Not performed, patient reason		
VITAL SIGNS	VITAL SIGNS		
Systolic BP: 145 mm[Hg]	Systolic BP: 140 mm[Hg]		
Diastolic BP: 88 mm[Hg]	Diastolic BP: 83 mm[Hg]		
Heart rate: 51 bpm	near rate. 54 opti		
DIAGNOSTIC FINDINGS	DIAGNOSTIC FINDINGS		
URINE PROTEIN, TOTAL, ELECTROPHORETIC QUANT:	URINE PROTEIN, TOTAL, ELECTROPHORETIC QUANT: Hbalc:		
HbA1c: Not performed, patient reason			

Figure 7: QRDA report and update with clinical results

Note also that the data sample here identifies the patient through an identifier which could be blinded, where in the pediatric sample, even the identifier is screened. The field metadata in the CDA header is easily adapted for de-identification and use of pseudonyms and blinding. Since the reports are not the full clinical document and contain

only data elements required for reporting, blinding can be effective for smaller populations than records that contain full clinical stories.

Flexible Workflow

QRDA leverages the broad-based interoperability characteristics of the underlying CDA which defines metadata to manage relationships between documents in a distributed, cross-enterprise exchange environment. These capabilities have been refined over many years, are widely implemented and support multiple, diverse reporting strategies including:

- Across multiple settings can be linked by patient/provider/encounter metadata and explicit episode identifiers
- On an encounter-by-encounter basis
- As a summary of pertinent data collected across multiple encounters, retaining the full context in either case

Several key fields in the CDA identify the location and circumstances of data collection including:

- Providers who participated in various roles (author, authenticator, attending, performer)
- Organizations that scope the participation of patients and providers (setting of the encounter, source of an order)
- Time/date stamp for release of the report as well as individual time/date stamps on pertinent findings
- Relationship to prior reports (replace, append, transform) and globally unique identifiers on all instances

The metadata in the CDA header is used in production today to support vastly different exchange architectures, including the centralized model of the National Health Service in England and the distributed model of the record locator service pioneered on large scale in Finland since 2001 and adapted for the IHE Cross-Enterprise Document Sharing. Thus, CDA is proven agnostic with respect to the specific setting for reporting and exchange, a key requirement identified in the AHIC use case.

Limitations of the Phase I Samples

The Phase I work created five sample reports compliant with a small number of measures. Development of a full reporting architecture will require a systematic analysis of report requirements and the mapping of these requirements to the underlying CDA specification.

Issues not covered in the prototype work that must be addressed in development of the QRDA include consideration of document types, terminology and value sets, clinical statement design, validation requirements, and recipient data transformation requirements.

The resources required for this work are considered in the project proposal for Phase II. While working through the requirements and testing against a full set of prioritized measures will take time, the issues identified are typical of any information analysis project and are not out of scale with those addressed in similar CDA implementations such as the HAI specification for the public health reporting, which has been piloted successfully and is in the HL7 DSTU process.

Outreach and Collaboration

A key component of the Phase I effort was developing an understanding of how QRDA fit with current requirements and how it relates to other parallel efforts.

Presentation and Discussion of QRDA

To understand requirements and begin to develop a cadre of volunteers who can continue to support and inform the effort, several interviews and group conference calls were held from August through early September (see Advisors:

The QRDA was presented and discussed in the following forums:

- HL7 Pediatrics Data Standards Special Interest Group (PeDSSIG) and the Structured Documents Technical Committee (SDTC) during the fall 2007 HL7 Working Group Meeting.
- Collaborative Workgroup B received a QRDA update on September 28, 2007 and a brief overview was provided during the full Collaborative meeting on October 16, 2007.
- IHE Quality TC received a presentation on QRDA at their meetings on October 4, 2007 and November 5, 2007.

In addition, several discussions have been held with potential partners and pilot participants, see the Appendix, *Potential Partners for Future Work*

Coordination and Collaboration

These formal presentations and discussions have been supplemented by review of published works and works-in-progress from the pertinent organizations. Aspects of these parallel efforts that relate to QRDA are summarized here.

American Health Information Community (AHIC) Quality Workgroup

The AHIC Quality Workgroup has released a "Pre-Decisional Document for Discussion Purposes Only" on September 28, 2007.[2] This assessment is based on that document, referred to as the "Quality Workgroup Draft Report" and notes from the meeting of October 3, 2007[1].

Section 3.2 of the document on Emerging HIT Strategies and Section 6 on Next Steps cite the CCD as an example of new and innovative approaches to "episode-based, patient-centered and longitudinal care tracking and measurement." Basing the core data-

gathering specification on an interoperable clinical data exchange standard supports this vision, as CDA was designed from the outset to facilitate interoperability across a diverse, distributed heterogeneous environment.

The Collaborative

The work of the Collaborative has been managed by Workgroup A, devoted to identifying and documenting current EHR workflow and data collection practices within physician practices and among software systems, and Workgroup B, devoted to measure definition for importation into EHR applications and performance measure data export from EHR applications.

The QRDA Phase I effort is directly related to the Workgroup B data export requirements. Preliminary findings indicate that it provides a standard syntax and model for EHR interoperability that meets the export requirements outlined by Workgroup B in the draft document dated January 17, 2007, v.1.

The Phase I QRDA project did not encompass an examination of import requirements. Review of the work of the Collaborative raises these pressing questions:

- Can the same rule set that validates that a QRDA export complies with a stated measure can also describe measure logic to EHR applications?
- If so, should the XML syntax for measure import developed by the Collaborative be mapped to this rule set so that vendors can work with a single syntax?
- If not, what are the gaps and how can industry ensure that basic building blocks such as data types and identifiers are consistent for quality reporting and clinical data?

NQF Health Information Technology Expert Panel (HITEP)

The HITEP was convened by the National Quality Forum (NQF) "to develop a set of common data elements and health care workflow changes to enable automation of performance measures through electronic health records (EHRs) and health information exchange." The impetus for this work was "Impact of Using Administrative Data for Clinical Quality Reporting: Comparing Claims-Based Methods with EHR-Based Methods," a study led by Paul Tang, MD, published in JAMIA and cited above in reference to the superiority of clinical data for reporting. [21]

HITEP recommends "... that a coded interdisciplinary problem list in the EHR be used in place of billing codes to identify patient conditions for quality measurement." QRDA is directly supportive of this strategy.

Integrating the Healthcare Enterprise

The IHE Quality Technical Framework, like all IHE Frameworks, relies on existing standards and refines and constrains them to support seamless integration. The Year 1 (2007-2008) draft framework for public comment, issued July 2, 2007, stated:

The Patient-level Quality Export of Quality Data (PEQD) profile addresses the need for consistent communication of Quality data to a local, regional or third party Analyzer / Aggregator for consistent, standardized evaluation of quality

structural, process and outcome measures. Recipients of Quality performance data include, but are not limited to, external governmental or private agencies, organizational Quality Management professionals, health care providers, and healthcare consumers (individuals and employers).[15]

The scope of year 1 in this draft edition, did not call for development of specific measures, but rather development of an approach consistent with existing profiles and use cases. From the outset, it appeared that QRDA could be integrated into the Quality Technical Framework as the "payload" in a report going to requesters of quality data. At the request of IHE, the QRDA team joined the IHE discussions when they met to consider profiles for development in 2008 and implementation in 2009. As a result of those discussions, IHE is anticipating integration of QRDA into the 2008-2009 PEQD profile for data exported from the EMR and for measure definition on import to the EMR.

Health Information Technology Standards Panel

The Population Health Technical Committee has circulated a review copy describing requirements for "HITSP Patient Level Quality Data Document Component," to be known as HITSP/C38, on September 18, 2007. This document describes the role of the Component thus:

"This Component supports the communication of patient-level quality data for quality measurement in a document-sharing environment. Patient encounter data are compiled from both the local systems and from longitudinal data available through a health information exchange prior to communicating the retrieved data described in this construct for analysis."[17]

The Component construct roadmap points to CDA as a base standard, used in conjunction with appropriate vocabularies in an exchange choreographed with IHE XDS. The "Patient Data Mapping" table describes selected data elements and their mapping to CDA. Preliminary review indicates consistency between this approach and QRDA, although QRDA also asserts conformance to applicable CCD templates.

The HITSP Population Health Technical Committee has based its work on the AHIC Expert Panel Specifications for Quality Measurement, developed by the NQF HITEP (further described below). Based on past patterns of adoption, coordination, and cross-participation, it is likely that HITSP will follow the lead of IHE in slating QRDA for adoption.

Related Efforts

In addition to these national-level strategic efforts, several related initiatives are taking place within the standards development community.

Standardizing Assessments and Supporting Health Information Exchange

Significantly, one of the gaps cited by the Quality Workgroup is lack of exchange standards for assessment instruments, including the Minimum Data Set. Shortly after the release of this draft, a contract was awarded by Assistant Secretary for Planning and Evaluation (ASPE), Department of Health and Human Services, to Foundation of

Research and Education, American Health Information Management Association on "Standardizing Assessments and Supporting Health Information Exchange."

This project will address gaps in infrastructure and standards adoption by "...applying HIT standards to federally-required assessment instruments and developing the infrastructure to exchange the assessment data." Deliverables from this project include:

- Create a sample HL7 clinical document architecture (CDA) for the exchange of MDS data and assess the potential and requirements for a general DA MDS solution.
- Create a sample HL7 Continuity of Care Document (CCD) incorporating data from the federally-required assessment data suitable for use in transfer of care between acute and long-term care facilities and assess the potential and requirements for a general CCD solution for acute/LTC transfer of care.

The QRDA is aligned with these efforts in meeting the need identified by the AHIC Quality Workgroup for longitudinal quality reporting based on established standards integrated into the electronic health record.

CDA for Common Document Types (CDA4CDT)

This initiative to develop a full set of interoperable CDA document type specifications grew out of the dictation/transcription industry and is expanding to include document management and natural language processing. The technical objective is being realized through a series of HL7 DSTU, the initial ones covering the History & Physical and Consult Notes and current work extending to Op Notes and, in conjunction with DICOM, Diagnostic Imaging Reports.

The marketing agenda for the project is to demonstrate how electronic documents are integral components of the electronic health record and that standardizing these e-documents can vastly increase the flow of reusable data in the EMR. Like QRDA, these efforts are compatible with the CCD and the emerging consensus around clinical data gathering and reporting.

Potential Partners and Pilot Participants

The Phase I effort included discussions with a large number of groups interested in developing pilot projects for standards-based quality measure reporting. These contacts are useful in assessing interest in quality reporting automation and the likelihood of finding partners and participants for a pilot in Phase II. For a full list of interested parties who have already been contacted, see the "Potential Partners for Future Work" appendix.

Stakeholders considering pilot projects include:

- Duke Clinical Research Institute interested in QRDA to support a variety of quality measurement and research initiatives.
- MedQuist a participant in the CDA4CDT project mentioned above with an interest in leveraging the structure and content of transcribed clinical reports for quality measurement and reporting.

• The New York Department of Health's eHealth Collaborative – interested in how QRDA will support their efforts to collect and publicly report quality measurement data.

Ideal pilot participants include provider organizations investing in electronic records for quality reporting and recipients of quality data with an interest in receiving data from clinical systems. Several of the Alliance organizations (e.g., CHCA and NACHRI) are good candidates for pilots, as are the priority improvement efforts identified through the Alliance Improve First initiative.

Should QRDA be developed in time to meet IHE publication requirements in 2008, it would be available for implementation in the 2009 Connectathon and the demonstration held at the annual Healthcare Information and Management Systems Society (HIMSS) trade show. The Connectathon is a laboratory setting where vendors come together to demonstrate their capability to exchange information according to IHE profiles.

Phase I Findings:

Standard Clinical Data for Quality Measure Reporting

Key findings from the QRDA Phase I project indicate that it is feasible to meet measure reporting requirements with a specification based on the HL7 CDA. The sample measure reports created for this project are standard clinical documents with these distinctions:

- The quality measure(s) being reported are identified.
- Quality measure data is singled out for validation, verifying that required, measuredefined data elements are present.
- Data not required for the measure is not present.
- Reports can also integrate a question/answer format (the format of much administrative claims reporting).
- Data collected across multiple settings/sources/encounters can be integrated into one or more reports.
- The document is not intended for a patient chart, so it can be blinded or made anonymous.
- Additional templates can be defined to meet the requirements of patient-level quality reporting if not covered by existing clinical templates.

Initial findings indicate that existing templates defining a subset of clinical data items for interoperability between electronic health record applications can convey quality measure compliance data. The current samples reuse templates developed for the CCD with added constraints that make it possible to test for measure compliance. At the same time, QRDA measure-specific validation will be more selective and strict than that required to pass CCD validation.

Current work in public health reporting indicates that compliance with data-gathering requirements can be validated at the point of care using simple, readily-available tools and open data standards.

Document management capabilities built into the underlying architecture can sustain multiple, varied workflow requirements. The CDA, and therefore QRDA, is designed for use in a wide variety of messaging and service environments and therefore can be used in a variety of implementation architectures, depending on reporting requirements.

This approach brings several potential benefits:

Better data: Use of existing standards for clinical data brings quality reporting into the realm of clinical rather than administrative data. Instead of replying to the administrative question "Was HbA1c tested?," the report conveys the presence or absence of results and, if present, the results themselves. The benefits of this approach have been examined and reported on in a study funded by the Centers for Medicare and Medicaid (CMS). [21] The study compared the use of claims-based data with data extracted from an EHR and found that clinical data was superior in the identification of populations, less subject to gamin, and a more accurate tool to manage quality improvement initiatives.

More data, easier to produce: Providers face an increasing reporting burden to meet the needs of public health, quality improvement, and clinical research, not to mention reimbursement and continuity of care. It should be clear that when data can be entered once then extracted to meet reporting requirements, providers will find it easier to participate in reporting programs.

Single standard, easier to implement: Vendors today face increasing pressure to bring applications into compliance with requirements for interoperability. By the summer of 2008, CCHIT requirements for EMR certification will include CCD problems, alerts and medications, and the general ability to import and export CDA documents. Approaching quality reporting using the same data constructs defined for continuity of care will make it easier to implement and encourage vendor adoption of EMR-based quality reporting, passing along the benefits to providers.

Implications for Registry Management

Today, registries collect administrative claims data designed for current registry databases. Moving to a standards-based quality reporting architecture will have several implications for existing registries, changing the workflow at both the data producing and consuming sites.

For data producers with an EMR, there will be a strong incentive to ensure that the EMR is standards-compliant. With a standards-compliant EMR, the burden of reporting will decrease and the reporting volume may increase.

For data producers with no EMR, there remain several advantages to QRDA. There is the potential to develop QRDA reports from dictated narrative reports, without the use of an EMR. Dictation/transcription vendors are strong supporters of the CDA and are potential partners in early QRDA pilots and implementations.

Providers with access to a data warehouse can also adopt QRDA. For example, Nemours would like to explore the use of QRDA in its data warehouse to ease the manual effort currently required in helping its specialty practices participate in multiple and varied improvement efforts.

Over time, leveraging existing source of clinical data in EMR systems, clinical documents and data warehouses, providers should see their overall ability to provide registry-ready data increase without a comparable increase in cost.

For consumers of quality data, QRDA offers a higher quality and larger data stream, with the short-term need to provide a transition from administrative or claims data to data from clinical records. The immediate impact will be higher-quality, more complete data that has undergone initial validation at the point of care. The data constraints embedded onto the QRDA can ensure quality data capture. For instance, if a data element necessary for a quality measure report is missing, coded inappropriately, or mismatched; the sending or receiving systems can use the exposed data parameters as validation rules.

How different is this data from today's submissions, and what will registries need to do to import it? QRDA supports automated transformation by requesters of quality data who need to incorporate the information into existing claims-based databases. The draft standard must be carefully constrained to support an automated transform, as needed, from the new clinical data into a legacy format acceptable to current registries.

Long-term Implications of Clinical Data for Quality Improvement

In the long run, adoption of standards for clinical data supporting quality improvement will support the incremental adoption of the electronic medical record among providers, ease the reporting burden, improve the quality of data, and increase the amount of data available.

For recipients of quality reporting data, the implications are farther-reaching. Putting quality data into the same semantic structures across clinical applications lays the foundation for broad-based queries and analysis that is not possible when working with data tailored for a single purpose. Much careful work is required to develop the coded data standards that will sustain initial and future investigation, however, the groundwork is sufficiently strong that it is possible to identify and take first steps in this direction.

Clinically based, standards-compliant quality data can become an integral component of decision support as more interoperable data becomes available to clinical decision support engines.

Collaboration Within the Interoperability Landscape

The Phase I effort included outreach and discussion with parallel efforts to standardize and facilitate quality measure reporting. Initial findings indicate that QRDA fills an important role that complements and completes these efforts – it is not competitive, although there are key aspects that must be coordinated across all efforts and development of the specification must continue to move forward to keep pace with developments under the Office of the National Coordinator, in quality improvement and within industry. American Health Information Community (AHIC) Quality Workgroup: QRDA supports the vision and appropriate aspects of the use case defined to date by AHIC, which cites CCD as an example of new and innovative approaches to "episode-based, patient-centered and longitudinal care tracking and measurement." Basing the core data-gathering specification on an interoperable clinical data exchange standard supports this vision, as CDA was designed from the outset to facilitate interoperability across a diverse, distributed heterogeneous environment.

The report of the AHIC Quality Workgroup Meeting of October 3, 2007 recommended that the work of HITEP be extended to "compare the Continuity of Care Document (CCD) standards to the priority areas and data elements reviewed by HITEP, to determine how the CCD applies to the minimum data set or "quality data set" needs of the Quality Enterprise (both current and future needs related to quality measurement)."[1]

The Collaborative for Performance Measure Integration with EHR Systems: The Phase I pilot work indicates that QRDA can meet requirements defined by the Collaborative for export of quality data from EHR systems. The key question is whether the validating rules developed for QRDA along with appropriate measure metadata associated with a QRDA template can also define the data import construct.

NQF Health Information Technology Expert Panel (HITEP): Recommendations of the Panel are a close fit with the QRDA, including these:

- Substitute higher quality or more accurate EHR data element
- Recommend HITSP action to standardize required coded data [22]

Initial work on QRDA indicates that the standard can fit the interoperability requirements for the high-priority measures identified by HITEP. Further work is required to confirm and implement this.

IHE Patient-level Export of Quality Data (PEQD): IHE has indicated that should QRDA be developed, it will adopt it for profiles managing both data export from the EMR and definition of data collection requirements within the EMR. Joint work is required to define and identify appropriate public utilities for management of measure-associated metadata. A public repository of measure templates defined according to QRDA data constructs is needed to support efficient import and validation.

Health Information Technology Standards Panel (HITSP) Population Health Technical Committee and the Certification Commission for Healthcare IT: HITSP is tasked with identifying interoperability solutions for the scenarios described in the AHIC Use Cases, and in 2007, the HITSP began working on the AHIC Quality Use Case. CCHIT has indicated that it will address quality reporting certification requirements.

The HITSP firmly believes that support for quality measures and reporting is a key component for the continuous improvement of health care and its delivery, as well as reduced costs for consumers and providers of care. In recognition of the importance of quality reporting, HITSP has endeavored to integrate support from the ground up for the necessary data elements and content in all interoperability specifications; however, the current guidance does not cover patient-level reporting from clinical sources. The HITSP

has indicated a strong preference for HL7 and IHE to coordinate on the creation and adoption of a common quality reporting document structure.

Insofar as QRDA is compatible with the CCD, a specification on the roadmap for 2008, it is possible to anticipate that when they do adopt quality requirements, they will follow HITSP recommendations and will seek standards that are compatible with existing requirements.

Timelines for Development and Collaboration

Standards development organizations work on different set timetables. The optimum schedule for development and release of QRDA as an HL7 DSTU and hand-off to IHE for development into an implementation profile has been discussed in both organizations. The figure that follows represents that optimum timetable.



Figure 8: Critical path timelines for standards development

The opportunity to submit QRDA both to HL7 and IHE raises the probability that it will become a future recommendation from HITSP and then be considered for adoption as a vendor certification criterion by CCHIT.

In summary, the opportunity exists *now* to develop a draft QRDA, bring it to ballot in the HL7 spring ballot cycle, and see it integrated immediately into the planning and development for vendor demonstrations at HIMSS 2009 and in the HITSP recommendations.

Conclusion

The QRDA initiative adopted a phased approach to development of a quality reporting standard to explore feasibility, potential benefit, and interest with minimal financial commitment. The results of this first effort indicate a high level of all three: feasibility, benefit, and interest. While further work is needed to establish the limits of reuse of the current set of CCD templates and to understand what it will take to scale up to and to maintain a specification that covers all measure reporting requirements, initial indications are that clinical reporting requirements can be met through existing specifications.

During the Phase I work, the approach to quality reporting through EMR extract of clinical data was confirmed and endorsed by the NQF HITEP; the QRDA was approved as a project in the appropriate domain committees within HL7, HITSP, and IHE, and a strong list of interested parties and potential partners was developed.

The reasons for this high level of interest are clearly based on the value of EMR-derived data for quality measurement and the efficiency to be gained by reducing or eliminating redundant data entry. Both factors – higher quality measurement and decreased burden of reporting – stand to augment and support the improvement goals of the Alliance when realized through the establishment and widespread adoption of the QRDA standard.

The desired outcome was described recently in the research paper on measuring quality using EHR systems:

Ideally, data are entered once by the most appropriate professional for the purpose of providing care, and reused multiple times for the purposes of measuring quality, paying for performance, and generating knowledge about the effectiveness of treatments. Reuse of data not only improves data quality, it reduces the cost of secondary use of data—a welcome relief for providers often burdened with reporting mandates as an additional task or practice cost. [21]

This approach is now recommended by NQF HITEP to HITSP, EHR vendors, CCHIT, and to NQF itself as a criterion for measure development and is cited as an integral and anticipated component of NQF's strategy for measure performance aggregation and reporting. [18]

The opportunity to make QRDA the specification that fulfills that vision for quality reporting now lies in securing strong support for future work.

Call to Action

The QRDA Initiative team, with support from the HL7 PeDSSIG, the Alliance for Pediatric Quality, AHIMA and IFMC, seeks to ensure momentum continues for rapid development and ultimate adoption of QRDA.

Those interested in learning more can contact Joy Kuhl at joy.kuhl@chca.com or Crystal Kallem at crystal.kallem@ahima.org.

Appendices

Recommended Next Steps

A full project proposal and proposed budget for Phase II will be composed separately from this report. This appendix briefly outlines three areas of recommended next steps for consideration:

- Specification and profile development
- Pilot implementation and testing
- Communication, education, and coordination

Specification and Profile Development

Recommendation: Develop and bring to ballot the QRDA as an HL7 DSTU in the spring 2008 HL7 ballot cycle.

The DSTU format has a lower threshold for approval than a normative standard. At the same time, it signals to industry that there is a stable platform for development. If developed for the spring HL7 ballot, the DSTU may be simultaneously integrated into an IHE profile. The initial DSTU should, at minimum, specify EMR data export parameters and include a mapping to a significant selection of high-priority measures (those identified as such by NQF HITEP). Later work should expand the mapping to incorporate all high-priority measures. If possible, leverage HITEP efforts to map priority measures to CCD.

At the appropriate time, in conjunction with the Collaborative, the initiative should explore development of a standard defining EMR measure import. The DSTU should be designed such that mapping additional measures to QRDA may not require new ballots if the criteria for compliance are met.

Recommendation: Support the work of the IHE Quality Domain to incorporate QRDA into its PEQD profile in 2008. The current profile combines a quality use case with directions for exchange of nonstructured forms. This should be replaced as soon as possible with interoperable, structured standard clinical data for measure reporting.

Pilot Deployment and Testing

Recommendation: Develop a pilot deployment and testing program for QRDA involving measure developers, providers, system vendors, and recipients of quality data.

The ideal pilot environment will include participation from at least one measure developer, and multiple providers and multiple requesters of quality data. Design should encompass real data exchange on both inpatient and outpatient measures for children and adults. Participation should be offered with preference given to Alliance benefactors and members. Careful consideration should be given to pilot design to study the impact of QRDA implementation on efficiency and reliability.

Recommendation: Support the 2009 IHE Connectation and IHE HIMSS demonstration of the PEQD profile by encouraging vendor participation.

Communication, Education, and Coordination

Recommendation: Design and execute a communication, education and coordination plan that informs, promotes adoption, and ensures smooth collaboration among the supporters of electronic quality reporting.

The speed with which the proposal for a QRDA has been integrated into national planning efforts is testimony to the effectiveness of the leadership and team approach to marketing and communication as well as the strong resources that participants have brought to the table. The project team should continue involvement in related efforts to ensure that all involved understand the scope and potential of this work and that those involved in development of QRDA are informed of and able to build upon the work of others. The high importance given to this work has prompted the development of multiple efforts, and only a strong commitment to communication, education, and coordination can ensure continued successful collaboration.

Potential Partners for Future Work

The following organizations could be approached for assistance in furthering the QRDA initiative. In addition to this list, there are a number of individuals who have expressed an interest in donating time to the project as advisors and volunteers.

Organization(s)	Comments
Alliance for Pediatric Quality (AAP, ABP, CHCA & NACHRI)	The Alliance is interested in accelerating the ability of its constituents to participate in improvement efforts; Continued leadership in QRDA offers substantial value to providers represented by the Alliance organizations; One or several identified Improve First projects might be good candidates for pilot implementations of QRDA. The Alliance supports the HL7 Pediatric Data Standards SIG, which would sponsor the project within HL7.
American College of Physicians (ACP)	ACP participates in the Collaborative/AMA project as well as HITSP, IHE, AHIC, AQA, and NCQA projects and is interested in getting involved.
American Health Information Management Association (AHIMA)	AHIMA is the premier association for health information management professionals dedicated to the effective management of personal health information needed to deliver quality healthcare to the public. The Association actively supports and engages in industry efforts aimed at improving the quality and integrity of data while reducing the collection and reporting challenges for healthcare organizations and providers. AHIMA was actively involved in Phase I of the QRDA initiative, and is a member of HL7 and the Collaborative for Performance Measure Integration with EHR Systems Workgroup B. AHIMA plans to provide continued support of the QRDA initiative and has offered staff resources to support ballot development.
American Medical Association (AMA), Collaborative for Performance Measure Integration with EHR Systems	AMA is one of the sponsoring organizations of the Collaborative for Performance Measure Integration with EHR Systems. It is interested in how QRDA can leverage the work of the Collaborative.

Organization(s)	Comments
CDA for Common Document Types (CDA4CDT)	CDA4CDT is a consortium of vendors and professionals in dictation/transcription, document management and natural language processing for HIT; high interest in promoting CDA adoption and demonstrating value of structured information in narrative.
Cerner Corporation	Cerner Pediatrics Benefits Task Force members are interested in collecting pediatric quality measure information through Cerner for performance improvement purposes. Members have expressed interest in alignment opportunities with the Alliance for Pediatric Quality and the QRDA Initiative. Cerner is an active participant in the HL7 Pediatric Data Standards SIG.
Child Health Corporation of America	CHCA is a business alliance of 42 leading children's hospitals in North America focused on assisting its Owner Hospitals in performance improvement. In addition to its role in the Alliance for Pediatric Quality, it provides substantial support to the HL7 Pediatric Data Standards SIG. A project underway at CHCA is a good candidate for a pilot implementation of QRDA.
Children's Hospital of Alabama	Representatives from Children's Hospital of Alabama are interested in exploring a collaboration with Eclipsys (vendor) and NACHRI in a QRDA pilot.
Duke Clinical Research Institute	Representatives from Duke are drafting a CDA implementation guide for reporting registry data and are interested in joining forces with the QRDA initiative. They have offered staff resources to support ballot development.
Health Information Management Systems Society (HIMSS) Pediatric Health IT SIG	The HIMSS PHIT SIG could help coordinate participation of HIMSS pediatric stakeholders. Audience includes directors of IT, hospital health information management professionals.
Iowa Foundation for Medical Care (IFMC)	IFMC is a nationally recognized healthcare value management company with extensive experience defining, implementing, and consulting on national quality measurement programs for CMS and the Joint Commission. It is also a member of the Collaborative for Performance Measure Integration with EHR systems, HL7, and the CCHIT Ambulatory Care workgroup.
Integrating the Healthcare Enterprise (IHE)	IHE seeks to improve quality measurement data collection and reporting processes.
MedQuist	MedQuist is interested in how CDA can be leveraged for quality reporting. MedQuist actively participates in the CDA4CDT project and would like to leverage structured transcribed documents for quality reporting.
National Association of Children's Hospitals and Related Institutions (NACHRI)	NACHRI could be a good candidate for a possible pilot to use QRDA DSTU for improvement projects with members.
National Quality Forum	The mission of NQF aims to improve the quality of American health care by setting national priorities and goals for performance measurement. NQF is exploring the fit of QRDA in plans for national quality measurement and data standards.
Nemours	A number of affiliated specialty practices are participating in registry-related improvement efforts, and Nemours expects participation to grow. The manual labor involved in helping these practices participate in these efforts

Organization(s)	Comments
	from an IT perspective is challenging. Nemours is interested in using standards, including QRDA with its data warehouse to make it easier to help
	its practices participate in improvement efforts.
New York Department of Health	The NY Department of Health/eHealth Initiative is an effort aimed at aggregating data for public reporting of quality measurement in New York.
Vermont Program for Quality in Health Care, Inc.	VPQHC's involvement in the Vermont Child Health Improvement Program at the University of Vermont and other improvement work makes it a strong potential pilot candidate and research partner.

References

- [1] AHIC Quality Workgroup Meeting, October 3, 2007, *Requirements Analysis Update*, PowerPoint presentation. http://www.dhhs.gov/healthit/ahic/quality/
- [2] American Health Information Community (AHIC) Quality Workgroup, "Analysis of Requirements for Health Information Technology to the Quality Workgroup's Future Vision for Longitudinal Quality Measurement and Improvement", DRAFT, Pre-Decisional Document For Discussion Purposes Only, Booz Allen Hamilton, September 28, 2007.
- [3] Bennett C, Iowa Foundation for Medical Care, "*Measure Definition Standards*," Oct. 10, 2007.
- [4] *CDA International: International Healthcare Interoperability Conference* (7th HL7 International Affiliates Conference), Cologne, Germany, August, 2006; http://www.alschulerassociates.com/library/presentations/The_World_According_to _CDA.zip
- [5] *CDA Release 2 Consult Note*. HL7 Implementation Guide. Sept 2007. Ann Arbor, Mich.: Health Level Seven, Inc. DRAFT, not released for implementation.
- [6] *CDA Release 2 Continuity of Care Document (CCD).* HL7 Implementation Guide. Jan 2007. Ann Arbor, Mich.: Health Level Seven, Inc.
- [7] CDA Release 2 History & Physical Note (H&P). HL7 Implementation Guide. Sept 2007. Ann Arbor, Mich.: Health Level Seven, Inc. DRAFT, not released for implementation;
- [8] Doctor's Office Quality Information Technology (DOQ-IT) Use Cases and HL7 Output Implementation Guide for Trial Use Version 1.1
- [9] Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A. *HL7 Clinical Document Architecture, Release 2*. J Am Med Inform Assoc. 2006;13:30–39. DOI 10.1197/jamia.M1888.
- [10] Dolin RH, Giannone G, Schadow G, "Enabling Joint Commission Medication Reconciliation Objectives with the HL7 / ASTM Continuity of Care Document Standard", Presented at: AMIA Fall 2007.
- [11] First Consulting Group, "CHCA Minimum Data Set", PowerPoint presentation, Child Health Corporation of America
- [12] *HL7 Clinical Document Architecture, Release 2.0.* ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc.
- [13] http://www.schematron.com/
- [14] http://www.w3.org/XML/

- [15] IHE Quality Technical Framework Year 1: 2007-2008 Volumes 1, 2, and 3; Revision 1.0, Publication Date: July 2, 2007, For Public Comment. Copyright © 2007: ACC, AHA, HIMSS, and RSNA.
- [16] Jones L, Office of the National Coordinator; Healthcare Information Technology Standards Panel, PowerPoint presentation on "The CCD and HITSP's Approach Toward a Healthcare Summary Document Architecture", Oct. 3, 2007
- [17] Patient Level Quality Data Document Component. HITSP/C38. Healthcare Information Technology Standards Panel. Sept. 17, 2007, version 0.0.1; Population Health Technical Committee; http://www.ansi.org/hitsp/
- [18] Rosenthal D, MD, MSc, MPH, National Quality Forum; PowerPoint presentation on "*Quality IT Landscape*" (quality_IT_landscape.ppt)
- [19] Rosenthal D, MD, MSc, MPH, National Quality Forum; PowerPoint presentation on *"Ongoing work on data taxonomy"* (pareto.ppt); describes analysis of 84 IOMrelated measures. (no date).
- [20] Specifications Manual for National Hospital Quality Measures Children's Asthma Care, Version 1.0, Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, Illinois, 2007.
- [21] Tang PC, et al. "Impact of Using Administrative Data for Clinical Quality Reporting: *Comparing Claims-Based Methods with EHR-Based Methods*", J Am Med Inform Assoc. 2007;14:10 –15. http://www.jamia.org/cgi/reprint/14/1/10.
- [22] Tang PC, MD, "Deriving Quality Measures from EHRs: *Realizing the Benefits*," VP, Chief Medical Information Officer Palo Alto Medical Foundation, PowerPoint presentation, HITEP tang.ppt.
- [23] The Collaborative for Performance Measure Integration with EHR Systems: *A Reference Guide for EHR Vendors*, Sept. 27, 2007; v4.
- [24] U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology, *Quality Detailed Use Case*, June 18, 2007.

Contact Information

Chad Bennett

Iowa Foundation for Medical Care The Collaborative for Performance Measure Integration with EHR Systems cbennett@ifmc.org

Crystal Kallem

American Health Information Management Association (AHIMA) HL7 Structured Documents Technical Committee crystal.kallem@ahima.org

Joy Kuhl

Alliance for Pediatric Quality HL7 Pediatric Data Standards Special Interest Group CCHIT Child Health Expert Panel joy.kuhl@chca.com

Feliciano Yu, MD

HL7 Pediatric Data Standards Special Interest Group The Children's Hospital of Alabama fyu@peds.uab.edu

Liora Alschuler

Alschuler Associates, LLC HL7 Structured Documents Technical Committee liora@alschulerassociates.com