CDAR2_QRDA_R1_DSTU_2009APR

Implementation Guide for CDA Release 2
Quality Reporting Document Architecture (QRDA)
Release 1

Based on HL7 CDA Release 2.0

(U.S. Realm)

Draft Standard for Trial Use

April 2009

Publication of this draft standard for trial use and comment has been approved by Health Level Seven, Inc. (HL7). Distribution of this draft standard for comment shall not continue beyond 24 months from the date of publication. It is expected that following this 24 month period, this draft standard, revised as necessary, will be submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. This draft standard is not an accredited American National Standard. Suggestions for revision should be submitted at http://www.hl7.org/dstucomments/index.cfm.

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Acknowledgments

This guide was produced and developed through the efforts of the Quality Reporting Document Architecture (QRDA) Project supported by The Child Health Corporation of America (CHCA) to develop and support a standard for quality reporting. Through this project, CHCA supports the Health Level Seven (HL7) Child Health Work Group (formerly the Pediatric Data Standards Special Interest Group) and others in developing a draft standard for reporting quality measure data.

The QRDA committee made up of representatives from the American Health Information Community (AHIC), American Health Information Management Association (AHIMA), Integrating the Healthcare Enterprise (IHE), Child Health Corporation of America (CHCA), the Collaborative for Performance Measure Integration with EHR Systems, MedAllies, and the Nationwide Health Information Network (NHIN) was instrumental in guiding the project so that alignment occurred between the interested organizations.

The co-editors also express their appreciation for the support and sponsorship of the HL7 Structured Documents Work Group and the Child Health Work Group.

Finally, we acknowledge the foundational work on HL7 Version 3 and the Reference Information Model (RIM), the HL7 domain committees, especially Patient Care, and the work done on Clinical Document Architecture (CDA) itself.

We also acknowledge the collaborative effort of the American Society for Standards and Materials (ASTM) and HL7, which produced the Continuity of Care Document (CCD). All these efforts were critical ingredients to the development of this DSTU and the degree to which it reflects these efforts will foster interoperability across the spectrum of health care.

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1 INTRODUCTION

1.1 Purpose

The Institute of Medicine (IOM) definition of quality is: "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge".[1] For knowledge about care quality to be evaluated, it must be gathered and communicated to the appropriate organizations.

The purpose of this document is to describe constraints on CDA Release 2 Header and Body elements for Quality Reporting Documents. Quality Reporting Document Architecture (QRDA) is a document format that will provide a standard structure with which to report quality measure data to organizations that will analyze and interpret the data that is received. Measuring quality in health care is complex. Accurate, interpretable data efficiently gathered and communicated is key in correctly assessing that quality care is delivered.

1.2 Scope

1.2.1 Background

The HL7 QRDA Project[2] develops standard specifications for communicating relevant information for improving the quality of health care. Health care institutions routinely collect and report performance measure data to improve the quality of care provided to patients. Current data collection and reporting activities rely on a variety of mechanisms that range from structured paper to electronic data entry formats—usually derived from claims-based data sets or manual data abstraction. The HL7 Pediatric Data Standards Special Interest Group (now the Child Health Work Group) pioneered the QRDA initiative with funding for Phase I from the Alliance for Pediatric Quality.[3] The initiative is aimed at developing an Electronic Health Record (EHR)-compatible standard for distributing data related to patient-level quality measures across disparate health care IT systems. Participating organizations are dedicated to the belief that such a standard will make it easier to support the analysis and tracking of health care quality, decrease the reporting burden for providers, and improve the quality of data used for measurement.

In the first phase of the QRDA initiative, participating organizations confirmed the feasibility of using the HL7 Clinical Document Architecture (CDA) as the foundation for the QRDA specification. It was concluded that CDA, a document markup standard that defines the structure and semantics of clinically-relevant documents for health care information exchange across EHRs, can provide the technical underpinnings for communicating pediatric and adult quality measures for both inpatient and ambulatory care settings. The project team developed sample QRDA instances from an adult use

[1] http://www.iom.edu/CMS/8089.aspx
[2] http://wiki.hl7.org/index.php?title=Quality_Reporting_Document_Architecture (username wiki, password wikiwiki)
[3] http://www.hl7.org/Library/Committees/pedsdata/QRDA%20Phase%20I%20Public%20Report.pdf

case developed for the Centers for Medicare & Medicaid Services (CMS) Doctor Office Quality–Information Technology (DOQ-IT) initiative and a sample pediatric quality measure from the Joint Commission Pediatric Asthma Measures.

1.2.2 Current Project

The current project aims to develop a QRDA Implementation Guide and other materials to make QRDA a Draft Standard for Trial Use (DSTU). This effort is supported by CHCA and MedAllies. The QRDA DSTU aims to, as its initial output, define three categories of quality reporting (see Section 1.4.2 Types of Quality Measure Reports.) The section of the DSTU that defines the QRDA Category I report has been sent to ballot, while the sections of the DSTU that define QRDA Category II and Category III reports are being presented for comment only.

The QRDA initiative is compatible with parallel industry efforts and organizations that are addressing the quality landscape, including American Health Information Community (AHIC), Healthcare Information Technology Standards Panel (HITSP), and Integrating the Healthcare Enterprise (IHE). The intent of QRDA is not to define the logic of the measure as applied within an EHR, but to model the measure data elements in CDA format so that they can be consistently communicated.

The goal of the project is to standardize the framework of quality reports and to define the way quality measure data should be structured to create interoperability between reporting and receiving systems.

In addition to defining a QRDA framework (see Section 2 QRDA Category I Report, Section 3 QRDA Category II Report), and Section 4 QRDA Category III Report)), the project will ballot measure-specific QRDA implementation guides (see Section 5 QRDA Category I: Neonatal Admission Temperature Implementation Guideion Guide and Section 6 QRDA Category I: Pediatric Body Mass Index Percentile Implementation Guideion Guide) as representative measures to vet and validate the entire QRDA process.

1.3 Audience

The audience for this document includes software developers and implementers of reporting capabilities with their EHR systems, and developers and analysts in receiving institutions, and local, regional, and national health information exchange networks who wish to create and/or process CDA reporting documents created according to this specification.

1.4 Definition of a Quality Measure and QRDA's Role

A quality measure is a mechanism that enables the user to quantify the quality of a selected aspect of care by comparing it to a criterion. A subtype of a quality measure is a clinical performance measure. Specifically, a clinical performance measure is a mechanism for assessing the degree to which a

provider competently and safely delivers clinical services that are appropriate for the patient in the optimal time period.[4, 5]

Quality measures are used for three general purposes: quality improvement, accountability, and research.[6] Without the ability to accurately communicate the data in these measures to external agencies, the benefit of collecting the information is limited. QRDA's role is to standardize the representation of measure-defined data elements to enable interoperability between all of the stakeholder organizations.

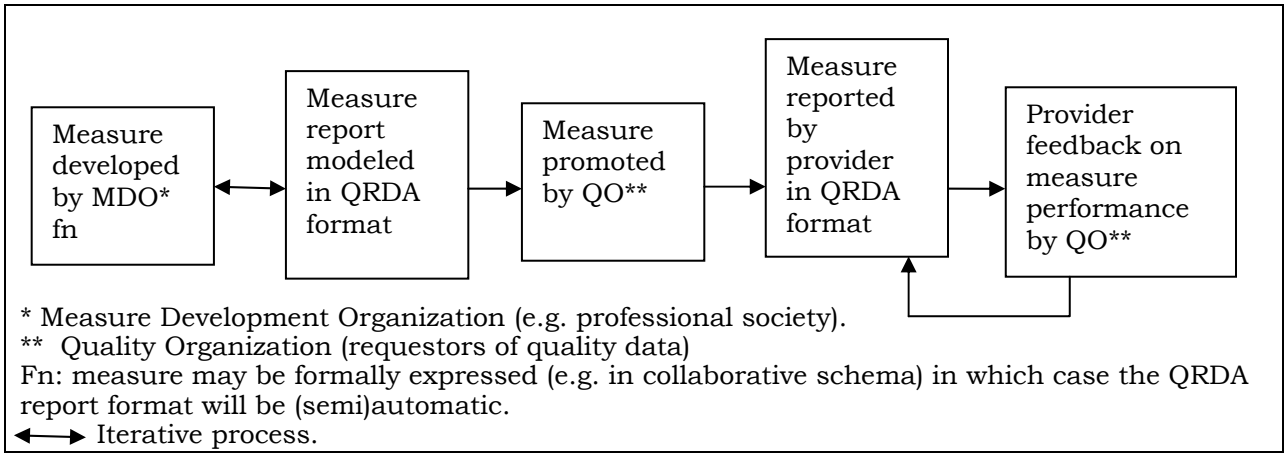
Note: A measure-specific implementation guide defines a formal representation of a measure, but does not necessarily specify the data elements, their context, and the granularity required to identify them within an EHR. For example, an observation that ACE Inhibitors are contraindicated may be represented in an allergy list, in a problem list, in a diagnosis list, as free text in a clinical note, even within a single organization. Separate efforts are in progress to encourage modification to measure specifications to accommodate to data representations in the EHR. Such efforts may reduce manual abstraction requirements and enable more direct coordination of QRDA with an electronic output of an EHR.

1.4.1 Process of Formalizing a Measure

Ideally, a process is in place whereby a measure is formally specified in a process that involves domain experts and a computable representation. From there, one could theoretically auto-generate the QRDA Category I, II, and III specifications. However, in many cases, the development of a QRDA specification will come before there is an agreed-upon formal representation of a particular measure. In these cases, care must be taken to have a planned collaboration process between the domain experts and the measure representation designers to reach a consensus that the intent is captured and the output is useful. A potential flow in the measure development and report modeling and reporting process is shown in the figure below.

[4] Center for Health Policy Studies, Harvard School of Public Health, Center for Quality of Care Research and Education. Understanding and choosing clinical performance measures for quality improvement: development of typology: final report. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 1995 Jan 31. Various pages.
[5] Lawthers AW, Palmer H. In search of a few good performance measures. In: Seltzer J, Nash DB, editors. Models for measuring quality in managed care: analysis and impact. New York (NY): Faulkner & Gray's Healthcare Information Center; 1997. p. 121-150. (Medical outcomes & practice guidelines library II).
[6] Obtained from AHRQ National Quality Measures Clearinghouse webpage: http://www.qualitymeasures.ahrq.gov/resources/measure_use.aspx#reflist 1 August 2008

Figure 1: High-level flow in quality measure development and reporting



1.4.1.1 Role of Professional Societies

Professional societies such as the AMA and CHCA should collaborate with technical implementers and/or Standards Development Organizations (SDOs) to standardize quality measure report modeling. The following bullet points highlight important aspects of the professional society's roles.

- Provide explicit and unambiguous measure specification.
- Provide uniformity in defining and categorizing measure descriptions.
- Promote standardization of naming conventions for quality measures.
- Participate in formalized processes for measure report modeling.
- Participate in formalized processes for measure specification modeling.

1.4.1.2 Role of Technical Groups

Technical groups, such as HL7 working groups, must collaborate with professional society measure developers to gain a granular understanding of the meaning and purpose of a large selection of measures to properly model the measure data for reporting. As the QRDA framework matures from these efforts, it is expected that technical groups within the professional organizations will ultimately be able to independently model the many existing and new measures that will be developed over time. The following bullet points highlight some important aspects of the technical group roles:

- Participate in formalized processes for measure report modeling.
- Determine current ability for capturing and modeling data elements in CDA and using the RIM.
- Provide practical insights to technical challenges.
- Participate in formalized processes for measure specification modeling.

1.4.2 Types of Quality Measure Reports

Three types of QRDA quality measure reports have been defined as described in the following sections.

1.4.2.1 QRDA Category I – Single Patient Report

A QRDA Category I report is an individual-patient-level quality report. Each report contains quality data for one patient for one or more quality measures, where the data elements in the report are defined by the particular measure(s) being reported on. A QRDA Category I report contains raw applicable patient data. When pooled and analyzed, each report contributes the quality data necessary to calculate population measure metrics (e.g., as contained in a QRDA Category III report).

1.4.2.2 QRDA Category II – Patient List Report

A QRDA Category II report is a multi-patient-level quality report. Each report contains quality data for a set of patients for one or more quality measures, where the data elements in the report are defined by the particular measure(s) being reported on.

Whereas a QRDA Category I report contains only raw applicable patient data, a QRDA Category II report includes flags for each patient indicating whether the patient qualifies for a measure's numerator, denominator, exclusion, or other aggregate data element. These qualifications can be pooled and counted to create the QRDA Category III report.

1.4.2.3 QRDA Category III – Calculated Report

A QRDA Category III report is an aggregate quality report. Each report contains calculated summary data for one or more measures for a specified population of patients within a particular health system over a specific period of time.

Whereas a QRDA Category I and a QRDA Category II report contain data for individual patients, a QRDA Category III report contains only calculated data (e.g., number meeting numerator criteria, number meeting denominator criteria) on the population.

HITSP's Quality Implementation Specification (HITSP IS06) describes a "processing entity," which is an application role that collects QRDA Category I reports and generates QRDA Category II and QRDA Category III reports. From the perspective of a processing entity, all data needed to generate QRDA Category II and QRDA Category III reports must be included in the collected QRDA Category I reports, as the processing entity will not have access to additional data sources.

1.5 Approach

1.5.1 Organization of this Guide

The requirements laid out in the body of this DSTU document are on track to become normative after a trial period of use and will be subject to change only through the ballot process. These cover the Header and high-level Body and section requirements. The document is organized into the following major sections:

The Framework Implementation Guide:

- Section 1 Introduction
- Section 2 QRDA Category I Report
- Section 3 QRDA Category II Report)
- Section 4 QRDA Category III Report)

The Measure-specific Implementation Guides:

- Section 5 QRDA Category I: Neonatal Admission Temperature Implementation Guideion Guide
- Section 6 QRDA Category I: Pediatric Body Mass Index Percentile Implementation Guideion Guide

1.5.1.1 Framework Guide

The framework portion describes and constrains CDA for Quality Reporting in a general manner such that when a specific measure is modeled and constrained, only additional measure-specific conformance statements will be needed.

1.5.1.2 Measure-specific Guides

The measure-specific guides further constrain the QRDA framework to express the full modeling of the measure data for reporting. Thus, a framework document coupled with the measure-specific `document constraints` add up to the measure-specific QRDA constraints.

1.5.2 Use of Templates

When valued in an instance, the template identifier (`templateId`) signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the templates in question.

1.5.2.1 Originator Responsibilities

An originator can apply a `templateId` if there is a desire to assert conformance with a particular template.

In the most general forms of CDA exchange, an originator need not apply a `templateId` for every template that an object in an instance document conforms to. When `templateIds` are required for conformance, it shall be asserted within the Implementation Guide (IG).

1.5.2.2 Recipient Responsibilities

A recipient may reject an instance that does not contain a particular `templateId` (e.g., a recipient looking to only receive CCD documents can reject an instance without the appropriate `templateId`).

A recipient may process objects in an instance document that do not contain a `templateId` (e.g., a recipient can process entries that contain Observation acts within a Problems section, even if the entries do not have `templateIds`).

If an object does not have a `templateId`, a recipient shall not report a conformance error about a failure to conform to a particular template on classes that do not claim conformance to that template and that are not required to be conformant by other templates.

1.5.3 Conventions Used in this Guide

This Implementation Guide is a conformance profile, as described in the Refinement and Localization section of the HL7 Version 3 standards. The base standard for this IG is the HL7 Clinical Document Architecture, Release 2.0. As defined in that document, this IG is both an annotation profile and a localization profile. Every aspect of the CDA R2 may not be described in this guide.

1.5.3.1 Explanatory Statements

As an annotation profile, portions of this IG summarize or explain the base standard; therefore, not all requirements stated here are original to the DSTU. Some originate in the base specification. Those requirements that do not add further constraints to the base standard and that can be validated through CDA.xsd do not have corresponding conformance statements.

Where no constraints are stated in this guide, QRDA instances are subject to and are to be created in accordance with the base CDA R2 specification. Where, for instance, the CDA R2 specification declares an attribute to be optional and the QRDA specification contains no additional constraints, that attribute remains optional for use in a QRDA instance.

1.5.3.2 Conformance Requirements

Conformance requirements for the QRDA framework are numbered sequentially and are displayed as shown in the following examples:

CONF-QRDA-I-1: Conformance statement for the QRDA Category I framework.

CONF-QRDA-II-1: Conformance statement for the QRDA Category II framework.

CONF-QRDA-III-1: Conformance statement for the QRDA Category III framework.

CONF-QRDA_NAT-1: Conformance statement for the QRDA Neonatal Admission Temperature measure-specific guide.

CONF-QRDA_BMI-1: Conformance statement for the QRDA Body Mass Index Percentile measure-specific guide.

1.5.3.3 Vocabulary Conformance

Measure-specific modeling and constraints should use and define the formalisms for value set constraints when applicable. In addition, when SNOMED codes are used, rules defined in "Using SNOMED CT® in HL7 Version 3" should be adhered to.

Formalisms for value set constraints are based on the latest recommendations from the HL7 Vocabulary Committee. Value set constraints can be "**STATIC**," meaning that they are bound to a specified version of a value set, or "**DYNAMIC**," meaning that they are

bound to the most current version of a value set. A simplified constraint is used when binding is to a single code.

Syntax for vocabulary binding to **DYNAMIC** or **STATIC** value sets is as follows:

The value for (`pathname of coded element`) (**SHALL** | **SHOULD** |**MAY**) be selected from Value Set `valueSetOID localValueSetName` **DYNAMIC** | **STATIC** (`valueSetEffectiveDate`).

CONF-ex1: The value for `ClinicalDocument/code` **SHALL** be selected from Value Set `2.16.840.1.113883.1.11.10870 DocumentType` **DYNAMIC**.

CONF-ex2: The value for `ClinicalDocument/code` **SHALL** be selected from Value Set `2.16.840.1.113883.1.11.10870 DocumentType` **STATIC** `20061017`.

Syntax for vocabulary binding to a single code is as follows:

The value for (`pathname of coded element`) (**SHALL** | **SHOULD** | **MAY**) be (`code` [`displayName`] `codeSystemOID` [`codeSystemName`]) **STATIC**.

CONF-ex3: The value for `ClinicalDocument/code` **SHALL** be `34133-9 Summarization of episode note 2.16.840.1.113883.6.1 LOINC` **STATIC**.

1.5.3.4 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XPath notation in conformance statements and elsewhere to identify the XML elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. The purpose of using this notation is to provide a mechanism that will be familiar to developers for identifying parts of an XML document.

1.5.3.5 Keywords

The keywords **SHALL**, **SHOULD, MAY, NEED NOT, SHOULD NOT** and **SHALL NOT** in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide. The keyword "**SHALL**" implies a lower cardinality of 1 but does not disallow NULL values. If NULL values are to be excluded, it will be via an additional explicit conformance statement.

1.5.3.6 XML Examples

XML examples appear in various figures in this document in `this fixed-width font`. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (…) as shown in the example below.

Figure 2: ClinicalDocument example

```
<ClinicalDocument mins="urn:h17-org:v3">
    …
</ClinicalDocument>
```

XPath expressions are used in the narrative and conformance requirements to identify elements because they are familiar to many XML implementers.

1.5.3.7 Contents of the Published Package

The published package contains the files indicated the following table:

Table 1: Contents of the Published Package

Filename	Description
CDAR2_QRDA_R1D1.doc	This Guide
Category I Framework (2)	Within this Guide
Category II Framework (3)	Within this Guide
Category III Framework (4)	Within this Guide
Category I Neonatal Admission Temperature (5)	Within this Guide
Category I Body Mass Index (6)	Within this Guide
QRDA_CategoryI.xml	Sample XML
QRDA_CategoryII.xml	Sample XML
QRDA_CategoryIII.xml	Sample XML
QRDA_CategoryI_Temperature.xml	Sample XML
QRDA_CategoryI_BMI.xml	Sample XML
Cda.xsl	Stylesheet

2 QRDA CATEGORY I REPORT

See Section 1.4.2 Types of Quality Measure Reports for an introduction and overview of QRDA Category I, QRDA Category II, and QRDA Category III reports.

2.1 Pseudonymization of Patient Identities and Anonymization of Data Elements

Quality Measure Reports must allow for the "pseudonymization" of patient identities and "anonymization" of data elements. A process will likely be in place where institutions can provide pseudonyms for patient identifiers that can be used in the QRDA report. In addition, the exceptional value (null value) of "masked" (MSK) can be used for data elements that need to be made anonymous. An exceptional value of MSK means that information on this item is available but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information. Note: using this null flavor does provide information that may be a breach of confidentiality, even though no detail data is provided. Its primary purpose is for those circumstances where it is necessary to inform the receiver that the information does exist without providing any detail.

CONF-QRDA-I-1: When needed the exceptional value of MSK **SHALL** be used to anonymize data elements.

2.2 Header Constraints

This section describes constraints that apply to the Quality Reporting Document Architecture (QRDA) document Category I report header.

2.2.1 Header Attributes

2.2.1.1 ClinicalDocument/realmCode

CONF-QRDA-I-2: The realmCode element **SHALL** be present where the value of @code is US.

Figure 3: realmCode Category I example

```
<realmCode code="US"/>
```

2.2.1.2 ClinicalDocument/typeID

CONF-QRDA-I-3: The value of typeID/@root **SHALL** be 2.16.840.1.113883.1.3 and value of typeID/@extension **SHALL** be POCD_HD000040.

2.2.1.3 ClinicalDocument/templateId

This ClinicalDocument/templateId element identifies the template that defines constraints on the content of a QRDA Category I document.

CONF-QRDA-I-4: A QRDA Category I report **SHALL** contain at least one `Clinical Document/templateId` element.

CONF-QRDA-I-5: The value of one `ClinicalDocument/templateId/@root` **SHALL** be `2.16.840.1.113883.10.20.12` representing conformance to the generic QRDA Category I framework constraints.

Figure 4: ClinicalDocument/templateId Category I example

```
<templateId root= "2.16.840.1.113883.10.20.12"/> <!-- conforms to the DSTU -->
```

2.2.1.4 ClinicalDocument/code

CONF-QRDA-I-6: A QRDA Category I report **SHALL** contain exactly one `ClinicalDocument/code` with a value of `55182-0 2.16.840.1.113883.6.1 LOINC` **STATIC**.

2.2.1.5 ClinicalDocument/title

CONF-QRDA-I-7: A QRDA Category I report **SHALL** contain exactly one `ClinicalDocument/title` element valued with a case-insensitive, text string containing `"QRDA Incidence Report"` or `"Quality measure Report"`.

2.2.2 Participants

This section describes the participants in a QRDA Category I report header.

2.2.2.1 recordTarget

A QRDA Category I report contains quality measure information about a single patient.

CONF-QRDA-I-8: A QRDA Category I report **SHALL** contain exactly one `ClinicalDocument/recordTarget/PatientRole.`

Figure 5: recordTarget Category I example

```
<recordTarget>
  <patientRole>
    <id extension="123456789" root="2.16.840.1.113883.19.5"/>
    <patient>
      <name>
        <given>Henry</given>
        <family>Levin</family>
        <suffix>the 7th</suffix>
      </name>
      <administrativeGenderCode
       code="M" codeSystem="2.16.840.1.113883.5.1"/>
      <birthTime value="19320924"/>
    </patient>
  </patientRole>
</recordTarget>
```

2.2.2.2 Author

The author may be a device, a person (e.g., a quality manager), or an organization (e.g., a processing entity).

CONF-QRDA-I-9: A QRDA Category I report **SHALL** contain one or more `ClinicalDocument/author/assignedAuthor/assignedPerson` and/or `ClinicalDocument/author/assignedAuthor/assignedAuthoringDevice`

Figure 6: assignedAuthor Category I example

```
<author>
  <time value="2000040714"/>
  <assignedAuthor>
    <id root="bc01a5d1-3a34-4286-82cc-43eb04c972a7"/>
    <assignedPerson>
      <name>
        <given>Nancy</given>
        <family>Nightingale</family>
        <suffix>N</suffix>
      </name>
    </assignedPerson>
    <representedOrganization>
      <id root="2.16.840.1.113883.19.5"/>
      <name>Good Health Clinic</name>
    </representedOrganization>
  </assignedAuthor>
</author>
```

2.2.2.3 Informant

A QRDA Category I report must have a stated source so that any data within the report can be validated. The source of the report is the reporting facility, represented using the CCD "Source of Information" construct, via the `informant` participant.

CONF-QRDA-I-10: A QRDA Category I report **SHALL** contain exactly one `ClinicalDocument/informant`, which represents the reporting facility.

CONF-QRDA-I-11: An organization source of information **SHALL** be represented with `informant`.

Figure 7: Informant Category I example

```
<informant>
  <assignedEntity>
    <id nullFlavor="NA"/>
    <representedOrganization>
      <id root="2.16.840.1.113883.19.5"/>
      <name>Good Health Clinic</name>
    </representedOrganization>
  </assignedEntity>
</informant>
```

2.2.2.4 Custodian

The custodian of the QRDA Category I report can be the sending or receiving party or an intermediary such as a processing entity.

CONF-QRDA-I-12: A QRDA Category I report **SHALL** contain exactly one `custodian/assignedCustodian/representedCustodianOrganization/id` element.

CONF-QRDA-I-13: The value of `custodian/assignedCustodian/representedCustodianOrganization/id` element `@root` **SHALL** be the `id` root of the custodian organization.

Figure 8: Custodian Category I example

```
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id root="2.16.840.1.113883.19.5"/>
      <name>Good Health Clinic</name>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

2.2.2.5 legalAuthenticator

A legal authenticator is a verifier who officially authenticates the accuracy of the document. An example would be a quality nurse manager who compiles a quality report and is responsible for verifying and sending the quality reports. A `legalAuthenticator` is recommended in a QRDA Category I report, but workflow may be such that in some institutions legal authenticator may not be identified.

CONF-QRDA-I-14: A QRDA Category I report **SHOULD** contain exactly one `legalAuthenticator` element.

CONF-QRDA-I-15: If present, a QRDA Category I report `legalAuthenticator` **SHALL** contain exactly one `ClinicalDocument/legalAuthenticator/time` element.

CONF-QRDA-I-16: If present, a QRDA Category I report `legalAuthenticator` **SHALL** contain exactly one `signatureCode` element.

CONF-QRDA-I-17: The value of a QRDA `ClinicalDocument/signatureCode/@code` **SHALL** be S.

CONF-QRDA-I-18: If present, a QRDA Category I report `legalAuthenticator` **SHALL** contain exactly one `assignedEntity` element that represents the legal authenticator of the document.

CONF-QRDA-I-19: The `ClinicalDocument/legalAuthenticator/assigned` entity **SHALL** contain an `id` element.

Figure 9: legalAuthenticator Category I example

```
<legalAuthenticator>
  <time value="20000408"/>
  <signatureCode code="S"/>
  <assignedEntity>
    <id root="bc01a5d1-3a34-4286-82cc-43eb04c972a7"/>
    <assignedPerson>
      <name>
         <given>Nancy</given>
         <family>Nightingale</family>
         <suffix>N</suffix>
      </name>
    </assignedPerson>
    <representedOrganization>
      <id root="2.16.840.1.113883.19.5"/>
      <name>Good Health Clinic</name>
    </representedOrganization>
  </assignedEntity>
</legalAuthenticator>
```

2.2.2.6 Participant scenarios

The following table shows a number of scenarios and the values for various participants.

Table 2: QRDA Category I Participant Scenarios

	Author	**Custodian**	**Encom-passing Encounter / encounter Participant**	**Encom-passing Encounter / responsible Party**	**Informant**	**Legal Authen-ticator**	**Participant**
SCENARIO: Nurse One captures temp < 36 in a neonate upon admission in the EHR. The Quality Manager uses EHR information to generate a QRDA Category I report.							
QRDA Category I report	Quality Manager	Varies	None	None	(aka "reporting entity") Good Health Clinic	Quality Manager	None
Temp observa-tion within the report	Nurse One	N/A (QRDA Custodian doesn't propagate and is meant to apply to report as a whole)	None	Attending Physician	None	N/A (QRDA Legal Authen-ticator is meant to apply to document as a whole)	Nurse One is participant / typeCode = "PRF" (overrides header serviceEvent / performer)

2.3 Body Constraints

A QRDA Category I report requires a `structuredBody`. The report will typically contain several sections and subsections. The top-level sections may be either Measure sections, where each section is reporting quality data defined by a single measure, or they may be Measure Set sections, each of which contains a single measure identifying a group of measures being reported, or they may be both. This is illustrated in Figure 10: Category I use of Measure Set and Measure sections. Figure 11: Sample QRDA Category I report shows an example of a QRDA Category I report demonstrating a Measure Set section containing a nested Measure section with its nested reporting parameters and patient data sections.

Figure 10: Category I use of Measure Set and Measure sections

```
Measure Set Section
  – Description and version of measure set
       Measure Section
        - Measure One entries
        - Measure Two entries
        - Measure Three entries
          Reporting Parameters Section
             Measures one, two and three reporting parameters entries
           Patient Data Section
             Measures one, two and three patient data entries
Measure Set Section
       Measure Section
        - Measure Four entries
        - Measure Five entries
          Reporting Parameters Section
             Measures four and five reporting parameters entries
           Patient Data Section
             Measures four and five patient data entries
Measure Section
 - Measure Six entries
  Reporting Parameters Section
      Measure six reporting parameters entries
  Patient Data Section
      Measure six patient data entries
Measure Section
 - Measure Seven entries
  Reporting Parameters Section
     Measure seven reporting parameters entries
  Patient Data Section
     Measure seven patient data entries
```

CONF-QRDA-I-20: A QRDA Category I report **SHALL** contain exactly one `ClinicalDocument/component/structuredBody`.

CONF-QRDA-I-21: A QRDA Category I report **SHALL** contain at least one and **MAY** contain more than one non-nested top-level Measure section each containing information about a single measure.

CONF-QRDA-I-22: The Measure section **SHALL** be a top-level section if it is not part of a measure set.

CONF-QRDA-I-23: A QRDA Category I report **MAY** contain one or more Measure Set sections.

CONF-QRDA-I-24: The Measure Set section **SHALL** contain one nested Measure section and **SHALL NOT** contain more than one nested Measure section.

CONF-QRDA-I-25: A QRDA Category I report **MAY** contain both Measure Set sections and individual top-level Measure sections.

Figure 11: Sample QRDA Category I report[7]

QRDA Incidence Report

Created On: May 13, 2008

Patient:	Henry Levin , the 7th	**MRN:**	123456789
Birthdate:	September 24, 1932	**Sex:**	Male

Table of Contents

- NQF Pneumonia Measure Set, V2.5

Measure Set: NQF Pneumonia Measure Set V2.5

... (optional) description of measure set ...

Measure Section

- NQF PN-1: Oxygenation Assessment, V2.5
- NQF PN-4: Adult Smoking Cessation Advice/Counseling, V2.5
- NQF PN-6a: Initial Antibiotic Selection for CAP in Immunocompetent - ICU Patient, V2.5

Reporting Parameters

- Reporting period: 01 Jan 2008 - 31 Mar 2008

Patient Data

- Admission Date: 13 Feb 2008
- Discharge Date: 20 Feb 2008
- ICD Diagnosis Codes: 481 (Pneumococcal pneumonia)
- Oxygen Saturation: 85%
- Antibiotics: Levofloxacin 500mg IV q24 hours
- Smoker: Yes
- Smoking Cessation Counseling Provided: Yes

[7] This is an example. All data elements are not represented.

2.4 Section Constraints

This section describes constraints that apply to the QRDA Category I report sections within the Body of the document.

2.4.1 Measure Set Section

A measure set is a group of individual quality measures applicable to patients with an identified health-related status such as a demographic profile (i.e., age and sex parameters germane to preventive health measure sets) or an abnormal health condition (e.g., pneumonia, diabetes mellitus).

Quality measures within a measure set may or may not have the same denominator. For example, measures within the Pneumonia (PN) measure set from the National Hospital Quality Measures manual use a consistent definition of pneumonia (from a specified ICD-9 value set) contributing to denominator inclusion, but other denominator inclusion criteria, such as age, vary according to the intent of the specific quality measure.

The Measure Set section will contain measures from the measure set that are applicable to the patient. It does not have to contain all of the measures within a given professionally defined measure set.

Measure sets can be used for either evaluation of individual measure compliance, for bundled measure set compliance, or alternatively, some graded compliance algorithm. QRDA provides infrastructure to manage all three potential uses of the data.

CONF-QRDA-I-26: The Measure Set section **SHALL** contain a `templateId` uniquely identifying the Measure Set name and version.

CONF-QRDA-I-27: The Measure Set section **SHALL** contain a `section/code` element.

CONF-QRDA-I-28: The value for `section/code` **SHALL** be `55185-3 Measure Set 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-QRDA-I-29: The Measure Set section **SHALL** be valued with `section/title` with a case-insensitive, text string containing "`Measure set: <measure set name>`".

In some workflows, a description of the measure set may be desired in the Category I document to ease human readability and understanding of the measure. Formal representation of the description is not defined in this IG, but is not precluded.

CONF-QRDA-I-30: The Measure Set section **MAY** contain a `section/text` element for the description of the measure set or **MAY** contain a formal representation of a description of the measure set.

Figure 12: Measure Set section Category I example

```
<component>
   <section>
      <templateId root="2.16.840.1.113883.19.1"/> <!-- templateId uniquely
       identifies the measure set (fake Id for illustration)-->
      <code code="55185-3"
            codeSystem="2.16.840.1.113883.6.1" />
      <title>Measure Set: NQF Pneumonia Measure Set V2.5</title>
      <text>... (optional) description of measure set ...</text>       ...
   <section>
</component>
```

CONF-QRDA-I-31: The nested Measure section **SHALL** contain at least one measure that belongs to the measure set.

CONF-QRDA-I-32: The nested Measure section **SHALL NOT** contain data about measures that are not in the measure set.

2.4.2 Measure Section

The Measure section contains information about the measure or measures and patient data about the measure being reported. The Measure section contains two nested sections: the Reporting Parameters section and the Patient Data section, which are required.

CONF-QRDA-I-33: The Measure section **SHALL** contain at least one `templateId` uniquely identifying each Measure name and version

CONF-QRDA-I-34: The Measure section **SHALL** contain a `section/code` element.

CONF-QRDA-I-35: The value for `section/code` **SHALL** be `55186-1 Measure 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-QRDA-I-36: A non-nested Measure section **SHALL** be valued with `section/title` with a case-insensitive, text string containing "`measure section: <measure name>`".

CONF-QRDA-I-37: A nested Measure section **SHALL** be valued with `section/title` with a case-insensitive, text string containing "`measure section`".

CONF-QRDA-I-38: A nested Measure section **SHALL** contain at least one `templateId` corresponding to each of the measures that the patient data in the Measure Set section applies to.

CONF-QRDA-I-39: A Measure section **SHALL** contain exactly one nested Reporting Parameters section (as described in Section 2.4.3 Reporting Parameters Section).

CONF-QRDA-I-40: A Measure section **SHALL** contain exactly one nested Patient Data section (as described in Section 2.4.4 Patient Data Section).

In some workflows, a description of the measure may be desired in the QRDA Category I report to ease human readability and understanding of the measure. Formal

representation of the measure description itself is not defined in this IG, but is not precluded.

CONF-QRDA-I-41: The Measure section **MAY** contain a `section/text` element for the description of the measure(s).

Figure 13: Measure section in Measure Set Category I example

```
<section>
         <!-- QRDA Category I measure-specific template ID for each measure in this
         Section (fake IDs for illustration). -->
         <templateId root="2.16.840.1.113883.19.2"/>
         <templateId root="2.16.840.1.113883.19.3"/>
         <templateId root="2.16.840.1.113883.19.4"/>
        <code code="55186-1" codeSystem="2.16.840.1.113883.6.1" />
         <title>Measure Section</title>
         <text>
            <list>
               <item>NQF PN-1: Oxygenation Assessment, V2.5</item>
               <item>NQF PN-4: Adult Smoking Cessation Advice/Counseling, V2.5</item>
               <item>NQF PN-6a: Initial Antibiotic Selection for CAP in
                Immunocompetent – ICU Patient, V2.5</item>
            </list>
         </text>
        ...
             <section>
                <code code="55187-9"
                      codeSystem="2.16.840.1.113883.6.1" />
                <title>Reporting Parameters</title>
              ...
             </section>
             <section>
                <code code="55188-7"
                      codeSystem="2.16.840.1.113883.6.1" />
                <title>Patient Data </title>
                ...
             </section>
          ...
</section>
```

2.4.2.1 Representation of the Measure(s)

The measure is represented as an act in `definition` mood. The version number or code of the professional society's definition of the measure is captured in the act's code.

CONF-QRDA-I-42: Each measure **SHALL** be represented with `act`.

CONF-QRDA-I-43: For each `act` in the Measure section, the value for `act/@classCode` in a measure act **SHALL** be `ACT 2.16.840.1.113883.5.6 ActClass` **STATIC**.

CONF-QRDA-I-44: For each `act` in the Measure section the `act/@moodCode` in a measure act **SHALL** be `DEF 2.16.840.1.113883.5.1001 ActMood` **STATIC**.

CONF-QRDA-I-45: For each `act` in the Measure section there **SHALL** be an `act/code` reflecting the measure name and version.*

CONF-QRDA-I-46: Each measure act **MAY** contain an `act/text` element containing a description of the measure.

* At time of publication it was noted that standard codes instead of local codes should be used for the value of `act/code` in each measure act representing the measure name and version; this needs to be discussed and vetted during the DSTU period. Fake LOINC codes are shown here and are presently NOT requested from LOINC.

Figure 14: MeasureAct Category I example

```
<entry typeCode="DRIV">
   <act classCode="ACT" moodCode="DEF">
      <!-- Fake code for illustration* -->
      <code code="11111-X"
            codeSystem="2.16.840.1.113883.6.1"
            displayName="Adult Smoking Cessation Advice/Counseling,V2.5"/>
      <text>... (optional) description of measure ...</text>
      <statusCode code="completed" />
   </act>
</entry>
```

2.4.3 Reporting Parameters Section

The Reporting Parameters section provides information about the reporting time interval and may contain other information that helps provide context for the patient data being reported.

CONF-QRDA-I-47: The Reporting Parameters section **SHALL** contain a `section/code` element.

CONF-QRDA-I-48: The value for `section/code` **SHALL** be `55187-9 Reporting Parameters 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-QRDA-I-49: The Reporting Parameters section **SHALL** be valued with `section/title` with a case-insensitive, text string containing "`Reporting Parameters`".

CONF-QRDA-I-50: The Reporting Parameters section **SHALL** contain exactly one Observation Parameters Act, represented as an `act`.

CONF-QRDA-I-51: The value for `act/@classCode` in an Observation Parameters Act **SHALL** be `ACT 2.16.840.1.113883.5.6 ActClass` **STATIC**.

CONF-QRDA-I-52: The value for `act/@moodCode` in an Observation Parameters Act **SHALL** be `EVN 2.16.840.1.113883.5.1001 ActMood` **STATIC**.

CONF-QRDA-I-53: The value for `act/code` **SHALL** be `252116004 Observation Parameters 2.16.840.1.113883.6.96 SNOMED-CT` **STATIC.**

CONF-QRDA-I-54: The reporting time period **SHALL** be represented with an `effectiveTime/low` element combined with a `high` element representing respectively the first and last days of the period reported.

Figure 15: Reporting parameters time element Category I example

```
<entry>
   <act classCode="ACT" moodCode="EVN">
       <code code="252116004"
             codeSystem="2.16.840.1.113883.6.96"
             displayName="Observation Parameters" />
       <effectiveTime>
          <low value="20080101" /> <!-- The first day of the period reported. -->
          <high value="20080331" /> <!-- The last day of the period reported. -->
       </effectiveTime>
   </act>
</entry>
```

2.4.4 Patient Data Section

The Patient Data section contains patient data elements and measure-specific grouping data elements as defined by the particular measure(s). All data needed by a processing entity (see above) generating QRDA Category II and/or QRDA Category III reports should be included.

A patient data element is information about a particular person (as opposed to a population). Examples include: individual's test results, individual's encounter location, individual's date of birth.

A measure-specific grouping data element defines a subgroup population criterion. These data elements define how patient data elements are to be cumulated into aggregate data elements. Examples include:

- a measure-specific grouping data element of "primary surgeon" indicates that the primary surgeon of an individual's operative procedure be captured in the QRDA Category I report, and that aggregate data elements in a QRDA Category III report are to be calculated per each primary surgeon;
- a measure-specific grouping data element of "outborn" indicates that the infant in a neonatal population was not born at the reporting hospital and will be cohorted into an "outborn" group in the QRDA Category III report.

This section should reuse CCD clinical statement templates when appropriate, such as the problem observation and result observation template to model the observations. Exact patterns are defined in the measure-specific QRDA IGs.

CONF-QRDA-I-55: The Patient Date section **SHALL** contain a `section/code` element.

CONF-QRDA-I-56: The value for `section/code` **SHALL** be `55188-7 Patient Data 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-QRDA-I-57: The Patient Data section **SHALL** be valued with `section/title` with a case-insensitive, text string containing "`Patient Data`".

CONF-QRDA-I-58: The Patient Data section **SHALL** contain patient data pertaining to measures stated in the Measure section.

CONF-QRDA-I-59: The measure data **SHALL** be represented as clinical statements.

CONF-QRDA-I-60: Measure data using SNOMED **SHALL** be represented per the "Using SNOMED CT® in HL7 Version 3" DSTU.

CONF-QRDA-I-61: Measure data **SHOULD** use CCD and other CDA IG templates where possible.

CONF-QRDA-I-62: A QRDA Category I report **SHALL** contain all patient data elements and measure-specific grouping data elements needed by a processing entity generating QRDA Category II and/or QRDA Category III reports.

3 QRDA CATEGORY II REPORT (DRAFT)

See Section 1.4.2 Types of Quality Measure Reports for an introduction and overview of QRDA Category I, QRDA Category II, and QRDA Category III reports.

3.1 Header Constraints

This section describes constraints that apply to the QRDA Category II report Header.

3.1.1 Header Attributes

3.1.1.1 ClinicalDocument/realmCode

CONF-QRDA-II-1: The `realmCode` element **SHALL** be present where the value of `@code` is `US`.

Figure 16: realmCode Category II example

```
<realmCode code="US"/>
```

3.1.1.2 ClinicalDocument/typeID

CONF-QRDA-II-2: The value of `typeID/@root` **SHALL** be `2.16.840.1.113883.1.3` and value of `typeID/@extension` **SHALL** be `POCD_HD000040`.

3.1.1.3 ClinicalDocument/templateId

This `ClinicalDocument/templateId` element identifies the template that defines constraints on the content of a QRDA Category II document.

CONF-QRDA-II-3: A category two QRDA report **SHALL** contain at least one `ClinicalDocument/templateId` element.

CONF-QRDA-II-4: The value of one `ClinicalDocument/templateId/@root` **SHALL** be `2.16.840.1.113883.10.20.13`, representing conformance to the generic Category II framework constraints.

Figure 17: ClinicalDocument/templateId Category II example

```
<templateId root= "2.16.840.1.113883.10.20.13"/> <!-- conforms to the DSTU -->
```

3.1.1.4 ClinicalDocument/code

CONF-QRDA-II-5: A QRDA Category II report **SHALL** contain exactly one `ClinicalDocument/code` with a value of `55183-8 2.16.840.1.113883.6.1 LOINC` **STATIC**.

3.1.1.5 ClinicalDocument/title

CONF-QRDA-II-6: A QRDA Category II report **SHALL** contain exactly one `ClinicalDocument/title` element valued with a case-insensitive, text string containing "`QRDA Patient List Report`".

3.1.2 Participants

This section describes the participants in the QRDA Category II report.

3.1.2.1 recordTarget

CDA requires a `recordTarget`. A QRDA Category II report contains information on many patients, and therefore nullifies this participation.

CONF-QRDA-II-7: The `patientRole` **SHALL** contain an `id` element where the value of `@nullFlavor` is `NA`.

Figure 18: Null flavor recordTarget Category II example

```
<recordTarget>
    <patientRole>
        <id nullFlavor="NA"/>
    </patientRole>
</recordTarget>
```

3.1.2.2 Author

The author may be a device (e.g., data aggregation software), a person (e.g., a quality manager), or an organization (e.g., a processing entity).

CONF-QRDA-II-8: A QRDA Category II **SHALL** contain one or more `ClinicalDocument/author/assignedAuthor/assignedPerson` and/or `ClinicalDocument/author/assignedAuthor/representedOrganization` and/or `ClinicalDocument/author/assignedAuthor/authoringDevice`.

The example below shows how a processing entity can be represented as the author.

Figure 19: AssignedAuthor as a processing entity Category II example

```
   <author>
      <time value="20080513"/>
      <assignedAuthor>
         <id nullFlavor="NA"/>
         <representedOrganization>
            <id root="2.16.840.1.113883.19.598"/>
            <name>Good Health Processing Entity</name>
         </representedOrganization>
      </assignedAuthor>
   </author>
```

3.1.2.3 Informant

A QRDA Category II report must have a stated source so that any data within the report can be validated. The source of the report is the reporting facility, represented using the CCD "Source of Information" construct, via the `informant` participant.

CONF-QRDA-II-9: A QRDA Category II report **SHALL** contain exactly one `ClinicalDocument/informant`, which represents the reporting facility.

CONF-QRDA-II-10: An organization source of information **SHALL** be represented with `informant`.

Figure 20: Informant Category II example

```
<informant>
   <assignedEntity>
      <id nullFlavor="NA"/>
      <representedOrganization>
         <id root="2.16.840.1.113883.19.5"/>
         <name>Good Health Clinic</name>
      </representedOrganization>
   </assignedEntity>
</informant>
```

3.1.2.4 Custodian

The custodian is the organization that is responsible for maintaining the QRDA Category II report. The custodian will vary. The custodian is not necessarily the reporting entity, as there may be workflows where the processing entity itself assumes custodianship.

CONF-QRDA-II-11: A QRDA Category II report **SHALL** contain exactly one `custodian/assignedCustodian/representedCustodianOrganization/id` element.

CONF-QRDA-II-12: The value of `custodian/assignedCustodian/representedCustodianOrganization/id` element `@root` **SHALL** be the `id` root of the custodian.

Figure 21: Custodian Category II example

```
<custodian>
   <assignedCustodian>
      <representedCustodianOrganization>
         <id root="2.16.840.1.113883.19.5"/>
         <name>Good Health Clinic</name>
      </representedCustodianOrganization>
   </assignedCustodian>
</custodian>
```

3.1.2.5 legalAuthenticator

A legal authenticator is a verifier who officially authenticates the accuracy of the document. An example would be the health care organization that compiles the quality report. A `legalAuthenticator` is required, but the value will vary depending on the workflow or rules of the organizations.

CONF-QRDA-II-13: A QRDA Category II report **SHALL** contain exactly one `legalAuthenticator` element.

CONF-QRDA-II-14: QRDA Category II report `legalAuthenticator` **SHALL** contain exactly one `ClinicalDocument/legalAuthenticator/time` element.

CONF-QRDA-II-15: A QRDA Category II report **SHALL** contain exactly one `signatureCode` element.

CONF-QRDA-II-16: The value of a QRDA `ClinicalDocument/signatureCode/@code` **SHALL** be S.

CONF-QRDA-II-17: A QRDA Category II report **SHALL** contain exactly one `assignedEntity` element that represents the `legalAuthenticator` of the document.

CONF-QRDA-II-18: The `ClinicalDocument/assignedEntity` **SHALL** contain an `id` element.

Figure 22: legalAuthenticator Category II example

```
<legalAuthenticator>
   <time value="20080513"/>
   <signatureCode code="S"/>
   <assignedEntity>
      <id nullFlavor="NA"/>
      <representedOrganization>
         <id root="2.16.840.1.113883.19.5"/>
         <name>Good Health Clinic</name>
      </representedOrganization>
   </assignedEntity>
</legalAuthenticator>
```

3.1.2.6 Participant Scenarios

The following table shows a number of scenarios and the values for various participants.

Table 3: QRDA Category II/III Participant Scenarios

	Author	**Custodian**	**Encompassing Encounter / encounter Participant**	**Encompassing Encounter / responsible Party**	**Informant**	**Legal Authenticator**	**Participant**
SCENARIO: The health care enterprise (e.g. Good Health Clinic) collecting the data sends QRDA Category I reports to a processing entity, which then generates the QRDA Category II and/or QRDA Category III reports. This scenario focuses on the participants in the corresponding QRDA Category II or QRDA Category III instance.							
QRDA Category II /III report	Device (scoped by Processing Entity)	Varies depending on workflow. Capture the entity that is in charge of maintaining the information.	None	None	(aka "reporting entity") Good Health Clinic	Varies depending on workflow and business rules.	None

3.2 Body Constraints

A QRDA Category II report requires a `structuredBody`. The report will typically contain several sections and subsections. The top-level sections may be either Measure sections, where each section is reporting quality data defined by a single measure, or they may be Measure Set sections, where each section contains one or more Measure sections, or they may be both. There will also be a single top-level Reporting Parameters section. This is illustrated in Figure 23: Category II/III use of Measure Set and Measure sections. Figure 24: Sample QRDA Category II Patient List Report shows an example of a QRDA Category II report.

Figure 23: Category II/III use of Measure Set and Measure sections

```
Reporting Parameter Section

Measure Set Section
       Measure Section
       Measure Section
       Measure Section

Measure Set Section
       Measure Section
       Measure Section
       Measure Section

Measure Section

Measure Section
```

CONF-QRDA-II-19: A QRDA Category II report **SHALL** contain exactly one `ClinicalDocument/component/structuredBody`.

CONF-QRDA-II-20: A QRDA Category II report **SHALL** contain exactly one Reporting Parameters section.

CONF-QRDA-II-21: A QRDA Category II report **SHALL** contain at least one and **MAY** contain more than one Measure Set section containing information about the measure set.

CONF-QRDA-II-22: A QRDA Category II report **SHALL** contain at least one and **MAY** contain more than one Measure section each containing information about a single measure.

Figure 24: Sample QRDA Category II Patient List Report

QRDA Patient List Report

Created On: May 13, 2008

Author: Good Health Processing Entity

Legal Authenticator: Good Health Clinic

Custodian: Good Health Clinic

Reporting Period January 1, 2007 - December 31, 2007

Table of Contents

- Reporting Parameters
- Retinopathy of Prematurity

Reporting Parameters

- Reporting period: 01 Jan 2007 - 31 Dec 2007

Retinopathy of Prematurity

Description: Retinopathy of Prematurity (ROP) incidence in neonates; BW >= 1500gm.

PatientId	ROP Present?	Alive at Discharge?	Numerator	Denominator	Exclusion
123456789	YES	YES	YES	YES	NO
123456788	NO	YES	NO	YES	NO
123456787	NO	YES	NO	YES	NO
123456786	YES	YES	YES	YES	NO
123456785	NO	YES	NO	YES	NO
123456784	NO	YES	NO	YES	NO
123456783	EXCL	NO	EXCL	YES	YES
123456782	YES	YES	YES	YES	NO
123456781	NO	YES	NO	YES	NO
123456780	NO	YES	NO	YES	NO
123456779	NO	YES	NO	YES	NO
123456778	NO	YES	NO	YES	NO
123456777	YES	YES	YES	YES	NO
123456776	EXCL	NO	EXCL	YES	YES

3.3 Section Constraints

This section describes constraints that apply to the QRDA Category II report sections. A section is required for each measure being reported.

3.3.1 Reporting Parameters Section

The Reporting Parameters section provides information about the reporting time interval and may contain other information that helps provide context for the patient data being reported.

CONF-QRDA-II-23: The Reporting Parameters section **SHALL** contain a `section/code` element.

CONF-QRDA-II-24: The value for `section/code` **SHALL** be `55187-9 Reporting Parameters 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-QRDA-II-25: The Reporting Parameters section **SHALL** be valued with `section/title` with a case-insensitive, text string containing "`Reporting Parameters`".

CONF-QRDA-II-26: The Reporting Parameters section **SHALL** contain exactly one Observation Parameters Act.

CONF-QRDA-II-27: The value for `act/@classCode` in an Observation Parameters Act **SHALL** be `ACT 2.16.840.1.113883.5.6 ActClass` **STATIC**.

CONF-QRDA-II-28: The value for `act/@moodCode` in an Observation Parameters Act **SHALL** be `EVN 2.16.840.1.113883.5.1001 ActMood` **STATIC**.

CONF-QRDA-II-29: The reporting time period in a Reporting Period Act **SHALL** be represented with an `effectiveTime/low` element combined with a `high` element representing respectively the first and last days of the period reported.

Figure 25: Reporting parameters section Catgory II example

```
<section>
   <code code="55187-9" codeSystem="2.16.840.1.113883.6.1"
   <title>Reporting Parameters</title>

   <text>
         <list>
            <item>Reporting period: 01 Jan 2007 - 31 Dec 2007</item>
         </list>
   </text>

  <entry>
    <act classCode="ACT" moodCode="EVN">
      <code code="252116004"
            codeSystem="2.16.840.1.113883.6.96"
            displayName="Observation Parameters" />
      <effectiveTime>
         <low value="20080101" /> <!-- The first day of the period reported. -->
         <high value="20080331" /> <!-- The last day of the period reported. -->
      </effectiveTime>
    </act>

  </entry>
</section>
```

3.3.2 Measure Section

Each QRDA Category II Measure section corresponds to one measure, and contains a measure identifier along with measure-specific data. Data for each patient listed in a QRDA Category II report's Measure section includes patient data elements, measure-specific grouping data elements, and qualification data elements.

A patient data element is information about a particular person (as opposed to a population). Examples include: individual's test results, individual's encounter location, individual's date of birth.

A measure-specific grouping data element defines a subgroup population criterion. These data elements define how patient data elements are to be cumulated into aggregate data elements. Examples include:

- a measure-specific grouping data element of "primary surgeon" indicates that the primary surgeon of an individual's operative procedure be captured in the QRDA Category I report, and that aggregate data elements in a QRDA Category III report are to be calculated per each primary surgeon;
- a measure-specific grouping data element of "outborn" indicates that the infant in a neonatal population was not born at the reporting hospital and will be cohorted into an "outborn" group in the QRDA Category III report.

A qualification data element is patient-level information about the status of quality compliance, e.g., assertion of whether a particular patient meets a measure's numerator criteria. In

Figure 24: Sample QRDA Category II Patient List Report, the patient data elements are "ROP Present?" and "Alive at Discharge?"; measure-specific grouping data elements, such as "outborn", are not present; and the qualification data elements are "Numerator", "Denominator", and "Exclusion".

CONF-QRDA-II-30: The Measure section **SHALL** contain a `templateId` uniquely identifying the Measure name and version

CONF-QRDA-II-31: The Measure section **SHALL** contain a `section/code` element.

CONF-QRDA-II-32: The value for `section/code` **SHALL** be `55186-1 Measure 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-QRDA-II-33: Each Measure section **SHALL** be valued with `section/title` with a case-insensitive, text string containing `"measure section: <measure name>"`.

CONF-QRDA-II-34: The Measure Section **MAY** contain a `section/text` element for the description of the measure.

3.3.2.1 Representation of the Measure Data Elements

Note to readers: This section is in draft form, and requires more review before being brought to formal ballot. It is presented here as a walk through of a detailed example. Conformance statements have yet to be created. The Structured Documents Working Group welcomes your review and feedback on the overall approach.

Figure 26: Measure section illustrates evolving design decisions. Each QRDA Category II Measure section contains an outer act in `event` mood for each patient (line 4). This outer act has `act/id` to uniquely identify the `act`, `act/code` corresponding to the measure, and `act/text` where optionally one can give a description of the measure.

Because the QRDA Category II report contains data on many patients, the participant relationship (line 13) is used to specify each patient's medical record number; `participant/typeCode` equals `RCT` (record target).

Patient data elements come next (lines 21, 31) and are components of the outer act (beginning on line 4). The complete representation of the data elements are to be described in the measure-specific IG. The QRDA Category II framework document recommends that the patient data elements use existing CCD and other CDA IG templates where possible, and uses SNOMED CT® per the "Using SNOMED CT® in HL7 Version 3" DSTU.

Measure-specific grouping data elements aren't present in this example.

Qualification data elements (beginning on line 49) come next. A key point here is that a measure defines its aggregate data elements, and the purpose of the qualification is to assert whether or not a patient is to be counted in the corresponding aggregate. For instance, the Healthcare Effectiveness Data and Information Set (HEDIS) "Treat Adults w/Acute Bronchitis" defines the following aggregate data elements:

- Eligible population by ER/urgent care visits
- Eligible population by non-ER/urgent care visits
- Exclusions for comorbid conditions

- Exclusions for completing diagnosis
- Exclusions for Medication History
- Numerator by ER/urgent care visits
- Numerator by non-ER/urgent care visits
- etc.

For each of these elements, the QRDA Category II report will say whether or not the patient qualified, whereas the QRDA Category III report will show the total number of patients that qualified. A patient that qualifies is given an integer value of `1`, whereas a value of `0` indicates the patient didn't qualify. Integer values are used to facilitate deriving the QRDA Category III aggregate data element values.

Figure 26: Measure section Category II example

```
<section>
<!-- One measure per section, so this FAKE templateID would represent the ROP measure
-->
   <templateId root="2.16.840.1.113883.19.5"/>
   <code code="55186-1" codeSystem="2.16.840.1.113883.6.1" />
   <title>Measure Section: Retinopathy of Prematurity</title>
   ...

<!-- Data for patient 123456789  -->
<entry typeCode="DRIV">
  <act classCode="ACT" moodCode="EVN">
    <id root="d71b78bb-0d69-470c-aaf5-fb15382edf84"/>
      <!-- Fake code for illustration -->
      <code code="22222-X" codeSystem="2.16.840.1.113883.6.1"
       displayName="Retinopathy of Prematurity (ROP)"/>
      <text>Retinopathy of Prematurity incidence in neonates; BW >= 1500gm.</text>
      <statusCode code="completed"/>

<!-- Patient details are represented via the CDA Clinical Statement generic
participant -->
      <participant typeCode="RCT">
        <participantRole classCode="PAT">
          <id extension="123456789" root="2.16.840.1.113883.19.5"/>
        </participantRole>
      </participant>

<!-- Patient data elements that determine numerator qualification -->
      <entryRelationship typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN" negationInd="false">
          <id root="f7a66e8a-f6e5-48fe-93e5-f0f1ed462c80"/>
          <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
          <statusCode code="completed"/>
          <value xsi:type="CD"  code="362.21" codeSystem="2.16.840.1.113883.6.2"
                 codeSystemName="ICD9CM" displayName="Retrolental Fibroplasia"/>
        </observation>
      </entryRelationship>

<!-- Patient data elements that determine exclusion qualification -->
      <entryRelationship typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN" negationInd="false">
          <id root="f6cf4175-cfd0-4b4b-9dc8-f9f28d1bde3d"/>
          <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
          <statusCode code="completed"/>
          <value xsi:type="CD"  code="371827001" codeSystem="2.16.840.1.113883.6.96"
                 displayName="Patient discharged alive"/>
        </observation>
      </entryRelationship>

<!--
Patient details related to Denominator inclusion/exclusion aren't included,
since it is assumed here that the Category II report only includes those meeting
denominator criteria.
      -->
```

```
<!-- Qualification data elements  -->
      <entryRelationship typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN">
          <id root="fe179f97-10bc-411f-8afe-7eb1419220db"/>
          <code code="NUM" codeSystem="codeSystemOID" displayName="Numerator"/>
          <statusCode code="completed"/>
          <value xsi:type="INT" value="1"/>
        </observation>
      </entryRelationship>
      <entryRelationship typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN">
          <id root="9a11fd9a-2fc4-48bf-b66e-7a288f977a99"/>
          <code code="DEN" codeSystem="codeSystemOID" displayName="Denominator"/>
          <statusCode code="completed"/>
          <value xsi:type="INT" value="1"/>
        </observation>
      </entryRelationship>
      <entryRelationship typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN">
          <id root="f7b6b575-d9e4-4c78-b71f-63e38996f010"/>
          <code code="EXCL" codeSystem="codeSystemOID" displayName="Exclusion"/>
          <statusCode code="completed"/>
          <value xsi:type="INT" value="0"/>
        </observation>
      </entryRelationship>
    </act>
  </entry>
...
</section>

<!-- Data for remaining patients would come next... -->
```

4 QRDA CATEGORY III REPORT (DRAFT)

See Section 1.4.2 Types of Quality Measure Reports for an introduction and overview of QRDA Category I, QRDA Category II, and QRDA Category III reports.

4.1 Header Constraints

This section describes constraints that apply to the QRDA Category III report Header.

4.1.1 Header Attributes

4.1.1.1 ClinicalDocument/realmCode

CONF-QRDA-III-1: The `realmCode` element **SHALL** be present where the value of `@code` is `US`.

Figure 27: realmCode Category III example

```
<realmCode code="US"/>
```

4.1.1.2 ClinicalDocument/typeID

CONF-QRDA-III-2: The value of `typeID/@root` **SHALL** be `2.16.840.1.113883.1.3` and value of `typeID/@extension` **SHALL** be `POCD_HD000040`.

4.1.1.3 ClinicalDocument/templateId

This `ClinicalDocument/templateId` element identifies the template that defines constraints on the content of a QRDA Category III document.

CONF-QRDA-III-3: A QRDA Category III report **SHALL** contain at least one `ClinicalDocument/templateId` element.

CONF-QRDA-III-4: The value of one `ClinicalDocument/templateId/@root` **SHALL** be `2.16.840.1.113883.10.20.14` representing conformance to the generic QRDA Category III framework constraints.

Figure 28: ClinicalDocument/templateId Category III example

```
<templateId root= "2.16.840.1.113883.10.20.14"/> <!-- conforms to the DSTU -->
```

4.1.1.4 ClinicalDocument/code

CONF-QRDA-III-5: A QRDA Category III report **SHALL** contain exactly one `ClinicalDocument/code` with a value of `55184-6 2.16.840.1.113883.6.1 LOINC` **STATIC**.

4.1.1.5 ClinicalDocument/title

CONF-QRDA-III-6: A QRDA Category III report **SHALL** contain exactly one `ClinicalDocument/title` element valued with a case-insensitive, text string containing "QRDA Calculated Summary Report."

4.1.2 Participants

This section describes the participants in the QRDA Category III report.

4.1.2.1 recordTarget

CDA requires a `recordTarget`. A QRDA Category II report contains information on many patients, and therefore nullifies this participation.

CONF-QRDA-III-7: The value of `patientRole` **SHALL** contain an `id` element where the value of `@nullFlavor` is `NA`.

Figure 29: Null flavor recordTarget Category III example

```
<recordTarget>
  <patientRole>
    <id nullFlavor="NA"/>
  </patientRole>
</recordTarget>
```

4.1.2.2 Author

The author may be a device (e.g., data aggregation software), a person (e.g., a quality manager), or an organization (e.g., a processing entity).

CONF-QRDA-III-8: A QRDA Category III **SHALL** contain one or more `ClinicalDocument/author/assignedAuthor/assignedPerson` and/or `ClinicalDocument/author/assignedAuthor/representedOrganization` and/or `ClinicalDocument/author/assignedAuthor/authoringDevice`.

The example shows how a processing entity can be represented as the author.

Figure 30: AssignedAuthor as a processing entity Category III example

```
<author>
  <time value="20080513"/>
  <assignedAuthor>
    <id nullFlavor="NA"/>
    <representedOrganization>
      <id root="2.16.840.1.113883.19.598"/>
      <name>Good Health Processing Entity</name>
    </representedOrganization>
  </assignedAuthor>
</author>
```

4.1.2.3 Informant

A QRDA Category II report must have a stated source so that any data within the report can be validated. The source of the report is the reporting facility, represented using the CCD "Source of Information" construct, via the `informant` participant.

CONF-QRDA-III-9: A QRDA Category III report **SHALL** contain exactly one `ClinicalDocument/informant`, who represents the reporting facility.

CONF-QRDA-III-10: An organization source of information **SHALL** be represented with `informant`.

Figure 31: Informant Category III example

```
<informant>
  <assignedEntity>
    <id nullFlavor="NA"/>
    <representedOrganization>
      <id root="2.16.840.1.113883.19.5"/>
      <name>Good Health Clinic</name>
    </representedOrganization>
  </assignedEntity>
</informant>
```

4.1.2.4 Custodian

The custodian is the organization that is responsible for maintaining the QRDA Category II report. The custodian is not necessarily the reporting entity, as there may be workflows where the processing entity itself assumes custodianship.

CONF-QRDA-III-11: A QRDA Category III report **SHALL** contain exactly one `custodian/assignedCustodian/representedCustodianOrganization/id` element.

CONF-QRDA-III-12: The value of `custodian/assignedCustodian/representedCustodianOrganization/id` element `@root` **SHALL** be the `id` root of the custodian.

Figure 32: Custodian Category III example

```
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id root="2.16.840.1.113883.19.5"/>
      <name>Good Health Clinic</name>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

4.1.2.5 legalAuthenticator

A legal authenticator is a verifier who officially authenticates the accuracy of the document. An example would be the health care organization that compiles the quality

report. A `legalAuthenticator` is required, but the value will vary depending on the workflow or rules of the organization.

CONF-QRDA-III-13: A QRDA Category III report **SHALL** contain exactly one `legalAuthenticator` element.

CONF-QRDA-III-14: A QRDA Category III report `legalAuthenticator` **SHALL** contain exactly one `ClinicalDocument/legalAuthenticator/time` element.

CONF-QRDA-III-15: A QRDA Category III report **SHALL** contain exactly one `signatureCode` element.

CONF-QRDA-III-16: The value of a QRDA `ClinicalDocument/signatureCode/@code` **SHALL** be S.

CONF-QRDA-III-17: A QRDA Category III report **SHALL** contain exactly one `assignedEntity` element the represents the `legalAuthenticator` of the document.

CONF-QRDA-III-18: The `ClinicalDocument/assigned` entity **SHALL** contain an `id` element.

Figure 33: legalAuthenticator Category III example

```
<legalAuthenticator>
  <time value="20080513"/>
  <signatureCode code="S"/>
  <assignedEntity>
    <id nullFlavor="NA"/>
    <representedOrganization>
      <id root="2.16.840.1.113883.19.5"/>
      <name>Good Health Clinic</name>
    </representedOrganization>
  </assignedEntity>
</legalAuthenticator>
```

4.1.2.6 Participant Scenarios

Table 3: QRDA Category II/III Participant Scenarios shows a number of scenarios and the values for various participants.

4.2 Body Constraints

A QRDA Category III report requires a `structuredBody`. The report will typically contain several sections and subsections. The top-level sections may be either Measure sections, where each section is reporting quality data defined by a single measure; or they may be Measure Set sections, where each section contains one or more Measure sections; or they may be both. There will also be a single top-level Reporting Parameters section. This is illustrated above in Figure 23: Category II/III use of Measure Set and Measure sections. Figure 34: Sample Category III QRDA Calculated Summary Report shows an example of a QRDA Category III report.

CONF-QRDA-III-19: A QRDA Category III report **SHALL** contain exactly one `ClinicalDocument/component/structuredBody`.

CONF-QRDA-III-20: A QRDA Category III report **SHALL** contain at least one and **MAY** contain more than one Measure Set section containing information about the measure set.

CONF-QRDA-III-21: A QRDA Category III report **SHALL** contain at least one and **MAY** contain more than one Measure section, each containing information about a single measure.

CONF-QRDA-III-22: A QRDA Category III report **SHALL** contain exactly one Reporting Parameters section.

Figure 34: Sample Category III QRDA Calculated Summary Report

QRDA Calculated Summary Report

Created On: May 13, 2008

Author: Good Health Processing Entity

Legal Authenticator: Good Health Clinic

Custodian: Good Health Clinic

Table of Contents

- Reporting Parameters
- Measure: BP Control in HTN (140/90)
- Measure: A1C Control <7%
- Measure: BP control in DM (130/80)
- Measure: Asthma control (18-56 yrs)

Reporting Parameters

- Reporting period: 01 Jan 2007 - 31 Dec 2007
- Aggregation level: Health care professional
- Aggregation level: Site of care

Measure Section: BP Control in HTN (140/90)

Description: Patients >= 18 years of age with hypertension, without IVD or Diabetes who have a BP < 140/90.

Provider	Location	Numerator	Denominator	Exclusions -Diabetes	Exclusions - IVD	Exclusions - Total	Percentage
Jones	**Good Health Clinic**	**4**	**39**	**2**	**0**	**2**	**10.26**
Smith	**Good Health Clinic**	**24**	**28**	**0**	**0**	**0**	**85.71**

Measure Section: A1C Control <7%

Description: Patients 18-75 years of age with diabetes who had at least one HgA1C measured in the past 12 months below 7.0%.

Provider	Location	Numerator	Denominator	Exclusions	Percentage
Jones	Good Health Clinic	28	33	3	80.00
Smith	Good Health Clinic	24	28	0	85.71

Measure Section: BP control in DM (130/80)

Description: Patients 18-75 years of age with a diagnosis of diabetes with the most recent BP below 130 systolic and 80 diastolic in the past year.

Provider	Location	Numerator	Denominator	Exclusions	Percentage
Jones	Good Health Clinic	37	40	1	92.50
Smith	Good Health Clinic	24	28	0	85.71

Measure Section: Asthma control (18-56 yrs)

Description: Patients 18-56 years of age with persistent asthma who were prescribed appropriate medication, including methylxanthines.

Provider	Location	Numerator	Denominator	Exclusions	Percentage
Jones	Good Health Clinic	33	37	0	89.19
Smith	Good Health Clinic	24	28	0	85.71

4.3 Section Constraints

This section describes constraints that apply to the QRDA Category III report sections. A section is required for each measure being reported.

4.3.1 Reporting Parameters Section

The Reporting Parameters section provides information about the reporting time interval and may contain other information that helps provide context for the patient data being reported.

CONF-QRDA-III-23: The Reporting Parameters section **SHALL** contain a `section/code` element.

CONF-QRDA-III-24: The value for `section/code` **SHALL** be `55187-9 Reporting Parameters 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-QRDA-III-25: The Reporting Parameters section **SHALL** be valued with `section/title` with a case-insensitive, text string containing `"Reporting Parameters"`.

CONF-QRDA-III-26: The Reporting Parameters section **SHALL** contain exactly one Observation Parameters Act.

CONF-QRDA-III-27: The value for `act/@classCode` in an Observation Parameters Act **SHALL** be `ACT 2.16.840.1.113883.5.6 ActClass` **STATIC**.

CONF-QRDA-III-28: The value for `act/@moodCode` in an Observation Parameters Act **SHALL** be `EVN 2.16.840.1.113883.5.1001 ActMood` **STATIC**.

CONF-QRDA-III-29: The reporting time period in a Reporting Period Act **SHALL** be represented with an `effectiveTime/low` element combined with a `high` element representing respectively the first and last days of the period reported.

Figure 35: Reporting parameters section Category III example

```
<section>
   <code code="55187-9" codeSystem="2.16.840.1.113883.6.1" />
   <title>Reporting Parameters</title>
   <text>
         <list>
            <item>Reporting period: 01 Jan 2007 - 31 Dec 2007</item>
            <item>Aggregation level: Healthcare professional</item>
            <item>Aggregation level: Site of care</item>
         </list>
   </text>
   <entry>
      <act classCode="ACT" moodCode="EVN">
         <id root="55a43e20-6463-46eb-81c3-9a3a1ad41225"/>
         <code code="252116004" codeSystem="2.16.840.1.113883.6.96"
          displayName="Observation Parameters"/>
          <effectiveTime>
               <low value="20070101"/>
               <high value="20071231"/>
         </effectiveTime>

         <entryRelationship typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
          <code nullFlavor="OTH"><originalText>Aggregation
                level</originalText></code>
               <value xsi:type="CD" code="223366009"
                codeSystem="2.16.840.1.113883.6.96"
                displayName="Healthcare professional"/>
            </observation>
         </entryRelationship>
         <entryRelationship typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
              <code nullFlavor="OTH"><originalText>Aggregation
             level</originalText></code>
            <value xsi:type="CD" code="43741000" codeSystem="2.16.840.1.113883.6.96"
             displayName="Site of care"/>
         </observation>
       </entryRelationship>
      </act>
   </entry>
</section>
```

4.3.2 Measure Section

Each QRDA Category III Measure section corresponds to one measure and contains a measure identifier, along with aggregate data elements and measure-specific grouping data elements.

An aggregate data element is a measure-specified calculated summary derived from patient data elements. Examples include: the number of patients meeting a measure's numerator criteria, the number of patients meeting a measure's denominator criteria, and the number of patients excluded due to weight criteria.

A measure-specific grouping data element defines a subgroup population criterion. These data elements define how patient data elements are to be cumulated into aggregate data elements. Examples include:

- a measure-specific grouping data element of "primary surgeon" indicates that the primary surgeon of an individual's operative procedure be captured in the QRDA Category I report, and that aggregate data elements in a QRDA Category III report are to be calculated per each primary surgeon;
- a measure-specific grouping data element of "outborn" indicates that the infant in a neonatal population was not born at the reporting hospital and will be cohorted into an "outborn" group in the QRDA Category III report.

In Figure 34: Sample Category III QRDA Calculated Summary Report, aggregate data elements are "Numerator", "Denominator", "Exclusions", and "Percentage"; and measure-specific grouping data elements are "Provider" and "Location".

CONF-QRDA-III-30: Each Measure section **SHALL** contain a `templateId` uniquely identifying the Measure name and version

CONF-QRDA-III-31: Each Measure section **SHALL** contain a `section/code` element.

CONF-QRDA-II-35: The value for `section/code` **SHALL** be `55186-1 Measure 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-QRDA-III-32: Each Measure section **SHALL** be valued with `section/title` with a case-insensitive, text string containing `"measure section: <measure name>"`.

CONF-QRDA-III-33: The Measure Section **MAY** contain a `section/text` element for the description of the measure.

4.3.2.1 Representation of the Measure Data Elements

Representation of a measure act within a Measure section will identify the constraints for each measure act. The measure act will contain `participant` elements if the specific measures require aggregation or grouping in specific ways such as by provider or location.

A key point is that a measure defines its aggregate data elements, and the purpose of the qualification in a QRDA Category II report is to assert whether or not a patient is to be counted in the corresponding aggregate. For instance, the HEDIS "Treat Adults w/Acute Bronchitis" defines the following aggregate data elements:

- Eligible population by ER/urgent care visits
- Eligible population by non-ER/urgent care visits
- Exclusions for comorbid conditions
- Exclusions for completing diagnosis
- Exclusions for Medication History
- Numerator by ER/urgent care visits

- Numerator by non-ER/urgent care visits
- etc.

For each of these elements, the QRDA Category II report will say whether or not the patient qualified, whereas the QRDA Category III report will show the total number of patients that qualified.

Each QRDA Category III Measure section contains an outer act in `event` mood for each unique combination of measure-specific grouping data elements. This outer act has `act/id` to uniquely identify the `act`, `act/code` corresponding to the measure, and `act/text` where optionally one can give a description of the measure.

CONF-QRDA-III-34: Measure data, whether aggregate data elements or measure-specific grouping data elements, **SHALL** be represented with clinical statements.

CONF-QRDA-III-35: Measure data using SNOMED **SHALL** be represented per the "Using SNOMED CT® in HL7 Version 3" DSTU.

CONF-QRDA-III-36: Measure data **SHOULD** use CCD and other CDA IG templates where possible.

CONF-QRDA-III-37: A QRDA Category III report Measure section **SHALL** contain a Measure Event Act in `event` mood for each unique combination of measure-specific grouping data elements.

CONF-QRDA-III-38: A Measure Event Act **SHALL** contain exactly one `act/code` to encode the particular measure.

CONF-QRDA-III-39: A Measure Event Act **SHALL** represent a measure-specific grouping data element of a performing provider with `act/performer [@typeCode="PRF"]` representing the provider associated with the patients whose measure data is being reported.

Figure 36: Act/performer Category III example representing a provider with which to group data

```
<performer>
    <assignedEntity>
         <id extension="00017" root="2.16.840.1.113883.19.5"/>
             <assignedPerson>
                 <name>
                     <given>Robert</given>
                     <family>Jones</family>
                     <suffix>MD</suffix>
                 </name>
             </assignedPerson>
    </assignedEntity>
</performer>
```

CONF-QRDA-III-40: A Measure Event Act **SHALL** represent a measure-specific grouping data element of `encounter location` with the CCD Location Participation (`2.16.840.1.113883.10.20.1.45`).

Figure 37: Location Category III example representing a clinic with which to group data

```
<participant typeCode="LOC">
    <templateId root="2.16.840.1.113883.5.90"/>
        <participantRole classCode="SDLOC">
            <playingEntity classCode="PLC">
                <name>Good Health Clinic</name>
            </playingEntity>
        </participantRole>
</participant>
```

CONF-QRDA-III-41: Aggregation data elements and measure-specific grouping data elements **SHALL** be components within a Measure Event Act.

CONF-QRDA-III-42: `entryRelationships` **SHALL** be used to link aggregation data elements and measure-specific grouping data elements with the corresponding Reporting Parameter section.

Figure 38: entryRelationship Category III example referring to the reporting parameters

```
<entryRelationship typeCode="REFR">
    <act classCode="ACT" moodCode="EVN">
        <id root="55a43e20-6463-46eb-81c3-9a3a1ad41225"/>
        <code code="252116004" codeSystem="2.16.840.1.113883.6.96"
         displayName="Observation Parameters"/>
    </act>
</entryRelationship>
```

In the QRDA Category III Measure section, aggregate data elements such as `numerator`, `denominator`, or `exclusion` are modeled as observations. The example shows the use of a local code. Standard codes, such as SNOMED, for these commonly used terms in quality reporting, would be preferred, but will have to be requested.

CONF-QRDA-III-43: An aggregate data element **SHALL** be represented with Observation.

CONF-QRDA-III-44: The value for `observation/@moodCode` in an aggregate data element **SHALL** be `EVN 2.16.840.1.113883.5.1001 ActMood` **STATIC**.

CONF-QRDA-III-45: An aggregate data element **SHOULD** contain at least one `observation/id`.

CONF-QRDA-III-46: An aggregate data element **SHALL** contain exactly one `observation/statusCode`.

CONF-QRDA-III-47: The value of `observation/statusCode` **SHALL** be `Completed`.

Figure 39: entryRelationship Category III observation of an integer value as a numerator example

```
<entryRelationship typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
        <id root="b61afff0-1654-4122-aa1d-7113d3b26c3a"/>
        <code code="NUM" codeSystem="TCNYcodeSystemOID" displayName="Numerator"/>
        <statusCode code="completed"/>
        <value xsi:type="INT" value="4"/>
    </observation>
</entryRelationship>
```

5 QRDA CATEGORY I: NEONATAL ADMISSION TEMPERATURE IMPLEMENTATION GUIDE

5.1 Introduction and Purpose

One of the primary purposes of balloting professional societies' measures is to help develop a robust framework from which the professional societies and their technical resources can develop QRDAs for all their measures over time. Model patterning for various measure types can be refined over time through the balloting of measure-specific guidelines and should become unnecessary after enough measures have gone through the HL7 technical balloting process. Some professional societies may continue to choose to vet their measure via HL7 ballot to validate the representation rather than the data elements. What should be scrutinized for here are the conformance statements representing the modeling of the representation of the measure rather than the validity of the clinical data elements of this Vermont-Oxford measure.

5.2 Rational for Selecting this Measure to Prototype QRDA

A Vermont-Oxford Neonatal Admission Temperature outcome measure was chosen by CHCA as the first of two measures to define and model in QRDA format. This outcome measure is a clear marker of the efforts to maintain a normal temperature in at-risk neonates.

Hypothermia on admission to the neonatal intensive care unit (NICU) is frequent for very low birth weight and preterm neonates, varies significantly among hospitals, and is associated with increased risks for morbidity and mortality. In the Vermont-Oxford Network Database for 2006, 61% of the 46,000 infants weighing 501 to 1,500 grams from 632 hospitals had admission temperatures below 36.5°C; 25% of the hospitals had rates over 76%; and rates varied dramatically among different units (VON 2007)[8]. The median temperatures on admission ranged from 35.3°C at 23 weeks to 36.4°C at 29 weeks.

In a study of over 5,000 infants weighing 401 to 1,499 grams from 15 centers in the NICHD Neonatal Research Network in 2002 and 2003, 50% had admission temperatures under 36°C. Furthermore, after adjusting for patient characteristics, admission temperature was inversely related to the risks for mortality and late-onset sepsis[9].

Given the wide variation in admission temperatures observed among different units, it is likely that improved attention to thermoregulation in the delivery room and during transport to the NICU can substantially reduce the frequency of hypothermia on admission, and may improve mortality and morbidity.

---

[8] Vermont-Oxford Network Annual VLBW Database Summary. Horbar JD, Carpenter JH, Kenny M, eds. Vermont-Oxford Network Burlington, VT.
2008.

[9] Laptook AR, Salhab W, Bhaskar B, and the Neonatal Research Network. Admission Temperature of Low Birth Weight Infants: Predictors and Associated Morbidities. Pediatrics 2007;119:e643-e649.

Although the cut-offs for defining hypothermia have varied among studies, Vermont-Oxford will use the World Health Organization (WHO) definition for at least moderate hypothermia and use a cut-off of 36°C.[10]

5.3 Measure Information

5.3.1.1 Measure Set

NA

5.3.1.2 Set Measure ID

NA

5.3.1.3 Outcome Measure Name

Neonatal Admission Temperature

5.3.1.4 Description

Infants 501 to 1,500 grams with first temperature measured within one hour of admission to the NICU below 36°C.

5.3.1.5 Rationale

Improved attention to thermoregulation in the delivery room and during transport to the NICU can substantially reduce the frequency of hypothermia on admission, and may improve mortality and morbidity.

5.3.1.6 Type of Measure

Outcome

5.3.1.7 Improvement Noted as presented in a Category III (Calculated) Report

Better quality of care (heat loss prevention) is associated with a lower score.

5.3.1.8 Numerator Statement

Infants 501 to 1,500 grams with first temperature taken within one hour of NICU admission below 36°C

5.3.1.8.1 Included Numerator Populations

Infants 501 to 1,500 grams with first temperature taken within one hour of NICU admission below 36°C

[10] World Health Organization. Thermal Protection of the newborn: a practical guide. Out of print. Available online at: http://who.int/reproductive-health/publications/MSM_97_2_Thermal_protection_of_the_newborn/MSM_97_2_table_of_contents_en.html.

5.3.1.8.2 Numerator Data Elements

Core body temperature

5.3.1.9 Denominator Statement

NICU admissions with a birth weight of 501 to 1,500 grams

5.3.1.9.1 Included Denominator Populations

NICU admissions with a birth weight of 501 to 1,500 grams

5.3.1.9.2 Excluded Denominator Populations

- Outborn infants admitted more than 28 days after birth
- Outborn infants who have been home prior to admission
- Infants without temperature taken within one hour of NICU admission

5.3.1.9.3 Denominator Data Elements

- NICU admission
- First temperature taken within one hour of admission
- Birth weight
- Age at admission
- Time of admission
- Inborn/outborn (location of birth)

5.3.1.9.4 Risk Adjustment

None

5.3.1.9.5 Sampling

No Sampling. All eligible cases reported.

5.4 Additional Header Constraints

This section of the IG describes additional Header constraints needed beyond the QRDA Category I framework constraints.

CONF-QRDA_NAT-1: QRDA Category I Neonatal Admission Temperature QRDA report **SHALL** contain exactly one `ClinicalDocument/recordTarget/patientRole/patient/birthTime.`

CONF-QRDA_NAT-2: The `birthTime` **SHALL** be precise to the minute and **MAY** be precise to the second.

Figure 40: Neonatal Admission Temperature recordTarget and birthTime example

```
<recordTarget>
   <patientRole>
     <id extension="123456789" root="2.16.840.1.113883.19.5" />
     <patient>
       <name>
         <given>Kari</given>
         <family>Kidd</family>
       </name>
     <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1"/>
     <birthTime value="200802022000"/>
    </patient>
  </patientRole>
</recordTarget>
```

5.5 Additional Body Constraints

A Neonatal Admission Temperature QRDA is a single-measure report. It is currently not part of a measure set.

CONF-QRDA_NAT-3: A Category I Neonatal Admission Temperature QRDA **SHALL** contain a non-nested top-level Measure section containing information about the Neonatal Admission Temperature measure.

5.6 Additional Section Constraints

5.6.1 Measure Section

CONF-QRDA_NAT-4: The value of the measure `templateId/@root` **SHALL** be `2.16.840.1.113883.10.20.12.1` representing conformance to the Neonatal Admission Temperature quality measure in a Category I QRDA.

CONF-QRDA_NAT-5: The Neonatal Admission Temperature Measure section **SHALL** contain exactly one `section/title` valued with a case-insensitive, text string containing `"Measure: Neonatal Admission Temperature"`.

5.6.1.1 Representation of the Measure

CONF-QRDA_NAT-6: The value for `act/code` **SHALL** be `NATV1-X` (Neonatal Admission Temperature, V1) `2.16.840.1.113883.6.1` `LOINC` **STATIC**.*

CONF-QRDA_NAT-7: The value for the `act/text` element **MAY** contain a case-insensitive, text string containing the description of the measure, `"Infants 501 to 1,500 grams with first temperature measured within one hour of admission to the NICU below 36 degrees Celsius."`

* At time of publication it was noted that standard codes instead of local codes should be used for the value of `act/code` in each measure act representing the measure name and version; this needs to be discussed and vetted during the DSTU period. Fake LOINC codes are shown here and are presently NOT requested from LOINC.

Figure 41: Neonatal Admission Temperature measure section example

```
<section>
       <!-- QRDA Category I measure-specific template ID . -->
       <templateId root="2.16.840.1.113883.10.20.12.1"/>
       <code code="55186-1" codeSystem="2.16.840.1.113883.6.1" />
       <title>Measure: Neonatal admission temperature</title>
       <text>Infants 501 to 1500 grams with first temperature measured within one hour
       of admission to the NICU below 36 degrees Celsius.
       </text>
       <entry typeCode="DRIV">
             <act classCode="ACT" moodCode="DEF">
                   <id root="92c9b9b2-b7ad-4cdf-aa9f-6fdd71c6a0ef"/>
                   <!-- Fake code for illustration* -->
                   <code code="NATV1-X" codeSystem="2.16.840.1.113883.6.1"
                       displayName="Neonatal admission temperature"/>
                   <text>Infants 501 to 1500 grams with first temperature measured
                       within one hour of admission to the NICU below 36 degrees
                       Celsius.</text>
                   <statusCode code="completed" />
             </act>
       </entry>
      ...
</section>
```

5.6.2 Reporting Parameters Section

The reporting period for the Neonatal Admission Temperature measure is annual. Reports are compiled upon discharge of the infant. The infant data is cohorted based on birth year, regardless if the infant is discharged in a different calendar year.

CONF-QRDA_NAT-8: The reporting time period in a Reporting Parameters Observation **SHALL** be represented with an `effectiveTime/low` element with a value of the first day of the calendar year combined with a `high` element with a value of the last day of the calendar year representing respectively the first and last days of the period reported.

Figure 42: Neonatal Admission Temperature reporting parameters section example

```
<section>
   <code code="55187-9" codeSystem="2.16.840.1.113883.6.1" />
    <title>Reporting Parameters</title>
    <text>Reporting period: 01 Jan 2008 - 31 Dec 2008</text>
       <entry>
          <act classCode="ACT" moodCode="EVN">
          <code code="252116004" codeSystem="2.16.840.1.113883.6.96"
          displayName="Observation Parameters" />
             <effectiveTime>
                <low value="20080101" /> <!--The first day of the period reported. -->
                <high value="20081231" /> <!--The last day of the period reported. -->
             </effectiveTime>
          </act>
       </entry></section>
```

5.6.3 Patient Data Section

The Patient Data section in the Neonatal Admission Temperature Measure section contains information about the infant's first documented core temperature value, the time the value was obtained, where the infant was born, the infant's birth weight, and the date and time of the NICU admission. The age of the infant is understood from the birth time data elements that are captured in the Header of the QRDA document.

5.6.3.1 Clinical Statement Conformance – Encounter Information

The following clinical statement conformance statements model the time and location of the admission to the Neonatal Intensive Care Unit (NICU).

CONF-QRDA_NAT-9: The Neonatal Admission Temperature QRDA Patient Data Section encounter information **SHALL** be represented with `encounter`.

CONF-QRDA_NAT-10: The value for `encounter/@classCode` in an encounter activity **SHALL** be `ENC 2.16.840.1.113883.5.6 ActClass` **STATIC**.

CONF-QRDA_NAT-11: The value for `encounter/@moodCode` in an encounter activity **SHALL** be `EVN 2.16.840.1.113883.5.1001 ActMood` **STATIC**.

CONF-QRDA_NAT-12: An Encounter activity **SHOULD** contain at least one `encounter/id`.

CONF-QRDA_NAT-13: An Encounter activity **SHALL** contain exactly one `encounter/code`.

CONF-QRDA_NAT-14: The value for `encounter/code` in the encounter activity **SHALL** be `IMP Inpatient 2.16.840.1.113883.5.4 ActCode`.

CONF-QRDA_NAT-15: An Encounter activity **SHALL** contain exactly one `encounter/statusCode`.

CONF-QRDA_NAT-16: The value for `encounter/statusCode` in the Encounter activity **SHALL** be `Completed 2.16.840.1.113883.5.14 ActStatus` **STATIC**.

CONF-QRDA_NAT-17: An Encounter activity **SHALL** contain exactly one `encounter/effectiveTime/low` and exactly one `encounter/effectiveTime/high`, to indicate date and time of admission and discharge, respectively.

CONF-QRDA_NAT-18: The `encounter/effectiveTime/low` **SHALL** be precise to the minute and **MAY** be precise to the second.

CONF-QRDA_NAT-19: The `encounter/effectiveTime/high` **SHALL** be precise at least to the day.

CONF-QRDA_NAT-20: A CCD location participation (`templateId 2.16.840.1.113883.10.20.1.45`) **SHALL** be represented with the participant participation.

CONF-QRDA_NAT-21: An Encounter activity **SHALL** contain one location participation.

CONF-QRDA_NAT-22: The value for `participant/participantRole/code` in a location participation **SHALL** be `PEDNICU Neonatal ICU 2.16.840.1.113883.5.111 ServiceDeliveryLocationRoleType` **STATIC**.

Figure 43: Neonatal ICU encounter example

```
<entry typeCode="DRIV">
   <encounter classCode="ENC" moodCode="EVN">
      <id root="cb94237e-3bc2-4ad3-9170-218bf4a08533"/>
      <code code="IMP" displayName="Inpatient" codeSystem="2.16.840.1.113883.5.83"/>
      <statusCode code="completed"/>
      <effectiveTime>
          <low value="200802022000"/>
          <high value="20080407"/>
      </effectiveTime>
      <participant typeCode="LOC">
      <templateId root="2.16.840.1.113883.10.20.1.45"/> <!-- Location participation
       template -->
         <participantRole classCode="SDLOC">
             <code code="PEDNICU" codeSystem="2.16.840.1.113883.5.111"
              displayName="Neonatal ICU"/>
         </participantRole>
      </participant>
   </encounter>
</entry>
```

5.6.3.2 Clinical Statement Conformance –Temperature (Numerator)

The following clinical statement conformance statements model the infant's body temperature value and the time the value was obtained.

CONF-QRDA_NAT-23: The Neonatal Admission Temperature QRDA Patient Data section **SHALL** contain exactly one Temperature Observation.

CONF-QRDA_NAT-24: A Temperature Observation **SHALL** be represented with `observation`.

CONF-QRDA_NAT-25: The value for `observation/@moodCode` in a Temperature Observation **SHALL** be `EVN 2.16.840.1.113883.5.1001 ActMood` **STATIC**.

CONF-QRDA_NAT-26: A Temperature Observation **SHOULD** contain at least one `observation/id`.

CONF-QRDA_NAT-27: A Temperature Observation **SHALL** contain exactly one `observation/statusCode`.

CONF-QRDA_NAT-28: The value of `observation/statusCode` **SHALL** be `Completed.`

CONF-QRDA_NAT-29: A Temperature Observation **SHALL** contain exactly one `observation/effectiveTime`, which represents the time the temperature was taken.

CONF-QRDA_NAT-30: The `observation/effectiveTime` **SHALL** be accurate to the minute and **MAY** be accurate to the second.

CONF-QRDA_NAT-31: A Temperature Observation **SHALL** contain exactly one `observation/code` where the value is `276885007 Core Body Temperature 2.16.840.1.113883.6.96 SNOMED-CT` **STATIC**.

CONF-QRDA_NAT-32: The `observation/value` **SHALL** be expressed using a valid UCUM Physical Quantity unit = "`Cel`" (degreesCelsius).

Figure 44: Neonatal Admission Temperature body temperature example

```
<entry typeCode="DRIV">
   <observation classCode="OBS" moodCode="EVN">
      <code code="276885007" codeSystem="2.16.840.1.113883.6.96"
            displayName="Core body temperature"/>
      <statusCode code="completed"/>
      <effectiveTime value="200802022015"/>
      <value xsi:type="PQ" value="35.6" unit="Cel"/>
   </observation>
</entry>
```

5.6.3.3 Clinical Statement Conformance – Infants Birth Weight

The following Clinical statement conformance statements model the birth weight of the infant.

CONF-QRDA_NAT-33: The Neonatal Admission Temperature QRDA Patient Data section **SHALL** contain exactly one Birth Weight Observation.

CONF-QRDA_NAT-34: The Birth Weight Observation **SHALL** be represented with `observation`.

CONF-QRDA_NAT-35: The value for `observation/@moodCode` in a Birth Weight Observation **SHALL** be `EVN 2.16.840.1.113883.5.1001 ActMood` **STATIC**.

CONF-QRDA_NAT-36: The Birth Weight Observation **SHOULD** contain at least one `observation/id`.

CONF-QRDA_NAT-37: The Birth Weight Observation **SHALL** contain exactly one `observation/statusCode`.

CONF-QRDA_NAT-38: The value of `observation/statusCode` **SHALL** be `Completed.`

CONF-QRDA_NAT-39: The Birth Weight Observation **SHALL** contain exactly one `observation/code` where the value is `47340003 birth weight 2.16.840.1.113883.6.96 SNOMED-CT` **STATIC**.

CONF-QRDA_NAT-40: The `observation/value` **SHALL** be expressed using a valid UCUM Physical Quantity unit = "`g`" (gram).

Figure 45: Neonatal Admission Temperature birth weight example

```
<entry typeCode="DRIV">
   <observation classCode="OBS" moodCode="EVN">
      <code code="47340003" codeSystem="2.16.840.1.113883.6.96" displayName="Birth
       weight"/>
      <statusCode code="completed"/>
      <value xsi:type="PQ" value="700" unit="g"/>
   </observation>
</entry>
```

5.6.3.4 Clinical Statement Conformance – Birth Location: Inborn Versus Outborn

The following conformance statements model the place of birth of the infant. The granularity of the desired measure data is only to the extent of whether the infant was born within the reporting hospital (inborn) or somewhere else (outborn). For this measure, it is not important at this time whether the birth "somewhere else" occurred in an ambulance, at another hospital, or at home, for example.

CONF-QRDA_NAT-41: A Born before Arrival Observation **SHALL** be represented with an `observation` element where the value of `@classCode` is `OBS` and the value of `@moodCode` is `EVN`.

CONF-QRDA_NAT-42: If the infant was born within the reporting hospital (inborn), `observation/@negationInd` **SHALL** be `false`. If the infant was born outside of the reporting hospital (outborn), `observation/@negationInd` **SHALL** be `true`.

CONF-QRDA_NAT-43: The value for `observation/code/@code` **SHALL** be `ASSERTION` and `observation/code/@codeSystem` **SHALL** be `2.16.840.1.113883.5.4 HL7 ActCode Complete` **STATIC**.

CONF-QRDA_NAT-44: An `observation/statusCode` element **SHALL** be present where the value of `@code` is `completed`.

CONF-QRDA_NAT-45: An `observation/value` element **SHALL** be present where the value of `@xsi:type` is `CD`, the value of `@code` is `169818001 Born before arrival 2.16.840.1.113883.6.96 SNOMED-CT` **STATIC**.

Figure 46: Neonatal Admission Temperature inborn infant modeled with assertion pattern and negation indicator example

```
<entry typeCode="DRIV">
   <observation classCode="OBS" moodCode="EVN" negationInd="false">
      <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
      <statusCode code="completed"/>
      <value xsi:type="CD" code="169818001" codeSystem="2.16.840.1.113883.6.96"
       displayName="Born before arrival"/>
   </observation>
</entry>
```

6 QRDA CATEGORY I: PEDIATRIC BODY MASS INDEX PERCENTILE IMPLEMENTATION GUIDE

6.1 Introduction and Purpose

One of the primary purposes of balloting professional societies' measures is to help develop a robust framework from which the professional societies and their technical resources can develop QRDAs for all their measures over time. Model patterning for various measure types can be refined over time through the balloting of measure-specific guidelines and should become unnecessary after enough measures have gone through the HL7 technical balloting process. Some professional societies may continue to choose to vet their measure via HL7 ballot to validate the representation rather than the data elements. What should be scrutinized for here are the conformance statements representing the modeling of the representation of the measure rather than the validity of the clinical data elements of this CHCA measure.

6.2 Rational for Selecting this Measure to Prototype QRDA

CHCA Body Mass Index (BMI) percentile measure was chosen by CHCA as the second of two measures to define and model in QRDA format. This is a process measure. A process measure captures an act that is associated with quality care. This measure is assessing the rate at which BMI percentile is captured. The pediatric growth charts for the U.S. population, including BMI for age and gender with percentile, are available online at http://www.cdc.gov/nchs/about/major/nhanes/growthcharts/clinical_charts.htm.

The dramatic increase in the prevalence of childhood obesity and its resultant comorbidities are associated with significant health and financial burdens, warranting strong and comprehensive prevention efforts.

BMI is the ratio of weight in kilograms to the square of height in meters. BMI is widely used to define overweight and obesity because it correlates well with more accurate measures of body fat and is derived from commonly available data—weight and height. It has also been correlated with obesity-related comorbid conditions in adults and children.[11] The BMI value can be plotted on a BMI percentile chart (or is calculated in an EHR) that informs the clinician of the value compared to other children of the same age and sex. For example, a BMI percentile of 90% would tell the clinician that this child had a BMI percentile greater than 90% of children his age, but less than 10% of children his age.

[11] Prevention of Pediatric Overweight and Obesity - AMERICAN ACADEMY OF PEDIATRICS POLICY STATEMENT - PEDIATRICS Vol. 112 No. 2 August 2003. Available online at: http://aappolicy.aappublications.org/cgi/reprint/pediatrics;112/2/424.pdf.

6.3 Measure Information

6.3.1 Measure Set

NA

6.3.2 Set Measure ID

NA

6.3.3 Performance Measure Name

BMI Percentile Recording

6.3.4 Description

Children ages two through18 who had an encounter in the measurement period AND whose weight was classified based on CDC BMI percentile for age and gender

6.3.5 Rationale

Monitoring the recording of the BMI can capture the degree to which providers are looking at the appropriate indicator of obesity.

6.3.6 Type of Measure

Process

6.3.7 Improvement Noted as presented in a Category III (Calculated) Report

A higher percentage of times that BMI percentile is captured indicates greater attention to childhood obesity.

6.3.8 Numerator Statement

Number of children ages two through18 who had an encounter in the measurement period AND whose weight was classified based on CDC BMI percentile for age and gender

6.3.9 Included Numerator Populations

Not Applicable (same as numerator statement)

6.3.10 Excluded Numerator Populations

None

6.3.10.1 Numerator Data Elements

- BMI percentile
- Principle diagnosis

6.3.11 Denominator Statement

Number of encounters with children ages two through 18 in the measurement period

6.3.11.1 Included Denominator Populations

All physical encounters:

- Inpatient
- Outpatient
- Home care

6.3.11.2 Excluded Denominator Populations

- Telephone encounters
- Email encounters

6.3.11.3 Denominator Data Elements

- Encounter type
- Age

6.3.11.4 Risk Adjustment

None

6.3.11.5 Sampling

No Sampling. All eligible cases reported.

6.4 Additional Header Constraints

This section of the IG describes additional Header constraints needed beyond the QRDA Category I framework constraints.

CONF-QRDA_BMI-1: Category I BMI QRDA report **SHALL** contain exactly one `ClinicalDocument/recordTarget/patientRole/patient/birthTime`.

CONF-QRDA_BMI-2: The `birthTime` **SHALL** be precise to the day and **MAY** be precise to the second.

Figure 47: Body Mass Index Percentile recordTarget and birthTime example

```
<recordTarget>
   <patientRole>
      <id extension="987654321" root="2.16.840.1.113883.19.5" />
      <patient>
         <name>
            <given>Ned</given>
            <family>Nuclear</family>
         </name>
         <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1" />
         <birthTime value="20050201"/>
      </patient>
   </patientRole>
</recordTarget>
```

6.5 Additional Body Constraints

A Body Mass Index QRDA is a single measure report. It is not currently part of a measure set.

CONF-QRDA_BMI-3: A Body Mass Index QRDA **SHALL** contain a non-nested top-level Measure section containing information about the Body Mass Index measure.

6.6 Additional Section Constraints

6.6.1 Measure Section

CONF-QRDA_BMI-4: The value of the section `templateId/@root` **SHALL** be `2.16.840.1.113883.10.20.12.2` representing conformance to the Body Mass Index Percentile Measure section in a Category I QRDA.

CONF-QRDA_BMI-5: The Body Mass Index Measure section **SHALL** contain exactly one `section/title` valued with a case-insensitive, text string containing, "`Measure: Body Mass Index Percentile`".

6.6.1.1 Representation of the Measure

CONF-QRDA_BMI-6: The value for `act/code` **SHALL** be `BMIV1-X Body Mass Index, V1 2.16.840.1.113883.6.1 LOINC` **STATIC**.

CONF-QRDA_BMI-7: The value for `act/text` element **MAY** contain a case-insensitive, text string containing the description of the measure, "`Children ages 2-18 who had an encounter in the measurement period AND whose weight was classified based on CDC BMI percentile for age and gender.`"

* At time of publication it was noted that standard codes instead of local codes should be used for the value of `act/code` in each measure act representing the measure name

and version; this needs to be discussed and vetted during the DSTU period. Fake LOINC codes are shown here and are presently NOT requested from LOINC.

Figure 48: Body Mass Index Percentile measure section example

```
<section>
   <!-- QRDA Category I measure-specific template ID . -->
   <templateId root=" 2.16.840.1.113883.10.20.12.2" />
    <code code="55186-1" codeSystem="2.16.840.1.113883.6.1" />
   <title>Measure: Body mass index percentile</title>
   <text>Children ages 2-18 who had an encounter in the measurement period AND whose
    weight was classified based on CDC BMI percentile for age and gender.</text>
   <entry typeCode="DRIV">
      <act classCode="ACT" moodCode="DEF">
         <id root="6bf74b3d-3edb-4be8-aa21-a54552aa9040"/>
         <!-- Fake code for illustration -->
         <code code="BMIV1-X" codeSystem="2.16.840.1.113883.6.1"
               displayName="Body mass index Percentile, V1"/>
         <text>Children ages 2-18 who had an encounter in the measurement period AND
          whose weight was classified based on CDC BMI percentile for age and
          gender.</text>
         <statusCode code="completed"/>
      </act>
   </entry>
  ...
</section>
```

6.6.2 Reporting Parameters Section

The reporting period for the Body Mass Index measure is either quarterly or monthly.

CONF-QRDA_BMI-8: The reporting time period in a Reporting Period Observation **SHALL** be represented with an `effectiveTime/low` element with a value of the first day of the month combined with a `high` element with a value of the last day of the month OR the reporting time period in a Reporting Period Observation **SHALL** be represented with an `effectiveTime/low` element with a value of the first day of the quarter combined with a `high` element with a value of the last day of the quarter representing respectively the first and last days of the period reported.

Figure 49: Body Mass Index Percentile reporting parameters section example

```
<section>
  <code code="55187-9" codeSystem="2.16.840.1.113883.6.1" />
  <title>Reporting Parameters</title>
  <text>Reporting period: 01 Apr 2008 - 30 Jun 2008</text>
     <entry>
        <act classCode="ACT" moodCode="EVN">
           <code code="252116004" codeSystem="2.16.840.1.113883.6.96"
                 displayName="Observation Parameters" />
           <effectiveTime>
             <low value="20080401" /> <!--The first day of the period reported.-->
             <high value="20080630" /> <!-- The last day of the period reported. -->
           </effectiveTime>
        </act>
     </entry></section>
```

6.6.3 Patient Data Section

The Patient Data section in the Body Mass Index Measure section contains information about the type of encounter, the principle diagnosis, and the BMI percentile containing the actual percentile value, therefore indicating that it was recorded. The age of the child is understood from the `birth time` data element in the Header of the QRDA document.

6.6.3.1 Clinical Statement Conformance – Encounter Information

The following clinical statement conformance statements model the encounter information and define a set of the allowable visit types for the measure.

CONF-QRDA_BMI-9: The Body Mass Index QRDA Patient Data Section encounter information **SHALL** be represented with `encounter`.

CONF-QRDA_BMI-10: The value for `encounter/@classCode` in an Encounter activity **SHALL** be `ENC 2.16.840.1.113883.5.6 ActClass` **STATIC**.

CONF-QRDA_BMI-11: The value for `encounter/@moodCode` in an Encounter activity **SHALL** be `EVN 2.16.840.1.113883.5.1001 ActMood` **STATIC**.

CONF-QRDA_BMI-12: An Encounter activity **SHOULD** contain at least one `encounter/id`.

CONF-QRDA_BMI-13: An Encounter activity **SHALL** contain exactly one `encounter/code`.

CONF-QRDA_BMI-14: The value for `encounter/code` in the Encounter activity **SHALL** be selected from Value Set `BMIPhysicalEncounter 2.16.840.1.113883.11.20.2.1` **STATIC** `20090215`

Table 4: Physical Encounter Value Set

Value Set: BMIPhysicalEncounter 2.16.840.1.113883.11.20.2.1 Code System: HL7 ActCode 2.16.840.1.113883.5.4	
Code	**Meaning**
AMB	Ambulatory
EMER	Emergency
HH	Home Health
IMP	Inpatient
SS	Short Stay

CONF-QRDA_BMI-15: An Encounter activity **SHALL** contain exactly one `encounter/effectiveTime` to indicate date and time of the encounter.

CONF-QRDA_BMI-16: The `encounter/effectiveTime` **SHALL** be accurate to the day and **MAY** be accurate to the second.

CONF-QRDA_BMI-17: The Encounter activity **SHALL** contain exactly one `entryRelationship` where the value of `@typeCode` **SHALL** be `COMP`, whose target act is a principal diagnosis organizer (as described in Section 6.6.3.2 Clinical Statement Conformance – Principle Diagnosis).

Figure 50: Body Mass Index Percentile ambulatory encounter example

```
<encounter classCode="ENC" moodCode="EVN">
   <id root="cd85b4ff-2626-433e-b438-eba7262bc4c4"/>
   <code code="AMB" displayName="Ambulatory" codeSystem="2.16.840.1.113883.5.83" />
   <statusCode code="completed"/>
   <effectiveTime>
      <low value="20080202"/>
   </effectiveTime>
  ...
</encounter>
```

6.6.3.2 Clinical Statement Conformance – Principle Diagnosis

The following clinical statement conformance statements model the patient's principle diagnosis for the visit where the BMI percentile was recorded as entry relationships with the encounter.

CONF-QRDA_BMI-18: The Principle Diagnosis Organizer **SHALL** be represented with `organizer`.

CONF-QRDA_BMI-19: The value for `organizer/@classCode` in a Principle Diagnosis Organizer **SHALL** be `CLUSTER 2.16.840.1.113883.5.6 ActClass` **STATIC**.

CONF-QRDA_BMI-20: The value for `organizer/@moodCode` in a Principle Diagnosis Organizer **SHALL** be `EVN 2.16.840.1.113883.5.1001 ActMood` **STATIC**.

CONF-QRDA_BMI-21: The value for `organizer/code` **SHALL** be `8319008 Principle diagnosis 2.16.840.1.113883.6.96 SNOMED-CT` **STATIC**.

CONF-QRDA_BMI-22: A Principle Diagnosis Organizer **SHALL** contain exactly one `organizer/statusCode`.

CONF-QRDA_BMI-23: The value for `organizer/statusCode` in a Principle Diagnosis Organizer **SHALL** be `Completed 2.16.840.1.113883.5.14 ActStatus` **STATIC**.

CONF-QRDA_BMI-24: A Principle Diagnosis Organizer **SHALL** contain one or more `organizer/component`.

CONF-QRDA_BMI-25: The target of the Principle Diagnosis Organizer `organizer/component` relationship **SHALL** be a Principle Diagnosis Observation.

CONF-QRDA_BMI-26: The Principle Diagnosis Observation **SHALL** be represented with an `observation` element where the value of `@classCode` is `OBS` and the value of `@moodCode` is `EVN`.

CONF-QRDA_BMI-27: The value for `code/@code` **SHALL** be `ASSERTION` and `code/@codeSystem` **SHALL** be `2.16.840.1.113883.5.4 HL7 ActCode Complete` **STATIC**.

CONF-QRDA_BMI-28: A `statusCode` element **SHALL** be present where the value of `@code` is `Completed`.

CONF-QRDA_BMI-29: The value for `value/@xsi:type` **SHALL** be `CD`.

CONF-QRDA_BMI-30: The value for `value/@code` **SHALL** be selected from `2.16.840.1.113883.6.2 ICD9 CM Diagnoses` or `2.16.840.1.113883.6.96 SNOMED-CT`.

Figure 51: Body Mass Index Percentile principle diagnosis example

```
<entryRelationship typeCode="COMP">
   <organizer classCode="CLUSTER" moodCode="EVN">
      <code code="8319008" codeSystem="2.16.840.1.113883.6.96"
       displayName="Principle diagnosis"/>
      <statusCode code="completed"/>
      <component>
         <observation classCode="OBS" moodCode="EVN">
            <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
            <statusCode code="completed"/>
            <value xsi:type="CD" code="102506008"
             codeSystem="2.16.840.1.113883.6.96" displayName="Well child"/>
         </observation>
      </component>
   </organizer>
</entryRelationship>
```

6.6.3.3 Clinical Statement Conformance – Body Mass Index Percentile

The following clinical statement conformance statements model the BMI percentile.

CONF-QRDA_BMI-31: The Body Mass Index Percentile QRDA Patient Data section **SHALL** contain exactly one Body Mass Index Percentile Observation.

CONF-QRDA_BMI-32: A Body Mass Index Percentile Observation **SHALL** be represented with `observation`.

CONF-QRDA_BMI-33: A Body Mass Index Percentile Observation **SHOULD** contain at least one `observation/id`.

CONF-QRDA_BMI-34: A Body Mass Index Percentile Observation **SHALL** contain exactly one `observation/statusCode`.

CONF-QRDA_BMI-35: The value of `observation/statusCode` **SHALL** be `Completed.`

CONF-QRDA_BMI-36: A Body Mass Index Percentile Observation **SHALL** contain exactly one `observation/effectiveTime`, which represents the time the percentile was measured.

CONF-QRDA_BMI-37: The `observation/effective Time` **SHALL** be accurate to the day and **MAY** be accurate to the second.

CONF-QRDA_BMI-38: A Body Mass Percentile Observation **SHALL** contain exactly one `observation/code` where the value is `TempSNOMEDcode Body Mass Percentile 2.16.840.1.113883.6.96 SNOMED-CT` **STATIC**.

CONF-QRDA_BMI-39: The value for `value/xsi:type` **SHALL** be `PQ`.

CONF-QRDA_BMI-40: The `observation/value` **SHALL** be expressed using a valid UCUM Physical Quantity Unit = "%" (percent).

Figure 52: Body Mass Index Percentile example

```
<entry typeCode="DRIV">
   <observation classCode="OBS" moodCode="EVN">
      <code code="1111111" codeSystem="2.16.840.1.113883.6.96"
            displayName="Body mass
       index percentile"/>
      <statusCode code="completed"/>
      <effectiveTime value="200802021500"/>
      <value xsi:type="PQ" value="70" unit="%"/>
   </observation>
</entry>
```

7 REFERENCES

- AMA Collaborative for Performance Measure Integration with EHR Systems
- CDA: Clinical Document Architecture Release 2: Last Published: 09/25/2005 9:14 PM – available through Health Level Seven®, Inc. All Rights Reserved.
- CCD: Continuity of Care Document - available through Health Level Seven®, Inc. All Rights Reserved.
- CMS Quality Net
- Collaborative for Performance Measure Integration within EHR Systems
- Collaborative for Performance Measure Integration with EHR Systems Work Group A Recommendations to full Collaborative
- HITSP Quality Interoperability Specification Version 1.0
- Laptook AR, Salhab W, Bhaskar B, and the Neonatal Research Network. Admission Temperature of Low Birth Weight Infants: Predictors and Associated Morbidities. Pediatrics 2007;119:e643-e649.
- LOINC®
- National Quality Forum
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- SNOMED CT®
- Using SNOMED CT in HL7 Version 3 - available through Health Level Seven®, Inc. All Rights Reserved.

APPENDIX A — GLOSSARY OF TERMS

Table 5: Glossary of Terms

Term	Description
Processing entity	See above.
QRDA Categories	
QRDA Category I report	See Section 1.4.2 Types of Quality Measure Reports for a description of QRDA Category I, QRDA Category II, and QRDA Category III reports.
QRDA Category II report	See Section 1.4.2 Types of Quality Measure Reports for a description of QRDA Category I, QRDA Category II, and QRDA Category III reports.
QRDA Category III report	See Section 1.4.2 Types of Quality Measure Reports for a description of QRDA Category I, QRDA Category II, and QRDA Category III reports.
QRDA Data Elements	
Aggregate data element	An aggregate data element is a measure-specified calculated summary derived from patient data elements. Aggregate data elements are included in QRDA Category III reports. Examples include: the number of patients meeting a measure's numerator criteria, the number of patients meeting a measure's denominator criteria, the number of patients excluded due to weight criteria.
Measure specific grouping data element	A measure-specific grouping data element defines a subgroup population criterion. These data elements define how patient data elements are to be cumulated into aggregate data elements. Examples include: a measure-specific grouping data element of "primary surgeon" indicates that aggregate data elements in a QRDA Category III report are to be calculated per each primary surgeon.
Patient data element	A patient data element is information about a particular person (as opposed to a population). Patient data elements are included in QRDA Category I and QRDA Category II reports. Examples include: individual's test results, individual's encounter location, individual's date of birth.
Qualification data element	A qualification data element is patient level information about the status of quality compliance. Qualification data elements are included in QRDA Category II reports. Examples include: assertion of whether a particular patient meets a measure's numerator criteria.

APPENDIX B — TEMPLATE IDS IN THIS GUIDE

The following table lists the template IDs used in this guide and their descriptions. Note that most are temporary template IDs as appropriate assignment and branching must be discusssed.

Table 6: Template IDs in this Guide

Template ID	Description
Document Templates	
2.16.840.1.113883.10	HL7 Registered Templates Root (for information)
2.16.840.1.113883.10.20	HL7 SDWG Registered Templates Root (for information)
2.16.840.1.113883.10.20.12	Asserts conformance to a Category I QRDA Report
2.16.840.1.113883.10.20.13	Asserts conformance to a Category II QRDA Report
2.16.840.1.113883.10.20.14	Asserts conformance to a Category III QRDA Report
Measure Specific Templates	
2.16.840.1.113883.10.20.12.1	Asserts conformance to a QRDA Neonatal Admission Temperature measure
2.16.840.1.113883.10.20.12.2	Asserts conformance to a QRDA Body Mass Index Percentile measure
Clinical Statement Templates	
2.16.840.1.113883.10.20.1.45	Asserts conformance to Location Participation
Value Set Templates	
2.16.840.1.113883.11.20.2.1	Subset of HL7 encounter values to represent allowable BMI Percentile measure encounters where BMI Percentile is documented.

APPENDIX C — CCD EXTERNALLY DEFINED CONSTRAINTS

This appendix lists the CCD conformance statements the template referenced from the body of this document in the QRDA Category III framework section and in the Category I Neonatal Admission Temperature section. These constraints are provided for reference only. For a complete description of these constraints of CCD, please refer to the original specification**.**

Encounter Location (CCD Template ID 2.16.840.1.113883.10.20.1.45.)

CCD-CONF-471 An encounter activity MAY contain one or more location participations.

CCD-CONF-472: A location participation (templateId 2.16.840.1.113883.10.20.1.45) SHALL be represented with participant participation.

CCD-CONF-473: The value for "participant / @typeCode" in a location participation SHALL be "LOC" 2.16.840.1.113883.5.90 ParticipationType STATIC.

CCD-CONF-474: A location participation SHALL contain exactly one participant / participantRole.

CCD-CONF-475: The value for "participant / participantRole / @classCode" in a location participation SHALL be "SDLOC" "Service delivery location" 2.16.840.1.113883.5.110 RoleClass STATIC.

CCD-CONF-476: Participant / participantRole in a location participation MAY contain exactly one participant / participantRole / code.

CCD-CONF-477: The value for "participant / participantRole / code" in a Location participation SHOULD be selected from ValueSet 2.16.840.1.113883.1.11.17660 ServiceDeliveryLocationRoleType 2.16.840.1.113883.5.111 RoleCode DYNAMIC.

CCD-CONF-478: Participant / participantRole in a location participation MAY contain exactly one participant / participantRole / playingEntity.

CCD-CONF-479: The value for "participant / participantRole / playingEntity / @classCode" in a location participation SHALL be "PLC" "Place" 2.16.840.1.113883.5.41 EntityClass STATIC.