Integrating the Healthcare Enterprise



5 IHE Quality, Research and Public Health Technical Framework Supplement

10 Quality Measure Execution—Early Hearing (QME-EH)

Trial Implementation

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IHE Quality, Research and Public Health Technical Framework Supplement – Quality Measure Execution-Early Hearing (QME-EH)

Foreword

This is a supplement to the IHE Quality, Research and Public Health (QRPH) Technical Framework V0.1. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

- This supplement is published for Trial Implementation on August 27, 2012 and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the QRPH Technical Framework. Comments are invited and may be submitted at http://www.ihe.net/qrph/qrphcomments.cfm.
- This supplement describes changes to the existing technical framework documents and where indicated amends text by addition (**bold underline**) or removal (**bold strikethrough**), as well as addition of large new sections introduced by editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.
- "Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume:

Replace Section X.X by the following:

General information about IHE can be found at: www.ihe.net

Information about the IHE QRPH domain can be found at: http://www.ihe.net/Domains/index.cfm

Information about the structure of IHE Technical Frameworks and Supplements can be found at: http://www.ihe.net/About/process.cfm and http://www.ihe.net/profiles/index.cfm

The current version of the IHE Technical Framework can be found at:

50 http://www.ihe.net/Technical Framework/index.cfm

CONTENTS

55	INTRODUCTION TO THIS SUPPLEMENT	5
	Profile Abstract	6
	CHANGE LOG	
	EDITORS/CONTRIBUTORS	6
	OPEN ISSUES AND QUESTIONS	
60	CLOSED ISSUES.	7
	VOLUME 1 – PROFILES	9
	COPYRIGHT PERMISSION	9
	1.7 HISTORY OF ANNUAL CHANGES	9
	X QUALITY MEASURE EXECUTION – EARLY HEARING (QME-EH) PROFILE	10
65	X.1 QME-EH ACTORS, TRANSACTIONS AND CONTENT MODULES	
	X.1.1 Actor Descriptions and Actor Profile Requirements	
	X.1.1.1 Content Creator	
	X.1.1.2 Content Consumer	
70	X.1.2 Content ModulesX.1.2.1 Quality Measure Execution Early Hearing Report	
70	X.12.1 Quanty Measure Execution Early Hearing Report X.2 QME-EH ACTOR OPTIONS	
	X.3 QME-EH Actor Groupings	
	X.4 QME-EH Overview	
	X.4.1 Concepts	
75	X.4.2 Use Cases $#I$ – Share Patient-level Data to Compute the Newborn Hearing Screening Prior t	o Hospital
	Discharge Measure	
	X.4.2.1 Use Case Description	
	X.4.2.2 Process Flow	
80	X.4.2.3 Alternate Process Flow	
80	X.5 QME-EH SECURITY CONSIDERATIONS	
	X.5.2 Risk Mitigations.	
	X.6 QRPH Cross Profile Considerations.	
	APPENDIX A ACTOR SUMMARY DEFINITIONS	
0.5		
85	APPENDIX B TRANSACTION SUMMARY DEFINITIONS	
	APPENDIX C PROFILE INPUTS	
	APPENDIX D CONTENT DOCUMENT DETAILS	21
	D.1 INDEX OF TEMPLATES DEFINED BY QME-EH	
	D.2 INDEX OF TEMPLATES INHERITED BY QME-EH	
90	D.3 HL7 QRDA (2.16.840.1.113883.10.20.24.1.1) [JULY 2012]	
	D.4 HL7 CONSOLIDATED CDA GENERAL HEADER CONSTRAINTS (2.16.840.1.113883.10.20.3)	
	D.5 DATA SET AND VALUE SETS ASSOCIATED WITH CDA DOCUMENT CONTENT MODULE	
	GLOSSARY	
	VOLUME 2 – TRANSACTIONS	27
05	VOLUME 2. CONTENT MODILIES	20

	5 NAMESPACES AND VOCABULARIES	28
	5.1 IHE FORMAT CODES	28
	6 QRPH CONTENT MODULES	29
	6.3 HL7 Version 3.0 CDA Content Modules	29
100	6.3.1 CDA Document Content Modules	29
	6.3.1.D QualityMeasureExecutionEarlyHearingReport 1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.1	29
	6.3.2 CDA Header Content Modules	
	6.3.2.H US Header Content Module	
	6.3.2.H.1 Header elements	
105	6.3.3 CDA Section Content Modules	
	6.3.3.7.S1 QmeehMeasureSection	
	6.3.3.7.S2 ReportingParametersSection.	
	6.3.3.7.S3 QmeehPatientDataSection	
	6.3.4 CDA Entry Content Modules	
110	6.3.4.E1 BirthingFacilityLocationAndId	
	6.3.4.E1.1Template Context	
	6.3.4.E1.2 Description	
	6.3.4.E1.3 Constraints Overview	
	6.3.4.E1.4 Constraints Enumerated	
115	6.3.4.E2 BirthObservation	40
	6.3.4.E2.1Template Context	40
	6.3.4.E2.2 Description	
	6.3.4.E2.3 Constraints Overview	41
	6.3.4.E2.4 Constraints Enumerated	
120	6.3.4.E4 DischargeObservation	
	6.3.4.E4.1Template Context	
	6.3.4.E4.2 Description	
	6.3.4.E4.3 Constraints Overview	
125	6.3.4.E4.4 Constraints Enumerated	43
125	6.3.4.E5 HearingScreeningDiagnosticStudyPerformed	
	6.3.4.E5.1Template Context	
	6.3.4.E5.2 Description	
	6.3.4.E5.3 Constraints Overview	
130	6.3.4.E5.4 Constraints Enumerated	
150	6.3.4.E6.1Template Context	
	6.3.4.E6.2 Description	
	6.3.4.E6.3 Constraints Overview	
	6.3.4.E6.4 Constraints Enumerated	48
135	6.5 NEW QRPH VALUE SETS	
155	6.5.V1 QmeehPatientStateValueSet	
	6.5.X2 JCIH-EHDI Hearing Screening TargetSite Value Set	
	0.3.A2 JCHI-EHDI Hearing Screening Targelshe Value Sel	

140 Introduction to this Supplement

This supplement is written for Trial Implementation. It is written as an addition to the Trial Implementation Quality, Research and Public Health Technical Framework.

This supplement also references the following documents¹. The reader should review these documents as needed:

- 1. PCC Technical Framework, Volume 1
 - 2. PCC Technical Framework, Volume 2
 - 3. PCC Technical Framework Supplement: CDA Content Modules
 - 4. IT Infrastructure Technical Framework Volume 1
 - 5. IT Infrastructure Technical Framework Volume 2
- 150 6. IT Infrastructure Technical Framework Volume 3
 - 7. HL7 Quality Report Document Architecture Standard [May, 2012]
 - 8. HL7 and other standards documents referenced in Volume 1 and Volume 2
 - 9. NQF Measure Evaluation v4.1, #1354, December 2009
- The Quality Measure Execution-Early Hearing (QME-EH) profile describes the content needed to communicate patient-level data to electronically monitor the performance of early hearing-loss detection and intervention (EHDI) initiatives for newborns and young children. The Newborn Hearing Screening measure (EHDI 1a) developed by the US National Quality Forum (NQF) has been selected as the sample measure for the Trial Implementation of this OME-EH profile. The
- EHDI 1a measure provides patient-level information to track performance against the goal to provide hearing screening for all newborns prior to discharge from a birthing facility. Where specific US measure content is specified in this profile, realm-specific options and definitions have been used.

165

¹ The first six documents are located on the IHE Website at http://www.ihe.net/Technical_Framework/index.cfm. The remaining documents can be obtained from their respective publishers.

Profile Abstract

The Quality Measure Execution-Early Hearing (QME-EH) content profile demonstrates the use of the HL7 Quality Reporting Document Architecture (QRDA) standards to implement the patient-level quality measure report for measures specific to newborn hearing screening. QRDA establishes the general implementation guidelines for using the HL7 Clinical Document Architecture Standard (CDA R2) to create all types of quality measure reports. QME-EH constrains QRDA for measures defined for the newborn hearing screening conducted as a part of the Early Hearing Detection and Intervention (EHDI) public health program.

175 Change Log

170

Date	Description of changes	Primary Editor
7/19/2012	Incorporated changes from Public Comment.	Lisa R. Nelson
5/16/2012	Updated Volume 1 to incorporate feedback from Wendy Scharber.	Lisa R. Nelson
5/9/2012	Finalized draft for Public Comment.	Lisa R. Nelson
5/7/2012	Worked out approach for addressing the processing logic to be used by profile actors.	Lisa R. Nelson
5/4/2012	Sent post f-2-f version for team review.	Lisa R. Nelson
4/29/2012	Revised the profile to clarify the relationship of this use-case specific implementation of the generalized approach for quality measure reporting defined by HL7 in the QRDA Implementation Guide for the use of CDA R2.	Lisa R. Nelson
4/27/2012	Addressed open issues marked as closed on 4/27/2012. Absorbed changes introduced by new DSTU balloted for QRDA (May2012). Added alternate flow for Use Case #1.	Lisa R. Nelson
4/23/2012	Added minor revisions during a group review.	Lisa R. Nelson
4/18/2012	Updated TF Supplement template to match current draft template. Narrowed the scope of the content profile to one EHDI Measure called Hearing Screening Prior To Discharge. Updated the definitions of the CDA content modules to further constrain the existing CDA content modules defined by the HL7 QRDA Implementation Guide.	Lisa R. Nelson

Editors/Contributors

Revision	Name	Email	Date
2.1 (Current)	Lisa Nelson	LisaRNelson@cox.net	2012-08-xx
2.0	Lisa Nelson	LisaRNelson@cox.net	2012-06-05
1.0	Lori Reed-Fourquet	lori.fourquet@sbcglobal.net	2011-06-17
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1.0	Terese Finitzo	tfinitzo@oz-systems.com	2011-06-17

Note: Contact information in this table is current as of the time it was entered.

Open Issues and Questions

- 1. This profile takes as input a measure definition which includes the data set and data processing logic required to execute the measure (See Appendix C). Due to current activities to clarify quality measures, these inputs are in the process of being finalized. Final adjustments to these inputs will be incorporated during the Public Comment period.
- It has been confirmed with IHE framework developers that the "share" term can be used on the process flow diagram between Content Creator and Content Consumer actors when a content profile is not specifying a particular transaction to be used to share the content document. However, there remains an open question about will the binding section(s) with XDR, XDS, XDM, (=XD*) needs to be included in the Content Profile; and , if yes, where and how the binding will be documented for the "sharing" of the content document. It is still being debated whether binding information belongs with the content modules (Volume 3) or with the definition of the transactions (Volume 2). This open issue should be specifically addressed during Public Comment.
 - 3. Editors need to post a sample QualityMeasureExecutionEarlyHearingReport following Public Comment changes.

Closed Issues

195

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- 1. RPE references have been removed − alignment is pending with updated RPE specification and the use of RPE for Quality Measurement\
- 2. 6.3.2.D Data Element Name column seems to have much more detail on conformance should this be pulled out into a separate column or even as conformance statements after the cells in the table? Template should be revisited.- resolved on 4/26/2012; template refactoring completed
 - 3. All open issues under Header element resolved on 4/27/2012 to comply with the May2012 QRDA Implementation Guide
 - 4. Add background material about hearing screening and quality measure/case reporting to inform readers about this public health program's activities. resolved on 4/27/2012; added to the Concepts section.
 - 5. Explain the different possibilities for (1) how data may flow to any of the three possible systems acting as Content Consumers; (2) in some cases, how the data could flow to all three systems; and (3) how these data will be used for computing the measure as the QualityMeasureExecutionEarlyHearingReport resolved on 4/27/2012; the alternate flow was clarified with EHDI team SMEs and was documented in use case 1.
 - 6. Confirmed the Value Sets and associated values.

- 7. Update all OIDs –resolved on 4/27/2012; value sets are confirmed. Editor instructions have been added to instruct IHE Publisher to update any previously published value sets with the new values.
 - 8. Do we need a LOINC Code for the EHDI 1a measure to use in the act/code entry of the measure section resolved on 5/8/2012; the new HL7 QRDA standard does not use a LOINC code in an Act to encode the entry in the measure section.
 - 9. Clarify the use of term "Share" on the process flow diagram between Content Creators and Content Consumers resolved on 5/8/2012. Publisher confirmed that use of the "Share" includes no implication of about particular types of transactions for data sharing/exchange. The term "share" can be used in the process flow diagram.

Volume 1 - Profiles

Copyright Permission

Add the following to the IHE Technical Frameworks General Introduction Copyright section:

No new additions

1.7 History of Annual Changes

Add the following bullet to the end of the bullet list in section 1.7

• Added the QualityMeasureExecutionEarlyHearingReport which defines the content for communication of patient-level quality data supporting calculation of the quality measure for hearing screening of newborns prior to discharge from a birthing facility.

Add Section X

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X Quality Measure Execution – Early Hearing (QME-EH) Profile

The purpose of the Quality Measure Execution-Early Hearing (QME-EH) content profile is to demonstrate how to use the HL7 Quality Reporting Document Architecture (QRDA) standard to implement a patient-level quality measure report for newborn hearing screening. QRDA is an implementation guide (IG) for the HL7 Clinical Document Architecture standard (CDA R2). It establishes general guidelines for creating several types of quality measure reports as CDA documents. QRDA "sets the stage" for measure-specific profiles to establish executable implementations.

The QME-EH profile shows implementers how to use a supplied measure definition for newborn hearing screening, with its required data set and data processing logic, to create and consume a CDA-based patient-level quality measure report. The profile specifies how to implement system capabilities required to create and consume a patient-level QRDA document containing quality measure data for the newborn hearing screening conducted as a part of the Early Hearing Detection and Intervention (EHDI) public health program.

250 X.1 QME-EH Actors, Transactions and Content Modules

Figure X.1-1 shows the actors directly involved in the QME-EH Profile and the relevant transactions between them. If a third party entity is involved to facilitate the sharing of this information, their involvement is depicted in the Share Content mechanism shown below.



Figure X.1-1: QME-EH Actor Diagram

The QME-EH Profile does not define any transactions, as depicted in table X.1-1.

Table X.1-1: QME-EH Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Content Creator	None	N/A	N/A
Content Consumer	None	N/A	N/A

240

260 X.1.1 Actor Descriptions and Actor Profile Requirements

There are two actors in the QME-EH profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is not addressed by this profile.

X.1.1.1 Content Creator

- Given the data set determined for the newborn screening measure definition, a Content Creator actor SHALL use the decision logic associated with the measure population definition to determine if the QualityMeasureExecutionEarlyHearingReport will be produced for each patient in their total accessible population. If the patient is in the measure population, the Content Creator actor SHALL be able to create the content of the
- QualityMeasureExecutionEarlyHearingReport in the required format. (Please see Appendix C for data set and decision logic for the quality measure entitled "Early Hearing Detection and Intervention (EHDI) 1a" as an example)

X.1.1.2 Content Consumer

A Content Consumer actor SHALL consume the discrete data in the machine readable entries contained in the QualityMeasureExecutionEarlyHearingReport. A Content Consumer actor SHALL process the consumed data according to the measure denominator and numerator definitions for the patient-level data. For example, to demonstrate the capability to consume the discrete data, the Content Consumer SHALL be able to show that it can determine if a consumed data set should be included in the denominator or included in the numerator, given the measure definition. For each QualityMeasureExecutionEarlyHearingReport consumed, the Content Consumer SHALL be able to show, via a humanly verifiable means, (1) the identifier of the data set consumed, (2) an indication if the data set should be counted in the denominator, and (3) an indication if the data set should be counted in numerator, given the measure definition.

X.1.2 Content Modules

This profile defines a single document content module called the QualityMeasureExecutionEarlyHearingReport.

X.1.2.1 Quality Measure Execution Early Hearing Report

The QualityMeasureExecutionEarlyHearingReport expresses the patient-level data required for newborn hearing screening. It is a specialization of a QRDA Category I document which in turn is a CDA R2. A QRDA Category I report is an individual-patient-level quality report. Each report contains quality data for one patient. A QRDA Category I report contains raw patient data required to perform a defined quality measure calculation. When pooled and analyzed by a Content Consumer, each report contributes the quality data necessary to calculate population measure metrics (e.g., as contained in a QRDA Category III report as specified in the HL7 QRDA Implementation Guide).

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The table X.1.2.1-1 below describes the type of data contained in a QualityMeasureExecutionEarlyHearingReport. The patient-level data set includes the data required to compute quality measures used to assess hearing screening of newborns prior to discharge from a birthing facility as specified in the quality measure "EHDI 1a" defined by the US Centers for Disease Control and Prevention (CDC) and endorsed by the National Quality Forum (NQF). The definition for the EHDI 1a measure and the associated data set, value sets and data processing logic is provided in Appendix C as an example of the type of EHDI quality measure enabled by this Profile. Please see also Appendix D for more information about the generic QRDA structure and its specific representation for QME-EH Profile. The CDA document specification in Volume 3 establishes the data representation rules that are required for implementers when creating and consuming the QualityMeasureExecutionEarlyHearingReport to execute the EHDI 1a measure.

Table X.1.2.1-1: QualityMeasureExecutionEarlyHearingReport

Type of Data	Description	CDA Section
Measure definition Data	Each MeasureSection in the report declares which measure(s) the data enclosed within the section is intended to support.	QmeehMeasureSection
Reporting Parameter Data Within each MeasureSection, the patient-le QRDA document provides information abo reporting time interval applicable for creatin consuming the data associated with that me set of measures. The reporting time interval jurisdictionally defined. This may contain of information that provides context for the pa data being reported.		ReportingParameterSection
Patient Data	Within each MeasureSection, the patient-level QRDA document encodes discrete data needed to process the data and execute the assessment defined for the quality measure or set of measures.	QmeehPatientDataSection

310 X.2 QME-EH Actor Options

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Options that may be selected for this Profile are listed in the table X.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table X.2-1: QME-EH - Actors and Options

Actor	Options	Volume & Section
Content Creator	None	
Content Consumer	None (see Note 1)	

Note 1: Unlike many of the other content profiles defined within IHE, the QME-EH profile defines specific capabilities for the Content Consumer. Implementers are encouraged to read section X.1.1.2 to review the requirements for the Content Consumer.

X.3 QME-EH Actor Groupings

This profile has no required actor groupings.

320 X.4 QME-EH Overview

X.4.1 Concepts

What is quality?

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The Institute of Medicine (IOM) definition of quality is "the degree to which health services for individuals and populations increases the likelihood of desired health outcomes and are consistent with current professional knowledge."²

What is newborn hearing screening?

In the US, the Preventive Services Task Force recommends screening for hearing loss in all newborn infants because good-quality evidence shows that early detection improves language outcomes. The US Joint Committee on Infant Hearing (JCIH) recommends hospital-based programs have protocols in place that include the timing of screening relative to nursery discharge. The newborn hearing screening is highly accurate procedure, leading to early identification and treatment of infants with hearing loss. Birthing facilities use one or a combination of two objective test methods to screen newborns for hearing loss. Both methods are highly effective, quick to perform, do not cause discomfort, and can be done while the baby is sleeping. All newborns should have a hearing screening to determine if they might have hearing loss, preferably while still in the birthing facility, but no later than 1 month of age.

In the US, the departments of health in all states and territories are responsible for the Early Hearing Detection and Intervention (EHDI) programs that direct birthing facilities to screen newborns for hearing loss prior to discharge, ascertain that follow-up audiologic care is timely, and assure that an infant detected with a hearing loss is connected to early intervention services. The birthing facilities are required to regularly report data to public health EHDI programs on the numbers of newborns screened, the numbers of newborns who passed the screening, and the numbers of those screened who did not pass the screening to assure any newborn not passing screening is linked to the follow-up services they need.

What are quality measures in the context of case reporting in public health?

The quality measures collected in case reports for public health are meaningful data metrics which can be used to support decision making that strengthen both clinical and public health

² http://www.iom.edu/Global/News Announcements/Crossing-the-Quality-Chasm-The-IOM-Health-Care-Quality-Initiative.aspx

³ Buz Harlor AD, Jr, Bower C. Hearing Assessment in Infants and Children: Recommendations Beyond Neonatal Screening. Pediatrics. 2009; 124 (4): 1252-1263. URL: www.pediatrics.org/cgi/doi/10.1542/peds.2009-1997

⁴ Joint Committee on Infant Hearing Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Pediatrics Vol. 120 No. 4 October 1, 2007 pp. 898 -921

policies and practices. For EHDI programs, the first quality measure reporting applies to the newborn hearing screening, e.g., the number of children screened prior to discharge from a birthing facility compared to a total number of live births within the reporting time period. Effectively implemented quality measures produce consistent (reliable) and credible (valid) results that provide a method to assess healthcare delivery against recognized standards. Such measures are critical in assuring all patients receive high-quality care with better outcomes.

X.4.2 Use Cases #1 – Share Patient-level Data to Compute the Newborn Hearing Screening Prior to Hospital Discharge Measure

X.4.2.1 Use Case Description

QualityMeasureExecutionEarlyHearingReports are prepared by a system that can compile the patient-level data required to execute a defined quality measure -- Content Creator. The Content Creator can be the Electronic Health Record (EHR) system at a birthing facility, a Quality

Measure Processing Entity, a Health Information Exchange (HIE) entity, or a jurisdictional Public Health EHDI Information System (EHDI-IS). The patient-level report is provided to a system responsible for computing the measure based upon defined criteria -- Content Consumer. The Content Consumer can be a Quality Measure Processing Entity, an HIE, or a jurisdictional Public Health EHDI-IS.

X.4.2.2 Process Flow

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This process flow diagram shows the movement of a QualityMeasureExecutionEarlyHearingReport between the Content Consumer and the possible Content Consumers.

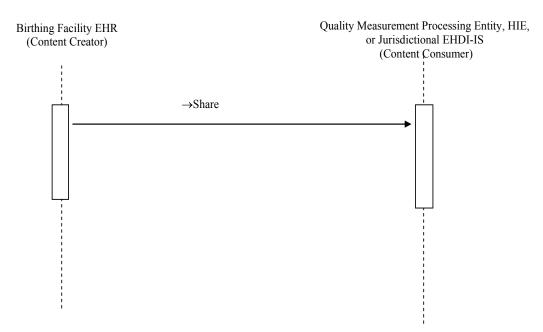


Figure X.4.2.2-1: Basic Process Flow in QME-EH Profile - Use Case #1

X.4.2.3 Alternate Process Flow

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In some cases, the Birthing Facility's EHR does not have all the data elements required to produce the QualityMeasureExecutionEarlyHearingReport. A third-party system (e.g. a Quality Measure Processing Entity, or HIE, or a jurisdictional Public Health EHDI-IS) compiles the full data set and plays the role of the Content Creator. A third-party system may also consume the patient-level data in order to calculate the quality measure. In this case the same system may play the role of both Content Creator and Content Consumer facilitating the flow of information between birthing facilities and public health.

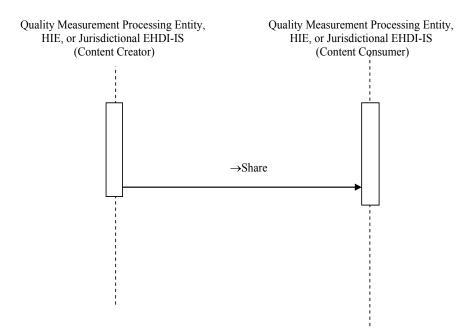


Figure X.4.2.3-1: Alternate Process Flow in QME-EH Profile – Use Case #1

X.5 QME-EH Security Considerations

X.5.1 Potential Risks

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Security risks for the QME-EH Profile are primarily associated with data access and data privacy. The Header of the document contains identity information for the patient which is considered protected health information. The body of the document also contains protected health information reflecting aspects of patient care. In the US, under Health Information Portability and Accountability Act (HIPAA), transmission of this electronic information presents both privacy and security risks. Data integrity could represent a risk for measure calculation.

X.5.2 Risk Mitigations

Implementors can minimize data security risks by implementing data security procedures considered standard best practices in the HIT industry. Use of security functionality included in the IHE Secure Authentication (XAU) and Audit Trail and Node Authentication (ATNA) Profiles provide mechanisms to log and monitor data access. Use of other IHE profiles such as Basic Patient Privacy and Consent (BPPC) Profile and Redaction Services (RSP) Profile address data privacy controls. When health information is shared to meet public health requirements information sharing regulations are often different and can vary by jurisdiction. Understanding of the jurisdictional and national governing policies is an important step for mitigating risk. Other

400 steps in risk mitigation include well planned and sustainable backup, archiving and data destruction policies and procedures. Designing content documents which permit data to be validated within the context of document will enable data integrity to be validated on sample sets of records without having to re-access the source EHR. Deeper integrity checking could utilize header information to track back to source EHR records, should that level of auditing be appropriate.

X.6 QRPH Cross Profile Considerations

Add the following to section X.6

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Below is an index of other profiles in the IHE Technical Framework which implementers may consider using in conjunction with this profile. The reference to the profile specification is included for further information.

Table X.6-1: Index of other IHE profiles implementers may consider using in conjunction with this profile

Profile Name	IHE Reference
Cross Enterprise Document Sharing (XDS)	ITI TF Vol. 1, 2.2.10
Media Interchange (XDR)	ITI TF Vol. 1, 2.2.18
Reliable Messages (XDM)	ITI TF Vol. 1, 2.2.15
Cross-enterprise Document Sharing Environment including Patient Cross – Reference (PIX)	ITI TF Vol. 1, 2.2.5
Patient Demographic Query (PDQ)	ITI TF Vol. 1, 2.2.8
Notification of Document Availability (NAV)	ITI TF Vol. 1, 2.2.12
Sharing Value Sets (SVS)	ITI TF Supplement
Document Metadata Subscription (DSUB)	ITI TF Supplement
Document Digital Signature (DSG)	ITI TF Supplement
Basic Patient Privacy Consents (BPPC)	ITI TF Vol. 1, 2.2.16

415 Appendix A Actor Summary Definitions

No new actors added with this supplement

Appendix B Transaction Summary Definitions

No new transactions are added with this supplement.

Appendix C Profile Inputs

This appendix contains the input required for this profile. It includes the Measure Definition for the EHDI 1a quality measure with the associated data set and data processing logic.

Table C-1: Profile Inputs

MEASURE DEFINITION				
Measure Title Hearing		Hearing S	Screening Prior to Hospital Discharge (EHDI-1a)	
	easure Nun		1354	
eMeasure	Identifier	(MAT)	31	
eMeasure	Version N	Number	0	
Measure	OID		1.3.6.1.4.1.19376.1.7.3.1.1.17.1.1.1.1	
Establis	hing the	Population		
Step 1	The time denomination		rths included in the estimate is given and applies to both the numerator and	
Step 2	All live births that occurred at a facility during the time period are selected.			
Comput	tation of	the Denom	inator	
Step 3	Result of step 2 is filtered to remove children who died prior to discharge without being screened.			
Comput	tation of	the Numer	ator	
Step 4	Result of step 3 is filtered to be limited to the subset that received a screen prior to discharge, or did not receive a screen due to medical reasons. This subset would include babies that have been screened, but are not yet discharged.			
Measure	e calcula	ıtion		
Step 5	Result of step 4 (i.e., the numerator) is divided by the result of step 3.			

Table C-2: Measure Data Set

Associated Measure Data Set

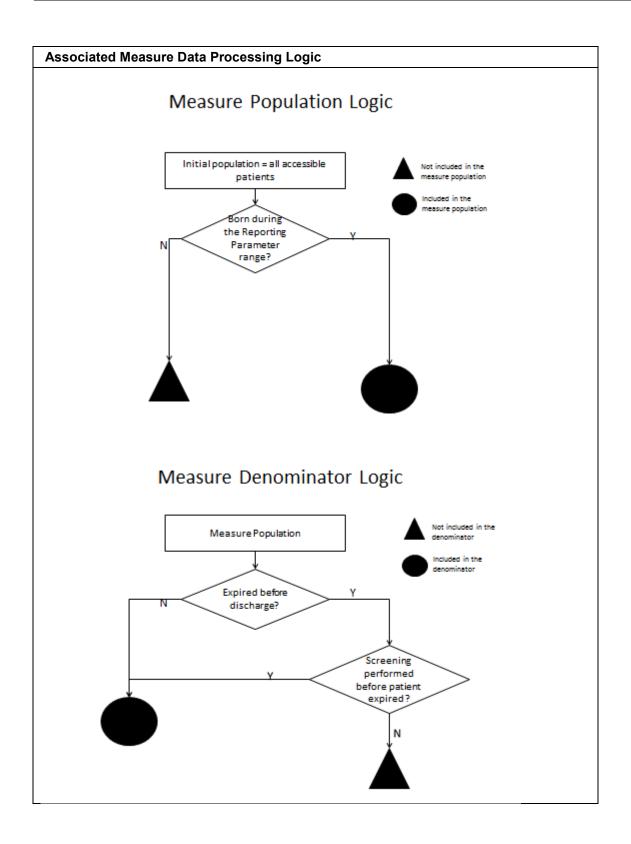
Data that are referenced in the HQMF measure definition specification that need to be in the document:

- 1. Facility (implied by "birth facility")
- 2. Date of Birth (implied by "during the measurement time period")
- 3. Date of Death (implied by "deceased prior to discharge")
- 4. Date of Discharge (implied by "deceased prior to discharge")
- 5. Overall Hearing Screening Outcome
 - a. Result
 - b. Not done reasons or exclusions (implied that value set must include medical and refusal)
- 6. Individual Ear Hearing Screening data
 - a. Result of screen

IHE Quality, Research and Public Health Technical Framework Supplement – Quality Measure Execution-Early Hearing (QME-EH)

Associated Measure Data Set

- b. Date of first screen (implicit)
- 7. Race
- 8. Ethnicity
- 9. Gender
- 10. Payer
- 11. Unique document target identifier



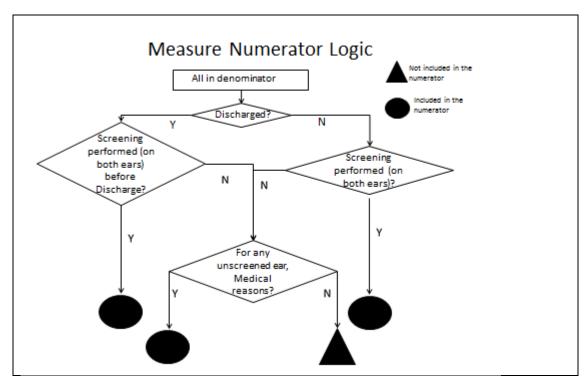


Figure C-3: Measure Processing Logic

Appendix D Content Document Details

Appendix D contains information from the HL7 QRDA Implementation Guide used in specifying the QME-EH Profile. It is aimed to provide implementers with background information about the CDA R2 constraints established by QRDA and further constrained in this Profile. The HL7 QRDA IG July 2012 and is available through the HL7 website at www.hl7.org.

435 D.1 Index of Templates Defined by QME-EH

The QualityMeasureExecutionEarlyHearingReport defines the following content module templates.

Table D.1-1: Index of Templates Defined by QME-EH

Template Name	OID	Reference
QualityMeasureExecutionEarlyHearingReport	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.1	
= QmeehMeasureSection	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.3	
= = ReportingParameterSection	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.4 (See note below.)	
= = QmeehPatientDataSection	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.5	

Note: This template will be used to record the conformances for the QRDA Reporting Parameter Section which is currently not templated in the QRDA IG.

D.2 Index of Templates Inherited by QME-EH

The QualityMeasureExecutionEarlyHearingReport inherits conformance rules from the following parent templates. The sections below describe each parent template in more detail.

Table D.2-1: Index of Templates Inherited by QME-EH

Parent Template Name Description	OID	Reference
HL7 Quality Reporting Document Architecture [May 2012]	2.16.840.1.113883.10.20.24.1.1	X.1.2.1.2.1
HL7 Consolidated CDA General Header Constraints	2.16.840.1.113883.10.20.22.1.1	X.1.2.1.2.5
FacilityLocation	2.16.840.1.113883.10.20.24.3.100	HL7 QRDA
DiagnosticStudyPerformed	2.16.840.1.113883.10.20.24.3.18	HL7 QRDA
ResultObservation	2.16.840.1.113883.10.20.22.4.2	HL7 QRDA
PatientPreference	2.16.840.1.113883.10.20.24.3.83	HL7 QRDA
Reason	2.16.840.1.113883.10.20.24.3.88	HL7 QRDA

The sections below list the templates used to constrain or inform the design of clinical statements used to encode patient level data utilized for computation of the measure. The material includes a discussion of the relevance of the template for this profile and a reference to the source document containing the definition of the template.

D.3 HL7 QRDA (2.16.840.1.113883.10.20.24.1.1) [July 2012]

Document conformances to the definition of the HL7 QRDA Implementation Guide are asserted and further constrained in this document.

The QRDA (July, 2012) Implementation Guide establishes a base structure for quality reporting documents as follows:

455 Measure Section
Reporting Parameters Section
Patient Data Section

CDA documents conforming to the QRDA "architecture" conforms to and provide further constraints on this general QRDA pattern.

As a type of QRDA document, the QualityMeasureExecutionEarlyHearingReport conforms to all the conformance requirements specified in the QRDA Implementation Guide plus the measure-specific conformances defined in this Profile, as shown below:

QmeehMeasureSection

470

485

490

EHDI la Measure Definition which establishes the needed data entries.

ReportingParametersSection

Jurisdiction specific reporting frequency rule, e.g. Daily, Monthly, Quarterly.

QmeehPatientDataSection

QualityMeasureExecutionEarlyHearingReport patient-level data set.

Each of the sections defined in the base QRDA document, except for the Reporting Parameters Section, are further constrained to be relevant for the EHDI Measure Set (with reduced trial implementation scope to the single EHDI-1a measure). The constrained sections are named with the prefix "Qmeeh". Conformance to the Reporting Parameters Section is not further constrained, but used exactly as defined in the QRDA specification, thus a new section is not defined with the Qmeeh prefix. A templateId is established for this section to support validation. The current QRDA specification does not establish templates for each section. To support future automation of specifications, this Profile defines templates for each content module.

D.4 HL7 Consolidated CDA General Header Constraints (2.16.840.1.113883.10.20.3)

The QRDA Implementation Guide inherits header conformances from the Consolidated CDA General Header.

D.5 Data Set and Value Sets Associated with CDA Document Content Module

The CDA document specification in Volume 3 establishes the data set that implementers of the Content Creator actor SHALL use when creating the

QualityMeasureExecutionEarlyHearingReport. Table below provides a visualization of the data set. The data elements in the left-hand column can be traced to the measure definition for the EHDI 1a measure. [Colors have been used to indicate relationship between dataset and the value sets used to constraint the content in the QualityMeasureExecutionEarlyHearingReport document.]

Table D.5-1 Measure Data Set Structure

DATASET: QualityMeasureExecutionEarlyHearingReport (EHDI 1a)				
Data Element Patient Information		Null processing		
Reporting Facility id:	Author/id			
Birthing Facility id:	BirthObservation/participation /id			
Birth date, time: BirthObservation/value				
Discharge date, time:	DischargeObservation/value	If not discharged, this data won't be included. [01]		

DATASET: Quali	Patient Information		•		
Deceased date,	DeceasedObservation/value	Null processing If not deceased, this data won't be included.[01]		11	
time:	Deceased observation/ value	If not deceased, this data v	won't be metaded.[0		
Data Element	Type of Screening Study	Time Stamp	NegationInd p	rocessing	
	Screening Type Code	Date the Hearing screening study observation was made.	NegationInd will be True if no screening was performed.		
Hearing Screening Diagnostic Study	Date	Reason for No Screening			
Performed	Date when Medical Reason was recorded	Reason Code			
	Date when Patient Reason was recorded	Reason Code			
Hearing Screening	Data Required to Verify Measure Data Elements				
Details	Date of Screening	Type of Screening	Screening Method	Result	
Hearing Screening Result Observation (Right Ear)	Date of Screening	Screening Type Code	Screening Method Code	Result	
	Date when decision was made not to screen	Reason for No Screening			
	Date when Medical Reason was recorded	Reason Code			
	Date when Patient Reason was recorded	Reason Code			
	Date of Screening	Screening Type Code	Screening Method Code	Result	
Hearing Screening Result Observation (Left Ear)	Date when decision was made not to screen	Reason for No Screening			
	Date when Reason was	D C 1			
(Left Ear)	recorded	Reason Code			

The table below is the index of value sets used to create a

QualityMeasureExecutionEarlyHearingReport. The reference column links to the location in the IHE Technical Framework where the metadata about the value set and the established terminology are specified.

Table D.5-2 Measure Value Sets

VALUE SET: QualityMeasureExecutionEarlyHearingReport (EHDI 1a)		
Value Set Name Purpose	OID	Reference
QmeehPatientStateValueSet	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.4.1	NEW
JCIH-EHDI Hearing Screening Procedure Value Set	1.3.6.1.4.1.19376.1.7.3.1.1.15.2.17	CDA SUP 6.5.K
JCIH-EHDI Hearing Screening Left Value Set	1.3.6.1.4.1.19376.1.7.3.1.1.15.2.8	CDA SUP 6.5.N
JCIH-EHDI Hearing Screening Right Value Set	1.3.6.1.4.1.19376.1.7.3.1.1.15.2.9	CDA SUP 6.5.M
JCIH-EHDI Evidence of Hearing Screening Performed Value Set	1.3.6.1.4.1.19376.1.7.3.1.1.15.2.18	CDA SUP 6.5.T
JCIH-EHDI Hearing Screening TargetSite Value Set	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.4.2	NEW
JCIH-EHDI Hearing Screening Method Value Set	1.3.6.1.4.1.19376.1.7.3.1.1.15.2.4	CDA SUP 6.5.L
JCIH-EHDI Procedure Declined Value Set	1.3.6.1.4.1.19376.1.7.3.1.1.15.2.20	CDA SUP 6.5.U
JCIH-EHDI Inpatient Screening Results Not Performed Value Set	1.3.6.1.4.1.19376.1.7.3.1.1.15.2.10	CDA SUP 6.5.S

IHE Quality, Research and Public Health Technical Framework Supplement – Quality Measure Execution-Early Hearing (QME-EH)

Glossary

Add the following terms to the IHE Technical Frameworks General Introduction Glossary:

No Glossary definitions added with this supplement

Volume 2 – Transactions

Add section 3.Y

No new transactions will be added with this supplement

Volume 3 – Content Modules

Add to section 5

5 Namespaces and Vocabularies

Add the following rows the QRPH TF-2:5.0 Namespaces and Vocabularies

codeSystem	codeSystemName	Description
NA		

5.1 IHE Format Codes

Add the following rows to QRPH TF-2:5.1.1 IHE Format Codes

Profile	Format Code	Media Type	Template ID	
2011 Profiles				
QME-EH	urn:ihe:qrph:qme-eh:2010	Text/XML	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.1	

6 QRPH Content Modules

6.3 HL7 Version 3.0 CDA Content Modules

6.3.1 CDA Document Content Modules

525 | *Add section 6.3.1.D*

6.3.1.D QualityMeasureExecutionEarlyHearingReport 1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.1

Tem	plate Name	QualityMeasur	QualityMeasureExecutionEarlyHearingReport		
Tei	mplate ID	1.3.6.1.4.1.193	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.1		
Parei	nt Template	2.16.840.1.113	883.10.20.24.1.1 (HL7 QRDA Document templa	ate [July 2012])	
7	General escription	This patient-level QRDA quality measure document gathers information about a newborn which is required to assess and report on the hearing screening prior to hospital discharge measure, as defined by the National Quality Forum in document NQF#1354 Measure Evaluation 4.1, December 2009.			
Document Code 55182-0 QRDA Incidence Report					
Title Quality Measure Report: Newborn Hearing Screening Price		re Report: Newborn Hearing Screening Prior to	Discharge		
Opt	Content Module Name		Template ID	Specification Document	Constraint
Structured Body					
[1*]	[1*] QmeehMeasureSection		1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.3		

Constraints

530

- 1. SHALL contain exactly one [1..1] typeId (CONF:5361).
 - a. This typeId shall contain exactly one [1..1] @root="2.16.840.1.113883.1.3" (CONF:5250).
 - b. This typeId shall contain exactly one [1..1] **@extension=**"POCD HD000040" (CONF:5251).

535

- 2. shall contain the following templateId (CONF) to assert the conformances of a QualityMeasureExecutionEarlyHearingReport
 - a. This typeId shall contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.1" for the QualityMeasureExecutionEarlyHearingReport template (CONF).

- 3. SHALL contain exactly one [1..1] id (CONF:5363).
 - a. This id SHALL be a globally unique identifier for the document (CONF:9991).

4. **shall** contain exactly one [1..1] **code=**"55182-0" Quality Measure Report 545 (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:12911). 5. SHALL contain exactly one [1..1] **title** (CONF:5254). a. Can either be a locally defined name or the display name corresponding to clinicalDocument/code (CONF:5255). b. The title for this document shall be a case insensitive string containing the phrase: "Ouality Measure Report: Newborn Hearing Screening Prior to 550 Discharge" (CONF). 6. SHALL contain exactly one [1..1] **effectiveTime** (CONF:5256). a. Signifies the document creation time, when the document first came into being. Where the CDA document is a transform from an original document in 555 some other format, the ClinicalDocument.effectiveTime is the time the original document is created. The time when the transform occurred is not currently represented in CDA (CONF:9995). b. This effective Time shall contain exactly one [1..1] US Realm Date and Time (DT.US.FIELDED) (2.16.840.1.113883.10.20.22.5.3) 560 (CONF:XXXX). [Lisa: figure out how to generalize this to international.] 7. SHALL contain exactly one [1..1] confidentialityCode, which SHOULD be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC 2010-04-21 (CONF:5259). 8. **SHALL** contain exactly one [1..1] **languageCode** which **SHALL** be selected from 565 ValueSet Language 2.16.840.1.113883.1.11.11526 DYNAMIC (CONF:5372). 9. MAY contain zero or one [0..1] setId (CONF:5261). a. If setId is present versionNumber **shall** be present. (CONF:6380).⁵ 10. MAY contain zero or one [0..1] **versionNumber** (CONF:5264). a. If versionNumber is present setId shall be present. (CONF:6387). 570 11. **SHALL** contain one or more [1..*] component such that it a. **SHALL** contain exactly one [1..1] **QmeehMeasureSection** (templateID 1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.3) which holds the report parameters and patientlevel data needed to assess the criteria specified for the measure and the data 575 being measured. b. **NOTE:** for trial implementation the profile scope has been constrained to include only one QmeehMeasureSection which will be for the EHDI 1a measure.

⁵ From CDA Normative Web edition: 4.2.1.7 ClinicalDocument.setId - Represents an identifier that is common across all document revisions and "Document Identification, Revisions, and Addenda" under 4.2.3.1 ParentDocument

⁶ From CDA Normative Web edition: 4.2.1.8 ClinicalDocument.versionNumber An integer value used to version successive replacement documents

Figure 6.3.1.D-1: document example

6.3.2 CDA Header Content Modules

Add section 6.3.2.H

595

6.3.2.H US Header Content Module

600 **6.3.2.H.1** Header elements

Name		QmeehHeader	QmeehHeader			
Template ID		1.3.6.1.4.1.193	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.1.2			
Parent Template		[Note: this template is a generalization of the US Realm Header (2.16.840.1.113883.10.20.22.1.1(open)) defined by the Consolidated CDA Implementation Guide.]				
General Description			This template describes constraints on the participations and actRelationships intended for the construct of a QualityMeasureExecutionEarlyHearingReport.		ips intended for	
Opt	Opt Content Module Name		Template ID	Specification Document	Constraint	
	Participations and ActRelationships					
[01]	legalAuthenticator				15	
[11]	11] author				14	
[11]	custodian				13	
[11]	recordTarget				12	

Constraints

The header for the Cardiac Report Content document shall support the following header constraints as noted in this section. Note that this content profile is realm agnostic. These header

605	constraints are based on the C-CDA header constraints but all references to US Realm specific types have been removed.
	12. SHALL contain exactly one [11] recordTarget (CONF:5266). The recordTarget records the patient whose health information is described by the clinical document; it must contain at least one patientRole element.
610	a. Such recordTargets shall contain exactly one [11] patientRole (CONF:5267).
	 i. This patientRole shall contain at least one [1*] id (CONF:5268) ii. This patientRole shall contain at least one [1*] addr (CONF:5271). 1. This addr shall contain at least one [1*] postalCode
615	(CONF: CRC-xxx).
	iii. This patientRole shall contain at least one [1*] telecom (CONF:5280).
	iv. This patientRole shall contain exactly one [11] patient (CONF:5283).
620	1. This patient shall contain exactly one [11] name (CONF:5284).
	a. This name shall contain exactly one [11] family (CONF: 7159).
	b. This name shall contain at least one [1*] given
625	(CONF: 7157).
	i. The second occurrence of given (given[2]) if provided, shall include middle name or middle initial (CONF:7163).
630	2. This patient shall contain exactly one [11] administrativeGenderCode, which shall be selected from ValueSet Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 DYNAMIC (CONF:6394).
	3. This patient shall contain exactly one [11] birthTime
625	(CONF:5298).
635	a. shall be precise to the minute (CONF).

```
<recordTarget>
               <patientRole>
                 <id extension="12345" root="2.16.840.1.113883.19"/>
640
                 <addr use="HP">
                    <streetAddressLine>17 Daws Rd.
                    <city>Blue Bell</city>
                    <state>MA</state>
                    <postalCode>02368</postalCode>
645
                    <country>US</country>
                 </addr>
                 <telecom value="tel:(781)555-1212" use="HP"/>
                 <patient>
                    <name use="L">
650
                       <prefix>Mr.</prefix>
                       <given>Adam</given>
                       <given>Frankie</given>
                       <family>Everyman</family>
                    </name>
655
                    <administrativeGenderCode code="M"
                          codeSystem="2.16.840.1.113883.5.1" displayName="Male"/>
                    <birthTime value="2012"/>
                 </patient>
               </patientRole>
660
             </recordTarget>
```

Figure 6.3.2.H.1-1: recordTarget example

- 13. SHALL contain exactly one [1..1] **author** (CONF). The author element represents the person who created the clinical document. If there are multiple procedures performed, there may be multiple authors for the content of this document.
 - a. the author shall contain exactly one [1..1] time (CONF:5445).
 - b. the author shall contain exactly one [1..1] **assignedAuthor** (CONF:5448).
 - i. This assigned Author SHALL contain at least one [1..*] id (CONF:5449).
 - ii. shall contain @root="the OID of the assigning authority" for at least one [1..*] id (CONF).
 - i. This assigned Author shall contain at least one [1..*] addr (CONF:5452).
 - iii. This assigned Author shall contain at least one [1..*] **telecom** (CONF:5428).
 - iv. This assignedAuthor shall contain exactly one [1..1] assignedPerson (CONF).
 - 1. This assignedPerson shall contain at least one [1..*] name (CONF).

665

670

675

```
<author>
               <time value="20050329224411+0500"/>
685
               <assignedAuthor>
                 <id extension="EXAMPLE123" root="2.16.840.1.113883.19.5"/>
                    <streetAddressLine>21 Streetname Ave.
                    <city>Somertown</city>
690
                    <state>MA</state>
                    <postalCode>02368</postalCode>
                    <country>US</country>
                  </addr>
                  <telecom use="WP" value="tel:(555)555-1003"/>
695
                  <assignedPerson>
                    <name>
                       <given>Arthur</given>
                       <family>Author</family>
                     </name>
700
                  </assignedPerson>
               </assignedAuthor>
             </author>
```

Figure 6.3.2.H.1-2: Person author example

- 705 14. SHALL contain exactly one [1..1] custodian (CONF:5519).
 - a. This custodian shall contain exactly one [1..1] assignedCustodian (CONF:5520).
 - i. This assignedCustodian SHALL contain exactly one [1..1] representedCustodianOrganization (CONF:5521).
 - 1. This representedCustodianOrganization SHALL contain at least one [1..*] id (CONF:5522).
 - 2. This representedCustodianOrganization shall contain exactly one [1..1] name (CONF:5524).
 - 3. This represented Custodian Organization SHALL contain exactly one [1..1] **telecom** (CONF:5525).
 - 4. This represented Custodian Organization SHALL contain at least one [1..*] addr (CONF:5559).

- 710
- 715

```
<custodian>
720
               <assignedCustodian>
                  <representedCustodianOrganization>
                     <id root="2.16.840.1.113883.19.5"/>
                     <name>Good Health Clinic</name>
                     <telecom value="tel:(555)555-1212" use="WP"/>
725
                     <addr use="WP">
                        <streetAddressLine>17 Daws Rd.</streetAddressLine>
                        <city>Blue Bell</city>
                        <state>MA</state>
                         <postalCode>02368</postalCode>
730
                         <country>US</country>
                     </addr>
                  </representedCustodianOrganization>
               </assignedCustodian>
             </custodian>
```

Figure 6.3.2.H.1-3: custodian example

- 15. **shall** contain exactly one [1..1] **legalAuthenticator** (CONF:13817).
 - a. The legal Authenticator **shall** contain exactly one [1..1] **time** (CONF:5580).
 - b. This legalAuthenticator, if present, shall contain exactly one [1..1] **signatureCode** (CONF:5583).
 - i. This signatureCode shall contain exactly one [1..1] @code="S" (CodeSystem: Participationsignature 2.16.840.1.113883.5.89) (CONF:5584).
 - c. This legalAuthenticator, if present, shall contain exactly one [1..1] **assignedEntity** (CONF:5585).
 - i. This assignedEntity shall contain at least one [1..*] id (CONF:5586).
 - ii. This assignedEntity MAY contain zero or one [0..1] code (CONF).
 - ii. This assignedEntity shall contain at least one [1..*]addr (CONF:5589).
 - iii. This assignedEntity SHALL contain at least one [1..*] **telecom** (CONF:5595).
 - 1. Such telecoms should contain @use (CONF).
 - iv. This assignedEntity SHALL contain exactly one [1..1] **assignedPerson** (CONF:5597).
 - 1. This assignedPerson shall contain at least one [1..*] name (CONF:5598).

The legalAuthenticator identifies the single person legally responsible for the document and must be present if the document has been legally authenticated.

760

735

740

745

750

```
<legalAuthenticator>
              <time value="20050329224411+0500"/>
              <signatureCode code="S"/>
              <assignedEntity>
765
                 <id extension="KP00017" root="2.16.840.1.113883.19"/>
                 <addr>
                    <streetAddressLine>21 North Ave.
                    <city>Burlington</city>
                    <state>MA</state>
770
                    <postalCode>02368</postalCode>
                    <country>US</country>
                 <telecom use="WP" value="tel:(555)555-1003"/>
                 <assignedPerson>
775
                    <name>
                       <given>Henry</given>
                       <family>Seven</family>
                    </name>
                 </assignedPerson>
780
               </assignedEntity>
             </legalAuthenticator>
```

Figure 6.3.2.H.1-4: legalAuthenticator example

6.3.3 CDA Section Content Modules

785 **6.3.3.7.S1 QmeehMeasureSection**

Measure Description	Template Name	Type / Class Code	OID
EHDI1a	NewbornHearingScreeningPriorToDischarge	Measure	8a4d92b2-37bf-6f1b-0137- ccd612a40d0e(See note below.)
EHDI1a	A LOINC code will be needed for this measure in the future		

Note: This OID is established for the measure in the HQMF e-measure definition.

Section Name	QmeehMeasureSection
Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.3
Parent Template	2.16.840.1.113883.10.20.24.2.2
General Description	The Measure Section template contains information about the measure or measures being reported. QRDA R1 referenced a quality measure by using an act/code under the assumption that standard codes, such as LOINC codes, would be created for the measures. QRDA R2 references the measure through reference to an externalDocument. The externalDocument/ids and version numbers are used to reference the measure. The measure section must contain a reference to at least one externalDocument id for all the measures being reported in the QRDA instance.

code		55186-1 Measure 2.16.840.1.113883.6.1 LOINC STATIC					
	title	Measure Sect	ire Section: Hearing Screening Prior to Hospital Discharge				
Opt	Content Module N	ame	Template ID	Specification Document	Constrain t		
Entries							
	Subsections						
[11] Reporting Parameter Section			1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.4				
[11]	QmeehPatientDataSection		1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.5				

Constraints

- 1. SHALL contain exactly one [1..1] templateId (CONF:12794) such that it
 - a. shall contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.3" (CONF).
- 2. The section **SHALL** have a parent templateID of 2.16.840.1.113883.10.20.24.2.2
 - a. The section **SHALL** conform to specifications for the MeasureSection established by the HL7 QRDA IG.
- 3. The section **SHALL** assert the templateId assigned to the definition of the measure(s) communicated in this section.
- 4. **A. SHALL** contain exactly one [1..1] @root='8a4d92b2-37bf-6f1b-0137-ccd612a40d0e'. The section/code/@code **SHALL** come from the LOINC document content code system and SHALL be **55186-** 1 to establish that the section is a type of MeasureSection.
- 5. **SHALL** contain exactly one [1..1] component such that it
 - a. **SHALL** contain exactly one [1..1] **ReportingParameterSection** (templateID 1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.4) which holds the reporting parameters for that measure.
- 6. **SHALL** contain exactly one [1..1] component such that it
 - a. **SHALL** contain exactly one [1..1] <u>OmeehPatientDataSection</u> (templateID 1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.5) which holds the patient-level data needed to assess the criteria specified for the measure and the data being measured.

6.3.3.7.S2 ReportingParametersSection

Section Name	ReportingPara	ReportingParametersSection				
Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.4					
Parent Template	Conforms to an untemplated section in the HL7 QRDA IG					
General Description	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.					
code	55187-9 Reporting Parameters 2.16.840.1.113883.6.1 LOINC STATIC.					
title	Reporting Parameters					
Opt Content Module Name		Template ID	Specification	Constrain		

795

790

800

Entries

Subsections

Constraints

810

No additional constraints are applied to the ReportingParametersSection defined in the HL7 QRDA IG.

6.3.3.7.S3 QmeehPatientDataSection

6.3.3.7	.S3 QmeehPatientDataSed	ction						
	Section Name	QmeehF	QmeehPatientDataSection					
	Template ID	1.3.6.1.4	4.1.19376.1.7.3.1.1.18.1.2.5					
	Parent Template	2.16.840	0.1.113883.10.20.17.2.4					
			ient Data section contains patient data ele data set as defined by the particular meas)-			
code 55188-7 Patient Data 2.16.840.1.113883.6.1 LOINC STATIC								
	title	Patient 1	Data For Measuring: Newborn Hearing S	creening Prior to D	ischarge			
Opt Content Module Name			Template ID	Specificatio n Document	Cons traint s			
			Entries					
[11]	BirthObservation		1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.1		6			
[01]	PatientCharacteristicExpired		2.16.840.1.113883.10.20.24.3.54		7			
[01]	DischargeObservation		1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.3		8			
[11]	HearingScreeningDiagnosticStudyPer	forme	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.4		9			

Constraints

1. SHALL contain one [1..1] templateId (CONF) such that it

Subsections

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- a. shall contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.5" (CONF).
- 2. **SHALL** contain one [1..1] **templateId** (CONF) such that it
 - a. templateID of 2.16.840.1.113883.10.20.17.2.4
 - b. The section **SHALL** conform to specifications for the PatientDataSection established by the HL7 QRDA IG.
- 3. **SHALL** contain exactly one [1..1] **code** with @xsi:type="CD"="55188-7" Patient data (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:3865).
- 4. **shall** contain exactly one [1..1] **title=**"Patient Data" (CONF:3866).
- 5. **SHALL** contain exactly one [1..1] **text** (CONF:3867).
- 6. **SHALL** contain one [1..1] **entry** such that it
 - a. **SHALL** contain exactly one [1..1] BirthObservation (templateID 1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.1) which holds the data criteria for date of birth and birthing facility ID for that measure (CONF).
- 7. MAY contain up to one [0..1] entry such that it
 - a. **SHALL** contain exactly one [1..1] PatientCharacteristicExpired (templateID 2.16.840.1.113883.10.20.24.3.54) which holds the data criteria for date of death, when death has occurred (CONF).
- 8. MAY contain up to one [0..1] entry such that it
 - a. **shall** contain exactly one [1..1] DischargeObservation (templateID 1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.3) which holds the data criteria for date of discharge (CONF).
- 9. **SHALL** contain one [1..1] **entry** such that it
 - a. **SHALL** contain exactly one [1..1] HearingScreeningDiagnosticStudyPerformed (templateID 1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.4) which encodes information required to assess if hearing screening was performed and records the patient or medical reason if no hearing screening at all was performed (CONF).

6.3.4 CDA Entry Content Modules

6.3.4.E1 BirthingFacilityLocationAndId

6.3.4.E1.1Template Context

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Used by:	OID
BirthObservation	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.1
Contains:	OID

6.3.4.E1.2 Description

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This entry encodes the Facility Location and Id information for the birthing facility.

6.3.4.E1.3 Constraints Overview

Entry Name	BirthingFacilityLocationAndId
Entry Type	Observation
Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.1.1
Parent Template	2.16.840.1.113883.10.20.24.3.100 (FacilityLocation listed in the QRDA [July 2012] Implementation Guide)
General Description	This data element encodes facility location and ID information for the facility where the newborn was born.
classCode	OBS
moodCode	EVN

 Xpath
 Card.
 Verb
 Data Type
 Reference
 Fixed Value

 id
 1..1
 SHALL
 1

6.3.4.E1.4 Constraints Enumerated

- 1. **SHALL** contain exactly one [1..1] id (CONF).
 - a. **SHALL** encode a unique id identifying the facility (CONF).
 - b. **shall** contain @root="the OID of the assigning authority" (CONF).
 - c. **MAY** contain a flavor of null if the birth occurred at home or at a location that does not have an authorized facility id (CONF).

6.3.4.E2 BirthObservation

6.3.4.E2.1Template Context

Used by:	OID
QmeehPatientData	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.5
Contains:	OID
BirthingFacilityLocationAndId	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.1.1

860 **6.3.4.E2.2 Description**

This entry encodes the date and time of birth for the Newborn and the Birthing Facility location and Id.

6.3.4.E2.3 Constraints Overview

Entry Name	BirthObservation
Entry Type	Observation
Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.1
Parent Template	none
General Description	This data element encodes the date and time of birth and the location and id of the birthing facility.
classCode	OBS
moodCode	EVN

Xpath	Card.	Verb	Data Type	Reference	Fixed Value
id	1*	SHALL	II	4	
code	11	SHALL	CD CWE	5	
statusCode	11	SHALL	CS	6	completed
effectiveTime	11	SHALL	TS	7	
value	11	SHALL	TS	8	
participant	11	SHALL		9	

6.3.4.E2.4 Constraints Enumerated

- 1. **SHALL** contain exactly one [1..1] @classCode.
 - a. **should** contain zero or one [0..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass).
- 2. **shall** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
- 3. **SHALL** contain one [1..1] templateId such that it
 - a. **SHALL** contain @root=" 1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.1".
- 4. **SHALL** contain at least one [1..*] id.
- 5. **SHALL** contain exactly one [1..1] code.
 - a. **SHALL** be selected from value set QmeehPatientStateValueSet (1.3.6.1.4.1.19376.1.7.3.1.1.18.1.4.1)
 - b. **SHALL** be a code representing the concept of "born".
 - c. **SHALL** include **originalText** to express the coded concept in human readable form.
- 6. **SHALL** contain exactly one [1..1] **statusCode=**"completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14).
- 7. **SHALL** contain exactly one [1..1] **effectiveTime**.

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a. Encodes the date and time that the quality data measure was recorded.

b. This effectiveTime SHALL contain exactly one [1..1] US Realm Date and Time (DT.US.FIELDED) (2.16.840.1.113883.10.20.22.5.3).

- 8. **SHALL** contain exactly one [1..1] **value** with @xsi:type="TS"
 - a. Encodes the official date and time of birth
 - b. **SHALL** contain exactly one [1..1] **Value**
 - c. This value SHALL contain exactly one [1..1] US Realm Date and Time (DT.US.FIELDED) (2.16.840.1.113883.10.20.22.5.3).
- 9. SHALL contain exactly one [1..1] participant (CONF) such that it
 - a. **shall** contain exactly one [1..1] **@typeCode=**"LOC" (CodeSystem:

2.16.840.1.113883.5.90 HL7ParticipationType) (CONF).

b. **shall** contain exactly one [1..1] BirthingFacilityLocationAndID (templateID 1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.1.1) (CONF).

6.3.4.E4 DischargeObservation

6.3.4.E4.1Template Context

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Used by:	OID
QmeehPatientData	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.5
Contains:	OID
None	

6.3.4.E4.2 Description

This entry encodes the discharge date and time for the Newborn.

6.3.4.E4.3 Constraints Overview

Entry Name	DischargeObservation
Entry Type	Observation
Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.3
Parent Template	none
General Description	This data element encodes the date and time of discharge.
classCode	OBS
moodCode	EVN

Xpath	Card.	Verb	Data	Reference	Fixed Value
			Type		

Xpath	Card.	Verb	Data Type	Reference	Fixed Value
id	1*	SHALL	II	4	
code	11	SHALL	CD CWE	5	
statusCode	11	SHALL	CS	6	Completed
effectiveTime	11	SHALL	TS	7	
value	11	SHALL	TS	8	

6.3.4.E4.4 Constraints Enumerated

- 1. **SHALL** contain exactly one [1..1] @classCode.
 - a. **should** contain zero or one [0..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass).
 - 2. **shall contain exactly one** [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
 - 3. **SHALL** contain one [1..1] templateId such that it
 - a. **SHALL** contain @root=" 1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.3
 - 4. **SHALL** contain at least one [1..*] id.
 - 5. **SHALL** contain exactly one [1..1] code.
 - a. **shall** be selected from value set QmeehPatientStateValueSet (1.3.6.1.4.1.19376.1.7.3.1.1.18.1.4.1)
 - b. **SHALL** be a code representing the concept of "discharged".
 - c. **SHALL** include **originalText** to express the coded concept in human readable form.
 - 6. **shall** contain exactly one [1..1] **statusCode=**"completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14).
 - 7. **SHALL** contain exactly one [1..1] **effectiveTime**.
 - a. Encodes the date and time that the quality data measure was recorded.
 - b. This effectiveTime SHALL contain exactly one [1..1] US Realm Date and Time (DT.US.FIELDED) (2.16.840.1.113883.10.20.22.5.3).
- 925 8. **SHALL** contain exactly one [1..1] **value** with @xsi:type="TS"
 - a. Encodes the official Date and time of Discharge
 - b. **SHALL** contain exactly one [1..1] **Value**
 - c. This value SHALL contain exactly one [1..1] US Realm Date and Time (DT.US.FIELDED) (2.16.840.1.113883.10.20.22.5.3).

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6.3.4.E5 HearingScreeningDiagnosticStudyPerformed

6.3.4.E5.1Template Context

Used by:	OID
QmeehPatientData	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.5
Contains:	OID
HearingScreeningResultObservation	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.5
Patient Preference	2.16.840.1.113883.10.20.24.3.83
Reason	2.16.840.1.113883.10.20.24.3.88

6.3.4.E5.2 Description

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This entry encodes the hearing screening measure data for the newborn and the minimum required data to evaluate the quality measure.

6.3.4.E5.3 Constraints Overview

Entry Name	HearingScreeningDiagnosticStudyPerformed	
Entry Type	Observation	
Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.4	
Parent Template	2.16.840.1.113883.10.20.24.3.18 (DiagnosticStudyPerformed)	
General Description	This entry directly contains encoded data to explain why hearing screening was not performed, if none was performed. Otherwise it encodes the hearing screening results which provide evidence of the hearing screening that was performed.	
classCode	OBS	
moodCode	EVN	
negationInd If the Hearing screening was not performed, as defined in the EHDI 1a qual measure, the negationInd for the observation is set to True.		

Xpath	Card.	Verb	Data Type	Reference	Fixed Value
templateId	11	SHALL			
@root	11	SHALL			1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.4
@extension	11	SHALL			
id	1*	SHALL	II	4	
code	11	SHALL	CD CWE	5	
statusCode	11	SHALL	CS	6	Completed
effectiveTime	11	SHALL	TS	7	

Xpath	Card.	Verb	Data Type	Reference	Fixed Value
templateId	11	SHALL			
@root	11	SHALL			1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.4
@extension	11	SHALL			
value	11	SHALL	TS		
entry Relationship	22	MAY		8	
@typeCode	11	SHALL			2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
observation	11	SHALL			
entry Relationship	01	MAY		9	
@typeCode	11	SHALL			2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
observation	11	SHALL			
entry Relationship	01	MAY		10	
@typeCode	11	SHALL			2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
observation	11	SHALL			

6.3.4.E5.4 Constraints Enumerated

- 1. SHALL contain exactly one [1..1] @classCode.
 - a. **should** contain zero or one [0..1] @classCode="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass).
- 2. **shall** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001).
- 3. **SHALL** contain one [1..1] templateId such that it
 - a. **SHALL** contain @root=" 1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.4
- 4. **SHALL** contain at least one [1..*] id.
- 5. **SHALL** contain exactly one [1..1] code.
 - a. **SHALL** be selected from value set JCIH-EHDI Hearing Screening Procedure Value Set (1.3.6.1.4.1.19376.1.7.3.1.1.15.2.17)
 - b. the concept Neonatal Hearing Test (procedure) **shall** be listed as the preferred term or one of the more specific concepts in that value set.
 - c. other concepts present in the patient's record and listed in the value set **SHALL** be listed as translations.
 - d. **SHALL** include **originalText** to express the coded concept in human readable form.

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- 6. **SHALL** contain exactly one [1..1] **statusCode=**"completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14).
- 7. **SHALL** contain exactly one [1..1] **effectiveTime**.

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- a. Encodes the date and time that the quality data measure was recorded.
- b. This effectiveTime SHALL contain exactly one [1..1] US Realm Date and Time (DT.US.FIELDED) (2.16.840.1.113883.10.20.22.5.3).
- 8. **SHALL** contain exactly [2..2] **entryRelationship**, one for the left and one for the right ear such that each
 - a. **SHALL** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002).
 - b. **shall** contain exactly one [1..1] HearingScreeningResultObservation (1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.5).
- 9. MAY directly contain zero or one [0..1] entryRelationship (CONF:11283) such that it
 - a. **shall** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:11284).
 - b. **shall** contain exactly one [1..1] <u>Patient Preference</u> (templateId:2.16.840.1.113883.10.20.24.3.83) (CONF:11495).
 - i. The PatientPreference Template shall be constrained **BY** JCIH-EHDI PROCEDURE DECLINED VALUE SET 1.3.6.1.4.1.19376.1.7.3.1.1.15.2.20
- 10. MAY directly contain zero or one [0..1] entryRelationship (CONF:11371) such that it
 - a. **shall** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:11372).
 - b. **shall** contain exactly one [1..1] <u>Reason</u> (templateId:2.16.840.1.113883.10.20.24.3.88) (CONF:11498).
 - i. The Reason Template shall be constrained BY JCIH-EHDI INPATIENT SCREENING PROCEDURE NOT PERFORMED VALUE SET 1.3.6.1.4.1.19376.1.7.3.1.1.15.2.10

6.3.4.E6 HearingScreeningResultObservation

6.3.4.E6.1Template Context

Used by:	OID
HearingScreeningDiagnosticStudyPerformed	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.2.5
Contains:	OID
Patient Preference	2.16.840.1.113883.10.20.24.3.83
Reason	2.16.840.1.113883.10.20.24.3.88

6.3.4.E6.2 Description

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This entry encodes the newborn hearing diagnostic study procedure information for the left or the right ear. If a procedure has not been performed it includes information to explain why.

6.3.4.E6.3 Constraints Overview

Entry Name	HearingScreeningResultObservation	
Entry Type	Procedure	
Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.5	
Parent Template	2.16.840.1.113883.10.20.24.3.64 (ProcedurePerformed)	
General Description This entry encodes the type of hearing screening procedure performed. It is appropriate targetSite codes and methodcodes. For a screening procedure to be performed, it encodes appropriate reasons or preferences to explain why		
classCode	OBS	
moodCode	EVN	
negationInd	If the Hearing screening procedure was not performed, as defined in the EHDI 1a quality measure, the negationInd for the procedure is set to True.	

Xpath	Card.	Verb	Data Type	Reference	Fixed Value
templateId	11	SHALL			
@root	11	SHALL			1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.5
@extension	11	SHALL			
code	11	SHALL		3	
effectiveTime	11	SHALL		4	
low	11	SHALL			
high	11	SHALL			
value	11	SHALL		5	
methodCode	11	SHALL		6	
targetsiteCode	11	SHALL		7	
entry Relationship	01	MAY		8	
@typeCode	11	SHALL			2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
observation	11	SHALL			
entry Relationship	01	MAY		9	
@typeCode	11	SHALL			2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR

 Xpath
 Card.
 Verb
 Data Type
 Reference
 Fixed Value

 observation
 1..1
 SHALL

6.3.4.E6.4 Constraints Enumerated

995	1. shall contain exactly one [11] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:11261).
	2. SHALL contain exactly one [11] templateId (CONF:11262) such that it
	a. shall contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.18.1.3.5" (CONF).
1000	b. shall contain exactly one [11] @extension (CONF:11264).
	3. shall contain exactly one [11] code (CONF).
	a. This code shall contain exactly one [11] @code, which shall be selected from value set JCIH-EHDI Hearing Screening Left Value Set (1.3.6.1.4.1.19376.1.7.3.1.1.15.2.8) or value set JCIH-EHDI Hearing
1005	Screening Right Value Set (1.3.6.1.4.1.19376.1.7.3.1.1.15.2.9).
	4. SHALL contain exactly one [11] effectiveTime (CONF).
	a. This effective Time shall contain exactly one [11] low (CONF:11670).
	b. This effective Time shall contain exactly one [11] high (CONF:11671).
	5. shall contain exactly one [11] value with @xsi:type="CD", where the @code
1010	shall be selected from ValueSet
	JCIHEHDIEvidenceOfHearingScreeningPerformedValueSet
	1.3.6.1.4.1.19376.1.7.3.1.1.15.2.18 DYNAMIC (CONF).
	6. SHALL contain exactly one [11] methodCode
1015	a. This code shall contain exactly one [11] @code, which shall be selected from value set JCIH-EHDI Hearing Screening Method Value Set (1.3.6.1.4.1.19376.1.7.3.1.1.15.2.4).
	7. SHALL contain exactly one [11] targetsiteCode

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8. MAY contain zero or one [0..1] entryRelationship (CONF:11283) such that it

(1.3.6.1.4.1.19376.1.7.3.1.1.18.1.4.2).

a. **shall** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:11284).

a. This code **shall** contain exactly one [1..1] @code, which **shall** be selected from value set JCIH-EHDI Hearing Screening TargetSite Value Set

b. **shall** contain exactly one [1..1] **Patient Preference** (templateId:2.16.840.1.113883.10.20.24.3.83) (CONF:11495).

i. The PatientPreference Template shall be constrained BY JCIH-EHDI PROCEDURE DECLINED VALUE SET
1.3.6.1.4.1.19376.1.7.3.1.1.15.2.20 (For more information about how to constrain this template to the specified value set, refer to the appendix in the QRDA

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IG for extensions to CDA R2 and review the use of the valueSet and valueSetVersion attributes.)

- 9. MAY contain zero or one [0..1] entryRelationship (CONF:11371) such that it
 - a. **shall** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:11372).
 - b. **shall** contain exactly one [1..1] **Reason** (templateId:2.16.840.1.113883.10.20.24.3.88) (CONF:11498).
 - i. The Reason Template shall be constrained BY JCIH-EHDI INPATIENT SCREENING PROCEDURE NOT PERFORMED VALUE SET 1.3.6.1.4.1.19376.1.7.3.1.1.15.2.10 (For more information about how to constrain this template to the specified value set, refer to the appendix in the QRDA IG for extensions to CDA R2 and review the use of the valueSet and valueSetVersion attributes.)
- 10. If there are no screening results for the left ear or no screening results for the right ear, the negationInd for the observation is set to True, and the entry shall contain at least one of either the Patient_Preference or Reason entry relationship to encode the reason why there is no evidence of hearing screening performed.

6.5 New QRPH Value Sets

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6.5.V1 QmeehPatientStateValueSet

Metadata Element	Description	Mandatory
Identifier	unique identifier of the value set	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.4.1
Name	name of the value set	QmeehPatientStateValueSet
Source	source of the value set, identifying the originator or publisher of the information	IHE Quality Research and Public Health Domain
Purpose	Brief description about the general purpose of the value set	Defines a set of concepts for Patient-states relevant to the measure.
Definition	A text definition describing how concepts in the value set were selected	Enumerated
Source URI	Most sources also have a URL or document URI that provides further details regarding the value set.	
Version	A string identifying the specific version of the value set.	Version 1.0
Status	Active (Current) or Inactive	Active
Effective Date	The date when the value set is expected to be effective	May 11, 2012
Expiration	The date when the value set is no	N/A

Metadata Element	Description	Mandatory
Date	longer expected to be used	
Creation Date	The date of creation of the value set	8/1/2010
Revision Date	The date of revision of the value set	N/A
Groups	The identifiers of the groups that include this value set. A group MAY also have an OID assigned.	IHE EHDI

QmeehPatientStateValueSet - values

	Value Set :	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.4.1	
	Vocabulary:	2.16.840.1.113883.6.96	
Sequence	SNOMED Code	Description	EHDI Concept
	442311008	Patient liveborn born in hospital	Born
	3950001	Birth	Born
	281050002	Livebirth	Born
	371828006	Patient deceased during stay (discharge status=dead)	Died
	18632008	Patient status determination, deceased	Died
	183665006	Discharged from hospital	Discharged
	183667003	Discharged from inpatient care	Discharged

1055 6.5.X2 JCIH-EHDI Hearing Screening TargetSite Value Set

Metadata Element	Description	Mandatory
Identifier	unique identifier of the value set	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.4.2
Name	name of the value set	JCIH-EHDI Hearing Screening TargetSite Value Set
Source	source of the value set, identifying the originator or publisher of the information	IHE Quality Research and Public Health Domain
Purpose	Brief description about the general purpose of the value set	Defines a set of concepts for the target site of hearing screening relevant to the measure.
Definition	A text definition describing how concepts in the value set were selected	Enumerated
Source URI	Most sources also have a URL or document URI that provides further	

Metadata Element	Description	Mandatory	
	details regarding the value set.		
Version	A string identifying the specific version of the value set.	Version 1.0	
Status	Active (Current) or Inactive	Active	
Effective Date	The date when the value set is expected to be effective	May 11, 2012	
Expiration Date	The date when the value set is no longer expected to be used	N/A	
Creation Date	The date of creation of the value set	8/1/2010	
Revision Date	The date of revision of the value set	N/A	
Groups	The identifiers of the groups that include this value set. A group MAY also have an OID assigned.	IHE EHDI	

QmeehPatientStateValueSet - values

	Value Set :	1.3.6.1.4.1.19376.1.7.3.1.1.18.1.4.2	
	Vocabulary:	2.16.840.1.113883.6.96	
Sequence	SNOMED Code	Description	EHDI Concept
	368592000	entire left ear	Left ear
	368570004	entire right ear	Right Ear

Sample EHDI Patient-Level Quality Measure Report

1060 A sample Quality Measure Execution – Early Hearing for EHDI can be found at:

[Sample Document will be posted following Public Comment and prior to release for Trial Implementation.]