Integrating the Healthcare Enterprise



5 IHE Quality, Research, and Public Health Technical Framework Supplement

10 Early Hearing Detection and Intervention (EHDI)

Rev. 2.1 – Trial Implementation

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Please verify you have the most recent version of this document. See <u>here</u> for Trial Implementation and Final Text versions and <u>here</u> for Public Comment versions.

Foreword

This is a supplement to the IHE Quality, Research and Public Health (QRPH) Technical Framework. 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 on August 10, 2016 for trial implementation 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

35 Framework. Comments are invited and may be submitted at http://www.ihe.net/QRPH_Public_Comments.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

40 *Amend Section X.X by the following:*

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **bold strikethrough**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

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General information about IHE can be found at <u>www.ihe.net</u>.

Information about the IHE Quality Research and Public Health domain can be found at http://www.ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at <u>http://www.ihe.net/IHE_Process</u> and <u>http://www.ihe.net/Profiles</u>.

The current version of the IHE QRPH Technical Framework can be found at <u>http://www.ihe.net/Technical_Frameworks</u>.

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Introduction to this Supplement

This QRPH Trial Implementation Supplement contains the Early Hearing Detection and Intervention (EHDI) Profile. The EHDI Profile addresses information exchange needed in the development of a hearing plan of care for a newborn. It specifies the content for a Hearing Plan of Care (HPoC) document. It also specifies the message constraints for a hearing screening device to report a screening observation. The EHDI Profile is intended to augment the information exchange and interoperability also facilitated by the NANI, EHDI-WD, and QME-EH Profiles.

310 The HPoC document established a dynamic record that is added to as the child's hearing status, needs, and interventions change over time. This document provides state EHDI programs with an excellent vision of the data elements that need to be collected for a hearing plan of care.

Open Issues and Questions

Open Issue List:

Item Count	Issue Description	Status
1	Request new LOINC Codes for sections specific to HPoC	Initiated LOINC request process at completion of Public Comment. Trial implementations should use the specified temporary codes until LOINC releases permanent ones.
2	Feedback needs to be solicited during and after trial implementation to find out if it would be easier on implementers to NOT USE negationInd in the template representing the hearing screening test.	Review after initial Trial Implementation.
3	Feedback needs to be solicited during trial implementation to determine if any implementers find issues with implementing the Form Receiver without also implementing the Form Manager.	Review after initial Trial Implementation.
4	Entry templates should be added to the HPoC Section which permits encoding of goals and outcomes from interventions.	Future consideration.
5	Add an extension to CDA ^{®1} R2 which supports recording a language communication element (with all its parts) to the recordTarget/guardian, the participant/associatedEntity/associatedPerson, and the section/subject/relatedSubject/subject.	Future enhancement
6	Need to revisit the semantic difference between an observation act and a procedure act. This nuance may affect interoperability with the Quality Measure logic.	Revisit when QME-EH is updated.

¹ CDA is the registered trademark of Health Level Seven International.

Item Count	Issue Description	Status
7	The LOINC Code used on the Hearing Screening Organizer and the Hearing Screening Results Organizer both indicate they are "panels", but the type on the organizer templates is set to "CLUSTER". During Trial Implementation, it should be explored with implementers and LOINC to see if the assigned concepts are semantically accurate/specific enough.	Consider during Trial Implementation
8	Some Value Set have been populated with concepts that may or may not be needed. The Value Sets will continue to use temporary codes during the Trial Implementation period. If implementers use/need the concepts then permanent codes will be requested prior to completing the Trial Implementation period.	Open
9	Consider if the EHDI Profile should be modified to include an option for Content Creators and Form Receiver CDA Exporters to create the Hearing Plan of Care information is a document format that aligns with the latest working advanced for the use of the C-CDA Care Plan Document template. This option would enable the EHDI Hearing Plan of Care Document to fit as a module with in a larger Care Plan for the child, which would qualitatively be better for care coordination. It also would increase implementer uptake, because any implementer of the C-CDA Care Plan Document could easily add a Hearing Plan of Care "container" into an overarching care plan. The C-CDA	Open
	Care Plan Document is required when certifying to 170.315(b)(9) for Meaningful Use incentives.	

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Closed Issues

Item Count	Issue Description	Status
1	How to formulate the 3 content profiles: Hearing Result Report, Hearing Screening Outcome Report, and Hearing Plan of Care, into the technical framework supplement? (These are the three documents needed to drive the document-based workflow in EHDI-WD.)	Closed – This profile will only specify the one content document (HPoC). EHDI-WD still requires the other two documents – and so specifying them still needs to be done – but it will not be in scope for this profile.
2	Do we need other documents for the Outcome Report and the Result Report, or not?	Closed. As of 11/26, we will focus only on the HPoC.

Item Count	Issue Description	Status
	•	
3	We need to make the code element of the Plan of Care section support a value set of relevant Plan of Care types. Previous Template for EHCP is: 1.3.6.1.4.1.19376.1.7.3.1.1.15.4.1 Can we have a new Template ID for the HPoC Document work? Yes. The root OID granted will be: 1.3.6.1.4.1.19376.1.7.3.1.1.26	Document Level LOINC 34817-7 Otorhinolary ngology Evaluation and management note Section Level LOINC 18776-5 Plan of Care For now, the section level code will remain the more generic code of 18776-5. This needs to be addressed with LOINC as they resolve the Care Plan, Plan of Care coding issues. The more specific code will be used in the Service Event to record that the Hearing Plan was Created. For this year, the ServiceEvent will not record that the Hearing Screening Outcome assessed was done. This may be reconsidered in the future. Once HPoC is published, a CP will be logged against EHCP to deprecate it.
4	Should the process flow for 4.2.2.3-1 use a loop structure?	Yes – add a loop, but not blue – also fix 4.2.2
5	Open questions about the use of C-CDA templates versus IHE templates. Design need is to be sure the template is international.	Discuss approach with QRPH on 3/7/2014. Need to discuss impact on Content Creator Content Consumer Form Manager Form Receiver Content Creator Will create these options.

Item Count	Issue Description	Status
6	How do we specify the QRPH Result Message Communication integration profile so we have a Device Observation Consumer further constrained to receive hearing screening data from a Device Observation Reporter using a PCD-01 transaction to communicate a HL7 ^{®2} Hearing Screening Result Message?	M aterial is completed
	Device Observation Reporter – The Device Observation Reporter (DOR) receives data from PCDs, including those based on proprietary formats, and maps the received data to transactions providing consistent syntax and semantics.	
	Device Observation Consumer – The actor responsible for receiving PCD data from the Device Observation Reporter, the Device Observation Filter, or both.	
7	Tasks to be completed for Vol2-4:	Completed.
	 Add actor options (if needed) Gather Value Sets for US Realm 	
	 Gather Value Sets for US Realm Establish Concept Domain bindings for UV Realm 	
	4. Finish PCD-01 Content Specification	
	5. Create Form Mapping 6.3.1.D1.4	
	6. Specify that NOK information from the message needs to be represented in the recordTarget.guardian header entry when the person is ward over the baby	
	7. Specify Participations for the Result Observation	
	8. Pull everything into the TS formatPull everything into the TS format	
8	Work with PCD Domain and IEEE to complete the process of registering the proposed Containment Tree terms and getting assigned codes.Update the message sample document after codes have been assigned.	Done.
9	Work with PCD Domain to complete the coding of the ORU^R01 message to include the containment tree examples	Done

² HL7 is the registered trademark of Health Level Seven International.

Item Count	Issue Description	Status
10	A decision needs to be made about what organization information should be provided in Volume 4 as the organization to contact with questions and responsible for sustaining the Technical Supplement. See V4: 4.R1.1 Comment Submission. Currently using:	New approach provided by Nichole. Use: <u>iheusa@himss.org</u> for the IHE USA Secretariat email address
	(alippitt@himss.org)	
11	Get new number for new transaction	QRPH-45 with name Communicate Hearing Screening Data
12	Checking with PCD Domain to confirm the needed MDC Concepts were added as documented in Volume 2.	It turns out that there is no need to reference the PCD-01 message structure due to the fact that this transaction uses a message structure balloted through HL7. The LOINC and SNOMED CT vocabulary is available and the structure fits the hearing screening data.
13	After the PCD Domain processes its CP to include the NK1 segment, create a CP to change the NK1 information in Volume 3 Chapter 7 to remove indication of it being an extension of the PCD-01 message. PCD wants to include the segment as optional "O", so the Hearing Screening Device Message would still have a further constraint to explain, since the usage here is "RE"	This profile no longer references PCD-01
14	The IHE Technical Supplement template doesn't address how to specify the option of implementing Realm Specific versions of the templates. We have created a US_Realm Option for the actors, but this may not be the preferred mechanism.	This is a template issue. This issue needs to be looked at to suggest the resolution during Public Comment.
15	Revisions to create a new QRPH-45 transaction and additional research seem to show that no reference to PCD-01 is actually required. This profile was intended to use the ORU^R01 specification defined in the HL7 spec. The whole "walk about" in PCD-01 land was unnecessary.	Consulting with Lynn.
16	IHE TS Template Issue: The diagramming tools are too limited and difficult to use. The tooling issue leads to greater inconsistency in the various diagrams that are produced. This feedback should be provided regarding the template.	If diagrams are done in ppt, the ppt file needs to be stored with the document on the ftp site.
17	IHE TS Template Issue: There needs to be an informative section added for each Use Case, following the Process Flow, where the anticipated types of systems which might play each actor role in the Use Case can be described.	This will be called Deployment Models. QME-EH shows an example of how to do this.
18	Add SNOMED CT and LOINC OIDs where concepts are currently available.	Done.
19	The EHDI Profile was developed before the Form Processor was introduced. Since no implementers have expressed a need for the Form Processor, this additional complexity has not been introduced into the profile.	Closed.

General Introduction

Appendix A - Actor Summary Definitions

Actor	Definition
Form Receiver CDA Exporter	The Form Receiver CDA Exporter SHALL conform to the requirements specified for the Form Receiver in the ITI RFD Profile. Additionally, this actor SHALL create and export a CDA document that meets the requirements of a specified document template defined by the profile in which the actor appears. Profiles that use this actor SHALL include a mapping from the data elements of the form data to the data elements of the CDA document template used to create the exported CDA.

Appendix B - Transaction Summary Definitions

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Transaction	Definition
[QRPH-45] Communicate Hearing Screening Data	This transaction is used to communicate hearing screening result information.

Glossary

Glossary Term	Definition
Transclusion	An inclusion within a template design makes use of another template by "virtually" copying the included template definitions, also known as transclusion. In essence this means that template definitions are included by reference and shown as-is on demand, i.e., at time of displaying the template or using it for the creation of validation scripts. Inclusion is automatic and transparent to the user.

Volume 1 – Profiles

X Early Hearing Detection and Intervention (EHDI) Profile

325 The EHDI Profile describes the content needed to create a hearing plan of care for a newborn. The EHDI Profile specifies a Hearing Plan of Care (HPoC) document that supports communication and care planning with providers who are a part of the newborn's care team. Information shared in the HPoC document helps to standardize care coordination for infants with suspected hearing loss. This information also provides interoperability between clinical EMR 330 systems and EHDI systems for increased efficiency and better data quality.

The Hearing Plan of Care document is specified to include a plan of care section which includes care instructions and recommended interventions based on jurisdictional guidelines and care best practices, given the clinical condition of the newborn. It also includes the newborn hearing screening outcome and the screening results used to assess that outcome. It also includes other

335 clinical information considered relevant in the detection and intervention process of developing a hearing plan of care for a newborn, such as risks relevant for hearing problems, procedures performed during the birth encounter, and other health problem concerns.

The EHDI Profile also specifies the message content for transmitting hearing screening observations from hearing screening devices to other systems that process the screening result

340 information. The message content also can be used to automate population of hearing screening results in the HPoC document.

Finally, the EHDI Profile also specifies the data element mapping needed to populate a form designed to capture structured data for hearing screening results and risk indicators. The form is used to manually capture hearing screening results and risk indicators when those data are not available for automated population.

X.1 Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://ihe.net/Technical_Frameworks/.

350 Figure X.1-1 shows the actors directly involved in the EHDI Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.

The EHDI Profile defines how to exchange data required to populate a newborn's Hearing Plan of Care document.

First, content for the creation of the HPoC document is defined. Optionally, the system that creates the HPoC document may receive hearing screening result information via an HL7

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Hearing Screening Message with the IHE Communicate Hearing Screening Data [QRPH-45] transaction.

360 Second, a form-based data collection method is defined using transactions from the ITI Retrieve Form for Data Capture (RFD) Profile. The optional RFD pre-population mechanism to supplement human data entry is constrained to use a standard CCD^{®3} document. The CCD document may be used to pre-populate a form designed to capture hearing screening results and risk indication information.

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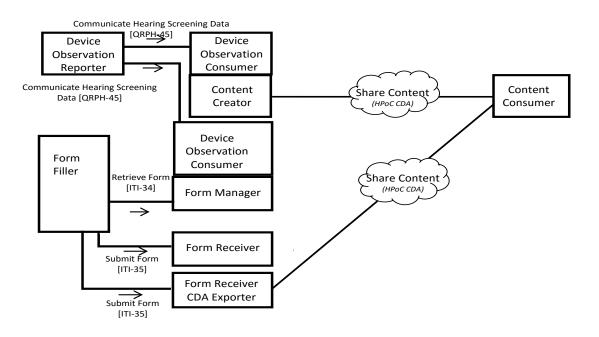


Figure X.1-1: EHDI Actor Diagram

370 Table X.1-1 lists the transactions used in the EHDI Profile. To claim support with this profile, an actor shall support all required transactions (labeled "R") and may support optional transactions (labeled "O").

³ CCD is the registered trademark of Health Level Seven International.

Actors	Transactions	Optionality	TF Reference
Device Observation Reporter	Communicate Hearing Screening Data [QRPH-45]	R	QRPH TF-2: 3.45
Device Observation Consumer	Communicate Hearing Screening Data [QRPH-45]	R	QRPH TF-2: 3.45
Content Creator	None		
Content Consumer	None		
Form Filler	Retrieve Form [ITI-34]	R	ITI TF-2b: 3.34
	Submit Form [ITI-35]	R	ITI TF-2b: 3.35
Form Manager	Retrieve Form [ITI-34] R ITI '		ITI TF-2b: 3.34
Form Receiver	Submit Form [ITI-35] R IT		ITI TF-2b: 3.35
Form Receiver CDA Exporter	Submit Form [ITI-35]	R	ITI TF-2b: 3.35

Table X.1-1: EHDI Profile - Actors and Transactions

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Table X.1-2 lists the content module(s) defined in the EHDI Profile. To claim support with this profile, an actor shall support all required content modules (labeled "R") and may support optional content modules (labeled "O").

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Table X.1-2: EDHI Profile - Actors and Content Modules

Actors	Content Modules	Optionality	Reference
Device Observation Reporter	None		
Device Observation Consumer	None		
Content Creator	Hearing Plan of Care 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1	R	QRPH TF-3: 6.3.1.D1
Content Creator (with US Realm Option)	Hearing Plan of Care 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1	R	QRPH TF-4: 6.3.1.D1
Content Consumer	Hearing Plan of Care 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1	R	QRPH TF-3: 6.3.1.D1
Content Consumer (with US Realm Option)	Hearing Plan of Care 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1	R	QRPH TF-4: 6.3.1.D1
Form Filler (with CCD Prepop Option)	CCD 2.16.840.1.113883.10.20.22.1.2	R	HL7 C-CDA R2.1
Form Manager	CCD 2.16.840.1.113883.10.20.22.1.2	R	HL7 C-CDA R2.1
Form Receiver	None	Note 1	

Actors	Content Modules	Optionality	Reference
Form Receiver CDA Exporter	Hearing Plan of Care 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1	R (Note 1)	QRPH TF-3: 6.3.1.D1
Form Receiver CDA Exporter (with US Realm Option)	Hearing Plan of Care 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1	R (Note 1)	QRPH TF-4: 6.3.1.D1

Note 1: The format for form data submitted in the [ITI-35] transaction is not constrained by this profile. Systems implementing the Form Receiver or the Form Receiver CDA Exporter are responsible for working directly with implementers of the Form Manager to understand how form data will be formatted.

X.1.1 Actor Descriptions and Actor Profile Requirements

385 Most requirements are documented throughout Volume 1 or in the Transactions specifications (Volume 2) or Content Modules (Volume 3, or, for US implementations, in Volume 4). This section documents any additional requirements on the profile's actors.

X.1.1.1 Content Creator

- The Content Creator includes processing logic to populate the HPoC document. This involves aggregating multiple screening results into one outcome assessment for each ear. The processing method is jurisdictionally defined and is not constrained by this profile. Correct processing can be determined through human comparison of the given jurisdictional method and the system generated screening outcomes.
- The Content Creator also includes the processing logic to generate planned interventions in the Plan of Care section of the HPoC document based on information documented in other sections of the HPoC document.

QRPH TF-1: Appendix D includes non-normative guidance about the processing logic used by Content Creators to populate the HPoC document.

QRPH TF-1: Appendix E includes non-normative guidance used by Content Creators to populate 400 the HPoC document Header.

X.1.1.2 Content Consumer

No additional requirements.

X.1.1.3 Form Filler

The Form Filler SHALL support XHTML format of the Retrieve Form transaction. See ITI TF-2b: 3.34.4.2.3.1

The Form Filler MAY support the pre-population option using a CCD document with the Retrieve Form [ITI-34] transaction.

The Form Filler SHALL be able to request a form designed to collect hearing screening result and hearing risk information. In a scenario where multiple tests results are created for the newborn before discharge, there is no expectation that the Form Filler, can request a particular

410 newborn before discharge, there is no expectation that the Form Filler can request a particular

form by Form Instance ID. Each form request retrieves a new form of the type used to record a screening result.

X.1.1.4 Form Manager

The Form Manger SHALL support XHTML for the Retrieve Form transaction. See ITI TF-2b: 3.34.4.2.3.1

The Form Manager SHALL accept pre-populated data in the form of a CCD, and return a form designed to collect hearing screening information. When a CCD document is not provided to pre-populate the form, the requested form is returned using just the data supplied in the Request Form message in [ITI-34]. (Note: The EHDI Profile does not reference a specific form;

420 therefore, it is left to implementers to determine the needed form and associate data available in the pre-pop data with their established form.)

The Form Manager is responsible for linking data sets, reconciling differences, and using data to pre-populate the form.

QRPH TF-1: Appendix C includes a sample form that Form Managers can review to visual a
 possible form representation for the information collected to support creation of an HPoC document.

X.1.1.5 Form Receiver

The Form Receiver SHALL process data from the form, thereby implementing accurate consumption of data represented in the form.

430 The Form Receiver processes screening results based on jurisdictional guidelines. Specification of those guides is outside the scope of this profile.

The format for form data submitted to the Form Receiver is not further constrained by this profile. Systems implementing the Form Receiver or the Form Receiver CDA Exporter are responsible for working directly with implementers of the Form Manager to understand how form data will be formatted.

435 form data will be formatted.

X.1.1.6 Form Receiver CDA Exporter

The Form Receiver CDA Exporter SHALL receive the populated form when it is submitted by the Form Filler.

440 The Form Receiver CDA Exporter SHALL be able to accumulate one or more hearing screening 440 result forms for a single patient and combine the results according to a jurisdictionally defined 440 method in order to formulate the outcome section of the HPoC. The method is not constrained by 440 this profile.

When the Form Receiver CDA Exporter produces an HPoC, the results received up to that point in time for the patient SHALL be aggregated into the HPoC document based on mapping rules

445 for the Form Receiver CDA Exporter specified in QRPH TF-3: 6.3.1.D.4 (Data Element Mappings for CDA Export).

Systems implementing the Form Receiver or the Form Receiver CDA Exporter are responsible for working directly with implementers of the Form Manager to understand how form data will be formatted

450 QRPH TF-1: Appendix D includes non-normative guidance about the processing logic used by Form Receiver CDA Exporter to populate the HPoC document.

QRPH TF-1: Appendix E includes non-normative guidance used by Form Receiver CDA Exporter to populate the HPoC document Header.

X.1.1.7 Device Observation Reporter (DOR)

455 The format of the information coming from the hearing screening device is not specified in this profile. This profile does not specify how the device formats the result information or how the Device Observation Reporter translates input files provided by the device.

Note: For US Realm implementations see QRPH TF-4: 4.R1.2.1 for additional US Realm message constraint information.

460 X.1.1.8 Device Observation Consumer (DOC)

The Device Observation Consumer SHALL be grouped with either the Content Creator or the Form Manager. This grouping enables the collected hearing screening results to be formulated into a Hearing Plan of Care document that shares the most conclusive screening result and the history of screening, and the other hearing plan of care information with the Content Consumer.

465 Note: For US Realm implementations see QRPH TF-4: 4.R1.2.1 for additional US Realm message constraint information.

X.2 Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table X.2-1. Dependencies between options when applicable are specified in notes.

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Actor	Option Name	Reference
Device Observation Reporter	None	
Device Observation Consumer	None	
Content Creator	Automated Result Capture	Section X.2.1
	US Realm	Section X.2.2
Content Consumer	US Realm	Section X.2.2
Form Filler	CCD Pre-Pop	Section X.2.3
Form Manager	Automated Result Capture	Section X.2.1
Form Receiver	None	

Table X.2-1: HPoC – Actors and Options

Actor	Option Name	Reference
Form Receiver CDA Exporter	US Realm	Section X.2.2

X.2.1 Automated Result Capture Option

The Automated Result Capture Option provides a more efficient and less error-prone method for capturing hearing screening results directly from the screening device. It eliminates manual entry of the screening result information.

A Content Creator that supports this option SHALL be grouped with the Device Observation Consumer defined in this profile.

A Form Manager that supports this option SHALL be grouped with a Device Observation

480 Consumer from this profile and shall consume messages conforming to the HL7 Version 2.6 Implementation Guide: Early Hearing Detection and Intervention (EHDI) Messaging, Release 1.

Note: For US Realm implementations see Volume 4 for additional US Realm message constraint information.

X.2.2 US Realm Option

485 The US Realm Option supports semantic data representation that uses code systems accepted as common standards in the United States which improves interoperability.

A Content Creator that supports this option SHALL create HPoC documents that conform to the US Realm template specifications. See QRPH TF-4:8 for US Realm specifics.

490 A Content Consumer that supports this option SHALL consume HPoC documents that conform to the US Realm template specifications.

A Form Receiver CDA Exporter that supports this option SHALL create HPoC documents that conform to the US Realm template specifications.

X.2.3 CCD Pre-pop Option

495 The CCD Pre-pop Option automates the re-use of information available in a standard CCD 495 document to efficiently populate fields of information required on a form designed to collect hearing screening information.

A Form Filler that supports this option SHALL supply a CCD document when initiating the Retrieve Form [ITI-34] transaction.

X.3 Required Actor Groupings

500 An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile *in addition to* all of the transactions required for the grouped actor (Column 2).

If this is a content profile, and actors from this profile are grouped with actors from a workflow or transport profile, the Content Bindings reference column references any specifications for mapping data from the content module into data elements from the workflow or transport transactions.

In some cases, required groupings are defined as at least one of an enumerated set of possible actors; this is designated by merging column one into a single cell spanning multiple potential grouped actors. Notes are used to highlight this situation.

510 Section X.5 describes some optional groupings that may be of interest for security considerations and Section X.6 describes some optional groupings in other related profiles.

EHDI Actor	EHDI Actor to be grouped with	Reference	Content Bindings Reference
Content Creator	None		
Device Observation Reporter	None		
Device Observation	Content Consumer	Section X.1.1.7	
Consumer Note 1	Form Manager	Section X.1.1.4	
Content Creator	None		
Content Consumer	None		
Form Filler	None		
Form Manager	None		
Form Receiver	None		
Form Receiver/CDA Exporter	None		

Table X.3-1: HPoC - Actor Groupings

Note 1: the Device Observation Consumer SHALL be grouped with either the Content Consumer or Form Manager.

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X.4 Overview

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Early Hearing Detection and Intervention (EHDI) is a United States-based (US) public health program that directs hospitals to screen newborns for hearing loss prior to hospital discharge. However, the UV Realm specifications in QRPH TF-3 support base requirements for other realms. The EHDI Profile specifies information to be documented and communicated which assists in the detection and delivery of care for hearing loss in newborns. The Hearing Plan of Care (HPoC) document can be made available to all authorized care providers as jurisdictionally directed by the Public Health EHDI program. The HPoC provides best practice hearing guidance on next steps and actions that must be initiated for each newborn following discharge from the hospital nursery. It includes clinical content pertinent to EHDI care programs such as screening 525

results, risk indicators for hearing loss, interventions, and most importantly care plan instructions for management of the patient. The EHDI Profile establishes standards for how to compile and exchange information for an HPoC. It is envisioned that this HPoC document will record a child's hearing plan of care from birth going forward over the course of their life.

530 **X.4.1 Concepts**

As an information artifact, a Hearing Plan of Care (HPoC) document is ultimately intended to compile several types of information relevant for a Hearing Plan of Care. It documents the child's active problems, procedures, screenings, and relevant risk indicators, and includes a plan of care related to hearing health, based on the medical history/evidence, and in keeping with best practices and jurisdictionally defined protocols. As the design evolves, it will also include diagnostic testing and other forms of intervention activities relevant for early hearing detection

and intervention.

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A hearing screening outcome is an overall interpretation of available hearing screening results gathered from one or more screening test. A hearing screening result is the actual measures reported from a screening device when a screening is performed. The measured result may include contextual information indicating how the measured result is interpreted, or it may include just the measured value produced by the device. A hearing screening outcome considers one or more screening result and assigns a value and possibly an interpretation, based on jurisdictionally defined practices.

545 **X.4.2 Use Cases**

X.4.2.1 Use Case #1: Share Hearing Plan of Care (HPoC)

X.4.2.1.1 Use Case Description

A system implementing the Content Creator generates an HPoC document and shares it with a system implementing the Content Consumer. For example, sharing could use mechanisms from XDS.b, XDR, XDM, Direct, or some other means of transport.

This scenario might apply to an EMR system that produces and shares an HPoC document with a Public Health EHDI-IS, a Health Information Exchange (HIE), or another EMR for a Primary Care Clinician or Specialist.

X.4.2.1.2 Processing Steps

555 X.4.2.1.2.1 Pre-conditions

The Content Creator has access to all the hearing screening result data and other clinical and demographic data needed to populate and construct a Hearing Plan of Care document.

X.4.2.1.2.2 Main Flow

The Content Creator creates and shares the HPoC document.

560 The Content Consumer receives/retrieves the HPoC document and processes it.

X.4.2.1.2.3 Post-conditions

Information and care planning instructions prepared by the Content Creator are now available in the system implementing the Content Consumer.

X.4.2.1.3 Process Flow

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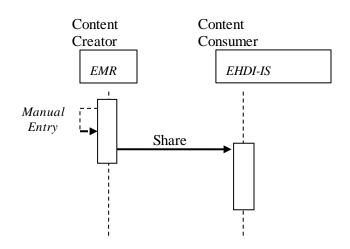


Figure X.4.2.1.3-1: Process Flow Diagram

X.4.2.2 Use Case #2: Collect Screening Results Then Share HPoC

570 X.4.2.2.1 Use Case Description

A screening device or system responsible for communicating screening results electronically provides the screening result to a system which consumes the results. The system which receives the results generates the HPoC document and shares it with a system implementing the Content Consumer. Sharing of the HPoC document could use mechanisms from XDS.b, XDR, XDM, Direct, or some other means of transport.

This scenario might apply to an EMR system or a Public Health EHDI-IS that can receive and process electronic results from screening devices then produce and share a HPoC document through a Health Information Exchange (HIE), or with another EMR system for a Primary Care Clinician or Specialist.

580 X.4.2.2.2 Processing Steps

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X.4.2.2.2.1 Pre-conditions

A Device Observation Reporter (DOR) is available to populate a Hearing Screening Result Message and initiate a [QRPH-45] transaction to send that information to a Device Observation Consumer. The hearing screening device itself could act as the Device Observation Reporter. Alternatively, a system that receives device information, by a means not defined in this profile, could act as the Device Observation Reporter.

The system acting as the Content Creator also has the ability to act as a Device Observation Consumer.

X.4.2.2.2.2 Main Flow

590 Step 1. The Content Creator, acting as a Device Observation Consumer receives and processes the hearing screening result data from the Device Observation Reporter.

Optionally repeat Step 1. The communication between Device Observation Reporter and Device Observation Consumer happens each time the newborn is screened. A newborn may be screened multiple times to establish a conclusive result for the birth encounter.

595 Step 2. The Device Observation Consumer/Content Creator processes all the screening results and other data needed to populate and construct a Hearing Plan of Care.

Step 3. The Content Creator creates and shares the HPoC document.

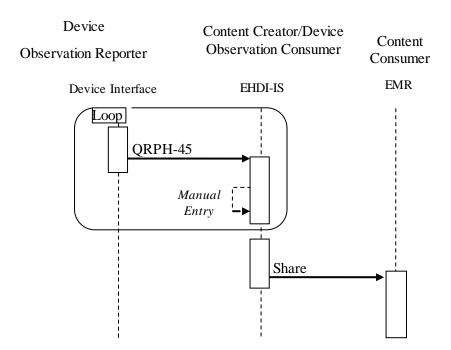
Step 4. The Content Consumer receives/retrieves the HPoC document and processes it.

X.4.2.2.2.3 Post-conditions

600 Information and care planning instructions prepared by the Content Creator are now available in the system implementing the Content Consumer.

X.4.2.2.3 Process Flow

Device Observation Consumer



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Figure X.4.2.2.3-1: Process Flow Diagram

X.4.2.3 Use Case #3: RFD for Newborn and Hearing Screening Result Data Capture and HPoC Export

X.4.2.3.1 Use Case Description

- 610 A system implementing the Form Filler interacts with a system implementing the Form Manager. The Form Manager provides a form-based mechanism which allows users of the Form Filler system to enter the data needed to populate an HPoC document. To minimize data entry, the Form Filler may provide a CCD document which the Form Manager can use to pre-populate the form. A Form Receiver CDA Exporter, receives the fully populated form, creates the HPoC Document, and then shares it with a system implementing the Content Consumer.
- Document, and then shares it with a system implementing the Content Consumer.

The HPoC Document could be shared using XDS.b, XDR, XDM, Direct, or some other means of transport.

This scenario might apply to an EMR system that interoperates with an EHDI-IS that can accept manual entry of hearing screening results then produce and share a HPoC document through a

620 Health Information Exchange (HIE), or with another EMR for a Primary Care Clinician or Specialist.

X.4.2.3.2 Processing Steps

X.4.2.3.2.1 Pre-conditions

The Form Filler creates a CCD document to supply data needed to populate the form used to gather Hearing Screening data elements. In this use case, the system implementing the Form Filler does not have the means to capture hearing screening information from the device, so this data is entered manually.

X.4.2.3.2.2 Main Flow

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Step 1. The Form Filler requests a form designed to gather the data needed for an HPoC document. It includes a CCD to pre-populate the form with available data.

Step 2. The Form Manager processes the pre-populated CCD and returns the populated form.

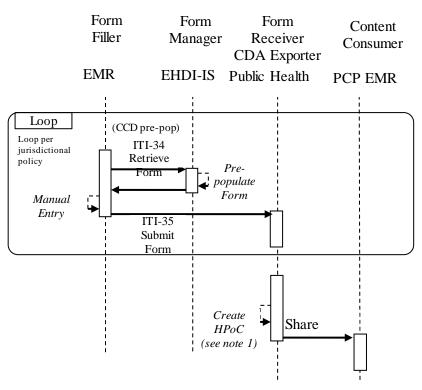
Step 3. The Form Filler submits the form for processing. The Form Receiver CDA Exporter receives the form data and then processes it to create and share an HPoC document.

Step 4. The Content Consumer receives/retrieves the HPoC document and processes it.

635 X.4.2.3.2.3 Post-conditions

Information and care planning instructions are now available in the system implementing the Content Consumer.

X.4.2.3.3 Process Flow



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Figure X.4.2.3.3-1: Process Flow Diagram

Note 1: Specification of the discharge event trigger mechanism to initiate creation of the Hearing Plan of Care document is out of scope for the EHDI Profile. The profile shows the HPoC is created "at the point of Discharge". This could be triggered manually or in an automated fashion. Document-based workflows are one means of creating standard processes for such workflows. Consult the IHE QRPH EHDI-WD Profile for more information on a document based workflow which includes triggering the production of a Hearing Plan of Care when the discharge care summary document becomes available. Also note, an HPoC MAY be generated at more times than just the discharge from the birth encounter.

X.4.2.4 Use Case #4: Automated Hearing Screening Result Data Capture and RFD650for Newborn and HPoC Export

X.4.2.4.1 Use Case Description

A system implementing the Form Filler interacts with a system implementing the Form Manager. The Form Manager provides a form-based mechanism which allows users of the Form Filler system to enter the data needed to populate an HPoC document. To minimize data entry, the Form Filler may provide a CCD document which the Form Manager can use to pre-populate the form.

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In this combination scenario, the Form Manager implements the Device Observation Consumer Option. This enables the Form Manager to automate the population of screening results gathered directly from the screening device. This minimizes the amount of information that needs to be manually populated by the Form Filler.

A Form Receiver CDA Exporter receives the fully populated form, creates the HPoC Document and then shares it with a system implementing the Content Consumer. The Form Receiver CDA Exporter includes the processing logic to needed to populate the document which involves aggregating multiple screening results into one outcome according to a jurisdictionally defined method. The method is not constrained by this profile.

This scenario might apply to an EMR system that interoperates with an EHDI-IS that can accept manual entry of hearing screening result. The EMR obtains the data from the EHDI-IS and then produces and shares an HPoC document through a Health Information Exchange (HIE), or with another EMR for a Primary Care Clinician or Specialist.

670 X.4.2.4.2 Processing Steps

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X.4.2.4.2.1 Pre-conditions

A Device Observation Reporter is available to populate a Hearing Screening Result Message and initiate a [QRPH-45] transaction to send that information to a Form Manager implementing the Device Observation Consumer Option.

675 The Form Filler creates a CCD document to supply data needed to populate the form used to gather HPoC data elements.

X.4.2.4.2.2 Main Flow

The Form Manager has the ability to act as a Device Observation Consumer and receives and processes the hearing screening result data from the screening device. It processes the screening results and other data needed to populate and construct a Hearing Plan of Care.

The Form Filler requests a form designed to gather the data needed for an HPoC document. It includes a CCD to prepopulate the form with available data.

The Form Manager processes the pre-populated CCD and returns the populated form.

The Form Filler submits the form for processing. The Form Receiver CDA Exporter receives the form data, processes it to create and share an HPoC document.

The Content Consumer receives/retrieves the HPoC document and processes it.

X.4.2.4.2.3 Post-conditions

Information and care planning instructions are now available in the system implementing the Content Consumer.

690 X.4.2.4.3 Process Flow

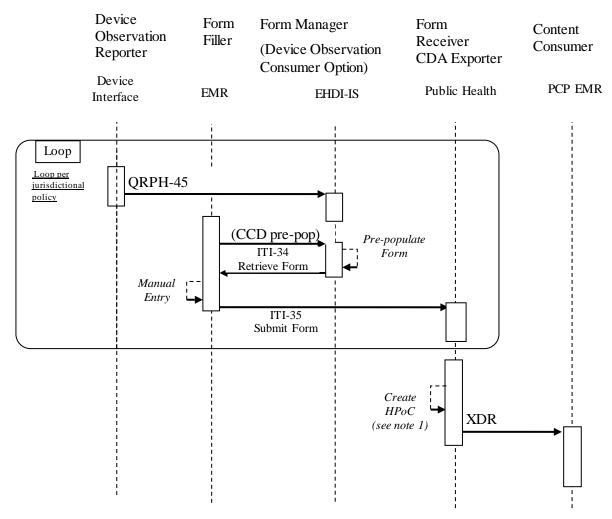


Figure X.4.2.4.3-1: Process Flow Diagram

Note 1: The trigger to initiate the Hearing Plan of Care document is out of scope for the EHDI Profile. The profile specifies it is created "at the point of Discharge". This could be triggered manually or in an automated fashion. Document-based workflows are one means of creating standard processes for such workflows. Consult the IHE QRPH EHDI-WD Profile for more information on a document based workflow which includes triggering the production of a Hearing Plan of Care when the discharge care summary document becomes available.

X.5 Security Considerations

700 EHDI includes clinical content related to the information subject. As such, it is anticipated that the transfers of Protected Health Information (PHI) SHOULD be processed using best practices. Systems implementing IHE transactions which transfer PHI SHOULD include capabilities described in the IHE ITI Audit Trail and Node Authentication (ATNA) Integration Profile. Other

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private security mechanisms MAY be used to secure content within enterprise managed systems. 705 Specifications for ATNA logging for RFD transactions are covered in QRPH CRD TF-2:5.

Actors responsible for creating persistent content, in the form of a saved form or CDA document, MAY include a digital signature using the ITI Digital Signature (DSG) Profile to assure that the form content submitted cannot be changed.

For security purposes, when sending information to Public Health, specifically to vital records Electronic Registration Systems, systems will also may need to know the identity of the user and the location to identify the of the data source. In this case, the ITI Cross-Enterprise User Assertion (XUA) and ATNA Profiles MAY be utilized to support this implementation.

X.6 Cross Profile Considerations

The following informative narrative is offered as implementation guidance.

715 X.6.1 ITI Document Sharing Profiles

The use of the IHE family of transactions for cross-enterprise document sharing is encouraged to support standards-based interoperability between systems acting as Content Creator and Content Consumer. The grouping of Content Creator and Content Consumer Actors with ITI actors from this family of profiles is defined in the PCC Technical Framework (PCC TF-2:3.1).

- 720 Document sharing profiles support infrastructure, security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) Profiles. A Time Client in CT might be grouped with the Content Creator and the Content Consumer. A Secure Node and/or a Secure Application in ATNA might be grouped with the Content Creator and the Content Creator and the Content Consumer.
- 725 Detailed description of these transactions can be found in the IHE IT Infrastructure Technical Framework.

X.6.2 Sharing Value Set (SVS)

Actors in the EHDI Profile may support the ITI Sharing Value Set (SVS) Profile in order to use a common uniform managed vocabulary for dynamic management of form mapping rules.

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Appendices

Appendix A – New Actors

The EHDI Profile does not define any new actors.

Appendix B – New Transactions

Transaction	Definition
[QRPH-45] Communicate Hearing Screening Data	This transaction is used to communicate hearing screening result information.

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Appendix C – Sample Form

A sample form is implemented using Excel and is included in the supporting materials for this technical supplement located at <u>ftp://ftp.ihe.net/TF_Implementation_Material/QRPH/EHDI/</u>.

Appendix D – HPoC Content Creator Processing Logic Guidance

740 The following material is not normative. It does not define specific processing requirements for the Content Creator in the Early Hearing Detection and Intervention (EHDI) Profile. The information in this appendix is intended to help implementers understand the processing capabilities that may be implemented in an application supporting the EHDI Content Creator.

D.1 Processing Logic for determining the hearing screening outcome

- 745 When a newborn's hearing is screened multiple times during the birth encounter, multiple hearing screening results are available for the baby. For quality assessment of the hearing screening process, all hearing screening and the associated results should be documented. The time of the hearing screening is a key factor in assessing the process quality and in determining the outcome that should be assigned for hearing screening during the encounter.
- 750 To automate outcome assessment, all hearing screening results should be captured and exchanged. The information captured needs to include the date/time when the screening was performed as well as the result. The information transmitted also needs to include associated visit information so the results associated with a specific encounter can be identified.
- When a set of hearing screenings is provided (along with the needed date/time and visit information) then the hearing screening outcome for the visit can be computed according to a jurisdictionally defined algorithm. For example, the defined algorithm could be to use the results of the final hearing screening as the screening outcome. Alternatively, the algorithm could set the screening outcome to be "refer" if any of screening results indicated to refer. The algorithm could set the screening outcome to be "pass" if any of the screening results indicated a pass. The
- algorithm could limit the number of hearing screenings to the first two performed. Each jurisdiction may establish their own criteria for determining the outcome of the hearing screening. The Content Creator needs to include whatever processing may be required when multiple hearing screening results are reported.

D.2 Processing Logic for populating a Plan of Care Section in the HPoC

A system supporting the EHDI Content Creator may populate the Plan of Care section of the HPoC with certain interventions based on jurisdictionally defined hearing care guidelines. Information documented in the HPoC may be used to determine which interventions to include in the Plan of Care section. Given a set of possible care planning actions, information about a baby's screening outcomes for left and right ear, reasons why screening was not performed, and other risk factors, an algorithm can be defined to determine which actions should be recommended in the plan of care.

For example, consider a scenario with the following set of care planning actions and see how a set of data elements can be used to determine the actions to be recommended in the plan of care.

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Set of Possible Care Planning Actions:

Review Hearing Screening with Family

Conduct risk indicator assessment for late onset hearing loss

Provide parents with information about hearing, speech, and language milestones

Conduct additional screening if there is parental concern for speech and language development at any well- child visit

Refer for outpatient screening

Refer for audiology assessment

Refer to early intervention specialist

Left Outcome	Left Reason not screened	Right Outcome	Right Reason not screened	Risks	Plan of Care Recommended Action
pass		pass		None	Review Hearing Screening with Family Conduct risk indicator assessment for late onset hearing loss Provide parents with information about hearing, speech, and language milestones Conduct additional screening if there is parental concern for speech and language development at any well- child visit
refer		refer		>=1	Review Hearing Screening with Family Provide parents with information about hearing, speech, and language milestones Refer for audiology assessment

Appendix E – Header Element Mappings

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Appendix E includes an analysis of the use cases to determine their relevance to the information included in the Hearing Plan of Care (HPoC) document header. This information helps to explain the meaning associated with the header elements of the CDA document implemented in the Early Hearing Detection and Intervention (EHDI) Profile as they relate to the data elements used in the profile environment.

Participation	Description of how this role pertains to the EHDI environment
RecordTarget (R) Guardian providerOrganization	Baby Birthplace is populated for the baby. Mother (or other edge cases); multiple allowed, so Dad can go here too. This will be the hospital where the baby is a patient when the screening was done.
Author (R)	There are cases where The current Healthcare Organization – Person, Organization, the parent Organization. May be the Hospital. The author will be the sending Hospital in the Organization. In some states, it is the Hospital's responsibility to make sure the child gets follow-up care Or more likely, the author would the state Public Health organization be the author of the plan. System Author is the system that creates the HPoC This question needs to be addressed for each implementation.
Custodian (R)	The state Public Health organization. In some states, it is the Hospital's responsibility to make sure the child gets follow-up care The custodian will be the same as the author. Or, this may be a "policy question" that needs to be negotiated for the implementation. This could be an HIE. This question needs to be addressed for each implementation.
Data Enterer	May be reserve this possibility for manual entry. May not be relevant.
Particip ant	NOK - Note that the CDA will support the baby's guardian to be expressed in the recordTarget.guardian element, so only relatives who are not wards over the child should be represented as NOK participants.
Informant	Not relevant at the document level.
Authenticator	The Authenticator role functions as specified in HL7 Digital Signature standard.
Legal Authenticator	The Legal Authenticator role functions as specified in the HL7 Digital Signature standard.

E.1 Header Participations – Hearing Plan of Care

Participation	Description of how this role pertains to the EHDI environment
Information Recipient	The Information Recipient, as defined in the CDA R2 standard, represents a recipient who should receive a copy of the document. NOTE: The information recipient is an entity to whom a copy of a document is directed, at the time of document authorship. It is not the same as the cumulative set of persons to whom the document has subsequently been disclosed, over the life-time of the patient. Such a disclosure list would not be contained within the document and it outside the scope of CDA. A document can have multiple information recipients. This role can be encoded so as to distinguish a receiver to which the document is "primarily directed" from a receiver to which the document is "secondarily directed". This nuance suggests the possibility for some very granular use cases where a specific physician is the primary information recipient. Also note, as consumers begin to have access to systems that permit them to create and receive CDA documents, a parent could be included as an information recipient. Specification of these very detailed use cases is outside the scope of the specific.

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E.2 Header Act Relationships

Participation	Describe how this context pertains to the profiled environment
ComponentOf.EncompassingEncounter	The current healthcare organization will be listed in the HealthcareFacility structure
DocumentationOf.ServiceEvent	The service event of the screening will be documented if it occurred and the service event of the creation of the Hearing Plan of Care will be documented.
InFulfillmentOf.Order	Out of Scope
Authorization.Consent	Out of Scope
RelatedDocument.ParentDocument	Out of Scope

Appendix F – Data Elements

Appendix F includes the brief definitions of data elements used in the Early Hearing Detection and Intervention (EHDI) Profile.

790 **F.1 Data Element Definitions for the Receiving System**

The data element label is a unique identifier for the data element. It can be a code used to identify the data element in the domain where it is used, or it can be an ID that is assigned within this profile to uniquely identify the data element concept.

The data element name is a human readable name for the concept.

795 The data element definition describes the meaning of the concept and expresses the information it represents in the form of a question.

The answer data type is one of several data types defined for use with the HL7 CDA R2 standard. All the answers to the question representing the data element must be of the same data type.

800 The name of the answer value set is assigned in this specification. The name uniquely identifies the particular set of allowable answers for this data element.

The Answer Value Sets are documented in QRPH TF-4:8.7.

Data Element Label	Data Element Name	Data Element Definition (i.e., what question does it answer)	Answer Data Type	Name of the Answer Value Set
Results.LeftEar Outcome		What was the outcome for the Left Ear?	CD	
Results.LeftEar Outcome effectiveTime		When was the screening outcome for the Left Ear determined?	TS	
ReasonLeftEar not screened		What was the reason for not performing any screening on the Left Ear?	CD	
Results.RightEar Outcome		What was the outcome for the Right Ear?	CD	
Results.RightEar Outcome effectiveTime		When was the screening outcome for the Right Ear determined?	CD	
Reason RightEar not screened		What was the reason for not performing any screening on the Right Ear?	CD	

F.1.1 Data Elements

Data Element Label	Data Element Name	Data Element Definition (i.e., what question does it answer)	Answer Data Type	Name of the Answer Value Set
Results.OutcomeAuthor		Who authored the outcomes	AssignedEntity	
Reason LeftEar not screened		What was the reason for not performing this screening on the Left Ear?	CD	
Results.LeftEar method of Screen		What method was used to screen the left ear?	CD	
Results.LeftEar effectiveTime for Screen		What time did the screening of the left ear begin and end? Or begin and take as a duration?	TS_IVL	
Results.LeftEar Result		What was the screening result for the left ear?	CD or value	
Results.LeftEar Reason No Result		What was the reason for the screening procedure not producing a result?	CD	
Result.LeftEar Result Performer		Who performed the Left Ear Screening?	Entity	
Result.LeftEar Result Author		Who authored the Left Ear Screening Result?	M ay be an Entity or a Device	
Reason RightEar not screened		What was the reason for not performing this screening on the Right Ear?	CD	
Results.RightEar method of Screen		What method was used to screen the Right ear?	CD	
Results.RightEar effectiveTime for Screen		What time did the screening of the Right ear begin and end?	TS_IVL	
Results.RightEar Result		What was the screening result for the Right ear?	CD or value	
Results.RightEar Reason No Result		What was the reason for the screening procedure not producing a result?	CD	
Result.RightEar Result Performer		Who performed the Right Ear Screening?	Entity	
Result.RightEar Result Author		Who authored the Right Ear Screening Result?	M ay be an Entity or Device	
RiskFactors. RiskIndicators		Which of the identified Risk Indicators are present?	CD	
Risk Factors Author		Who Authored the Risk Factors?	Entity	

Data Element Label	Data Element Name	Data Element Definition (i.e., what question does it answer)	Answer Data Type	Name of the Answer Value Set
HPoC Problems.Problem List		What is the history of the Active and Inactive Concerns which are relevant for Hearing Care Planning?		
Problems. Problem List		What is the history of the Active and Inactive Concerns?	CD	
Problems Author		Who Authored the Problem Section?	Entity	
HPoC Procedures. History of Procedures		What is the history of procedures which are relevant for Hearing Care Planning?	CD	
Procedures. History of Procedures		What is the history of procedures?	CD	
Procedures Author		Who Authored the Procedures Section?	Entity	
Plan of Care. Instructions		What instructions are provided?	CD	
Plan of Care. Interventions		What interventions are recommended?	CD	
Plan of Care Section Author		Who authored the Hearing Plan of Care Section	Entity or Device, may be both?	
HPOC Document Author		Who authored the Hearing Plan of Care Document	Entity or Device, may be both?	
HPOC Document Custodian		Who is the custodian of the Hearing Plan of Care Document	Jurisdictionally Defined	

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Volume 2 – Transactions

3 IHE QRPH Transactions

This section defines each IHE transaction in detail, specifying the standard used, the information transferred, and the conditions under which the transaction is required or optional.

3.45 QRPH-45 Communicate Hearing Screening Data

810 This section specifies Transaction [QRPH-45] of the IHE Quality, Research and Public Health Framework, which is used to transmit Hearing Screening data between Device Observation Reporter and Device Observation Consumer Actors.

This transaction is similar to the Communicate PCD Data [PCD-01] transaction defined to communicate device data in the IHE Patient Care Devices Technical Framework PCD TF-2:3.1.

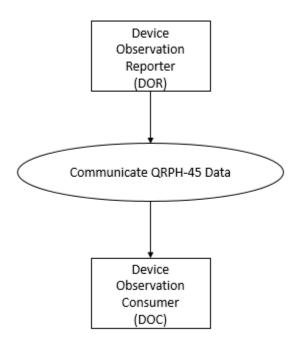
- 815 Both the [QRPH-45] and the [PCD-01] transactions constrain a HL7 ORU message. However, the message semantics in a [QRPH-45] transaction are not based on the ISO/IEEE 11073-10101 nomenclature/terminology and the ISO/IEEE 11073-270 10201 domain information model. The message structure in a [QRPH-45] transaction is defined by the HL7 Version 2.6 Implementation Guide: Early Hearing Detection and Intervention (EHDI) Messaging, Release 1 standard. The
- 820 concept semantics are represented using LOINC or SNOMED-CT concepts as specified in the HL7 Version 2.6 Implementation Guide.

Note that these actor names are linked to abstract functions rather than to physical devices; a Device Observation Reporter may be implemented in a freestanding system or it may be implemented in the Patient Care Device itself.

825 **3.45.1 Scope**

This transaction is used to communicate data from a Device Observation Reporter (DOR) to a Device Observation Consumer (DOC).

3.45.2 Use Case Roles



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Figure 3.45.2-1: Communicate Hearing Screening Data

Actor:	Device Observation Reporter (DOR)
Role:	Sends Hearing Screening Data to DOC
Actor:	Device Observation Consumer (DOC)
Role:	Receives Hearing Screening Data from DOR

3.45.3 Referenced Standards

835 The [QRPH-45] transaction uses an information model and a nomenclature from the HL7 Version 2.6 Implementation Guide: Early Hearing Detection and Intervention (EHDI) Messaging, Release 1.

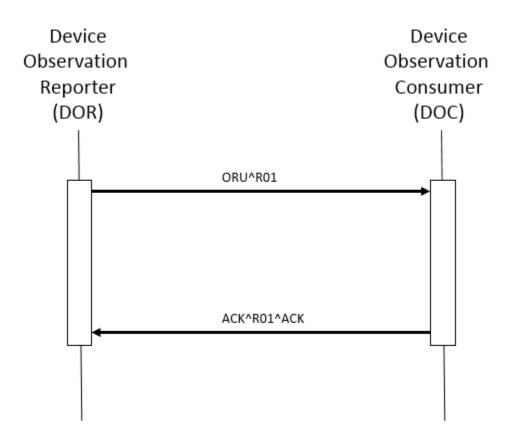
HL7 V2.6 Chapter 7 Observation Reporting defines the general HL7 syntax and coding requirements related to observation reporting. The ORU^R01 message type is used for the QRPH-45 transaction.

3.45.4 Interaction Diagram

The following interaction diagrams illustrate potential implementations.

The [QRPH-45] transaction is used to communicate Hearing Screening data from a Device Observation Reporter (DOR) to a Device Observation Consumer (DOC).

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3.45.4.1 Communicate Hearing Screening Data (ORU^R01) static

850 The [QRPH-45] transaction is used to communicate hearing screening results from a Device Observation Reporter to a Device Observation Consumer (DOC).

3.45.4.1.1 Trigger Events

The ORU^R01^ORU_R01 message is an unsolicited update initiated by the Device Observation Reporter. The ORU^R01 can be sent with or without a preceding order, since it is common in a

855 clinical setting for hearing screening data to be reported without a specific order having been transacted in the information system (that is, the reporting is the result of a "standing order" for screening newborn hearing).

The Device Observation Reporter may be implemented directly on a medical device. It also can be implemented on a gateway or intermediary device as an application which implements the

860 Device Observation Reporter. The system acting as the Device Observation Reporter receives data from one or more patient care devices using either standards-based or proprietary protocols which are outside the current scope of the IHE QRPH or PCD Technical Framework.

In general, the Device Observation Reporter sends periodic reports at an interval of between several times per minute (high acuity) and a maximum interval of 24 hours (chronic, home

865 health) with a typical interval of 1 minute. The minimum and maximum intervals are configured per implementation. The Device Observation Reporter may also send aperiodic reports for "event type" information. The Device Observation Reporter shall not do interpolation of data received from the device source.

3.45.4.1.2 Message Semantics

870 Refer to the HL7® standard for the ORU message of HL7® 2.6 Chapter 7 and the general message semantics.

Examples of ORU^R01^ORU_R01 messages are included in the supplemental materials for this profile.

- The Device Observation Reporter shall support the Message Semantics for the ORU^R01
 message as specified in the HL7 Version 2.6 Implementation Guide: Early Hearing Detection and Intervention (EHDI) Messaging, Release 1. Table 3.45.4.1.1-1 contains the segment communication requirements of the message profile. The Device Observation Reporter shall not send the segments with a Usage of "X" in Table 3.45.4.1.1-1. The key segments for this transaction are in bold and include the MSH, PID, NK1, PV1, OBR and OBX segments. The data found in these segments are key to reporting newborn hearing screening results. Data found in the other segments may be important but are not essential to enable the Device Observation
 - Consumer to interpret the message.

Segment	Meaning	Usage	Card	HL7® chapter
MSH	Message Header	R	[11]	2
[{SFT}]	Software Segment	Х	[00]	2
[UAC]	User Authentication Credential	Х	[00]	
{	PATIENT_RESULT begin			
[PATIENT begin			

Table 3.45.4.1.2-1: Segments in the Communicate Hearing	n Screening Data Message
Table 5.45.4.1.2-1. Segments in the Communicate fielding	y Scieering Data Messaye

Segment	Meaning	Usage	Card	HL7® chapter
PID	Patient Identification	R	[11]	3
[PD1]	Additional Demographics	Х	[00]	3
[{NTE}]	Notes and Comments	Х	[0 0]	2
[{NK1}]	Next of Kin/Associated Parties	RE	[0*]	3
[VISIT begin			
PV1	Patient Visit	R	[11]	3
[PV2]	Patient Visit – Additional Info	Х	[00]	3
]	VISIT end			
]	PATIENT end			
{	ORDER_OBSERVATION begin			
[ORC]	Order Common	Х	[00]	4
OBR	Observation Request	R	[13]	7
[{NTE}]	Notes and Comments	Х	[00]	2
[{ROL}]	Role for Observation	Х	[00]	15
[{	TIMING_QTY begin			
TQ1	Timing/Quantity	Х	[00]	4
[{TQ2}]	Timing/Quantity Order Sequence	Х	[00]	4
}]	TIMING_QTY end			
[CTD]	Contact Data	Х	[00]	11
[{	OBSERVATION begin			
OBX	Observation Result	RE	[1*]	7
[{NTE}]	Notes and comments	Х	[00]	2
}]	OBSERVATION end			
[{FT1}]	Financial Transaction	Х	[00]	6
[{CTI}]	Clinical Trial Identification	Х	[00]	7
[{	SPECIMEN begin			
SPM	Specimen	Х	[00]	7
[{OBX}]	Observation related to Specimen	Х	[00]	7
}]	SPECIMEN end			
}	ORDER_OBSERVATION end			
}	PATIENT_RESULT end			
[DSC]	Continuation Pointer	Х	[00]	2

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3.45.4.1.2.1 Implementer Guidance and Explanation

The message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.

- 890 The patient identification (PID) segment is used to communicate patient identifying information. In the referenced standard, race (PID-10) and EthnicGroup (PID-22) are required but may be empty (RE). The UV Realm relaxes this requirement to make inclusion of this information optional.
 - (PID-10) Race, usage relaxed to O.
- (PID-22) EthnicGroup, usage relaxed to O.

The Next of Kin segment is used to communicate information about the newborn's contacts.

The Patient Visit segment is used to communicate information on a visit-specific basis and permits results to be associated with the encompassing encounter to supply the visit context for the screening.

- 900 The observation request (OBR) segments are used to capture information about the hearing screening panel performed. One OBR is used to report the newborn hearing loss panel comments and risk factors. A second OBR is used for the newborn hearing screen panel of the right ear. A third OBR is used for the newborn hearing screen panel of the left ear.
- The Observation Result (OBX) segments within the OBRs contain information regarding 905 comments, risk factors, hearing screening results for the left ear or the right ear, screening technique (observation method), screening equipment identifier (brand, model, version, instance data, serial number (optional)), duration of screening, reason for screening not performed (if not performed). This includes identification of the specific type of observation, the observation itself, and when the observation was made, i.e., the date and time of the screening.
- 910 Refer to the HL7 Version 2.6 Implementation Guide: Early Hearing Detection and Intervention (EHDI) Messaging, Release 1 for the detailed specifications of the ORU^R01 message content in each segment.

3.45.4.1.3 Expected Actions

The ORU^R01^ORU_R01 message is sent from the DOR to the DOC. Upon receipt, the DOC validates the message and responds with an acknowledgement as defined in Section 3.45.4.2.

The DOC will process the contents of the ORU according to the features and functions of its application. That functionality is not constrained by this transaction

3.45.4.2 Acknowledge Communicate Hearing Screening Data (ACK^R01^ACK)

Guaranteed delivery is required. The Device Observation Consumer SHALL generate and return an ACK message L always be returned to the Device Observation Reporter. All other acknowledgement methods are beyond the scope of this document. Refer to the HL7 Version 2.6 Implementation Guide: Early Hearing Detection and Intervention (EHDI) Messaging, Release 1, in Chapter 5.3, for MSA specifications and for value set bindings for ERR-3 (HL7 Error Code) and ERR-4 (Severity).

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Segment	Name	Usage	Cardinalit y	Comments/Descriptions
M SH	Message Header	R	[11]	This message header (MSH) segment contains information describing how to parse and process the message. This includes identification of message delimiters, sender, receiver, message type, timestamp, etc.
MSA	Message Acknowledgment	R	[11]	The Message Acknowledgment Segment (MSA) contains the information sent as acknowledgment to the result message received by the device or information system.
[{ERR}]	Error	CE	[0*]	This segment is sent if there is an error identified in the message. If MSA-1 (Message Acknowledgment) is not valued as AA or CA.

Table 3.45.4.2-1: ACK^R01^ACK Abstract Message Syntax

3.45.5 Security Considerations

There are no unusual security or privacy concerns associated with this transaction. There are no mandatory security controls but the implementer is encouraged to use the underlying security and privacy profiles from the ITI Domain that are appropriate to the transports such as the Audit Trail and Node Authentication (ATNA) Profile. The operational environment risk assessment, following ISO 80001, will determine the actual security and safety controls employed.

Volume 3 – Content Modules

935 **5 Namespaces and Vocabularies**

Add to Section 5.1.1 Code Systems

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.96	SNOM ED CT	Systemized Nomenclature for Medicine
2.16.840.1.113883.6.1	LOINC	Logical Observation Identifiers, Names and Codes

Add to Section 5.1.1 IHE Format Codes

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Profile	Format Code	Media Type	Template ID
HPoC International Realm	urn:ihe:qrph:HPoCUV:20 13	Text/XML	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1
HPoC US Realm	urn:ihe:qrph:HPoCUS:20 13	Text/XML	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1

6 Content Modules

6.3.1 CDA Document Content Modules

945 Add to Section 6.3.1.D Document Content Modules

6.3.1.D1 Hearing Plan of Care (HPoC) Document Content Module

6.3.1.D1.1 Format Code

Profile	Format Code	Media Type	Template ID
HPoC UV Realm	urn:ihe:qrph:HPoCUV:2014	Text/XML	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1

950 6.3.1.D1.2 Parent Template

This document does not assert a parent template.

Design note: The HPoC template is an adaptation of the IHE Medical Document template (1.3.6.1.4.1.19376.1.5.3.1.1.1) defined by IHE PCC for use in the UV Realm.

The Medical Document template incorporates several header constraints established in the
original (2008) Health Story Project (HL7 General Header Constraints templateId
(2.16.840.1.113883.10.20.3)). (See PCC TF-2: 6.3.1.1.3 for additional background on the
Medical Document template.) The Consolidated CDA (2012) joint project between IHE and HL7 has produced a newer, harmonized US Realm Header template which is an improvement of the prior Health Story General Header. This template design also is an adaptation of the newer HL7
Consolidated CDA R1.1 US Realm Header template. It has been generalized to address the IHE UV Realm requirements.

6.3.1.D1.3 Referenced Standards

All standards which are reference in this document are listed below with their common abbreviation, full title, and link to the standard.

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Table 6.3.1.D1.3-1: HPoC - Referenced Standards

Abbreviati on	Title	URL
CDA R2	HL7 CDA Release 2.0	https://www.hl7.org/implement/standards/pro duct_brief.cfm?product_id=7
C-CDA R2.1	HL7 Consolidated CDA Release 1.1	http://www.hl7.org/implement/standards/prod uct_brief.cfm?product_id=258
LOINC©	Logical Observation Identifiers, Names and Codes	https://loinc.org/

Abbreviati on	Title	URL
SNOMED	Systemized Nomenclature for Medicine	http://www.ihtsdo.org/snomed-ct/
HL7 EHDI Message	HL7 Version 2.6 Implementation Guide: Early Hearing Detection and Intervention (EHDI) Messaging, Release 1 [V26_IG_EHDI_R1_D2_2013JAN]	https://www.hl7.org/implement/standards /product_brief.cfm?product_id=344

6.3.1.D1.4 Data Element Requirement Mappings to CDA

This section identifies the mapping of data between referenced standards into the CDA implementation guide. Table 6.3.1.D1.4-1 provides a high-level mapping from key Form Data
Elements to HPoC structures. Detailed data element mappings require realm-specific templates to be specified. See QRPH TF-4 for EHDI for available realm-specific detailed data element mappings.

 Table 6.3.1.D1.4-1: Data Element Mappings to HPoC Header Elements

Clinical Data Element	CDA pseudo xPath (Note 1)
Patient's name	recordTarget.patientRole.patient.name
Patient's mother or other responsible guardian	recordTarget.patientRole.patient.guardian.person.name
Author of Hearing Plan of Care document	author.assignedAuthor.person.name
Custodian of the Hearing Plan of Care document	custodian.assignedCustodian.custodianOrganization.name
Service event associated with assessing the hearing screening results and creating the Hearing Plan of Care	documentationOf.serviceEvent.code
Organization who performed the services of assessing the hearing screening results and creating the Hearing Plan of Care	documentationOf.serviceEvent.performer.assignedEntity.organization.name
The type of encounter after which this Hearing Plan of Care is created.	componentOf.encompassingEncounter.code

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Note 1: The pseudo xPath notation uses class names (represented in camel case) from the CDA RMIM diagram to aid implementers in navigating the CDA R2 schema for the document header. The syntax does not represent the exact xPath statement associated with the element.

Table 6.3.1.D1.4-2: Data Element Mappings to HPoC Body Elements

Clinical Data Element	CDA pseudo xPath (Note 1)
The instructions included in the Hearing Plan of Care	HearingPlanOfCare.HPoCInstructions.text
The hearing screening outcome for the left ear	HearingScreening.HearingScreeningOrganizer. HearingScreeningOutcomeObservation-Left.value
If no hearing screening was performed on the left ear, the reason why.	HearingScreening.HearingScreeningOrganizer. HearingScreeningOutcomeObservation-Left.ReasonNotScreened.code

Clinical Data Element	CDA pseudo xPath (Note 1)
The hearing screening outcome for the right ear	HearingScreening.HearingScreeningOrganizer. HearingScreeingOutcomeObservation-Right.value
If no hearing screening was performed on the right ear, the reason why.	HearingScreening.HearingScreeningOrganizer. HearingScreeningOutcomeObservation-Right.ReasonNotScreened.code
An indicator if screening was not performed	HearingScreening.HearingScreeningOrganizer. HearingScreeningResultsOrganizer. HearingScreeningResult.negationInd
If no hearing screening was performed, the reason why.	HearingScreening.HearingScreeningOrganizer. HearingScreeningResultsOrganizer. HearingScreeningResult.ReasonNotScreened.code
The ear to which this information pertains.	HearingScreening.HearingScreeningOrganizer. HearingScreeningResultsOrganizer. HearingScreeningResult.targetSiteCode
If hearing screening was performed, the result produced.	HearingScreening.HearingScreeningOrganizer. HearingScreeningResultsOrganizer. HearingScreeningResult.value
If hearing screening was performed, the method used.	HearingScreening.HearingScreeningOrganizer. HearingScreeningResultsOrganizer. HearingScreeningResult.methodCode
A hearing risk that is present	RiskIndicatorsForHearingLoss. RiskIndicatorforHearingLossObservation.value
A problem documented	HPoCProblems.HPoCProblemConcern.ProblemObservation.value
A procedure performed	HPoCProcedures.HPoCProcedureActivityProcedure.code

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Note 1: For data elements that are represented in the structured body of the CDA document, the pseudo xPath notation uses template names (represented in Pascal case) to aid implementers in navigating the CDA R2 structures which are used to encode the data in the document. The syntax does not represent the exact xPath statement associated with the element.

Add to Section 6.3.1 Document Content Modules

985 6.3.1.D1.5 HPoC Document Content Module Specification

Template Name	emplate Name HearingPlanOfCare Document (V2)	
Template ID 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1:2016-09-01		
Parent Template	This template does not inherit constraints from another template.	

General Description	This document is the hearing plan of care for a newborn. It includes the hearing plan of care instructions and planned care activities. It includes the results of the hearing screening provided prior to discharge as well as information about hearing risk indicators which may be available. It includes the newborn's problems list, highlighting the concerns which are likely to be relevant for a hearing plan of care. It also includes treatment procedures performed on the newborn during the birth encounter, highlighting the procedures which are likely to be relevant for a hearing plan of care.
Document Code	"34817-7" Hearing Screening Evaluation and Management Note (CodeSystem: LOINC 2.16.840.1.113883.6.1)

Template Type	Template Title	Opt and Card	templateId
Document	Hearing Plan Of Care Document		1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1:20 16-09-01
Header	Hearing Plan Of Care Header	[11]	n/a
	recordTarget	[11]	n/a
	author	[1*]	n/a
	custodian	[11]	n/a
	documentationOf/serviceEvent	[11]	n/a
	componentOf/encompassingEncounter	[11]	n/a
Section	Hearing Plan of Care Section (V2)	[11]	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.1: 2016-09-01
Section	Hearing Screening Section (V2)	[11]	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.2: 2016-09-01
Section	Risk Indicators for Hearing Loss Section (V2)	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.3: 2016-09-01
Section	Problems Section (V2)	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.4: 2016-09-01
Section	Procedures Section (V2)	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.6: 2016-09-01

6.3.1.D1.5.1 Hearing Plan of Care Document (V2)

990 [ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1:2016-09-01(open)]

Template Design Relationships

995

This template is a generalization of the IHE US Realm HPoC Document template. It references section templates which are generalized for the UV Realm and are adapted from section

5 templates defined by the IHE PCC where there are similar purposes. Entry templates which have been generalized from the US Realm designs so that their structure is consistent but no US Realm vocabularies are required.

Template Purpose

	This document records information for the hearing plan of care for a newborn. It includes
1000	hearing plan of care instructions and planned care activities. It includes the results of the hearing
	screening provided prior to discharge as well as information about hearing risk indicators which
	may be available. It includes the newborn's problems list, highlighting the concerns which are
	likely to be relevant for a hearing plan of care. It also includes treatment procedures performed
	on the newborn during the birth encounter, highlighting the procedures which are likely to be
1005	relevant for a hearing plan of care.

	1. SHALL contain exactly one [11] realmCode.
	2. SHALL contain exactly one [11] typeId.
	a. This typeId SHALL contain exactly one [11]
1010	<pre>@root="2.16.840.1.113883.1.3".</pre>
	b. This typeId SHALL contain exactly one [11] @extension= "POCD_HD000040".
	3. SHALL contain exactly one [11] templateId such that it
	a. contains exactly one [11]
	<pre>@root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1".</pre>
1015	b. SHALL contain exactly one [11] @extension="2016-09-01"
	4. SHALL contain exactly one [11] id such that it
	a. is a globally unique identifier for the document.
	5. SHALL contain exactly one [11] code such that it
1000	a. contains exactly one [11] @code="34817-7" Hearing Screening Evaluation and
1020	Management Note (CodeSystem: LOINC 2.16.840.1.113883.6.1) STATIC
	6. SHALL contain exactly one [11] title such that it
	a. can either be a locally defined name or the display name corresponding to clinicalDocument/code.
	7. SHALL contain exactly one [11] effectiveTime
1025	8. SHALL contain exactly one [11] confidentialityCode , such that it
	a. is selected from ValueSetHL7 BasicConfidentialityKind
	2.16.840.1.113883.1.11.16926 CNE, STATIC 2010-04-21.
	9. SHALL contain exactly one [11] languageCode , such that it
1000	a. is selected from ValueSet Language 2.16.840.1.113883.1.11.11526 CNE,
1030	DYNAMIC.
	10. MAY contain zero or one [01] setId such that
	a. CONDITIONAL if setId is present versionNumber SHALL be present.
	11. MAY contain zero or one [01] versionNumber such that
	12. CONDITIONAL if versionNumber is present setId SHALL be present. THE
1035	COMPONENT/STRUCTUREDBODY SHALL CONFORM TO THE SECTION CONSTRAINTS BELOW.
	a. SHALL contain exactly one [11] Hearing Plan of Care Section (V2) (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.1:2016-09-01).

	b. SHALL contain exactly one [11] Hearing Screening Section (V2) (templateId:
	1.3.6.1.4.1.19376.1.7.3.1.1.26.1. 3.2:2016-09-01).
1040	c. MAY contain zero or one [01] Risk Indicators for Hearing Loss (V2) (templateId:
	1.3.6.1.4.1.19376.1.7.3.1.1.26.1. 3.3:2016-09-01).
	d. SHOULD contain zero or one [01] Problems Section (V2) (templateId:
	1.3.6.1.4.1.19376.1.7.3.1.1.26.1. 3.4:2016-09-01).
	e. SHOULD contain zero or one [01] Procedure Section (V2) (templateId:
1045	1.3.6.1.4.1.19376.1.7.3.1.1.26.1. 3.6:2016-09-01).

Implementer Guidance:

The clinicalDocument.effectiveTime element should indicate that the Hearing Plan of Care was created after the time of the event designated to trigger its creation. In some cases policy that defines when the HPoC should be created may include a time-offset from the triggering event.

1050 **6.3.1.D1.5.1.1** Plan of Care Conformance Constraints

6.3.1.D1.5.1.2 Hearing Screening Section Conformance Constraints

6.3.1.D1.5.1.3 Risk Indicators for Hearing Loss Section Conformance Constraints

6.3.1.D1.5.1.4 Problems Section Conformance Constraints

6.3.1.D1.5.1.5 Procedures Section Conformance Constraints

1055 **6.3.1.D1.6 HPoC Example**

Example xml document is located at ftp://ftp.ihe.net/TF_Implementation_Material/QRPH/EHDI/

Add to Section 6.3.2 Header Content Modules

6.3.2 CDA Header Content Modules

1060 **6.3.2.H1** Hearing Plan of Care (HPoC) Header Content Modules

The header for the Hearing Plan of Care (HPoC) document shall support the following header constraints as noted in this section. Note that this content profile is realm agnostic. These header constraints are based on the C-CDA header constraints but all references to US Realm specific types have been removed.

1065 **6.3.2.H1.1 recordTarget**

- 1. **SHALL** contain exactly one [1..1] recordTarget.
 - a. Such record Targets **SHALL** contain exactly one [1..1] **patientRole**.
 - i. This patientRole **SHALL** contain at least one [1..*] **id**.

1070	ii.	This pa	tientRol	e SHALL contain at least one [1*] addr .
	iii.			e SHALL contain at least one [1*] telecom.
				e SHALL contain exactly one [11] patient.
				tient SHALL contain exactly one [11] name.
				tient SHALL contain exactly one [11]
1075			•	istrativeGenderCode, which MAY be selected from
			Value	SetAdministrative Gender (HL7 V3)
			2.16.	840.1.113883.1.11.1 DYNAMIC .
		3.	This pa	tient SHALL contain exactly one [11] birthTime .
			a.	SHALL be precise to year.
1080			b.	should be precise to day.
		4.		atient MAY contain zero or one [01] sdtc:deceasedInd , the @value SHALL be true if the recordTarget has died.
		5.	This pa	atient MAY contain zero or one [01]
				decceasedTime, where the @value SHALL record the
1085				nd time when the recordTarget died.
		6.	-	atient MAY contain zero or one [01]
				nulitpleBirthInd, where the @value SHALL be true if ordTarget was part of a multiple birth.
		7.	-	atient MAY contain zero or one [01]
1090				mulitpleBirthOrderNumber, where the @value SHALL integer that represents their birth order position.
		8.	This pa	tient should contain one or more [1*] guardian.
			а.	The guardian, if present, should contain zero or one [01] code, which shall be selected from ValueSet
1095				PersonalandLegalRelationshipRoleType
				2.16.840.1.113883.11.20.12.1 DYNAMIC .
			b.	The guardian, if present, SHOULD contain zero or more [0*] addr.
			с.	The guardian, if present, MAY contain zero or more [0*]
1100				telecom.
			d.	The guardian, if present, SHALL contain exactly one [11] guardianPerson.
				i. This guardian Person SHALL contain at least one
				[1*] name.
1105				ii. This guardian Person MAY contain zero or one [01]
				birthplace.
				 The birthplace, if present, SHALL contain exactly one [11] place.
				1. This place SHALL contain exactly
1110				one[11] addr .

1115	 2. This addr SHOULD contain zero or one [01] country, which SHALL be selected from ValueSet CountryValueSet 2.16.840.1.113883.3.88.12. 80.63 DYNAMIC. 3. This addr MAY contain zero or one
	[01] postalCode
1120	9. This patient MAY contain zero or one [01] birthplace .
1120	 a. The birthplace, if present, SHALL contain exactly one [11] place.
	i. This place should contain exactly one [11] addr.
	1. This addr should contain zero or one [01] country.
1125	2. This addr MAY contain zero or one [01] postalCode.
	10. This patient should contain zero or more [0*]
	languageCommunication.
1130	a. The languageCommunication, if present, SHALL contain exactly one [11] languageCode , which SHALL be selected from ValueSet Language
	2.16.840.1.113883.1.11.11526 DYNAMIC.
1135	b. The languageCommunication, if present, MAY contain zero or one [01] modeCode, which SHALL be selected from ValueSetLanguageAbilityMode Value Set 2.16.840.1.113883.1.11.12249 DYNAMIC.
1140	c. The languageCommunication, if present, SHOULD contain zero or one [01] proficiencyLevelCode , which SHALL be selected from ValueSet LanguageAbilityProficiency
	2.16.840.1.113883.1.11.12199 DYNAMIC .
	 d. The languageCommunication, if present, MAY contain zero or one [01] preferenceInd.
1145	6.3.2.H1.2 author
1110	1. SHALL contain at least one [1*] author.
	a. Such authors SHALL contain exactly one [11] time.
	b. Such authors SHALL contain exactly one [11] assignedAuthor.
	i. This assigned Author SHALL contain exactly one [11] id such that it

1150

- 1. **SHALL** contain exactly one [1..1] @root.
- ii. This assigned Author \mathbf{SHOULD} contain zero or one [0..1] \mathbf{code} .

		This assigned Author groups a contain at least one [1, *] 11
		This assigned Author SHALL contain at least one [1*] addr .
		This assigned Author SHALL contain at least one [1*] telecom.
	V.	This assigned Author SHOULD contain zero or one [01] assignedPerson .
1155		 The assigned Person, if present, SHALL contain at least one [1*] name.
	vi.	This assignedAuthor should contain zero or one [01]
		assignedAuthoringDevice.
1160		 The assignedAuthoringDevice, if present, SHALL contain exactly one [11] manufacturerModelName.
		 The assigned Authoring Device, if present, SHALL contain exactly one [11] softwareName.
	vii.	There SHALL be exactly one assignedAuthor/assignedPerson, or exactly one assignedAuthor/assignedAuthoringDevice, or exactly one of each.
1165		
	6.3.2.H1.3 custodian	
	1. SHALL contain e	exactly one [11] custodian.
	a. This cus	stodian SHALL contain exactly one [11] assignedCustodian.
1170	i.	This assignedCustodian SHALL contain exactly one [11]
		representedCustodianOrganization.
		 This representedCustodianOrganization SHALL contain at least one [1*] id.
		2. This represented Custodian Organization SHALL contain exactly one
1175		[11] name.
		 This represented Custodian Organization SHALL contain exactly one [11] telecom.
		a. This telecom should contain zero or one [01] @use
1180		 This represented Custodian Organization SHALL contain exactly one [11] addr.

6.3.2.H1.4 participant

No further constraints specified.

6.3.2.H1.5 informant

1185 No further constraints specified.

6.3.2.H1.6 authenticator

No further constraints specified.

6.3.2.H1.7 legalAuthenticator

No further constraints specified.

1190 **6.3.2.H1.8 dataEnterer**

No further constraints specified.

6.3.2.H1.9 informationRecipient

No further constraints.

6.3.2.H1.10 componentOf/EncompassingEncounter

1195

11/5		
	1. MAY contain zero or one [01] cc	mponentOf.
	a. The componentOf, if pre encompassingEncount	sent, SHALL contain exactly one [11]
	encompassingEncount	.er.
	i. This encompassi	ngEncounter SHALL contain at least one [1*] id .
1200	ii. This encompassi	ngEncounter should contain at least one [1*] code
		e, if present, SHALL be selected from Concept Domain CEncounterType.
	iii. This encompassi	ngEncounter shall contain exactly one [11]
	effectiveTime	
1205	iv. This encompassi	ngEncounter SHALL contain exactly one [11] location.
	1. Thisloca	tion SHALL contain exactly one [11]
	healthC	CareFacility.
		his healthCareFacility SHALL contain exactly one [11] serviceProviderOrganization.
1210		his healthCareFacility SHALL contain exactly one [11] .ocation.

Implementer Guidance:

The code element of the encompassingEncounter records the type of encounter. When constrained for use in a particular realm, the vocabulary binding in this template constrains the set of codes used to represent a birth encounter. An id element is used to encode the encounterID of the associated encounter.

6.3.2.H1.11 documentationOf/ServiceEvent

- 1. **MAY** contain zero or more [0..*] documentationOf.
- 1220

- a. The documentationOf, if present, **SHALL** contain exactly one [1..1] **serviceEvent**.
 - i. This serviceEvent **should** contain exactly one [1..1] code

	 The code, if present, SHALL contain exactly one [11] @code, which SHOULD be selected from Concept Domain CD_HPoCServiceEventType.
1225	ii. This serviceEvent SHALL contain exactly one [11] effectiveTime .
	1. This effectiveTime shall contain exactly one [11] low .
	iii. This serviceEvent should contain zero or more [0*] performer.
	1. The performer, if present, SHALL contain exactly one [11]
	@typeCode (CodeSystem: HL7ParticipationType
1230	2.16.840.1.113883.5.90 STATIC).
	a. The performer participant represents clinicians who actually and principally carry out the service Event. In a transfer of
	care this represents the healthcare providers involved in the
	current or pertinent historical care of the patient.
1235	Preferably, the patient's key healthcare care team members
	would be listed, particularly their primary physician and any
	active consulting physicians, therapists, and counselors.
	2. The performer, if present, MAY contain zero or one [01]
1240	functionCode.
1240	a. The functionCode, if present, should contain zero or one
	[01] @codeSystem, which SHOULD be selected from
	CodeSystem participationFunction (2.16.840.1.113883.5.88) STATIC .
	3. The performer, if present, SHALL contain exactly one [11]
1245	assignedEntity.
1245	
	a. This assigned Entity SHALL contain at least one [1*] id .
	b. This assigned Entity should contain zero or one [01] code.
	i. The code, if present, shall contain exactly one
1250	[11] @code, which SHOULD be selected from
1230	Concept Domain CD_ServiceEventPerformerType.

Implementer Guidance:

One of the documentationOf elements SHOULD record the service event of creating the Hearing Plan of Care.

1255 Additionally, other documentationOf elements MAY record the derived screening outcome for each ear.

When the Hearing Plan of Care is developed by a system, Implementers will need to determine who should be listed as the performer of the service event associated with creation of the hearing plan of care. This may be someone who is responsible for reviewing the generated plan before it is completed. This implementation detail is out of scope for the EHDI Profile. Each time a baby

1260 is completed. This implementation detail is out of scope for the EHDI Profile. Each time a baby is screened, a serviceEvent should be added the effectiveTime information should provide the actual start and stop date/time (to the minute) when the screening service was performed. The

timing information needs to be accurate enough to indicate the order in which the screening was performed.

1265 6.3.2.H1.12 inFulfillmentOf/Order

6.3.2.H1.13 authentication/consent

6.3.2.H1.14 relatedDocument/ParentDocument

6.3.3 CDA Section Content Modules

1270 Add within Section 6.3.3 Section Content Modules

6.3.3.S1 Hearing Plan of Care Section (V2)

[Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.1:2016-09-01(open)]

Template Design Relationships

1275 This template is an adaptation of the IHE Care Plan section template (1.3.6.1.4.1.19376.1.5.3.1.3.31).

This template also adapts and generalizes the design of the C-CDA R2.1 Plan of Care section template (2.16.840.1.113883.10.20.22.2.10) by narrowing the purpose to address only the hearing plan of care.

1280 **Template Purpose**

The Hearing Plan of Care section contains data that defines pending orders, planned interventions (treatments (procedures)), scheduled appointments (visits (encounters)), planned testing services (observations), intended actions (act) for the patient or family members to perform, and instructions which are related to the hearing plan of care. It is limited to

- 1285 prospective, unfulfilled, or incomplete orders and requests only, which are indicated by the @moodCode of the entries within this section. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and clinical reminders.
- 1290 Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and health-care quality improvements, including widely accepted performance measures. The plan may also indicate that patient education will be provided (act).
 - 1. **SHALL** contain exactly one [1..1] templateId such that it
 - a. **SHALL** contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.1".
 - b. **SHALL** contain exactly one [1..1] @extension="2016-09-01"

1295

	2.	SHALL contain exactly one [11] code such that it
		 a. contain exactly one [11] @code="18776-5-HPOC" Plan of Care for Hearing (CodeSystem:LOINC 2.16.840.1.113883.6.1 STATIC).
1300	3.	SHALL contain exactly one [11] title.
	4.	SHALL contain exactly one [11] text.
	5.	MAY contain zero or more [0*] entry such that each
		a. contain exactly one [11] HPoC Activity Act (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.2).
1305	6.	MAY contain zero or more $[0^*]$ entry such that each
		a. contain exactly one [11] HPoC Activity Encounter (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.3).
	7.	MAY contain zero or more $[0^*]$ entry such that each
1310		 a. contain exactly one [11] HPOC Activity Observation (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.4).
	8.	MAY contain zero or more $[0^*]$ entry such that each
		a. contain exactly one [11] HPoC Activity Procedure (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.5).
	9.	MAY contain zero or more [0*] entry such that each
1315		a. contain exactly one [11] HPoC Activity Substance Administration (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.6).
	10	MAY contain zero or more $[0^*]$ entry such that each
		a. contain exactly one [11] HPoC Activity Non-Medicinal Supply (V2) (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.7:2016-09-01).
1320	11	MAY contain zero or more [0*] entry such that each
		a. contain exactly one [11] HPoC Instructions (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.1).

Implementer Guidance:

When no information exists to be exchanged in a defined section, the section element may be encoded with a nullFlavor of "NI". (See the CDA Examples Task Force wiki page for examples, General Patterns.)

6.3.3.S2 Hearing Screening Section (V2)

[Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.2:2016-09-01(open)]

Template Design Relationships

1330 This template adapts the IHE Results section template (1.3.6.1.4.1.19376.1.5.3.1.3.27). This template also adapts and generalizes the C-CDA R2.1 Results section template (2.16.840.1.113883.10.20.22.2.3.1) narrowing the purpose to address only hearing screening results and adding an outer organizer structure to record hearing screening outcome assessment which is derived from the individual screening results and other factors.

1335 **Template Purpose**

The Hearing Screening section includes a screening outcome observation for each ear, which summarizes the screening results gathered for each ear. It also documents the individual screening result observations generated by the screening device each time the left ear is tested and each time the right ear is tested.

- 1340 The methodologies for summarizing screening result observations into a single screening outcome observation are jurisdictionally defined and are not specified or constrained within this template.
- 1345

1350

- 1. **SHALL** contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.2".
 - b. **SHALL** contain exactly one [1..1] @extension="2016-09-01"
- 2. **SHALL** contain exactly one [1..1] code such that it
 - a. contain exactly one [1..1] @code="30954-2-HPOC" Relevant diagnostic tests and/or laboratory data for Hearing Screening (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**).
- 3. **SHALL** contain exactly one [1..1] title.
- 4. **SHALL** contain exactly one [1..1] text.
- 5. **SHALL** contain exactly one [1..1] **entry** such that it
 - a. contain exactly one [1..1] Hearing Screening Organizer (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.8).

1355

Implementer Guidance:

Methodologies for summarizing hearing screening result observations into a single hearing screening outcome for an ear are jurisdictionally defined. Systems implementing this profile as a Content Creator are required to process hearing screening results based upon a methodology which is outside the scope of the EHDI Profile.

1360 which is outside the scope of the EHDI Profile. When no information exists to be exchanged in a defined section

When no information exists to be exchanged in a defined section, the section element may be encoded with a nullFlavor of "NI". (See the CDA Examples Task Force wiki page for examples, General Patterns.)

This nullFlavor encoding should be used when no information has been provided about Newborn Hearing Screening being performed or not performed for medical reasons before the newborn is discharged from the birth encounter. This profiles assumes the workflow at a birthing facility include sending information to positively assert that a baby who is not screened for medical reasons. This does not constitute a "no information" screening section and nullFlavor of "NI" does not apply.

1370 6.3.3.S3 Risk Indicators for Hearing Loss (V2)

[Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.3:2016-09-01(open)]

Template Design Relationships

The design is adapted and generalized from templates being developed for C-CDA R2.0 which are intended to track identified risks.

1375 **Template Purpose**

The Risk Indicators for Hearing Loss section indicates if specific risks relevant to hearing loss are present. Use of null flavors, to encode information indicating that an assessment of the risk was not performed or to record that no information is currently available in the system, is out of scope for this template.

1380

- 1. **SHALL** contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.3".
- 2. **SHALL** contain exactly one [1..1] @extension="2016-09-01" SHALL contain exactly one [1..1] code (CONF:15433) such that it
- 1385

1390

- a. contain exactly one [1..1] @code=" 58232-0" Hearing Loss Risk Indicators (CodeSystem:LOINC 2.16.840.1.113883.6.1) STATIC.
- 3. **SHALL** contain exactly one [1..1] title.
- 4. **SHALL** contain exactly one [1..1] text.
- 5. **SHOULD** contain zero or more [0..*] **entry** such that each
 - a. contain exactly one [1..1] Risk Indicator for Hearing Loss Observation (V2)(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.15:2016-09-01).

Implementer Guidance:

When no information exists to be exchanged in a defined section, the section element may be encoded with a nullFlavor of "NI". (See the CDA Examples Task Force wiki page for examples, 1395 General Patterns.)

6.3.3.S4 Problems Section (V2)

[Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.4:2016-09-01(open)]

Template Design Relationships

This template is an adaptation of the IHE Active Problems section template (1.3.6.1.4.1.19376.1.5.3.1.3.6).

This template adapts the purpose of the UV Realm IHE Active Problem Section. It is altered to include historical problem concerns as well as active concerns in the problem list.

Template Purpose

This section lists and describes all clinical problems at the time the document is generated. 1405 Current (active) and historical (completed) concerns should be listed.

- 1. **MAY** contain zero or one [0..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.5.3.1.3.6".
- 2. **SHALL** contain exactly one [1..1] templateId such that it

1410	a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.4".
	b. SHALL contain exactly one [11] @extension="2016-09-01"
	3. SHALL contain exactly one [11] code such that it
	a. contain exactly one [11] @code="11450-4" Problem List (CodeSystem:LOINC 2.16.840.1.113883.6.1) STATIC.
1415	4. SHALL contain exactly one [11] title.
	5. SHALL contain exactly one [11] text.
	6. SHALL contain at least one [1*] entry such that each
	a. contain exactly one [11] Problem Concern (V2) (templateId:
	1.3.6.1.4.1.19376.1.5.3.1.4.5.2:2016-09-01).
1420	Implementer Guidance:
	When no information exists to be exchanged in a defined section, the section element may be encoded with a nullFlavor of "NI". (See the CDA Examples Task Force wiki page for examples General Patterns.)

6.3.3.S5 Intentionally blank

1425 6.3.3.S6 Procedures Section (V2)

[Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.6:2016-09-01(open)]

Template Design Relationships

This template is an adaptation of the IHE Coded List of Surgeries section template (1.3.6.1.4.1.19376.1.5.3.1.3.12). Machine readable entries associated with this template have been modified to align with structural representations for procedure entries established by C-CDA R2.1. This template also is an adaptation and generalization of the C-CDA R2.1

Procedures section template (2.16.840.1.113883.10.20.22.2.7.1). It does not utilize the Procedure Activity Observation as direct entry of the section and permits use of that template within the context of a Procedure Activity Procedure or Procedure Activity Act.

1435 **Template Purpose**

1430

This section defines all interventional, surgical, or therapeutic procedures or treatments pertinent to the patient historically at the time the document is generated. It does not include diagnostic procedures. Diagnostic and screening procedures are recorded in a Result Section. Procedures recorded in this section are encoded using one of two machine readable entry templates. A

- 1440 Procedure Activity Procedure entry is used to record procedures that alter the physical condition of a patient (Splenectomy). A Procedure Activity Act entry is for all other types of procedures (dressing change). If a procedure produces new information about a patient, that information is recorded using the Procedure Activity Observation template as an entry relationship to the procedure or act entry with which the observation is associated. The Activity Observation
- 1445 template is only used as a subordinate act to the procedure of act entries associated with this section.

- 1. **SHALL** contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.6".
 - b. **SHALL** contain exactly one [1..1] @extension="2016-09-01"
- 2. **SHALL** contain exactly one [1..1] **code** such that it
 - a. contain exactly one [1..1] @code="47519-4" History of Procedures (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**).
- 3. **SHALL** contain exactly one [1..1] title.
 - 4. **SHALL** contain exactly one [1..1] text.
 - 5. **MAY** contain zero or more [0..*] **entry** such that it
 - a. contain exactly one [1..1] Procedure Activity Procedure
 - (V2)(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.18:2016-09-01).

Implementer Guidance:

1460 When no information exists to be exchanged in a defined section, the section element may be encoded with a nullFlavor of "NI". (See the CDA Examples Task Force wiki page for examples, General Patterns.)

6.3.3.S7 Intentionally blank

1465 **6.3.4 CDA Entry Content Modules**

Add to Section 6.3.4.E Entry Content Modules

6.3.4.E1 HPoC Instructions

[Act type: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.1(open)]

1470 **Template Design Relationships**

This template is an adaptation of the IHE UV Realm Instructions template. A Concept Domain is added to express the type of instructions relevant to a hearing plan of care.

The design adapts and generalizes the C-CDA R2.1 Instructions template (2.16.840.1.113883.10.20.22.4.20).

1475 **Template Purpose**

The Instructions template records instructions. The act/code defines the type of instruction. Awareness of the instructions by the patient or care giver can be represented with the generic participant and the participant/awarenessCode.

1480

1450

1455

1. SHALL contain exactly one [1..1]@classCode="ACT" (CodeSystem:HL7ActClass 2.16.840.1.113883.5.6 STATIC).

	 SHALL contain exactly one [11] @moodCode="INT" (CodeSystem: ActMood
	2.16.840.1.113883.5.1001 STATIC) .
	3. SHALL contain exactly one [11] templateId such that it
1485	a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.1".
	4. SHALL contain exactly one [11] code such that it
	a. is selected from the Concept Domain CD_HPoCInstructions cwe .
	5. SHALL contain exactly one [11] text such that
	a. contains exactly one [11] reference such that it
1490	i. contains exactly one [11] @value such that it
	1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	6. SHALL contain exactly one [11] statusCode such that it
	a. contains exactly one [11] @code="completed" Completed (CodeSystem:
1495	ActStatus 2.16.840.1.113883.5.14 STATIC) .
	7. SHALL contain exactly one [11] effectiveTime such that it
	a. contain exactly one [11] low
	b. contain exactly one [11] high.
	6.3.4.E2 HPoC Activity Act
1500	[Act type: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.2(open)]

Template Design Relationships

The design is an adaption and generalization of the C-CDA R2.1 Plan of Care Activity Act template (2.16.840.1.113883.10.20.22.4.39). A Concept Domain is added to express the type of care activities relevant to a hearing plan of care.

1505 **Template Purpose**

This is the generic template for the Plan of Care Activity.

- 1. SHALL contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
- 1510

1515

- 2. **SHALL** contain exactly one [1..1] @moodCode, such that it
 - a. isselected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30.
 - 3. MAY contain zero or one [0..1] templateId such that it
 - a. contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.39".
 - 4. SHALL contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.2".
 - 5. **SHALL** contain at least one [1..*] id.
 - 6. **SHALL** contain exactly one [1..1] code, such that it

1520	 a. is selected from Concept Domain CD_HPoCActivityAct CWE. 8. SHALL contain exactly one [11] text such that a. contains exactly one [11] reference such that it
	i. contains exactly one [11] @value such that it
1525	 begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	1. SHALL contain exactly one [11] statusCode.
	2. SHALL contain exactly one [11] effectiveTime such that it
	a. contain exactly one [11] low
	b. contain exactly one [11] high.
1530	6.3.4.E3 HPoC Activity Encounter
	[Encounter: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.3(open)]
	Template Design Relationships
1535	The design is an adaptation and generalization of the C-CDA R2.1 Plan of Care Activity Encounter template (2.16.840.1.113883.10.20.22.4.40). A Concept Domain is added to express the type of encounters relevant to a hearing plan of care.
	Template Purpose
	This is the template for the Plan of Care Activity Encounter.
1540	 SHALL contain exactly one [11]@classCode="ENC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
	2. SHALL contain exactly one [11] @moodCode, such that it
	a. is selected from ValueSet Plan of Care moodCode
	(Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30.
1545	3. MAY contain zero or one [01] templateId such that it
	a. contain exactly one [11] @root="2.16.840.1.113883.10.20.22.4.40".
	4. SHALL contain exactly one [11] templateId such that it
	a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.3".
	5. SHALL contain at least one [1*] id.
1550	6. SHALL contain exactly one [11] code, such that it
	a. is selected from Concept Domain CD_HPoCActivityEncounter cwE .
	7. SHALL contain exactly one [11] text such that
	a. contains exactly one [11] reference such that it
	i. contains exactly one [11] @value such that it
1555	 begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).

3. **SHALL** contain exactly one [1..1] statusCode.

- 4. **SHALL** contain exactly one [1..1] **effectiveTime** such that it
 - a. contain exactly one [1..1] low

- 1560
- b. contain exactly one [1..1] high.

6.3.4.E4 HPoC Activity Observation

[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.4(open)]

Template Design Relationships

The design is an adaptation and generalization on the C-CDA R2.1 Plan of Care Activity Observation template (2.16.840.1.113883.10.20.22.4.44). A Concept Domain is added to express the type of observations relevant to a hearing plan of care.

Template Purpose

This is the template for the Plan of Care Activity observation. An observation activity is used to record diagnostic tests and screenings which produce results.

1570		
	1.	<pre>SHALL contain exactly one [11] @classCode="OBS" (CodeSystem:HL7ActClass 2.16.840.1.113883.5.6 STATIC).</pre>
	2.	SHALL contain exactly one [11] @moodCode, such that it
1575		a. is selected from ValueSet Plan of Care moodCode (Observation) 2.16.840.1.113883.11.20.9.25 STATIC 2011-09-30.
	3.	MAY contain zero or one [01] templateId such that it
		a. contain exactly one [11] @root="2.16.840.1.113883.10.20.22.4.44".
	4.	SHALL contain exactly one [11] templateId such that it
		a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.4".
1580	5.	SHALL contain at least one [1*] id.
	8.	SHALL contain exactly one [11] code , such that it
		a. is selected from Concept Domain CD_HPoCActivityObservation cwe .
	9.	SHALL contain exactly one [11] text such that
		a. contains exactly one [11] reference such that it
1585		i. contains exactly one [11] @value such that it
		 begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	5.	SHALL contain exactly one [11] statusCode.
	6.	SHALL contain exactly one [11] effectiveTime such that it
1590		a. contain exactly one [11] low
		b. contain exactly one [11] high.
	6.3.4.E5	HPoC Activity Procedure

[Procedure: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.5(open)]

Template Design Relationships

1595 The design is an adaptation and generalization of the C-CDA R2.1 Plan of Care Activity Procedure template (2.16.840.1.113883.10.20.22.4.41). A Concept Domain is added to express the type of procedures relevant to a hearing plan of care.

Template Purpose

This is the template for the Plan of Care Activity procedure. A procedure activity is used to record treatment or surgical procedures which produce health outcomes that change a patient's health status or condition.

	1.	<pre>SHALL contain exactly one [11]@classCode="PROC" (CodeSystem:HL7ActClass 2.16.840.1.113883.5.6 STATIC).</pre>
1605	2.	SHALL contain exactly one [11] @moodCode, such that is
		a. is selected from ValueSet Plan of Care moodCode
		(Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30.
	3.	MAY contain zero or one [01] templateId such that it
1610		a. contain exactly one [11] @root="2.16.840.1.113883.10.20.22.4.41".
	4.	SHALL contain exactly one [11] templateId such that it
		a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.5".
	5.	SHALL contain at least one [1*] id.
	6.	SHALL contain exactly one [11] code , such that it
1615		a. is selected from Concept Domain CD_HPoCActivityProcedure cwe .
	7.	SHALL contain exactly one [11] text such that
		a. contains exactly one [11] reference such that it
		i. contains exactly one [11] @value such that it
1620		1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	7.	SHALL contain exactly one [11] statusCode.
	8.	SHALL contain exactly one [11] effectiveTime such that it
		a. contain exactly one [11] low
		b. contain exactly one [11] high.

1625 **6.3.4.E6 HPoC Activity SubstanceAdministration**

[SubstanceAdministration: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.6(open)]

Template Design Relationships

The design is an adaptation and generalization of the C-CDA R2.1 Plan of Care Activity

1630 Substance Administration template. A Concept Domain is added to express the type of substance administrations relevant to a hearing plan of care.

Template Purpose

This is the template for the Plan of Care Activity for administering substances.

1635	1.	<pre>SHALL contain exactly one [11]@classCode="SBADM" (CodeSystem:HL7ActClass 2.16.840.1.113883.5.6 STATIC).</pre>
	2.	SHALL contain exactly one [11] @moodCode, which SHALL be selected from ValueSet Plan of Care moodCode (SubstanceAdministration/Supply) 2.16.840.1.113883.11.20.9.24 STATIC 2011-09-30 .
1640	3	SHALL contain exactly one [11] templateId such that it
1040	5.	a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.6".
	4.	
	5.	a. is selected from Concept Domain CD_HPoCActivitySubstanceAdministrationType
1645		CWE.
	6.	SHALL contain exactly one [11] text such that
		a. contains exactly one [11] reference such that it
		i. contains exactly one [11] @value such that it
1650		1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	7.	SHALL contain exactly one [11] statusCode.
	8.	SHALL contain exactly one [11] effectiveTime such that it
		a. contain exactly one [11] low
		b. contain exactly one [11] high.
1655	9.	SHOULD contain zero or one [01] effectiveTime such that it
		a. contain exactly one [11] @operator="A"
		b. contain exactly one [11] @xsi:type="PIVL_TS" or "EIVL_TS".
	10.	. MAY contain zero or one [01] repeatNumber such that it
1660		a. CONDITIONAL In "INT" (intent) mood, the repeatNumber defines the number of allowed administrations. For example, a repeatNumber of "3" means that the substance can be administered up to 3 times. In "EVN" (event) mood, the
		repeatNumber is the number of occurrences. For example, a repeatNumber of "3" in a substance administration in "EVN" means that the represented administration is
1665	11	the 3rd in a series.
1665		. SHALL contain exactly one [11] consumable . SHOULD include doseQuantity OR rateQuantity.
	12.	. SHOULD INCLUDE QUAILILY ON TALE QUAILILY.

6.3.4.E7 HPoC Activity Non-Medicinal Supply (V2)

[Supply: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.7:2016-09-01(open)]

Template Design Relationships

1670 The design is an adaptation and generalization of the C-CDA R2.1 Plan of Care Activity Supply template. A Concept Domain is added to express the type of non-medicinal supplies that are relevant to a hearing plan of care.

Template Purpose

This is the template for the Plan of Care Activity for supplying non-medicinal medical Equipment.

	1.	SHALL contain exactly one [11] @classCode= "SPLY" (CodeSystem:HL7ActClass
		2.16.840.1.113883.5.6 STATIC).
	2.	SHALL contain exactly one [11] @moodCode, which SHALL be selected from ValueSet Plan
1680		of Care moodCode (SubstanceAdministration/Supply)
		2.16.840.1.113883.11.20.9.24 STATIC 2011-09-30 .
	3.	SHALL contain exactly one [11] templateId such that it
		a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.7".
		b. SHALL contain exactly one [11] @extension="2016-09-01"
1685	4.	SHALL contain at least one [1*] id.
	5.	MAY contain exactly one [11] code, such that it
		a. is selected from Concept Domain CD_HPoCActivityNon-MedicinalSupplyType cwe .
	6.	SHALL contain exactly one [11] text such that
		a. contains exactly one [11] reference such that it
1690		i. contains exactly one [11] @value such that it
		1. begins with a '#' and points to its corresponding narrative (using the
		approach defined in CDA Release 2, Section 4.3.5.1).
	7.	SHALL contain exactly one [11] statusCode.
	8.	SHOULD contain zero or one [01] effectiveTime such that it
1695		a. CONDITIONAL if present, contain zero or one [01] high.
	9.	SHOULD contain zero or one [01] quantity.
	10.	MAY contain zero or one [01] participant such that it
		a. contain exactly one [11] @typeCode="PRD" Product (CodeSystem:
		HL7ParticipationType 2.16.840.1.113883.5.90 STATIC) .
1700		b. contain exactly one [11] <u>Product Instance</u>
		(templateId:2.16.840.1.113883.10.20.22.4.37).
	6.3.4.E8	Hearing Screening Organizer (V2)

[Organizer: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.8:2016-09-01(open)]

Template Design Relationships

1705 This design adapts and generalizes the C-CDA R2.1 Result Organizer template (2.16.840.1.113883.10.20.22.4.1). A Concept Domain is added to express the type of Organizer it is. The design is specific to the requirements for assessing the screening outcome for each ear, as assessed after performing zero or more hearing screening tests on each ear.

Template Purpose

- 1710 This organizer records the outcome assessment of the hearing screening and the associated results used to determine the outcome assessment. It includes a component for the "screening outcome" for the left ear and a component "screening outcome" for the right ear. Each of the outcome observations carries an optional indication of the reason screening was not performed. The Hearing Screening Organizer also includes the set of result observations which were
- 1715 gathered. They are a third component and are organized in a Results Organizer.

Implementer Guidance

1725

The effectiveTime of the organizer is an interval that spans the effectiveTimes of the contained result observations.

If screening results become available that were performed after the baby is discharged from the birth encounter, these results need to be represented in a separate organizer which would be related temporally with the encounter associated with the screening event.

The effectiveTime/low will match the time of the triggering event that indicated the start of the encounter where the screening information was being collected. The effectiveTime/high will match the time of the triggering event that indicated the end of the encounter where the screening information was being collected.

Note: If any Result Observation within the Result Organizer has a statusCode of 'active', the Result Organizer must also have as statusCode of 'active'.

	1.	SHALL contain exactly one [11] @classCode=="CLUSTER" (CodeSystem:HL7ActClass
1730		2.16.840.1.113883.5.6) STATIC
	2.	<pre>SHALL contain exactly one [11] @moodCode="EVN" Event (CodeSystem: ActMood</pre>
		2.16.840.1.113883.5.1001) STATIC .
	3.	SHALL contain exactly one [11] templateId such that it
		a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.8".
1735		b. SHALL contain exactly one [11] @extension="2016-09-01"
	4.	SHALL contain at least one [1*] id.
	5.	SHALL contain exactly one [11] code such that it
		a. is selected from Concept Domain CD_HearingScreeningOrganizer cwe .
	6.	SHALL contain exactly one [11] statusCode such that it
1740		a. contain exactly one [11] @code, which is selected from ValueSet Result Status
		2.16.840.1.113883.11.20.9.39 STATIC .
	7.	SHALL contain exactly one [11] effectiveTime such that it
		a. contain exactly one [11] low

1745	 b. contain exactly one [11] high. 8. SHALL contain exactly one [11] component such that it
	a. contain exactly one [11] Hearing Screening Outcome Observation – Left Ear (V2) templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.9:2016-09-01).
	9. SHALL contain exactly one [11] component such that it
1750	a. contain exactly one [11] Hearing Screening Outcome Observation – Right Ear (V2) templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.11:2016-09-01).

- 10. **SHALL** contain exactly one [1..1] component such that it
 - a. contain exactly one [1..1] Hearing Screening Results Organizer (V2) templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.12:2016-09-01).

6.3.4.E9 Hearing Screening Outcome Observation – Left

```
1755 [Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.9:2016-09-01(open)]
```

Template Design Relationships

This template is a generalization of the IHE US Realm Hearing Screening Outcome Observation - Left template. A Concept Domain is added to express value set binding for the code(s) to represent the type of observation within a realm-specific implementation. The design is specific to the requirements for assessing the screening outcome for the Left Ear, as assessed after performing zero or more hearing screening tests on the left ear.

Template Design Note

When the template design is not specific for a particular target site, then the targetSiteCode is used to add information about a particular target site (see HearingScreeningResult template). When the template, by design, is specific for a particular target site, then that information is precoordinated into the code that is used and the targetSiteCode is not used as that would be redundant and could cause confusion or inconsistency. This design principle is established in the HL7 TermInfo DSTU (2013).

1770 **Template Purpose**

This observation records the assessment of the screening for the left ear. It uses a jurisdictionally defined algorithm for aggregating multiple screening results into a final assessment observation. When screening is not performed on an ear, the reason for not performing the screening is also recorded.

1775

- 1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) **STATIC**.
- 2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) STATIC.
- 3. **MAY** contain zero or one [0..1] @negationInd.
- 4. **SHALL** contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.9".

	b. SHALL contain exactly one [11] @extension="2016-09-01"
	5. SHALL contain at least one [1*] id.
5	6. SHALL contain exactly one [11] code such that it
	a. is selected from Concept Domain CD_HearingScreeningOutcomeObservation-Left CW E .
	7. SHALL contain exactly one [11] text such that
	a. contains exactly one [11] reference such that it
	i. contains exactly one [11] @value such that it
	 begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	8. SHALL contain exactly one [11] statusCode such that it
	 a. contain exactly one [11] @code, which is selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 STATIC.
	9. SHALL contain exactly one [11] effectiveTime .
	a. Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards).
)	10. SHALL contain exactly one [11] value
	a. be declared as data type xsi:type = "CD"
	b. is selected from Concept Domain CD_HearingScreeningOutcomeObservationValues CWE .
	11. MAY contain zero or one [01] methodCode.
	a. be selected from Concept Domain CD_HearingScreeningMethods CNE, STATIC .
	12. SHALL NOT contain a [11] targetSiteCode.
	13. MAY contain zero or one [01] author.
	14. MAY contain zero or one [01] entryRelationship.
)	 a. CONDITIONAL The entryRelationship, if present, SHALL contain exactly one [11] @typeCode="RSON" Has Reason (CodeSystem:HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b. CONDITIONAL The entryRelationship, if present, SHALL contain exactly one [11] Reason Not Screened (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.10).

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6.3.4.E10 Reason Not Screened

Detection and Intervention (EHDI)

1815 [Act: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.10(open)]

Template Design Relationships

This template is a generalization of the IHE US Realm Reason Not Screened template. A Concept Domain is added to express value set binding for the code(s) to represent the reasons for not performing hearing screening within a realm-specific implementation.

1820 **Template Purpose**

This template documents the reason why hearing screening was not performed.

- 1. SHALL contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
- 2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem:ActMood 2.16.840.1.113883.5.1001) STATIC.
- 3. **SHALL** contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.10".
- 4. **SHALL** contain exactly one [1..1] **code**, such that is
 - a. is selected from Concept Domain CD_ReasonNotScreened **cwe**.
- 5. **SHALL** contain exactly one [1..1] text such that
 - a. contains exactly one [1..1] **reference** such that it
 - i. contains exactly one [1..1] @value such that it
 - 1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).

1835 6.3.4.E11 Hearing Screening Outcome Observation – Right (V2)

[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.11:2016-09-01(open)]

Template Design Relationships

This template is a generalization of the IHE US Realm Hearing Screening Outcome Observation - Right template. A Concept Domain is added to express value set binding for the code(s) to represent the type of observation within a realm-specific implementation. The design is specific to the requirements for assessing the screening outcome for the Right Ear, as assessed after performing zero or more hearing screening tests on the right ear.

Template Design Note

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1845 When the template design is not specific for a particular target site, then the targetSiteCode is used to add information about a particular target site (see HearingScreeningResult template). When the template, by design, is specific for a particular target site, then that information is precordinated into the code that is used and the targetSiteCode is not used as that would be redundant and could cause confusion or inconsistency. This design principle is established in the HL7 TermInfo DSTU (2013).

Template Purpose

This observation records the assessment of the screening for the right ear. It uses a jurisdictionally defined algorithm for aggregating multiple screening results into a final assessment observation. When screening is not performed on an ear, the reason for not performing the screening is also recorded.

- 1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) **STATIC**.
- 2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) STATIC.

	3. MAY contain zero or one [01] @negationInd.
	4. SHALL contain exactly one [11] templateId such that it
	a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.11".
	b. SHALL contain exactly one [11] @extension="2016-09-01"
1865	SHALL contain at least one [1*] id.
	6. SHALL contain exactly one [11] code such that it
	 a. is selected from Concept Domain CD_HearingScreeningOutcomeObservation-Right CWE.
	7. SHALL contain exactly one [11] text such that
1870	a. contains exactly one [11] reference such that it
	i. contains exactly one [11] @value such that it
	1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	8. SHALL contain exactly one [11] statusCode such that it
1875	 a. be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 CNE, STATIC.
	9. SHALL contain exactly one [11] effectiveTime .
1880	a. Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards).
	10. SHALL contain exactly one [11] value
	a. be declared as data type xsi:type = "CD"
	 b. is selected from Concept Domain CD_HearingScreeningOutcomeObservationValues CWE.
1885	11. MAY contain zero or one [01] methodCode.
	a. be selected from Concept Domain CD_HearingScreeningMethods CNE, STATIC .
	12. SHALL NOT contain a [11] targetSiteCode .
	13. MAY contain zero or one [01] author.
	14. MAY contain zero or one [01] entryRelationship.
1890	 a. CONDITIONAL The entryRelationship, if present, SHALL contain exactly one [11] @typeCode="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) STATIC.
	b. CONDITIONAL The entryRelationship, if present, SHALL contain exactly one [11] Reason Not Screened (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.10).
1895	6.3.4.E12 Hearing Screening Results Organizer (V2)
	[Organizer: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.12:2016-09- 01(open)]
	Template Design Relationships
1900	The design is an adaptation and generalization of the C-CDA R2.1 Result Organizer (V3) (2.16.840.1.113883.10.20.22.4.1:2015-08-01). A Concept Domain is added to express value set

binding for the code(s) to represent the type of hearing screening results organizer within a realm-specific implementation.

Template Purpose

This organizer records the hearing screening results used to determine the outcome assessments.

1905 Implementer Guidance

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The effectiveTime of the organizer is an interval that spans the effectiveTimes of the contained result observations.

	1.	SHALL contain exactly one [11] @classCode=="CLUSTER" (CodeSystem:HL7ActClass
1910		2.16.840.1.113883.5.6) STATIC.
	2.	<pre>SHALL contain exactly one [11] @moodCode="EVN" Event (CodeSystem: ActMood</pre>
		2.16.840.1.113883.5.1001) STATIC .
	3.	SHALL contain exactly one [11] templateId such that it
		a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.12".

- b. **SHALL** contain exactly one [1..1] @extension="2016-09-01"
- 4. **SHALL** contain at least one [1..*] id.
- 5. **SHALL** contain exactly one [1..1] **code** such that it
 - a. is selected from Concept Domain <u>CD_HearingScreeningResultsOrganizer</u> **cwE**.
- 6. **SHALL** contain exactly one [1..1] **statusCode** such that it
 - a. beselected from ValueSetResult Status 2.16.840.1.113883.11.20.9.39 CNE, STATIC.
- 7. **SHALL** contain zero or more [0..*] **component** such that it
 - a. contain exactly one [1..1] Hearing Screening Result Observation (V2) templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.13:2016-09-01).

1925 **6.3.4.E13 Hearing Screening Result Observation (V2)**

[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.13:2016-09-01(open)]

Template Design Relationships

This template is an adaptation of the IHE Result Observation template

1930 (1.3.6.1.4.1.19376.1.5.3.1.3.27). The design also is an adaptation and generalization of the C-CDA R2.1 Result Observation template (2.16.840.1.113883.10.20.22.4.2). A Concept Domain is added to express value set binding for the code(s) to represent the types of hearing screening results within a realm-specific implementation.

Hearing screening devices return a value which results from interpreting their internal readings to produce a result from the device. In the future, if raw values will be returned from the device, then an interpretation code element would be needed and the associated reference ranges could be defined. For now, the value returned from the test is sufficient for both capturing the measure result and interpreting the result. In this template, the negationInd attribute of the observation act SHALL function as defined for Observation.ActionNegationInd in the HL7 V3 Core Principles. This negation behavior affects the action of the act and is further constrained by other elements of the act class which are the elements of the act class which are not considered related to the document's context.

Template Design Note

When the template design is not specific for a particular target site, then the targetSiteCode is used to add information about a particular target site (see HearingScreeningResult template). When the template, by design, is specific for a particular target site, then that information is precoordinated into the code that is used and the targetSiteCode is not used as that would be redundant and could cause confusion or inconsistency. This design principle is established in the HL7 TermInfo DSTU (2013).

1950 **Template Purpose**

This observation records the result of screening an ear. When the screening device returns an invalid reading, the reason for this invalid result may be recorded if it is known or determinable.

1955	1.	SHALL contain exactly one [11]@classCode= "OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) STATIC.
	2.	SHALL contain exactly one [11] @moodCode= "EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) STATIC .
	3.	SHALL contain exactly one [11] templateId such that it
		a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.13".
1960		b. SHALL contain exactly one [11] @extension="2016-09-01"
	4.	SHALL contain at least one [1*] id.
	5.	SHALL contain exactly one [11] code such that it
		a. is selected from Concept Domain CD_HearingScreeningTest cwe .
	6.	SHALL contain exactly one [11] text such that
1965		a. contains exactly one [11] reference such that it
		i. contains exactly one [11] @value such that it
		1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	7.	SHALL contain exactly one [11] statusCode such that it
1970		 a. be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 CNE, STATIC.
	8.	SHALL contain exactly one [11] effectiveTime .
1975		a. Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards).
1970	9.	SHALL contain exactly one [11] value, such that it
	5.	a. be declared as data type xsi:type = "CD"

	b. be selected from Concept Domain CD_HearingScreeningTestResultValues CNE ,
	STATIC.
1980	10. CONDITIONAL: SHALL NOT contain a value when negationInd="true".
	11. SHALL contain zero or one [01] methodCode , such that it
	a. be selected from Concept Domain CD_HearingScreeningMethods CNE, STATIC .
	12. CONDITIONAL: SHALL NOT contain a methodCode when negationInd="true".
	13. SHALL contain exactly one [11] targetSiteCode , such that it
1985	a. be selected from Concept Domain CD_HearingScreeningTargetSites CNE, STATIC .
	14. MAY contain zero or one $[01]$ author.
	15. MAY contain zero or one [01] performer .
	16. CONDITIONAL: SHALL contain exactly one [11] entryRelationship when negationInd="true", such that it
1990	a. SHALL contain exactly one [11] @typeCode="RSON" Has Reason (CodeSystem:
1770	HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b. SHALL contain exactly one [11] <u>Reason Not Screened</u> (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.14).
1995	 CONDITIONAL: SHALL NOT contain an entryRelationship with @typeCode="RSON" when negationInd="false".

6.3.4.E14 Intentionally Blank

6.3.4.E15 Risk Indicator for Hearing Loss Observation (V2)

[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.15:2016-09-01(open)]

2000 **Template Design Relationships**

This template is an adaptation and generalization of the IHE US Realm Risk Indicator for Hearing Loss Observation template. A Concept Domain is added to express value set binding within a realm-specific implementation for the code(s) to represent the types of reasons for no assessable result to be returned when a baby is screened.

2005 Template Purpose

This template records a set of hearing related risks which may be assessed. Each clinical statement indicates if a particular risk is present or not. Risks that are not assessed do not have to be included. (Use of nullFlavors to express exceptional cases for the risk not being assessed will be considered in a future version.)

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- 1. SHALL contain exactly one [1..1]@classCode="OBS" (CodeSystem:HL7ActClass 2.16.840.1.113883.5.6 STATIC).
- 2. SHALL contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).

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3. **SHALL** contain exactly one [1..1] templateId such that it

a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.15". b. **SHALL** contain exactly one [1..1] @extension="2016-09-01" 4. **SHALL** contain at least one [1..*] id. 5. **SHALL** contain exactly one [1..1] code such that it 2020 a. is selected from Concept Domain CD_RiskFactor **CNE**. 6. **SHALL** contain exactly one [1..1] text such that a. contain exactly one [1..1] reference such that it i. contains exactly one [1..1] @value such that it 1. begins with a '#' and points to its corresponding narrative (using the 2025 approach defined in CDA Release 2, Section 4.3.5.1). 7. **SHALL** contain exactly one [1..1] **statusCode** such that it a. contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 STATIC). SHOULD contain zero or one [0..1] effectiveTime. 2030 9. **SHALL** contain exactly one [1..1] **value**, such that it: a. be defined as data type @xsi:type="CD" b. be selected from Concept Domain CD_RiskFactorsForHearing **cwe**.

6.3.4.E16 Problem Concern (V2)

[Act: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.16:2016-09-01(open)]

2035 **Template Design Relationships**

This template is a transclusion of the IHE UV Realm Problem Concern Act template (1.3.6.1.4.1.19376.1.5.3.1.4.5.2).

Template Purpose

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The problem concern template is a "tracker" which allows one or more problem observations to 2040 be grouped together and tracked over time as being associated with this particular concern.

- 1. SHALL contain exactly one [1..1]@classCode="ACT" Act (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
- 2. SHALL contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).
- 3. **SHALL** contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.5.3.1.4.5.2".
- 4. **SHALL** contain exactly one [1..1] templateId such that it

a. contain exactly one [1..1]

- **@root=**"11.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.16".
- b. **SHALL** contain exactly one [1..1] @extension="2016-09-01"

6.3.4.E17 Intentionally blank

2055 6.3.4.E18 Procedure Activity Procedure (V2)

[Procedure: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.18:2016-09-01(open)]

Template Design Relationships

This template is a transclusion of the IHE UV Realm Procedure Entry template (1.3.6.1.4.1.19376.1.5.3.1.4.19).

Template Purpose

This clinical statement represents procedures whose immediate and primary outcome (postcondition) is the alteration of the physical condition of the patient. Examples of these procedures are an appendectomy, hip replacement and a creation of a gastrostomy.

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- 1. SHALL contain exactly one [1..1] @classCode="PROC" Procedure (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) STATIC.
- 2. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 STATIC 2011-04-03.
- 2070
- 3. SHALL contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.5.3.1.4.19".
- 4. **SHALL** contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1]
 - @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.18".
 b. SHALL contain exactly one [1..1] @extension="2016-09-01"

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6.3.4.E19 Intentionally blank

6.3.4.E20 Intentionally blank

6.3.4.E21 Intentionally blank

6.4 Section not applicable

2080 This heading is not currently used in a CDA document.

Add to Section 6.5 Value Sets

UV Concept Domain	Default Vocabulary Binding or Single Code Binding	Value Set OID
Header		
CD_HPoCEncounterType.	VS_HPoCEncounterType	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.1
CD_HPoCServiceEventType	VS_HPoCServiceEventType	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.2
Plan of Care Section		
CD_HPoCInstructions	VS_HPoCInstructions	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.3
CD_HPoCActivityAct	VS_HPoCActivityAct	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.4
CD_HPoCActivityEncounter	VS_HPoCActivityEncounter	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.5
CD_HPoCActivityObservation	VS_HPoCActivityObservation	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.6
CD_HPoCActivityProcedure	VS_HPoCActivityProcedure	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.7
CD_HPoCActivitySubstanceAdminist ration	VS_HPoCActivitySubstanceAdministration	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.8
CD_HPoCActivityNon- MedicinalSupply	VS_HPoCActivtyNon-MedicinalSupply	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.9
CD_HPoCActivitySubstanceAdminist rationType	No set of concepts has consensus support for identifying different types of substances that are administered. Since this is not yet defined, any data element with a binding to this concept domain must be indicated as optional.	
CD_HPoCActivityNon- MedicinalSupplyType	No set of concepts has consensus support for identifying different types of things that are supplied. Since this is not yet defined, any data element with a binding to this concept domain must be indicated as optional.	
Hearing Screening Section		
CD_HearingScreeningOrganizer	VS_NewbornHearingScreeningOutcomeRe sultsOrganizer	single code 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.20
CD_HearingScreeningOutcomeObser vation-Left	VS_HearingScreeningOutcomeObservation - Left Ear	single code 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.21
CD_HearingScreeningOutcomeObser vation-Right	VS_HearingScreeningOutcomeObservation - Right Ear	single code 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.22
CD_HearingScreeningOutcomeObser vationValues	VS_HearingScreeningOutcomeObservation Values	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.10
CD_ReasonNotScreened	VS_ReasonNotScreened	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.11
CD_HearingScreeningResultsOrganiz er	VS_HearingScreeningResultsOrganizer	single code 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.23
CD_HearingScreeningTest	VS_NeonatalHearingScreeningTest	single code 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.24

UV Concept Domain	Default Vocabulary Binding or Single Code Binding	Value Set OID
CD_HearingScreeningTargetSites	VS_HearingScreeningTargetSites	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.12
CD_HearingScreeningMethods	VS_HearingScreeningMethods	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.13
CD_HearingScreeningTestResultValu es	VS_HearingScreeningTestResultValues	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.14
Risk Indicators for Hearing Loss		
CD_RiskFactor	VS_Risk Factor	single code 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.15
CD_RiskFactorsForHearing	VS_RiskFactorsForHearing	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.16
Problems Section		
This section does not use a Concept Domain	VS_HPoCProblemObservations	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.17
Procedures Section		
CD_HPoCActivitySubstanceAdminist rationType	No set of concepts has consensus support for identifying different types of substances that are administered. Since this is not yet defined, any data element with a binding to this concept domain must be indicated as optional.	
CD_HPoCActivityNon- MedicinalSupply	No set of concepts has consensus support for identifying different types of things that are supplied. Since this is not yet defined, any data element with a binding to this concept domain must be indicated as optional.	

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Appendices

None

Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

None

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Volume 4 – National Extensions

Add appropriate country section

4 National Extensions

4.R1 National Extensions for US Realm

4.R1.1 Comment Submission

2100 This national extension document was authored under the sponsorship and supervision of HIMSS and RSNA, who welcome comments on this document and the IHE USA initiative. Comments should be directed to:

IHE USA, Secretariat

Email: <u>iheusa@himss.org</u>

2105 **4.R1.2 Early Hearing Detection and Intervention (EHDI)**

4.R1.2.1 Hearing Screening Message – US Realm Specifications

In the referenced HL7 Version 2.6 Implementation Guide: Early Hearing Detection and Intervention (EHDI) Results, Release 1 standard, race (PID-10) and EthnicGroup (PID-22) are required but may be empty (RE). The UV Realm specification relaxed this requirement. The US Realm does not relax this requirement.

- (PID-10) Race, usage is RE
- (PID-22) EthnicGroup, usage is RE

4.R1.2.2 Hearing Plan of Care – US Realm Specifications

The convention for numbering sections in QRPH TF-4 is to duplicate the exact Technical Framework numbering as used in the Universal portion of the profile. In essence, this section provides replacement sections for the spots where the realm specific material replaces the UV Realm material.

6 Design Overview

2120 The table below provides a summarized view of all the templates used in the HPoC Document and the associated cardinalities. This summarization is provided to give implementers a view of the full "templated CDA" structure of the HPoC. It is non-normative. The normative specification for each content module is provided in Section 8 below.

Template Type	Template Title	Opt and Card	templateld
Document	HearingPlanOfCare		1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.1
Header	HearingPlanOfCareHeader	[11]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.2.1
	recordTarget	[11]	n/a
	author	[1*]	n/a
	custodian	[11]	n/a
	documentationOf/serviceEvent	[11]	
	componentOf/encompassingEncounter	[11]	
Section	Hearing Plan of Care	[11]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.1
Entry	HPoC Instructions	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.1
Entry	HPoC Activity Act	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.2
Entry	HPoC Activity Encounter	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.3
Entry	HPoC Activity Observation	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.4
Entry	HPoC Activity Procedure	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.5
Entry	HPoC Activity SubstanceAdministration	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.6
Entry	HPoC Activity Non-Medicinal Supply	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.7
Section	Hearing Screening	[11]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.2
Entry	Hearing Screening Organizer	[11]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.8
Entry	Hearing Screening Outcome Observation–Left Ear	[11]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.9
Sub-Entry	Reason Not Screened	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.10
Entry	Hearing Screening Outcome Observation-Right Ear	[11]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.11

Template Type	Template Title	Opt and Card	templateld
Sub-Entry	Reason Not Screened	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.10
Entry	Hearing Screening Results Organizer	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.12
Entry	Hearing Screening Result Observation	[1*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.13
Sub-Entry	Reason Not Screened	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.14
	Comment Activity		2.16.840.1.113883.10.20.22.4 .64
Section	Risk Indicators for Hearing Loss	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.3
Entry	Risk Indicator for Hearing Loss Observation	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.15
Section	Problems	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.4
Entry	Problem Concern	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.16
Sub-section	HPoC Problems	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.5
Entry	HPoC Problem Concern	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.17
Section	Procedures	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.6
Entry	Procedure Activity Procedure	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.18
Entry	Procedure Activity Act	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.19
Sub-Section	HPoC Procedures	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.7
Entry	HPoC Procedure Activity Procedure	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.20
Entry	HPoC Procedure Activity Act	[0*]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.4.21

7 Intentionally Blank

8 US Realm

2130 Section 8 contains US Realm template definition for the EHDI Profile.

> The template definitions contained in the EHDI Profile have been manually generated. Conformance statements may be included when material has been copied from other machine generated template definitions. In the context of the EHDI Profile all conformance statement identifiers, indicated as CONF:xxxx or as CONF: with a specific id number to follow, are invalid and should be ignored.

2135

QRPH TF-4: Appendix G includes additional implementer guidance specific to some of the information represented in the EHDI US Realm templates.

Document Templates 8.4

6.3.1.D1.1 HPoC Document Format Code

Profile	Format Code	Media Type	Template ID
HPoC US Realm	urn:ihe:qrph:HPoCUS:20 14	Text/XML	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1

2140 6.3.1.D1.5 Hearing Plan Of Care Document (V2)

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1:2016-09-01(open)]

Template Name	HearingPlanOfCare Document (V2)
Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1:2016-09-01
Parent Template	This template does not inherit constraints from another template.
General Description	This document is the US Realm version of the hearing plan of care for a newborn. It includes the hearing plan of care instructions and planned care activities. It includes the results of the hearing screening provided prior to discharge as well as information about hearing risk indicators which may be available. It includes the newborn's problems list, highlighting the concerns which are likely to be relevant for a hearing plan of care. It also includes treatment procedures performed on the newborn during the birth encounter, highlighting the procedures which are likely to be relevant for a hearing plan of care.
Document Code	"34817-7" Hearing Screening Evaluation and Management Note (CodeSystem: LOINC 2.16.840.1.113883.6.1)

Template Type	Template Title	Opt and Card	templateId
Document	Hearing Plan Of Care Document (V2)		1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.1:2016-09-01

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Treader	freating Fian Of Care freater (V2)	[1]	.2.2.1:2016-09-01				
	recordTarget	[11]	n/a				
	author	[1*]	n/a				
	custodian	[11]	n/a				
	documentationOf/serviceEvent	[11]	n/a				
	componentOf/encompassingEncounter	[11]	n/a				
Section	Hearing Plan of Care Section (V2)	[11]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.1:2016-09-01				
Section	Hearing Screening Section (V2)	[11]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.2:2016-09-01				
Section	Risk Indicators for Hearing Loss Section (V2)	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.3:2016-09-01				
Section	Problems Section (V2)	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.4:2016-09-01				
Section	HPoC Problems Sub-Section (V2)	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.5:2016-09-01				
Section	Procedures Section (V2)	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.6:2016-09-01				
Section	HPoC Procedures Sub-Section (V2)	[01]	1.3.6.1.4.1.19376.1.7.3.1.1.26 .2.3.6:2016-09-01				

Template Design Relationships

This template is an adaptation of the IHE UV Realm HPoC Document template. It references section templates which have been adapted for the US Realm. These adapted section templates 2150 include entry templates which have been adapted for the US Realm. Machine readable entries associated with US Realm templates have been modified to use vocabulary constraints established for the Hearing Plan of Care in the US Realm.

Template Purpose

This document records information for the hearing plan of care for a newborn. It includes hearing plan of care instructions and planned care activities. It includes the results of the hearing screening provided prior to discharge as well as information about hearing risk indicators which may be available. It includes the newborn's problems list, highlighting the concerns which are likely to be relevant for a hearing plan of care. It also includes treatment procedures performed on the newborn during the birth encounter, highlighting the procedures which are likely to be relevant for a hearing plan of care.

1. **SHALL** contain exactly one [1..1] **realmCode**="US".

	2. SHALL contain exactly one [11] typeId.
	a. This typeId SHALL contain exactly one [11]
2165	@root="2.16.840.1.113883.1.3".
	b. This typeId SHALL contain exactly one [11] @extension="POCD_HD000040".
	3. SHALL contain exactly one [11] templateId such that it
	a. contains exactly one [11]
	<pre>@root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1".</pre>
2170	b. SHALL contain exactly one [11] @extension="2016-09-01"
	4. SHALL contain exactly one [11] templateId such that it
	a. contains exactly one [11]
	<pre>@root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.2.1".</pre>
	b. SHALL contain exactly one [11] @extension="2016-09-01"
2175	5. SHALL contain exactly one [11] id such that it
	a. is a globally unique identifier for the document.
	6. SHALL contain exactly one [11] code such that it
	a. contains exactly one [11] @code="34817-7" Hearing Screening Evaluation
2 100	and Management Note (CodeSystem: LOINC 2.16.840.1.113883.6.1)
2180	STATIC
	7. SHALL contain exactly one [11] title such that it
	a. can either be a locally defined name or the display name corresponding to
	clinicalDocument/code.
0105	8. SHALL contain exactly one [11] effectiveTime such that it
2185	a. is conformant US Realm Date and Time (DTM.US.FIELDED) (2.16.840.1.113883.10.20.22.5.4).
	 9. SHALL contain exactly one [11] confidentialityCode, such that it
	 a. is selected from ValueSetHL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 CNE, STATIC 2010-04-21.
2190	10. SHALL contain exactly one [11] languageCode, such that it
2170	a. is selected from ValueSet Language 2.16.840.1.113883.1.11.11526 CNE,
	DYNAMIC.
	11. MAY contain zero or one [01] setId such that
	a. CONDITIONAL if setId is present versionNumber SHALL be present.
2195	12. MAY contain zero or one [01] versionNumber such that
	a. CONDITIONAL if versionNumber is present setId SHALL be present.

Implementer Guidance:

The clinicalDocument.effectiveTime element should indicate that the Hearing Plan of Care was created after the time of the event designated to trigger its creation. In some cases, policy that defines when the HPoC should be created may include a time-offset from the triggering event.

6.3.2.H1 Hearing Plan Of Care Header (V2)

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.2.1:2016-09-01(open)]

2205 **Template Design Relationships**

This template is an adaptation of the header template adopted by IHE for use in the UV Realm. Machine readable entries associated with US Realm templates have been modified to use vocabulary constraints established for the Hearing Plan of Care in the US Realm.

This template design has been adapted based on the design for the HL7 Consolidated CDA R1.1 US Realm Header template.

Template Purpose

2210

2215

This template constrains only the recordTarget, author, custodian, documentationOf/serviceEvent and componentOf/encompassingEncounter elements of the header. It adds constraints for the recordTarget.guardian role and the author (when it is a system). It also adds vocabulary constraints for the serviceEvent to encode the service of creating a hearing plan of care and encompassingEncounter to encode the type of encounter.

6.3.2.H1.1 RecordTarget

	1. SHALL contain exactly one [11] recordTarget.
	a. Such recordTargets SHALL contain exactly one [11] patientRole.
2220	i. This patientRole SHALL contain at least one $[1*]$ i.d.
	ii. This patientRole SHALL contain at least one $[1*]$ addr.
	1. The content of addr shall be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2).
	iii. This patientRole SHALL contain at least one $[1*]$ telecom.
2225	1. Such telecoms should contain zero or one [01] @use, which shall be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC .
	iv. This patientRole SHALL contain exactly one [11] patient.
	1. This patient SHALL contain exactly one [11] name.
2230	a. The content of name SHALL be a conformant US Realm Patient Name (PTN.US.FIELDED) (2.16.840.1.113883.10.20.22.5.1).
	2. This patient SHALL contain exactly one [11]
	administrativeGenderCode, which SHALL be selected from
2235	ValueSet Administrative Gender (HL7 V3)
	2.16.840.1.113883.1.11.1 DYNAMIC .
	3. This patient SHALL contain exactly one [11] birthTime.
	a. SHALL be precise to year.
	b. SHALL be precise to day.

2240	4. This patient MAY contain zero or one [01] sdtc:deceasedInd , where the @value SHALL be true if the recordTarget has died.
	5. This patient MAY contain zero or one [01] sdtc:decceasedTime , where the @value SHALL record the date and time when the recordTarget died.
2245	6. This patient MAY contain zero or one [01] sdtc:mulitpleBirthInd , where the @value SHALL be true if the recordTarget was part of a multiple birth.
2250	7. This patient MAY contain zero or one [01] sdtc:mulitpleBirthOrderNumber, where the @value SHALL
2250	 be an integer that represents their birth order position. 8. This patient MAY contain zero or one [01] religiousAffiliationCode, which SHALL be selected from ValueSet Religious Affiliation Value Set
2255	 2.16.840.1.113883.1.11.19185 DYNAMIC. 9. This patient MAY contain zero or one [01] raceCode, which shall be selected from ValueSet Race Value Set 2.16.840.1.113883.1.11.14914 DYNAMIC. Where the
2260	ethnicGroupCode holds the person's primary race. 10. This patient MAY contain zero or many [0*] sdtc:raceCode, which SHALL be selected from ValueSet Race Value Set 2.16.840.1.113883.1.11.14914 DYNAMIC . Where the ethnicGroupCode holds the person's additional races.
2265	11. This patient MAY contain zero or one [01] ethnicGroupCode, which SHALL be selected from ValueSet EthnicityGroup 2.16.840.1.114222.4.11.837 DYNAMIC. Where the ethnicGroupCode holds the person's primary ethnic groups.
2270	12. This patient MAY contain zero or many [0*] sdtc:ethnicGroupCode, which SHALL be selected from ValueSet EthnicityGroup 2.16.840.1.114222.4.11.837 DYNAMIC . Where the sdtc:ethnicGroupCode holds information about additional ethnic groups.
	13. This patient should contain one or more [1*] guardian.a. The guardian, if present, should contain zero or one
2275	[0.1] code, which SHALL be selected from ValueSet PersonalandLegalRelationshipRoleType 2.16.840.1.113883.11.20.12.1 DYNAMIC .
	 b. The guardian, if present, SHOULD contain zero or more [0*] addr. i. The content of addr SHALL be a conformant US
2280	Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2).
	c. The guardian, if present, MAY contain zero or more [0*] telecom.

2285	i. The telecom, if present, SHOULD contain zero or one [01] @use , which SHALL be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC .
	d. The guardian, if present, SHALL contain exactly one
	[11] guardianPerson.
2290	i. This guardianPerson SHALL contain at least one $[1^*]$ name.
	1. The content of name SHALL be a
	conformant US Realm Person Name
2205	(PN.US.FIELDED)
2295	(2.16.840.1.113883.10.20.22.5.1.1).
	ii. This guardianPerson MAY contain zero or one
	[01] birthplace.
	1. The birthplace, if present, SHALL contain exactly one [11] place.
2300	1. This place SHALL contain exactly
	one $[11]$ addr.
	2. This addr should contain zero or
	one [01] country, which SHALL
2305	be selected from ValueSet
2303	CountryValueSet 2.16.840.1.113883.3.88.12.
	80.63 DYNAMIC .
	3. This addr MAY contain zero or
	one $[01]$ postalCode, which
2310	shall be selected from ValueSet
	PostalCodeValueSet
	2.16.840.1.113883.3.88.12.
	80.2 DYNAMIC .
2215	4. If country is US, this addr SHALL
2315	contain exactly one [11] state, which SHALL be selected from
	ValueSet
	2.16.840.1.113883.3.88.12.80.1
	StateValueSet DYNAMIC.
2320	14. This patient MAY contain zero or one [01] birthplace.
	a. The birthplace, if present, shall contain exactly one
	[11] place.
	i. This place SHALL contain exactly one [11]
	addr.
2325	1. This addr should contain zero or one [01]
	country, which SHALL be selected from

	ValueSet CountryValueSet
	2.16.840.1.113883.3.88.12.80.63 DYNAMIC.
	2. This addr MAY contain zero or one [01]
2330	postalCode, which shall be selected from
	ValueSet PostalCodeValueSet
	2.16.840.1.113883.3.88.12.80.2 DYNAMIC .
	3. If country is US, this addr shall contain exactly
2335	one [11] state, which SHALL be selected from ValueSet 2.16.840.1.113883.3.88.12.80.1
2333	StateValueSet Dynamic.
	15. This patient should contain zero or more [0*]
	languageCommunication.
	a. The languageCommunication, if present, SHALL contain
2340	exactly one [11] languageCode, which SHALL be
	selected from ValueSet Language
	2.16.840.1.113883.1.11.11526 DYNAMIC .
	b. The languageCommunication, if present, MAY contain
	zero or one $[01]$ modeCode, which SHALL be selected
2345	from ValueSet LanguageAbilityMode Value Set
	2.16.840.1.113883.1.11.12249 DYNAMIC .
	c. The languageCommunication, if present, should
	contain zero or one [01] proficiencyLevelCode, which SHALL be selected from ValueSet
2350	LanguageAbilityProficiency
2000	2.16.840.1.113883.1.11.12199 DYNAMIC .
	d. The languageCommunication, if present, MAY contain
	zero or one [01] preferenceInd.
	6.3.2.H1.2 author
2355	1. SHALL contain at least one $[1*]$ author.
	a. Such authors SHALL contain exactly one [11] time.
	i. The content SHALL be a conformant US Realm Date and Time (DTM.US.FIELDED) (2.16.840.1.113883.10.20.22.5.4).
	b. Such authors SHALL contain exactly one [11] assignedAuthor.
2360	i. This assignedAuthor SHALL contain exactly one [11] id such that it
	1. SHALL contain exactly one [11] @root.
	a. If this assignedAuthor is an assignedPerson the
	assignedAuthor id SHALL contain exactly one [11]
	@root="2.16.840.1.113883.4.6" National Provider
2365	Identifier.
	ii. This assigned Author SHOULD contain zero or one [0.1] code.
	1. The code, if present, SHALL contain exactly one [11] @code,
	which should be selected from ValueSet Healthcare

2370	Provider Taxonomy (HIPAA) 2.16.840.1.114222.4.11.1066 DYNAMIC .							
2370	iii. This assignedAuthor shall contain at least one [1*] addr.							
	1. The content SHALL be a conformant US Realm Address							
	(AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2).							
	iv. This assigned Author SHALL contain at least one [1*] telecom.							
2375	1. Such telecoms should contain zero or one [01] @use , which shall be selected from ValueSet Telecom Use (US Realm							
	Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC .							
	v. This assignedAuthor should contain zero or one [01]							
2200	assignedPerson.							
2380	1. The assignedPerson, if present, SHALL contain at least one [1*] name.							
	a. The content SHALL be a conformant US Realm Person							
	Name (PN.US.FIELDED)							
2385	(2.16.840.1.113883.10.20.22.5.1.1). vi. This assignedAuthor should contain zero or one [01]							
2303	assignedAuthoringDevice.							
	1. The assignedAuthoringDevice, if present, SHALL contain							
	exactly one [11] manufacturerModelName.							
2390	 The assignedAuthoringDevice, if present, SHALL contain exactly one [11] softwareName. 							
	vii. There shall be exactly one assignedAuthor/assignedPerson or exactly							
	one assignedAuthor/assignedAuthoringDevice, or exactly one of each.							
	Note: Correct representation of maiden name uses the following patterns:							
2395	<name use="L"></name>							
	<given>Mary</given>							
	<family qualifier="SP">Jones</family>							
	<name use="SRCH"></name>							
2400	<given>Mary</given>							
	<family qualifier="BR">S mith</family>							

	The use at	tribute	e of the	name e	element	is not	always	provided,	but is in	cluded	in this	example.
2405	The value	"L" i	ndicates	"Legal	l Name'	" and	the value	e "SRCH"	' indicate	s this	is a nar	ne use for
	searching.											

The qualifier attribute can optionally be used with the name part sub-elements of name. In this example it is used with the family element. The value "SP" indicates "Spouse's family name" and the value "BR" indicates name given at birth.

2410 **6.3.2.H1.3 custodian**

	1. SHALL contain exactly one [11] custodian.
	a. This custodian SHALL contain exactly one [11] assignedCustodian.
	i. This assignedCustodian shall contain exactly one [11]
2415	representedCustodianOrganization.
	1. This represented Custodian Organization SHALL contain at least one $[1*]$ i.e.
	a. Such ids should contain zero or one [01]
2420	@root="2.16.840.1.113883.4.6" National Provider Identifier.
	2. This representedCustodianOrganization SHALL contain exactly one [11] name.
	3. This representedCustodianOrganization SHALL contain exactly
	one $[11]$ telecom.
2425	a. This telecom SHOULD contain zero or one [01] @use, which SHALL be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 DYNAMIC .
	4. This representedCustodianOrganization SHALL contain exactly
2430	one [11] addr.
	a. The content of addr SHALL be a conformant US Realm Address (AD.US.FIELDED) (2.16.840.1.113883.10.20.22.5.2).
	6.3.2.H1.10 ComponentOf/EncompassingEncounter
2435	
	1. MAY contain zero or one [0.1] componentOf.
	a. The componentOf, if present, SHALL contain exactly one [11]

- encompassingEncounter.
 - i. This encompassing Encounter **shall** contain at least one [1..*] id.
 - ii. This encompassing Encounter **SHOULD** contain at least one [1..*] code.
 - 1. The code, if present, **SHALL** be selected from Value Set VS_HPoCEncounterType (1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.1) **STATIC**.

2445	iii. This encompassingEncounter SHALL contain exactly one [11] effectiveTime.
	iv. This encompassingEncounter SHALL contain exactly one [11] location.
	1. This location SHALL contain exactly one [11]
	healthCareFacility.
2450	a. This healthCareFacility SHALL contain exactly one [11] serviceProviderOrganization .
	b. This healthCareFacility SHALL contain exactly one [11] location.
	Implementer Guidance:
2455	The code element of the encompassingEncounter records the type of encounter. The vocabulary binding in this template constrains the set of codes used to represent a birth encounter. This value set may be created from concepts in the ICD code system for the US Realm template.
	6.3.2.H1.11 DocumentationOf/ServiceEvent
2460	1. MAY contain zero or more [0*] documentationOf.
	a. The documentationOf, if present, SHALL contain exactly one [11]
	serviceEvent.
	i. This serviceEvent SHOULD contain exactly one [11] code.
0465	1. This code SHALL be selected from Value Set
2465	VS_HPoCServiceEvents
	(1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.2) STATIC . ii. This serviceEvent SHALL contain exactly one [11] effectiveTime.
	1. This effectiveTime shall contain exactly one [11] effectiveTime.
	iii. This serviceEvent should contain zero or more [0*] performer.
2470	1. The performer, if present, SHALL contain exactly one [11]
2470	etypeCode (CodeSystem: HL7ParticipationType
	2.16.840.1.113883.5.90 STATIC).
	a. The performer participant represents clinicians who
	actually and principally carry out the serviceEvent. In a
2475	transfer of care this represents the healthcare providers
	involved in the current or pertinent historical care of the
	patient. Preferably, the patient's key healthcare care team members would be listed, particularly their
	primary physician and any active consulting physicians,
2480	therapists, and counselors.
	2. The performer, if present, MAY contain zero or one [01] functionCode.
	a. The functionCode, if present, should contain zero or
	one [01] @codesystem, which should be selected

2485	<pre>from CodeSystem participationFunction (2.16.840.1.113883.5.88) STATIC. 3. The performer, if present, SHALL contain exactly one [11] assignedEntity.</pre>
	a. This assignedEntity SHALL contain at least one [1*] id.
2490	i. Such ids should contain zero or one [01]
	@root="2.16.840.1.113883.4.6" National Provider Identifier.
	b. This assignedEntity should contain zero or one [01]
	code.
2495	i. The code, if present, SHALL contain exactly one [11] @code, which SHOULD be selected from CodeSystem NUCCProviderTaxonomy (2.16.840.1.113883.6.101) STATIC .
Implementer	Guidance:

2500 One of the documentationOf elements should record the service event of creating the Hearing Plan of Care.

Additionally, other documentationOf elements optionally can record the derived screening outcome for each ear.

When the Hearing Plan of Care is developed by a system, Implementers will need to determine who should be listed as the performer of the service event associated with creation of the hearing plan of care. This may be someone who is responsible for reviewing the generated plan before it is completed. This header template implementation detail is out of scope for the EHDI Profile.

8.4.1 Document Template Structured Body

2510	1.		<pre>mponent/structuredBody sHALL conform to the section constraints below. sHALL contain exactly one [11] Hearing Plan of Care Section (V2)(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.1:2016-09- 01).</pre>
2515		b.	SHALL contain exactly one [11] Hearing Screening Section (V2) (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.2:2016-09-01).
		c.	MAY contain zero or one [01] Risk Indicators for Hearing Loss (V2)(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.3:2015-09-01).
2520		d.	SHOULD contain zero or one [01] Problems Section (V2)(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.4:2016-09-01).
		e.	SHOULD contain zero or one [01] Procedure Section (V2) (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.6:2016-09-01).

8.5 Section Templates

2525 6.3.3.S1 Hearing Plan of Care – Section (V2)

[Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.1:2016-09-01(open)]

Template Design Relationships

This template is an adaptation of the IHE Universal Hearing Plan of Care section template. Machine readable entries associated with this template have been modified to use US Realm vocabulary constraints established for this purpose.

This template adapts the design of the C-CDA R2.1 Plan of Care section template (2.16.840.1.113883.10.20.22.2.10) by narrowing the purpose to address only the hearing plan of care.

Template Purpose

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- 2535 The Hearing Plan of Care section contains data that defines pending orders, planned interventions (treatments (procedures)), scheduled appointments (visits (encounters)), planned testing services (observations), intended actions (act) for the patient or family members to perform, and instructions which are related to the hearing plan of care. It is limited to prospective, unfulfilled, or incomplete orders and requests only, which are indicated by the
- 2540 @moodCode of the entries within this section. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and clinical reminders. Clinical reminders are placed here to provide prompts for disease prevention and management,
- 2545 patient safety, and health-care quality improvements, including widely accepted performance measures. The plan may also indicate that patient education will be provided (act).
 - 1. MAY contain zero or one [0..1] templateId such that it
 - a. **SHALL** contain exactly one [1..1]
 - **@root**="2.16.840.1.113883.10.20.22.2.10".
- 2550 2. SHALL contain exactly one [1..1] templateId such that it
 - a. **SHALL** contain exactly one [1..1]
 - @root = "1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.1".
 - b. **SHALL** contain exactly one [1..1] @extension="2016-09-01"
 - 3. **SHALL** contain exactly one [1..1] code such that it
 - a. contain exactly one [1..1] @code="18776-5" Plan of Care for Hearing (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC).
 - 4. **SHALL** contain exactly one [1..1] title.
 - 5. **SHALL** contain exactly one [1..1] text.
 - 6. MAY contain zero or more [0..*] entry such that each
 - a. contain exactly one [1..1] HPoC Activity Act (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.2).
 - 7. MAY contain zero or more [0..*] entry such that each

a. contain exactly one [1..1] HPoC Activity Encounter (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.3). 8. MAY contain zero or more [0..*] entry such that each 2565 a. contain exactly one [1..1] HPOC Activity Observation (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.4). 9. MAY contain zero or more [0..*] entry such that each a. contain exactly one [1..1] HPoC Activity Procedure (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.5). 2570 10. MAY contain zero or more [0..*] entry such that each a. contain exactly one [1..1] HPoC Activity SubstanceAdministration (V2)(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.6:2016-09-01). 11. MAY contain zero or more [0..*] entry such that each 2575 a. contain exactly one [1.,1] HPoC Activity Non-Medicinal Supply (V2) (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.7:2016-09-01). 12. MAY contain zero or more [0..*] entry such that each a. contain exactly one [1..1] HPoC Instructions (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.1). 2580 Implementer Guidance:

When no information exists to be exchanged in a defined section, the section element may be encoded with a nullFlavor of "NI". (See the CDA Examples Task Force wiki page for examples, General Patterns. <u>http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force</u>)

6.3.3.S2 Hearing Screening – Section (V2)

2585 [Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.2:2016-09-01(open)]

Template Design Relationships

This template adapts the IHE UV Realm Hearing Screening section template. Machine readable entries associated with this template have been modified to use US Realm vocabulary constraints established for this purpose.

2590 This template adapts the C-CDA R2.1 Results section template (2.16.840.1.113883.10.20.22.2.3.1) narrowing the purpose to address only hearing screening results. A more complex organizer structure is used to record hearing screening results.

Template Purpose

The Hearing Screening section includes a screening outcome observation for each ear, which summarizes the screening results gathered for each ear. It also documents the individual screening result observations generated by the screening device each time an ear is tested.

The methodologies for summarizing screening result observations into a single screening outcome observation are jurisdictionally defined and are not specified or constrained within this template.

2600 1. SHALL contain exactly one [1..1] templateId such that it

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a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.2".

- 2. **SHALL** contain exactly one [1..1] code such that it
 - a. contain exactly one [1..1] @code="30954-2-HPOC" Relevant diagnostic tests and/or laboratory data for Hearing Screening (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC).
- 3. **SHALL** contain exactly one [1..1] title.
- 4. **SHALL** contain exactly one [1..1] text.
- 5. **SHALL** contain exactly one [1..1] entry such that it
 - a. contain exactly one [1..1] Hearing Screening Organizer (V2)(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.8:2016-09-01).

Implementer Guidance:

Methodologies for summarizing hearing screening result observations into a single hearing screening outcome for an ear are jurisdictionally defined. Systems implementing this profile as a Content Creator are required to process hearing screening results based upon a methodology which is outside the scope of this profile.

When no information exists to be exchanged in a defined section, the section element may be encoded with a nullFlavor of "NI". (See the CDA Examples Task Force wiki page for examples, General Patterns.)

This nullFlavor encoding should be used when no information has been provided about Newborn Hearing Screening being performed or not performed for medical reasons before the newborn is discharged from the birth encounter. This profiles assumes the workflow at a birthing facility include sending information to positively assert that a baby who is not screened for medical reasons. This does not constitute a "no information" screening section and nullFlavor of "NI" does not apply.

2625 **6.3.3.S3 Risk Indicators for Hearing Loss – Section (V2)**

[Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.3:2016-09-01(open)]

Template Design Relationships

This template is an adaptation of the IHE UV Realm Risk Indicators for Hearing Loss section template. Machine readable entries associated with this template have been modified to use US Realm vocabulary constraints established for this purpose.

The design is adapted from templates being developed for C-CDA R2.0 which are intended to track identified risks.

Template Purpose

The Risk Indicators for Hearing Loss section indicates if specific risks relevant to hearing loss are present or not. Use of null flavors, to encode information indicating that an assessment of the risk was not performed or to record that no information is currently available in the system, is out of scope for this template. (Alternate representations using a nullFlavor section or an alternate entry patterns for nullFlavor expressions will be considered for a future version.)

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2640	 SHALL contain exactly one [11] templateId such that it a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.3".
	b. SHALL contain exactly one [11] @extension="2016-09-01"
	2. SHALL contain exactly one $[11]$ code (<u>CONF:15433</u>) such that it
	a. contain exactly one [11] @code="58232-0"Hearing Loss Risk Indicators (CodeSystem: LOINC 2.16.840.1.113883.6.1) STATIC.
2645	3. SHALL contain exactly one [11] title.
	4. SHALL contain exactly one [11] text.
	5. SHOULD contain zero or more $[0*]$ entry such that each
	a. contain exactly one [11] Risk Indicator for Hearing Loss Observation (V2)(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.15:2016-09-01).
2650	Implementer Guidance:
	When no information exists to be exchanged in a defined section, the section element may be encoded with a nullFlavor of "NI". (See the CDA Examples Task Force wiki page for examples, General Patterns.)

6.3.3.S4 Problems – Section (V2)

2655 [Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.4:2016-09-01(open)]

Template Design Relationships

This template is an adaptation of the IHE UV Realm Problems section template. Machine readable entries associated with this template have been modified to use US Realm vocabulary constraints established for this purpose.

2660 This template adapts the design of the C-CDA R2.1 Problem section template (2.16.840.1.113883.10.20.22.2.5.1) the same entries are used, but an additional optional subsection is added which can be used to indicate concerns which may be relevant for hearing screening.

Template Purpose

- 2665 This section lists and describes all clinical problems at the time the document is generated. At a minimum, all current and historical problems should be listed.
 - 1. MAY contain zero or one [0..1] templateId such that it
 - a. contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.5.1".
 - b. **SHALL** contain exactly one [1..1] @extension="2015-08-01"
- 2670 2. SHALL contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.4".
 - b. **SHALL** contain exactly one [1..1] @extension="2016-09-01"
 - 3. SHALL contain exactly one [1..1] code such that it
 - a. contain exactly one [1..1] @code="11450-4" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1) **STATIC**.

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4. **SHALL** contain exactly one [1..1] title.

- 5. **SHALL** contain exactly one [1..1] text.
- 6. **SHALL** contain at least one [1..*] entry such that each
 - a. contain exactly one [1..1] **Problem Concern** (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.16).
- 7. MAY contain zero or one [0..1] component such that it
 - a. contain exactly one [1..1] <u>HPoC Problems Sub-Section (V2)</u> (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.5:2016-09-01).

Implementer Guidance:

2685 When no information exists to be exchanged in a defined section, the section element may be encoded with a nullFlavor of "NI". (See the CDA Examples Task Force wiki page for examples, General Patterns.)

6.3.3.S5 HPoC Problems – Sub-Section (V2)

[Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.5:2016-09-01(open)]

2690 **Template Design Relationships**

This template is an adaptation of the IHE US Realm Problems section template. The section.code element is constrained to a LOINC code that is a specialization of concept established for the Problem List in the LOINC ontology. The entry components use a more tightly constrained. They are limited to only those concerns including a problem observation that comes from a set of problems defined to be relevant to hearing screening. The entry is only an id pointer to concerns within the problem list which match the defined inclusion criteria.

Template Purpose

This sub-section gathers information within the Problem section for certain clinical problems which are identified as relevant to hearing care planning. Current and historical problems are identified as "pertinent" through the use of a value set established to identify problem observations considered relevant for hearing care planning. Concerns from the Problem section which include a problem observation that matches one of the concepts in the established value set are gathered within this specialized sub-section in order to be readily available for more efficient review or processing when the hearing plan of care is accessed.

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- 1. SHALL contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.5".
 - b. **SHALL** contain exactly one [1..1] @extension="2016-09-01"
- 2. SHALL contain exactly one [1..1] code such that it
 - a. contain exactly one [1..1] @code="11450-4-HPOC" HPOC Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1) STATIC.
- 3. **SHALL** contain exactly one [1..1] title.
- 4. **SHALL** contain exactly one [1..1] text.
- 5. **SHALL** contain at least one [1..*] entry such that they

2715 a. contain exactly one [1..1] HPoC Problem Concern (V2) (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.17:2016-09-01).

Implementer Guidance:

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When no information exists to be exchanged in a defined section, the section element may be encoded with a nullFlavor of "NI". (See the CDA Examples Task Force wiki page for examples, General Patterns.)

An HPoC Problem Concern does not repeat the full content of a Problem Concern. It "points to" a Problem Concern in the parent section using the associated id of the Problem Concern listed there.

6.3.3.S6 Procedures – Section (V2)

2725 [Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.6:2016-09-01(open)]

Template Design Relationships

This template is an adaptation of the IHE Universal Procedures section template. Machine readable entries associated with this template have been modified to use US Realm vocabulary constraints established for this purpose.

2730 This template is an adaption of the C-CDA R2.1 Procedures section template (2.16.840.1.113883.10.20.22.2.7.1). It does not utilize the Procedure Activity Observation as direct entry of the section and permits use of that template within the context of a Procedure Activity Procedure or Procedure Activity Act.

Template Purpose

- 2735 This section defines all interventional, surgical, or therapeutic procedures or treatments pertinent to the patient historically at the time the document is generated. It does not include diagnostic procedures. Diagnostic and screening procedures are recorded in a Result Section. Procedures recorded in this section are encoded using one of two machine readable entry templates. A Procedure Activity Procedure entry is used to record procedures that alter the physical condition
- of a patient (Splenectomy). A Procedure Activity Act entry is for all other types of procedures 2740 (dressing change). If a procedure produces new information about a patient, that information is recorded using the Procedure Activity Observation template as an entry relationship to the procedure or act entry with which the observation is associated. The Activity Observation template is only used as a subordinate act to the procedure of act entries associated with this 2745 section.

- 1. SHALL contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.6".
 - b. **SHALL** contain exactly one [1..1] @extension="2016-09-01"
- 2. **SHALL** contain exactly one [1..1] code such that it
 - a. contain exactly one [1..1] @code="47519-4" History of Procedures (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC).
 - 3. **SHALL** contain exactly one [1..1] title.

- 4. **SHALL** contain exactly one [1..1] text.
- 5. MAY contain zero or more [0..*] entry such that it
 - a. contain exactly one [1..1] <u>Procedure Activity Procedure (V2)</u> (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.18:2016-09-01).
- 6. MAY contain zero or more [0..*] entry such that it
 - a. contain exactly one [1..1] **Procedure Activity Act** (V2)(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.19:2016-09-01).
- 2760 7. MAY contain zero or one [0..1] component such that it
 - a. contain exactly one [1..1] <u>HPoC Relevant Procedures Sub-Section</u> (V2)(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.7:2016-09-01).

Implementer Guidance:

When no information exists to be exchanged in a defined section, the section element may be encoded with a nullFlavor of "NI". (See the CDA Examples Task Force wiki page for examples, General Patterns.)

6.3.3.S7 HPoC Relevant Procedures – Sub-Section (V2)

[Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.7:2016-09-01(open)]

Template Design Relationships

2770 This template is an adaptation of the IHE US Procedures section template. The entry components use a more tightly constrained design. They are limited to only those treatment procedures or treatment acts that come from a value set defined to indicate the type of procedures or acts that are relevant to hearing screening. The entry is only an id pointer to the procedures or acts, from the list of procedures, which match the defined inclusion criteria.

2775 **Template Purpose**

This sub-section gathers information within the Procedures section for certain clinical procedures which are identified as relevant to hearing care planning. Procedures are identified as "pertinent" through the use of a value set established to identify procedure acts and other more general acts considered relevant for hearing care planning. Procedures and acts from the Procedure section which match one of the concepts in the established value sets (one for procedures, another for other acts) are gathered within this specialized sub-section in order to be readily available for more efficient review or processing when the hearing plan of care is accessed.

- 1. SHALL contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.7".
 - b. **SHALL** contain exactly one [1..1] @extension="2016-09-01"
- 2. SHALL contain exactly one [1..1] code (CONF:15425) such that it
 - a. contain exactly one [1..1] @code="47519-4-HPOC" HPOC History of Procedures (CodeSystem: LOINC 2.16.840.1.113883.6.1 STATIC).
- 3. **SHALL** contain exactly one [1..1] title.

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- 4. **SHALL** contain exactly one [1..1] text.
 - 5. MAY contain zero or more [0..*] entry such that each

- a. contain exactly one [1..1] HPoC Procedure Activity Procedure (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.20).
- 6. MAY contain zero or more [0..*] entry such that each
 - a. contain exactly one [1..1] HPoC Procedure Activity Act (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.21).

Implementer Guidance:

When no information exists to be exchanged in a defined section, the section element may be encoded with a nullFlavor of "NI". (See the CDA Examples Task Force wiki page for examples, General Patterns.)

An HPoC Procedure Activity Procedure or Procedure Activity Act does not repeat the full content of the entry. It "points to" the entry in the parent section using the associated id of the entry listed there.

8.6 Entry Templates

2805 6.3.4.E1 HPoC Instructions

[Act type: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.1(open)]

Template Design Relationships

This template is an adaptation of the IHE UV Realm Instructions template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

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The design is based on the C-CDA R2.1 Instructions template (2.16.840.1.113883.10.20.22.4.20). A different value set is used to express the type of instructions relevant to a hearing plan of care.

Template Purpose

- 2815 The Instructions template records instructions. The act/code defines the type of instruction. Awareness of the instructions by the patient or care giver can be represented with the generic participant and the participant/awarenessCode.
 - 1. **SHALL** contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**).
 - 2. **SHALL** contain exactly one [1..1] @moodCode="INT" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**).
 - 3. SHALL contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.1".
 - 4. SHALL contain exactly one [1..1] code such that it
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- a. is selected from ValueSet VS_HPoCPatientInstructions
- (1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.3) **CWE, DYNAMIC**.
- 5. **SHALL** contain exactly one [1..1] text such that
 - a. contains exactly one [1..1] reference such that it

	i. contains exactly one $[11]$ evalue such that it						
2830	1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).						
	6. SHALL contain exactly one [11] statusCode such that it						
	a. contains exactly one [11] @code="completed" Completed (CodeSystem:						
2835	ActStatus 2.16.840.1.113883.5.14 STATIC).						
	7. SHALL contain exactly one [11] effectiveTime such that it						
	a. contain exactly one [11] low						
	b. contain exactly one [11] high.						
	6.3.4.E2 HPoC Activity Act						
2840	[Act type: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.2(open)]						
	Template Design Relationships						
	This template is a specialization of the IHE UV Realm HPoC Activity Act template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.						
2845	The design is a specialization of the C-CDA R2.1 Plan of Care Activity Act template (2.16.840.1.113883.10.20.22.4.39). A value set is added to express the type of care activities relevant to a hearing plan of care.						
Template Purpose							
	Template Purpose						
2850	Template Purpose This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received.						
2850	This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received. 1. SHALL contain exactly one [11] @classCode="ACT" (CodeSystem: HL7ActClass						
2850	 This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received. 1. SHALL contain exactly one [11] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC). 						
2850 2855	This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received. 1. SHALL contain exactly one [11] @classCode="ACT" (CodeSystem: HL7ActClass						
	 This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received. 1. SHALL contain exactly one [11] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC). 2. SHALL contain exactly one [11] @moodCode, such that it 						
	 This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received. 1. SHALL contain exactly one [11]@classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC). 2. SHALL contain exactly one [11]@moodCode, such that it a. is selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 						
	 This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received. 1. SHALL contain exactly one [11] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC). 2. SHALL contain exactly one [11] @moodCode, such that it a. is selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30. 						
	 This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received. 1. SHALL contain exactly one [11] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC). 2. SHALL contain exactly one [11] @moodCode, such that it a. is selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30. 3. MAY contain zero or one [01] templateId such that it a. contain exactly one [11] @root="2.16.840.1.113883.10.20.22.4.39". 4. SHALL contain exactly one [11] templateId such that it 						
2855	 This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received. 1. SHALL contain exactly one [11] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC). 2. SHALL contain exactly one [11] @moodCode, such that it a. is selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30. 3. MAY contain zero or one [01] templateId such that it a. contain exactly one [11] @root="2.16.840.1.113883.10.20.22.4.39". 4. SHALL contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.2". 						
2855	 This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received. 1. SHALL contain exactly one [11] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC). 2. SHALL contain exactly one [11] @moodCode, such that it a. is selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30. 3. MAY contain zero or one [01] templateId such that it a. contain exactly one [11] @root="2.16.840.1.113883.10.20.22.4.39". 4. SHALL contain exactly one [11] templateId such that it a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.2". 5. SHALL contain at least one [1*] id. 						
2855	 This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received. SHALL contain exactly one [11] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC). SHALL contain exactly one [11] @moodCode, such that it a. is selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30. MAY contain zero or one [01] templaterd such that it a. contain exactly one [11] @root="2.16.840.1.113883.10.20.22.4.39". SHALL contain exactly one [11] emplaterd such that it a. contain exactly one [11] eroot="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.2". SHALL contain at least one [11] code, such that it 						
2855 2860	 This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received. SHALL contain exactly one [11] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC). SHALL contain exactly one [11] @moodCode, such that it a. is selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30. MAY contain zero or one [01] templateId such that it a. contain exactly one [11] @root="2.16.840.1.113883.10.20.22.4.39". SHALL contain at least one [11] eroot="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.2". SHALL contain exactly one [11] code, such that it a. is selected from VS_HPoCActivityAct 						
2855	 This is the generic template for the Plan of Care Activity. This template is used to record actions the patient or patient's family should perform and education that should be received. SHALL contain exactly one [11] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC). SHALL contain exactly one [11] @moodCode, such that it a. is selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30. MAY contain zero or one [01] templaterd such that it a. contain exactly one [11] @root="2.16.840.1.113883.10.20.22.4.39". SHALL contain exactly one [11] emplaterd such that it a. contain exactly one [11] eroot="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.2". SHALL contain at least one [11] code, such that it 						

	a. contains exactly one $[11]$ reference such that it
	i. contains exactly one $[11]$ evalue such that it
2870	1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	9. SHALL contain exactly one $[11]$ statusCode.
	10. SHALL contain exactly one $[11]$ effectiveTime such that it
	a. contain exactly one [11] low
2875	b. contain exactly one [11] high.
	6.3.4.E3 HPoC Activity Encounter
	[Encounter: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.3(open)]
	Template Design Relationships
2880	This template is a specialization of the IHE UV Realm HPoC Activity Encounter template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.
	The design is based on the C-CDA R2.1 Plan of Care Activity Encounter template (2.16.840.1.113883.10.20.22.4.40). A value set is added to express the type of encounter activities relevant to a hearing plan of care.
2885	Template Purpose
	This is the template for the Plan of Care Activity Encounter. This template is used to record scheduled appointments with a specific care provider.

	1.	SHALL contain exactly one [11] @classCode="ENC" (CodeSystem: HL7ActClass
2890		2.16.840.1.113883.5.6 STATIC).
	2.	SHALL contain exactly one [11] @moodCode, such that it
		a. is selected from ValueSet Plan of Care moodCode
		(Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30.
2895	3.	MAY contain zero or one $[01]$ templateId such that it
		a. contain exactly one [11] @root="2.16.840.1.113883.10.20.22.4.40".
	4.	SHALL contain exactly one [11] templateId such that it
		a. contain exactly one $[11]$ @root=" $1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.3$ ".
	5.	SHALL contain at least one $[1*]$ id.
2900	6.	SHALL contain exactly one $[11]$ code, such that it
		a. is selected from VS_HPoCActivityEncounter
		1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.5 CWE, DYNAMIC .
	7.	SHALL contain exactly one [11] text such that
		a. contains exactly one $[11]$ reference such that it

2905	i. contains exactly one [11] @value such that it
	1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section
	4.3.5.1).
	11. SHALL contain exactly one $[11]$ statusCode.
2910	12. SHALL contain exactly one $[11]$ effectiveTime such that it
	a. contain exactly one [11] low
	b. contain exactly one [11] high.
	6.3.4.E4 HPoC Activity Observation
	[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.4(open)]
2915	Template Design Relationships
	This template is a specialization of the IHE UV Realm HPoC Activity Observation template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.
2920	The design is based on the C-CDA R2.1 Plan of Care Activity Observation template (2.16.840.1.113883.10.20.22.4.44). A value set is added to express the type of observation activities relevant to a hearing plan of care.
	Template Purpose

This is the template for the Plan of Care Activity observation. This template is used to record diagnostic tests and screenings which produce results.

2925		
	1.	SHALL contain exactly one [11] @classCode="OBS" (CodeSystem: HL7ActClass
		2.16.840.1.113883.5.6 STATIC).
	2.	SHALL contain exactly one [11] @moodCode, such that it
		a. is selected from ValueSet Plan of Care moodCode (Observation)
2930		2.16.840.1.113883.11.20.9.25 STATIC 2011-09-30.
	3.	MAY contain zero or one [01] templateId such that it
		a. contain exactly one [11] @root="2.16.840.1.113883.10.20.22.4.44".
	4.	SHALL contain exactly one [11] templateId such that it
		a. contain exactly one $[11]$ @root=" $1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.4$ ".
2935	5.	SHALL contain at least one $[1^*]$ id.
	6.	SHALL contain exactly one $[11]$ code, such that it
		a. is selected from VS_HPoCActivityObservation
		1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.6 CNE, DYNAMIC .
	7.	SHALL contain exactly one [11] text such that
2940		a. contains exactly one [11] reference such that it
		i. contains exactly one [11] @value such that it

1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).

- 2945
- 8. **SHALL** contain exactly one [1..1] statusCode.
 - 9. SHALL contain exactly one [1..1] effectiveTime such that it
 - a. contain exactly one [1..1] low
 - b. contain exactly one [1..1] high.

6.3.4.E5 HPoC Activity Procedure

```
2950 [Procedure: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.5(open)]
```

Template Design Relationships

This template is a specialization of the IHE UV Realm HPoC Activity Procedure template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

The design is a specialization of the C-CDA R2.1 Plan of Care Activity Procedure template (2.16.840.1.113883.10.20.22.4.41). A value set is added to express the type of procedure activities relevant to a hearing plan of care.

Template Purpose

This is the template for the Plan of Care Activity procedure. This template is used to record treatment or surgical procedures which produce health outcomes that change a patient's health status or condition.

1. **SHALL** contain exactly one [1..1] @classCode="PROC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**). 2965 2. **SHALL** contain exactly one [1..1] @moodCode, such that is a. is selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 **STATIC** 2011-09-30. 3. MAY contain zero or one [0..1] templateId such that it 2970 a. contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.41". 4. **SHALL** contain exactly one [1..1] templateId such that it a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.5". 5. **SHALL** contain at least one [1..*] id. 6. **SHALL** contain exactly one [1..1] code, such that it 2975 a. is selected from VS HPoCActivityProcedure 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.7 **DYNAMIC**. 7. **SHALL** contain exactly one [1..1] text such that a. contains exactly one [1..1] reference such that it i. contains exactly one [1..1] @value such that it

2980

- 1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
- 8. **SHALL** contain exactly one [1..1] statusCode.
- 9. SHALL contain exactly one [1..1] effectiveTime such that it
- 2985

- c. contain exactly one [1..1] low
- d. contain exactly one [1..1] high.

6.3.4.E6 HPoC Activity SubstanceAdministration (V2)

```
[SubstanceAdministration: templateId
1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.6:2016-09-01(open)]
```

2990 **Template Design Relationships**

This template is a specialization of the IHE UV Realm HPoC Activity Substance Administration template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

The design is based on the C-CDA R2.1 Plan of Care Activity Substance Administration template. A value set is added to express the type of substance administration activities relevant to a hearing plan of care. The consumable participation is also added to represent the material or drug administered.

Template Purpose

This is the template for the Plan of Care Activity for administering substances.

3000	
	 SHALL contain exactly one [11] @classCode="SBADM" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
	2. SHALL contain exactly one [11] @moodCode, which SHALL be selected from
	ValueSet Plan of Care moodCode (SubstanceAdministration/Supply)
3005	2.16.840.1.113883.11.20.9.24 STATIC 2011-09-30.
	3. SHALL contain exactly one [11] templateId such that it
	a. contain exactly one $[11]$ @root=" $1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.6$ ".
	b. SHALL contain exactly one [11] @extension="2016-09-01"
	4. SHALL contain at least one $[1^*]$ id.
3010	5. SHALL contain exactly one [11] text such that
	a. contains exactly one [11] reference such that it
	i. contains exactly one $[11]$ evalue such that it
3015	1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	6. SHALL contain exactly one [11] statusCode.
	7. SHALL contain exactly one [11] effectiveTime such that it
	a. contain exactly one [11] low

	b. contain exactly one [11] high.
3020	8. SHOULD contain zero or one $[01]$ effectiveTime such that it
	a. contain exactly one [11] @operator="A"
	b. contain exactly one [11] @xsi:type="PIVL_TS" or "EIVL_TS".
	9. MAY contain zero or one [01] repeatNumber such that it
3025	a. CONDITIONAL In "INT" (intent) mood, the repeatNumber defines the number of allowed administrations. For example, a repeatNumber of "3" means that the substance can be administered up to 3 times. In "EVN" (event) mood, the repeatNumber is the number of occurrences. For example, a repeatNumber of "3" in a substance administration in "EVN" means that the represented administration is the 3rd in a series.
3030	10. MAY contain zero or one $[01]$ routeCode, such that it
	a. is selected from ValueSet Medication Route FDA Value Set
	2.16.840.1.113883.3.88.12.3221.8.7 DYNAMIC .
	11. MAY contain zero or one $[01]$ approachSiteCode, such that it
	a. Is selected from ValueSet Body Site Value Set
3035	2.16.840.1.113883.3.88.12.3221.8.9 CNE, DYNAMIC.
	12. SHOULD contain zero or one [01] doseQuantity
	 a. CONDITIONAL The doseQuantity, if present, SHALL contain zero or one [01] @unit, selected from ValueSet UnitsOfMeasureCaseSensitive 2.16.840.1.113883.1.11.12839 CWE, DYNAMIC.
3040	 b. Pre-coordinated consumable: If the consumable code is a pre-coordinated unit dose (e.g., "metoprolol 25mg tablet") then doseQuantity is a unitless number that indicates the number of products given per administration (e.g., "2", meaning 2 x "metoprolol 25mg tablet").
3045	c. Not pre-coordinated consumable: If the consumable code is not pre- coordinated (e.g., is simply "metoprolol"), then doseQuantity must represent a physical quantity with @unit, e.g., "25" and "mg", specifying the amount of product given per administration.
	13. MAY contain zero or one [01] rateQuantity.
3050	 a. CONDITIONAL The rateQuantity, if present, SHALL contain exactly one [11] @unit, selected from ValueSet UnitsOfMeasureCaseSensitive 2.16.840.1.113883.1.11.12839 CWE, DYNAMIC.
	14. MAY contain zero or one [01] maxDoseQuantity.
	15. MAY contain zero or one $[01]$ administrationUnitCode, such that it
	a. be selected from ValueSet Medication Product Form Value Set
3055	2.16.840.1.113883.3.88.12.3221.8.11 CWE , DYNAMIC .
	16. SHALL contain exactly one [11] consumable such that it
	a. contain exactly one [11] Medication Information
	(V2)(templateId:2.16.840.1.113883.10.20.22.4.23:2014-06-09).
20.00	17. MAY contain zero or one [01] performer.
3060	18. MAY contain zero or more $[0*]$ participant such that it

	a. contain exactly one [11] @typeCode="CSM" (CodeSystem:
	HL7ParticipationType 2.16.840.1.113883.5.90) STATIC.
	b. contain exactly one [11] Drug Vehicle
	(templateId:2.16.840.1.113883.10.20.22.4.24).
3065	19. MAY contain zero or more $[0*]$ entryRelationship such that it
	a. contain exactly one [11] @typeCode="RSON" (CodeSystem:
	HL7ActRelationshipType 2.16.840.1.113883.5.1002) STATIC.
	b. contain exactly one [11]
	Indication(V2)(templateId:2.16.840.1.113883.10.20.22.4.19:2014
3070	-06-09).
	20. MAY contain zero or one $[01]$ entryRelationship such that it
	a. contain exactly one [11] @typeCode="SUBJ" (CodeSystem:
	HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b. contain exactly one [11] @inversionInd="true".
3075	c. contain exactly one [11] <u>Instruction</u>
	(V2)(templateId:2.16.840.1.113883.10.20.22.4.20:2014-06-09).
	21. MAY contain zero or one $[01]$ entryRelationship such that it
	a. contain exactly one [11] @typeCode="REFR" (CodeSystem:
	HL7ActRelationshipType 2.16.840.1.113883.5.1002) STATIC .
3080	b. contain exactly one [11] <u>Medication Supply Order</u>
	(V2)(templateId:2.16.840.1.113883.10.20.22.4.17:2014-06-09).
	22. MAY contain zero or more $[0*]$ entryRelationship such that each
	a. contain exactly one [11] @typeCode="REFR" (CodeSystem:
	HL7ActRelationshipType 2.16.840.1.113883.5.1002) STATIC .
3085	b. contain exactly one [11] Medication Dispense (V2)
	(templateId:2.16.840.1.113883.10.20.22.4.18:2014-06-09).
	23. MAY contain zero or one $[01]$ entryRelationship such that it
	a. contain exactly one [11] @typeCode="CAUS" (CodeSystem:
	HL7ActRelationshipType 2.16.840.1.113883.5.1002) STATIC .
3090	b. contain exactly one [11] <u>Reaction Observation</u>
	(V2)(templateId:2.16.840.1.113883.10.20.22.4.9:2014-06-09).
	24. MAY contain zero or more $[0*]$ precondition such that it
	a. contain exactly one [11] @typeCode="PRCN" (CodeSystem:
	HL7ActRelationshipType 2.16.840.1.113883.5.1002) STATIC .
3095	b. contain exactly one [11] Precondition for Substance Administration
	(V2)(templateId:2.16.840.1.113883.10.20.22.4.25:2014-06-09).
	25. SHOULD include doseQuantity OR rateQuantity.

6.3.4.E7 HPoC Activity Non-medicinal Supply (V2)

3100 [Supply: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.7:2016-09-01(open)]

Template Design Relationships

This template is a specialization of the IHE UV Realm HPoC Activity Non-medicinal Supply template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

3105 The design is based on the C-CDA R2.1 Plan of Care Activity Non-medicinal Supply template. A value set is added to express the type of non-medicinal supply activities relevant to a hearing plan of care. The participant participation is added to represent the device or equipment being supplied.

Template Purpose

3110 This is the template for the Plan of Care Activity for supplying non-medicinal medical Equipment.

	1.	SHALL contain exactly one [11] @classCode="SPLY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
3115	2.	SHALL contain exactly one $[11]$ $moodcode$, which SHALL be selected from ValueSet
		Plan of Care moodCode (SubstanceAdministration/Supply)
		2.16.840.1.113883.11.20.9.24 STATIC 2011-09-30.
	3.	SHALL contain exactly one [11] templateId such that it
		a. contain exactly one $[11]$ @root=" $1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.7$ ".
3120		b. SHALL contain exactly one [11] @extension="2016-09-01"
	4.	SHALL contain at least one $[1*]$ id.
	5.	SHALL contain exactly one [11] text such that
		a. contains exactly one [11] reference such that it
		i. contains exactly one [11] @value such that it
3125		 begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	6.	SHALL contain exactly one [11] statusCode.
		SHOULD contain zero or one [01] effectiveTime such that it
3130		a. CONDITIONAL if present, contain zero or one [01] high.
0100	8.	SHOULD contain zero or one [01] quantity.
		MAY contain zero or one [01] participant such that it
).	a. contain exactly one [11] @typeCode="PRD" Product (CodeSystem:
		HL7ParticipationType 2.16.840.1.113883.5.90 STATIC).
3135		
5155		b. contain exactly one [11] <u>Product Instance</u> (templateId:2.16.840.1.113883.10.20.22.4.37).
		(ccmpracera.z.io.oro.i.iii)000.ro.zo.zo.i.o//.

6.3.4.E8 Hearing Screening Organizer (V2)

[Organizer: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.8:2016-09-01(open)]

3140 **Template Design Relationships**

This template further constrains of the IHE US Realm Hearing Screening Organizer section template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

The design is builds upon on the C-CDA R2.1 Result Organizer template.

3145 **Template Purpose**

This organizer records the outcome assessment of the hearing screening and the associated results used to determine the outcome assessment. It includes a component for the "screening outcome" for the left ear and a component "screening outcome" for the right ear. Each of the outcome observations carries an optional indication of the reason screening was not performed.

3150 The Hearing Screening Organizer also includes the set of result observations which were gathered. They are a third component and are organized in a Results Organizer.

Implementer Guidance

The effective Time of the organizer is an interval that spans the effective Times of the contained result observations.

3155 If screening results become available that were performed after the baby is discharged from the birth encounter, these results need to be represented in a separate organizer which would be related temporally with the encounter associated with the screening event.

The effective Time/low will match the time of the triggering event that indicated the start of the encounter where the screening information was being collected. The effective Time/high will match the time of the triggering event that indicated the end of the encounter where the screening

information was being collected.

3160

Note: If any Result Observation within the Result Organizer has a statusCode of 'active', the Result Organizer must also have as statusCode of 'active'.

3165	1. SHALL contain exactly one [11] @classCode= = "CLUSTER" (CodeSystem:
	HL7ActClass 2.16.840.1.113883.5.6) STATIC
	2. SHALL contain exactly one [11] @moodCode="EVN" Event (CodeSystem: ActMood
	2.16.840.1.113883.5.1001) STATIC .
	3. SHALL contain exactly one [11] templateId such that it
3170	a. contain exactly one $[11]$ @root=" $1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.8$ ".
	b. SHALL contain exactly one [11] @extension="2016-09-01"
	4. SHALL contain at least one $[1^*]$ id.
	5. SHALL contain exactly one $[11]$ code such that it
	a. contain exactly one [11] @code=" 54111-0" Newborn Hearing Loss Pane
3175	(CodeSystem: LOINC 2.16.840.1.113883.6.1) STATIC.

	6.	SHALL contain exactly one [11] statusCode such that it
		a. contain exactly one [11] @code, which is selected from ValueSet Result
		Status 2.16.840.1.113883.11.20.9.39 STATIC .
	7.	SHALL contain exactly one [11] effectiveTime such that it
3180		a. contain exactly one [11] low
		b. contain exactly one [11] high.
	8.	SHALL contain exactly one [11] component such that it
		a. contain exactly one [11] Hearing Screening Outcome Observation – Left Ear (v2) templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.9:2016-09-01).
3185	9.	SHALL contain exactly one [11] component such that it
		a. contain exactly one [11] Hearing Screening Outcome Observation – Right Ear (V2) templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.11:2016-09-01).
	10.	SHALL contain exactly one [11] component such that it
3190		a. contain exactly one [11] Hearing Screening Results Organizer (V2) templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.12:2016-09-01).

6.3.4.E9 Hearing Screening Outcome Observation-Left (V2)

[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.9:2016-09-01(open)]

Template Design Relationships

3195 This template is a further constraint of the IHE UV Realm Hearing Screening Outcome Observation - Left template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

Template Purpose

3205

3210

This observation records the assessment of the screening for the left ear. It uses a jurisdictionally defined algorithm for aggregating multiple screening results into a final assessment observation. When screening is not performed on an ear, the reason for not performing the screening is also recorded.

1.	SHALL contain	exactly one	[11] @clas	ssCode="OBS"	Observation	(CodeSystem:
	HL7ActClass	2.16.840.	1.113883.5	5.6) STATIC .		

- 2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) **STATIC**.
- 3. MAY contain zero or one [0..1] @negationInd.
- 4. SHALL contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.9".
 - b. **SHALL** contain exactly one [1..1] @extension="2016-09-01"
- 5. **SHALL** contain at least one [1..*] id.
- 6. **SHALL** contain exactly one [1..1] code such that it

3215	a. contain exactly one [11] @code=" 73741-1" Newborn Hearing screen panel of Ear - left (CodeSystem: LOINC 2.16.840.1.113883.6.1) STATIC .
	7. SHALL contain exactly one $[11]$ text such that
	a. contains exactly one [11] reference such that it
	i. contains exactly one [11] @value such that it
3220	 begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	8. SHALL contain exactly one $[11]$ statusCode such that it
	a. contain exactly one [11] @code, which is selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 STATIC .
3225	9. SHALL contain exactly one [11] effectiveTime .
	a. Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards).
	10. SHALL contain exactly one [11] value , such that it
3230	a. be declared as data type xsitype $=$ "CD"
	b. be selected from Value Set VS_HearingScreeningOutcomeObservationValues 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.10 CNE, STATIC.
	11. MAY contain zero or one [01] methodCode.
3235	a. be selected from Value Set VS_HearingScreeningMethods 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.13 CNE, STATIC.
	12. MAY contain zero or one [01] targetSiteCode .
	a. be selected from Value Set VS_HearingScreeningTargetSites 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.12 CNE, STATIC.
	13. MAY contain zero or one [01] author .
3240	14. MAY contain zero or one $[01]$ entryRelationship.
	 a. CONDITIONAL The entryRelationship, if present, SHALL contain exactly one [11] @typeCode="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b. CONDITIONAL The entryRelationship, if present, SHALL contain exactly one
3245	[11] Reason Not Screened (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.10).

6.3.4.E10 Reason Not Screened

[Act: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.10(open)]

Template Design Relationships

3250 This template is a further constraint of the IHE UV Realm Reason Not Screened template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

Template Purpose

This template documents the reason why hearing screening was not performed.

3255	
	1. SHALL contain exactly one [11] @classCode="ACT" (CodeSystem: HL7ActClas
	2.16.840.1.113883.5.6 STATIC).
	2. SHALL contain exactly one [11] @moodCode="EVN" (CodeSystem: ActMood
	2.16.840.1.113883.5.1001) STATIC .
3260	3. SHALL contain exactly one [11] templateId such that it
	a. contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.10"
	4. SHALL contain exactly one $[11]$ code, such that is
	a. be selected from Value Set VS_ReasonNotScreened
	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.11 CNE, STATIC.
3265	5. SHALL contain exactly one $[11]$ text such that
	a. contains exactly one $[11]$ reference such that it
	i. contains exactly one [11] @value such that it
	1. begins with a '#' and points to its corresponding narrative
	(using the approach defined in CDA Release 2, Section
3270	4.3.5.1).

6.3.4.E11 Hearing Screening Outcome Observation-Right (V2)

[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.11:2016-09-01(open)]

Template Design Relationships

3275 This template is a further constraint of the IHE US Realm Hearing Screening Outcome Observation - Right template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

Template Purpose

- This observation records the assessment of the screening for the right ear. It uses a jurisdictionally defined algorithm for aggregating multiple screening results into a final assessment observation. When screening is not performed on an ear, the reason for not performing the screening is also recorded.
- 3285

3290

- 1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) **STATIC**.
- 2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) **STATIC**.
- 3. MAY contain zero or one [0..1] @negationInd.
- 4. SHALL contain exactly one [1..1] templateId such that it
 - a. contain exactly one [1..1] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.11".

	h arrest contain and the set [1, 1] and the set of set of set
	b. SHALL contain exactly one [11] @extension="2016-09-01"
	5. SHALL contain at least one [1*] id.
	6. SHALL contain exactly one [11] code such that it
3295	a. contain exactly one [11] @code=" 73744-5" Newborn Hearing screen panel of Ear - right (CodeSystem: LOINC 2.16.840.1.113883.6.1) STATIC .
	7. SHALL contain exactly one $[11]$ text such that
	a. contains exactly one [11] reference such that it
	i. contains exactly one $[11]$ evalue such that it
3300	 begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	8. SHALL contain exactly one [11] statusCode such that it
	a. be selected from ValueSet Result Status
	2.16.840.1.113883.11.20.9.39 CNE, STATIC.
3305	9. SHALL contain exactly one [11] effectiveTime.
	a. Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards).
	10. SHALL contain exactly one [11] value , such that it
3310	a. be declared as data type $xsitype = CD'$
	b. be selected from Value Set VS_HearingScreeningOutcomeObservationValues 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.10 CNE, STATIC.
	11. MAY contain zero or one [01] methodCode.
3315	a. be selected from Value Set VS_HearingScreeningMethods 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.13 CNE, STATIC.
	12. MAY contain zero or one [01] targetSiteCode .
	a. be selected from Value Set VS_HearingScreeningTargetSites 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.12 CNE, STATIC.
	13. MAY contain zero or one [01] author .
3320	14. MAY contain zero or one $[01]$ entryRelationship.
	a. CONDITIONAL The entryRelationship, if present, SHALL contain exactly one [11] @typeCode="RSON" Has Reason (CodeSystem:
	HL7ActRelationshipType 2.16.840.1.113883.5.1002) STATIC .
3325	b. CONDITIONAL The entryRelationship, if present, SHALL contain exactly one [11] Reason Not Screened (templateId:
5545	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.10).

6.3.4.E12 Hearing Screening Results Organizer (V2)

[Organizer: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.12:2016-09-01(open)]

3330 Template Design Relationships

This template is a further constraint of the IHE UV Realm Hearing Screening Results Organizer template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

The design is a further constraint of the C-CDA Result Organizer (2.16.840.1.113883.10.20.22.4.1).

Template Purpose

3335

This organizer records the hearing screening results used to determine the outcome assessments.

Implementer Guidance

The effectiveTime of the organizer is an interval that spans the effectiveTimes of the contained result observations.

	1.	SHALL contain exactly one [11] @classCode= ="CLUSTER" (CodeSystem:
		HL7ActClass 2.16.840.1.113883.5.6) STATIC.
	2.	SHALL contain exactly one [11] @moodCode="EVN" Event (CodeSystem: ActMood
3345		2.16.840.1.113883.5.1001) STATIC .
	3.	MAY contain zero or one [01] templateId such that it
		a. contain exactly one $[11]$ @root="2.16.840.1.113883.10.20.22.4.1".
		b. SHALL contain exactly one [11] @extension="2015-08-01"
	4.	SHALL contain exactly one [11] templateId such that it
3350		a. contain exactly one $[11]$ @root=" $1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.12$ ".
		b. SHALL contain exactly one [11] @extension="2016-09-01"
	5.	SHALL contain at least one $[1*]$ id.
	6.	SHALL contain exactly one $[11]$ code such that it
3355		a. contain exactly one [11] @code=" 417491009" Neonatal Hearing Test (Procedure) (CodeSystem: SNOMED CT 2.16.840.1.113883.6.96) STATIC .
	7.	SHALL contain exactly one [11] statusCode such that it
		a. be selected from ValueSet Result Status
		2.16.840.1.113883.11.20.9.39 CNE, STATIC.
	8.	SHALL contain zero or more $[0*]$ component such that it
3360		a. contain exactly one [11] Result Observation templateId:
		1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.13).

6.3.4.E13 Hearing Screening Result Observation (V2)

[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.13:2016-09-3365 01(open)]

Template Design Relationships

This template is a further constraint of the IHE UV Realm Hearing Screening Result Observation template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

- 3370 The design is an adaptation of the C-CDA Result Observation template (2.16.840.1.113883.10.20.22.4.2). Hearing screening devices return a value which results from interpreting their internal readings to produce a result from the device. In the future, if raw values will be returned from the device, then an interpretation code element would be needed and the associated reference ranges could be defined. For now, the value returned from the test is
- 3375 sufficient for both capturing the measure result and interpreting the result.

Template Purpose

This observation records the result of screening an ear. When the screening device returns an invalid reading, the reason for this invalid result may be recorded if it is known or determinable.

In this template the negationInd attribute of the observation act SHALL function as defined for 3380 Observation. ActionNegationInd in the HL7 V3 Core Principles. This negation behavior affects the action of the act and is further constrained by other elements of the act class which are the elements of the act class which are not considered related to the document's context. For example: elements like id and statusCode are not affected by the negation which the Observation.ActionNegationInd mechanism is used.

3385	
	1. SHALL contain exactly one [11] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) STATIC .
	2. shall contain exactly one [11] @moodCode="EVN" Event (CodeSystem: ActMood
	2. SHALL contain exactly one [11] @moodcode="EVN" Event (CodeSystem: Actmood 2.16.840.1.113883.5.1001) STATIC.
3390	3. CONDITIONAL: WHEN THE HEARING SCREENING WAS NOT PERFORMED: SHALL contain
	exactly one [11] @negationInd="true" Event (CodeSystem: ActMood
	2.16.840.1.113883.5.1001) STATIC .
	4. MAY contain zero or one $[01]$ templateId such that it
	a. contain exactly one $[11]$ @root="2.16.840.1.113883.10.20.22.4.2".
3395	b. SHALL contain exactly one [11] @extension="2015-08-01"
	5. SHALL contain exactly one [11] templateId such that it
	a. contain exactly one $[11]$ @root=" $1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.13$ ".
	b. SHALL contain exactly one [11] @extension="2016-09-01"
	6. SHALL contain at least one $[1*]$ id.
3400	7. SHALL contain exactly one [11] code such that it

	a. contain exactly one [11] @code=" 417491009" Neonatal Hearing Test (Procedure) (CodeSystem: SNOMED CT 2.16.840.1.113883.6.96) STATIC .
	8. SHALL contain exactly one [11] text such that
	a. contains exactly one [11] reference such that it
3405	i. contains exactly one $[11]$ @value such that it
	 begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	9. SHALL contain exactly one $[11]$ statusCode such that it
3410	a. be selected from ValueSet Result Status
	2.16.840.1.113883.11.20.9.39 CNE, STATIC.
	10. SHALL contain exactly one [11] effectiveTime .
3415	a. Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards).
	11. SHALL contain exactly one [11] value , such that it
	a. be declared as data type xsitype $=$ "CD"
	b. be selected from Value Set VS_HearingScreeningTestResultValues 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.14 CNE, STATIC.
3420	12. CONDITIONAL: SHALL NOT contain a value when negationInd="true".
	13. SHALL contain zero or one [01] methodCode.
	a. be selected from Value Set VS_HearingScreeningMethods 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.13 CNE, STATIC.
	14. CONDITIONAL: SHALL NOT contain a methodCode when negationInd="true".
3425	15. SHALL contain zero or one [01] targetSiteCode .
	a. be selected from Value Set VS_HearingScreeningTargetSites 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.12 CNE, STATIC.
	16. CONDITIONAL: SHALL NOT contain a methodCode when negationInd="true".
	17. MAY contain zero or one [01] author .
3430	18. SHOULD contain zero or one [01] performer .
	 CONDITIONAL: SHALL contain exactly one [11] entryRelationship when negationInd="true", such that it
3435	 a. shall contain exactly one [11] @typeCode="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 static).
5455	 b. The entryRelationship, if present, SHALL contain exactly one [11] Reason Not Screened (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.10).
	20. CONDITIONAL: SHALL NOT contain an entryRelationship with @typeCode="RSON" when negationInd="false".
3440	21. MAY contain zero or one $[01]$ entryRelationship.

c. **CONDITIONAL** The entryRelationship, if present, **SHALL** contain exactly one [1..1] @typeCode="REFR" Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) **STATIC**.

3445

d. **CONDITIONAL** The entryRelationship, if present, **SHALL** contain exactly one [1..1] **Comment Activity** (templateId: 2.16.840.1.113883.10.20.22.4.64).

6.3.4.E14 Comment Activity

[act: templateId 2.16.840.1.113883.10.20.22.4.64 (open)]

Template Design Relationships

This template is a transclusion of the HL7 Comment Activity template (2.16.840.1.113883.10.20.22.4.64).

Template Purpose

Comments are free text data that cannot otherwise be recorded using data elements already defined by this specification. They SHALL NOT be used to record information that can be recorded elsewhere. For example, a free text description of the severity of an allergic reaction would not be recorded in a comment.

- 1. SHALL contain exactly one [1..1] @classCode="ACT" Act (CodeSystem: HL7ActClass
 - 2.16.840.1.113883.5.6 **STATIC**) (CONF:9425).
 2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood

3460

3475

3455

- 2.16.840.1.113883.5.1001 **STATIC**) (CONF:9426).
- 3. SHALL contain exactly one [1..1] templateId (CONF:9427) such that it
 - a. **SHALL** contain exactly one [1..1]
 - @root="2.16.840.1.113883.10.20.22.4.64" (CONF:10491).

6.3.4.E15 Risk Indicator for Hearing Loss Observation (V2)

3465 [Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.15:2016-09-01(open)]

Template Design Relationships

This template is a further constraint of the IHE UV Realm Risk Indicator for Hearing Loss Observation template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

Template Purpose

This template records a set of hearing related risks which may be assessed. Each clinical statement indicates if a particular risk is present or not. Risks that are not assessed do not have to be included. (Use of nullFlavors to express exceptional cases for the risk not being asses will be considered in a future version.)

	1. SHALL contain exactly one [11] @classCode="OBS" (CodeSystem: HL7ActClass
	2.16.840.1.113883.5.6 STATIC).
2400	2. SHALL contain exactly one [11] @moodCode="EVN" (CodeSystem: ActMood
3480	2.16.840.1.113883.5.1001 STATIC).
	3. SHALL contain exactly one [11] templateId such that it
	a. contain exactly one $[11]$ @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.15".
	b. SHALL contain exactly one [11] @extension="2016-09-01"
	4. SHALL contain exactly one [11] templateId such that it
3485	a. contain exactly one $[11]$ @root=" $1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.15$ ".
	b. SHALL contain exactly one [11] @extension="2016-09-01"
	5. SHALL contain at least one $[1*]$ id.
	6. SHALL contain exactly one $[11]$ code such that it
3490	a. contain exactly one [11] @code=" 80943009" Risk Factor (CodeSystem: SNOMED CT 2.16.840.1.113883.6.96).
	7. SHALL contain exactly one $[11]$ text such that
	a. contain exactly one [11] reference such that it
	i. contains exactly one $[11]$ evalue such that it
3495	1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	8. SHALL contain exactly one [11] statusCode such that it
	a. contain exactly one [11] @code="completed" Completed (CodeSystem:
	ActStatus 2.16.840.1.113883.5.14 STATIC).
3500	9. SHOULD contain zero or one [01] effectiveTime.
	10. SHALL contain exactly one $[11]$ value such that it:
	a. be defined as data type @xsitype="CD"
	b. be selected from ValueSet VS_RiskFactorsForHearing
	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.16 CWE, DYNAMIC .
3505	11. MAY contain zero or one $[01]$ entryRelationship.
	a. CONDITIONAL The entryRelationship, if present, SHALL contain exactly one [11] @typeCode="REFR" Refers to (CodeSystem:
	HL7ActRelationshipType 2.16.840.1.113883.5.1002) STATIC .
3510	b. CONDITIONAL The entryRelationship, if present, SHALL contain exactly one [11] Comment Activity (templateId: 2.16.840.1.113883.10.20.22.4.64).
	6.3.4.E16 Problem Concern
	[Act: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.16(open)]

Template Design Relationships

This template is an adaptation of the IHE UV Realm Problem Concern template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

This template is a design copy of the C-CDA R2.1 Problem Concern template (2.16.840.1.113883.10.20.22.4.3). This design for the Problem Concern directly references the HL7 C-CDA R2.1 Problem Observation template (transclusion). This design ensures that all structural and vocabulary constrains for expressing problem observations in the US Realm will be consistent.

Template Purpose

3520

The problem concern template is a "tracker" which allows one or more problem observations to be grouped together and tracked over time as being associated with this particular concern.

3525	
	1. SHALL contain exactly one [11] @classCode="ACT" Act (CodeSystem: HL7ActClass
	2.16.840.1.113883.5.6 STATIC).
	2. shall contain exactly one [11] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).
3530	3. MAY contain zero or one $[01]$ templateId such that it
	a. contain exactly one [11]
	@root="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.16".
	b. SHALL contain exactly one [11] @extension="2016-09-01"
	4. MAY contain zero or one $[01]$ templateId such that it
3535	a. contain exactly one $[11]$ @root="2.16.840.1.113883.10.20.22.4.3".
	5. SHALL contain exactly one [11] templateId such that it
	a. contain exactly one [11]
	<pre>@root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.16".</pre>
	6. SHALL contain at least one $[1*]$ i.d.
3540	7. SHALL contain exactly one $[11]$ code such that it
	a. contain exactly one [11] @code="CONC" Concern (CodeSystem:
	HL7ActClass 2.16.840.1.113883.5.6 STATIC).
	8. SHALL contain exactly one $[11]$ text such that
	a. contain exactly one [11] reference such that it
3545	i. contain exactly one $[11]$ @value such that it
	1. begin with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
	9. SHALL contain exactly one $[11]$ statusCode, such that it
	a. be selected from ValueSet ProblemAct statusCode
3550	2.16.840.1.113883.11.20.9.19 CNE, STATIC $2011-09-09$.
	The effectiveTime element records the starting and ending times during which the concern was active on the Problem List.
	10. SHALL contain exactly one $[11]$ effectiveTime.
	a. This effective Time shall contain exactly one [11] low.
3555	b. This effective Time should contain zero or one [01] high.
	11. SHALL contain at least one $[1*]$ entryRelationship such that each

a. contain exactly one [1..1] @typeCode="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).

- 3560

b. contain exactly one [1..1] **Problem Observation** (V3)(templateId:2.16.840.1.113883.10.20.22.4.4:2015-08-01).

6.3.4.E17 HPoC Problem Concern (V2)

[Act: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.17:2016-09-01(open)]

Template Design Relationships

This template is an adaptation of the IHE US Realm Problem Concern template. The entry uses a more tightly constrained design. Entries are limited to only those procedures defined to be 3565 relevant to hearing screening. The entry is only an id pointer to concerns within the procedure list which match the defined inclusion criteria.

Template Purpose

The problem concern template is a "tracker" which allows one or more problem observations to be grouped together and tracked over time as being associated with this particular concern. The 3570 HPOC Problem Concern template further includes constraints which identify the concerns being tracked which include a Problem Observation that is relevant for Hearing Screening.

	1.	CONDITIONAL For each Problem Concern entry in the Problems Section where at least
3575		One Problem Observation (V3)
		(templateId:2.16.840.1.113883.10.20.22.4.4:2015-08-01) has a value
		element with an @code that is present in Value Set VS_HPoCProblemObservations
		1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.17:
	2.	SHALL contain exactly one [11] @classCode="ACT" Act (CodeSystem: HL7ActClass
3580		2.16.840.1.113883.5.6 STATIC).
	3.	SHALL contain exactly one [11] @moodCode="EVN" Event (CodeSystem: ActMood
		2.16.840.1.113883.5.1001 STATIC).
	4.	SHALL contain exactly one [11] templateId such that it
		a. contain exactly one $[11]$ eroot="2.16.840.1.113883.10.20.22.4.3".
3585		b. SHALL contain exactly one [11] @extension="2016-09-01"
	5.	SHALL contain exactly one [11] id such that it
		a. references the id of the associated Problem Concern Entry where the
		conditional conformance statement for the value element of the Problem
		Concern entry is true.
3590	6.3.4.E18	3 Procedure Activity Procedure (V2)

[Procedure: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.18:2016-09-01(open)]

Template Design Relationships

This template is a further constraint of the IHE UV Realm Procedure Activity Procedure template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

This template is an adaptation of the Procedure Activity Procedure template. It references, by transclusion, other C-CDA R2.1 templates used within Procedure Activity Procedure template including: Indication, Instruction, Medication Activity, Product Instance, and Service Delivery Location. It also supports an optional procedure activity observation template which can be used

3600 Location. It also supports an optional procedure activity observation template which can be used to document new information about the patient that is discovered during the course of providing care or performing a treatment.

Template Purpose

This clinical statement represents procedures whose immediate and primary outcome (postcondition) is the alteration of the physical condition of the patient. Examples of these procedures are an appendectomy, hip replacement and a creation of a gastrostomy.

		SHALL contain exactly one [11] @classCode="PROC" Procedure (CodeSystem:
		HL7ActClass 2.16.840.1.113883.5.6) STATIC .
3610		SHALL contain exactly one [11] @moodCode, which SHALL be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 STATIC 2011-04-03.
	3.	SHALL contain exactly one [11] templateId such that it
		a. contain exactly one $[11]$ @root="2.16.840.1.113883.10.20.22.4.14".
		b. SHALL contain exactly one [11] @extension="2016-09-01"
3615	4.	SHALL contain at least one $[1^*]$ id.
	5.	SHALL contain exactly one [11] code such that it
		a. contain zero or one [01] originalText.
		i. CONDITIONAL The original Text, if present, SHALL contain exactly one
		[11] reference such that it
3620		1. contains exactly one $[11]$ @value such that it
		a. begin with a '#' and point to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
3625		 b. be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96), and or CPT-4 (CodeSystem: 2.16.840.1.113883.6.12) or ICD10 PCS (CodeSystem: 2.16.840.1.113883.6.4).
	6.	SHALL contain exactly one [11] text such that
		a. contains exactly one $[11]$ reference such that it
3630		i. contains exactly one [11] @value such that it
		 begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).

3635	 7. SHALL contain exactly one [11] statusCode, such that it a. be selected from ValueSet ProcedureAct statusCode 2.16.240.1.112002.11.20.0.22 CNR DWNAMC
	2.16.840.1.113883.11.20.9.22 CNE, DYNAMIC. 8. SHOULD contain zero or one [01] effectiveTime.
	 9. MAY contain zero or one [01] priorityCode, such that it
	a. be selected from ValueSet Act Priority Value Set
3640	2.16.840.1.113883.1.11.16866 CNE, DYNAMIC.
0010	10. MAY contain zero or one [01] methodCode such that it
	a. does not conflict with the method inherent in Procedure / code.
	11. SHOULD contain zero or more $[0*]$ targetSiteCode such that each
	a. CONDITIONAL if present, contain exactly one [11] @code such that it
3645	i. be selected from ValueSet Body Site Value Set
	2.16.840.1.113883.3.88.12.3221.8.9 CNE, DYNAMIC .
	12. MAY contain zero or more $[0*]$ specimen such that each
	a. CONDITIONAL if present, SHALL contain exactly one [11] specimenRole such that it
3650	i. contain zero or more $[0*]$ is such that each
	1. the Procedure/specimen/specimenRole/id REFERENCES a Result Organizer/specimen/specimenRole/id to indicate it is referring to the same specimen.
3655	b. Note: This specimen is for representing specimens obtained from a procedure which may also undergo a testing observation in order to be assessed.
	13. SHOULD contain zero or more $[0*]$ performer such that each
	a. CONDITIONAL if present SHALL contain exactly one [11] assignedEntity such that it
	i. contain at least one [1*] id.
3660	ii. contain exactly one $[11]$ addr.
	iii. contain exactly one [11] telecom.
	iv. contain zero or one $[01]$ represented Organization such that it
	1. CONDITIONAL if present, SHOULD contain zero or more $[0*]$ id
	2. CONDITIONAL if present, MAY contain zero or more $[0*]$ name
3665	3. CONDITIONAL if present, SHALL contain exactly one [11]
	telecom
	4. CONDITIONAL if present, SHALL contain exactly one $[11]$ addr
	14. MAY contain zero or more $[0*]$ participant such that each
2/70	a. contain exactly one [11] @typeCode="DEV" Device (CodeSystem:
3670	HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b. contain exactly one [11] <u>Product Instance</u> (templateId:2.16.840.1.113883.10.20.22.4.37).
	15. MAY contain zero or more [0*] participant such that each
	10. Mar contain 2010 of more [o.,] participant such unt cach

3675	a. contain exactly one [11] @typeCode="LOC" Location (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 STATIC).
0010	b. contain exactly one [11] Service Delivery Location
	(templateId:2.16.840.1.113883.10.20.22.4.32).
	16. MAY contain zero or more $[0*]$ entryRelationship such that each
	a. contain exactly one [11] @typeCode="COMP" Has Component (CodeSystem:
3680	HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b. contain exactly one [11] @inversionInd="true".
	c. contain exactly one [11] encounter such that it
	i. This encounter SHALL contain exactly one [11] @classCode="ENC" Encounter (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6
3685	STATIC).
	ii. This encounter SHALL contain exactly one [11] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).
	iii. This encounter SHALL contain exactly one [11] id.
	1. Set the encounter ID to the ID of an encounter in another
3690	section to signify they are the same encounter.
	17. MAY contain zero or one $[01]$ entryRelationship such that it
	a. contain exactly one [11] @typeCode="SUBJ" Has Subject (CodeSystem:
	HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b. contain exactly one [11] @inversionInd="true" true.
3695	c. contain exactly one [11] <u>Instructions</u>
	(V2)(templateId:2.16.840.1.113883.10.20.22.4.20:2014-06-09).
	18. MAY contain zero or more $[0*]$ entryRelationship such that it
	a. contain exactly one [11] @typeCode="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
3700	b. contain exactly one [11] Indication (V2)
	(templateId:2.16.840.1.113883.10.20.22.4.19:2014-06-09).
	19. MAY contain zero or more $[0*]$ entryRelationship such that it
	a. contain exactly one [11] @typeCode="COMP" Has Component (CodeSystem:
	HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
3705	b. contain exactly one [11] Medication
	Activity (V2)(templateId:2.16.840.1.113883.10.20.22.4.16:2014-06-09).
	20. MAY contain zero or more $[0*]$ entryRelationship such that it
	a. contain exactly one [11] @typeCode="COMP" Has Component (CodeSystem:
3710	HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b. contain exactly one [11] <u>Procedure Activity Observation</u> (V2)(templateId: 2.16.840.1.113883.10.20.22.4.13:2014-06-09).

6.3.4.E19 Procedure Activity Act (V2)

3715 [Act: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.19:2016-09-01(open)]

Template Design Relationships

This template is a further constraint of the IHE UV Realm Procedure Activity Act template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose.

- 3720 This template is an adaptation of the C-CDA Procedure Activity Procedure template). It references, by transclusion, other C-CDA R2.1 templates used within Procedure Activity Procedure template including: Indication, Instruction, Medication Activity, and Service Delivery Location. It also supports an optional procedure activity observation template which can be used to new information about the patient that is discovered during the course of providing care or 3725
- performing a treatment.

Template Purpose

This clinical statement represents acts of care which cannot be categorized as a "procedure" but whose immediate and primary outcome (post-condition) is the alteration of the physical condition of the patient. Examples of these acts of care are a dressing change, teaching or feeding a patient or providing comfort measures.

3730

	1.	SHALL contain exactly one [11] @classCode="ACT" Act (CodeSystem: HL7ActClass
		2.16.840.1.113883.5.6 STATIC).
3735	2.	SHALL contain exactly one [11] @moodCode, which SHALL be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 STATIC 2011-04-03.
	3.	SHALL contain exactly one [11] templateId such that it
		a. contain exactly one $[11]$ @root="2.16.840.1.113883.10.20.22.4.14".
		b. SHALL contain exactly one [11] @extension="2016-09-01"
	4.	SHALL contain at least one $[1^*]$ id.
3740	5.	SHALL contain exactly one [11] code such that it
		a. contain zero or one [01] originalText.
		i. CONDITIONAL The original Text, if present, SHALL contain exactly one [11] reference such that it
		1. contain exactly one [11] @value such that it
3745		a. begin with a '#' and point to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).
		b. be selected from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96).
3750	6.	SHALL contain exactly one [11] text such that
		a. contains exactly one [11] reference such that it
		i. contains exactly one [11] @value such that it

	1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section
3755	4.3.5.1).
	7. SHALL contain exactly one [11] statusCode, such that it
	a. be selected from ValueSet ProcedureAct statusCode
	2.16.840.1.113883.11.20.9.22 CNE, DYNAMIC.
	8. SHOULD contain zero or one $[01]$ effectiveTime.
3760	9. MAY contain zero or one [01] priorityCode, such that it
	a. be selected from ValueSet Act Priority Value Set
	2.16.840.1.113883.1.11.16866 CNE, DYNAMIC.
	10. SHOULD contain zero or more $[0*]$ performer such that each
3765	a. CONDITIONAL if present SHALL contain exactly one [11] assignedEntity such that it
	i. contain at least one $[1*]$ id.
	ii. contain exactly one [11] addr.
	iii. contain exactly one [11] telecom.
	iv. contain zero or one $[01]$ representedOrganization such that it
3770	1. CONDITIONAL if present, SHOULD contain zero or more $[0*]$ id
	2. CONDITIONAL if present, MAY contain zero or more $[0*]$ name
	3. CONDITIONAL if present, SHALL contain exactly one [11]
	telecom
	4. CONDITIONAL if present, SHALL contain exactly one $[11]$ addr
3775	11. MAY contain zero or more $[0^*]$ participant such that each
	a. contain exactly one [11] @typeCode="LOC" Location (CodeSystem:
	HL7ParticipationType 2.16.840.1.113883.5.90) STATIC.
	b. contain exactly one [11] <u>Service Delivery Location</u>
	(templateId:2.16.840.1.113883.10.20.22.4.32).
3780	12. MAY contain zero or more $[0*]$ entryRelationship such that each
	a. contain exactly one [11] @typeCode="COMP" Has Component (CodeSystem:
	HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b. contain exactly one [11] @inversionInd="true".
	c. contain exactly one $[11]$ encounter such that it
3785	i. This encounter SHALL contain exactly one [11] @classCode="ENC"
	Encounter (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
	ii. This encounter SHALL contain exactly one [11] @moodCode="EVN"
	Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC).
3790	iii. This encounter SHALL contain exactly one [11] id.
	1. Set the encounter ID to the ID of an encounter in another
	section to signify they are the same encounter.
	13. MAY contain zero or one $[01]$ entryRelationship such that it

	a.	contain exactly one [11] @typeCode="SUBJ" Has Subject (CodeSystem:
3795		HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b.	contain exactly one [11] @inversionInd="true" true.
	с.	contain exactly one [11] Instructions
		(V2)(templateId:2.16.840.1.113883.10.20.22.4.20:2014-06-09).
	14. May co	ontain zero or more $[0*]$ entryRelationship such that it
3800	a.	contain exactly one [11] @typeCode="RSON" Has Reason (CodeSystem:
		HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b.	contain exactly one [11] Indication (V2)
		(templateId:2.16.840.1.113883.10.20.22.4.19:2014-06-09).
	15. мау со	ontain zero or more $[0*]$ entryRelationship such that it
3805	a.	contain exactly one [11] @typeCode="COMP" Has Component (CodeSystem:
		HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b.	contain exactly one [11] Medication
		Activity (V2) (templateId:2.16.840.1.113883.10.20.22.4.16:2014-
2010	16	06-09).
3810		ontain zero or more $[0*]$ entryRelationship such that it
	a.	contain exactly one [11] @typeCode="COMP" Has Component (CodeSystem:
		HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC).
	b.	contain exactly one [11] Procedure Activity Observation
		(V2)(templateId: 2.16.840.1.113883.10.20.22.4.13:2014-06-09).

3815 **6.3.4.E20 HPoC Procedure Activity Procedure (V2)**

[Procedure: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.20:2016-09-01(open)]

Template Design Relationships

This template is an adaptation of the IHE US Realm Procedure Activity Procedure template. 3820 Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose. This entry uses a more tightly constrained design. It is limited to only those procedures that match to a set of procedures defined, in a value set, to be relevant to hearing screening. The entry contains an id pointer to procedures within the procedure list which match the defined inclusion criteria

3825 **Template Purpose**

The HPOC Procedure Activity Procedure template identifies the procedures within the procedure section that are relevant for Hearing Screening.

3830

1. **CONDITIONAL** For each Procedure Activity Procedure entry(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.18) in the Procedure Section where the code element has an @code that is present in Value Set VS_HPoCProcedureActivityProcedure 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.19:

- 2. SHALL contain exactly one [1..1] @classCode="PROC" Procedure (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC).
- 3. SHALL contain exactly one [1..1] @moodCode, which SHALL be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 STATIC 2011-04-03.
- 4. SHALL contain exactly one [1..1] templateId such that it
 - a. **SHALL** contain exactly one [1..1]
 - @root = "1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.20".
 - b. **SHALL** contain exactly one [1..1] @extension="2016-09-01"
- 5. **SHALL** contain exactly one [1..1] id such that it
 - a. references the id of the associated Procedure Activity Procedure where the conditional conformance statement for the code element of the Procedure Activity Procedure entry is true.

3845 **6.3.4.E21 HPoC Procedure Activity Act (V2)**

[Act: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.21:2016-09-01(open)]

Template Design Relationships

This template is an adaptation of the IHE US Realm Procedure Activity Act template. Machine readable entries associated with this template use US Realm vocabulary constraints established for this purpose. This entry uses a more tightly constrained design. It is limited to only those treatment acts that match to a set of acts defined, in a value set, to be relevant to hearing screening. The entry contains an id pointer to acts within the procedure list which match the defined inclusion criteria

Template Purpose

3855 The HPOC Procedure Activity Act template identifies the acts within the procedure section that are relevant for Hearing Screening.

1.	CONDITIONAL For each Procedure Activity Act entry(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.18) in the Procedure Section where the code element has an @code that is present in Value Set VS_HPoCProcedureActivityAct 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.18:
2.	SHALL contain exactly one [11] @classCode="ACT" Act (CodeSystem: HL7ActClass
	2.16.840.1.113883.5.6 STATIC).
3.	SHALL contain exactly one [11] @moodCode, which SHALL be selected from ValueSet
	MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 STATIC 2011-04-03.
4.	SHALL contain exactly one [11] templateId such that it
	a. SHALL contain exactly one [11] @root="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.21".
	b. SHALL contain exactly one [11] @extension="2016-09-01"
5.	SHALL contain exactly one [11] is such that it
	2. 3. 4.

3840

3835

a. references the id of the associated Procedure Activity Act where the conditional conformance statement for the code element of the Procedure Activity Act entry is true.

8.7 Value Set Definitions

3880

3875 The sections that follow define value sets used in the templates used by templates defined in QRPH TF-4 for the Early Hearing Detection and Intervention (EHDI) Profile.

6.5.1 VS_HPoCEncounterType 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.1

This value set contains a list of coded encounter types used when a Hearing Plan of Care is created or updated. These are the same concepts as those used in the VS HPoCActivityEncounters

Code	Display Name	Code System Name	Code System OID
185175005	Seen in primary care center (finding)	SNOMED-CT	2.16.840.1.113883.6.96
307778003	Seen in primary care establishment (finding)	SNOMED-CT	2.16.840.1.113883.6.96
276492007	Seen by member of Primary Health Care Team (finding)	SNOM ED-CT	2.16.840.1.113883.6.96
703978000	Referral to primary care service (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
276490004	Refer to member of Primary Health Care Team (procedure)	SNOM ED-CT	2.16.840.1.113883.6.96
308456006	Referral to audiologist (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
306247008	Referral to pediatric audiologist (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.1.004	Referral to Geneticist	SNOMED-CT	2.16.840.1.113883.6.96
308469005	Referral to geneticist (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
306279004	Referral to clinical geneticist (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.1.005	Referral to Early Intervention Specialist	SNOMED-CT	2.16.840.1.113883.6.96
308452008	Referral to speech and language therapist (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
306173009	Referral to speech and language therapy service (procedure)	SNOM ED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
309622001	Child referral- speech therapy (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
306174003	Referral to community- based speech and language therapy service (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
306175002	Referral to hospital-based speech and language therapy service (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
306360000	Referral to community- based speech and language therapist (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
306361001	Referral to hospital-based speech and language therapist (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
308480005	Referral to ear, nose and throat surgeon (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
183544005	Referral to ear, nose and throat service (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
183452005	Emergency hospital admission (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
32485007	Hospital admission (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
8715000	Hospital admission, elective (procedure)	SNOMED-CT	2.16.840.1.113883.6.96

6.5.2 VS_HPoCServiceEvent 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.2

3885

This value set holds a list of coded service acts for a hearing plan of care. A plan can be created, updated (where a plan is modified), or reconciled (where a plan is transformed to include content from other plans).

Code	Display Name	Code System Name	Code System OID
IHE-TSC- 7.3.1.1.2.5.2.001	HPoC Created	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.2.002	HPoC Appended	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.2.003	HPoC Transformed	SNOMED-CT	2.16.840.1.113883.6.96

6.5.3 VS_HPoCInstructions 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.3

3890 This value set holds a list of coded instruction types for use in a Hearing Plan of Care.

Code	Display Name	Code System Name	Code System OID
IHE-TSC- 7.3.1.1.2.5.3.001	Conduct additional hearing screening if there is parental concern for speech and language development	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.3.002	Aggressively treat the middle ear disease if it is detected.	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.3.003	Refer to specialist if vision screening indicates to refer	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.3.004	Refer to specialist if ongoing developmental screening indicates to refer	SNOMED-CT	2.16.840.1.113883.6.96

6.5.4 VS_HPoCActivityAct 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.4

3895

This value set holds a list of coded concepts representing plan of care acts (activities that are not observations or procedures) used in a Hearing Plan of Care. For example, these are actions that a patient or caregiver can perform.

Code	Display Name	Code System Name	Code System OID
IHE-TSC- 7.3.1.1.2.5.4.001	Participate in parental support group	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.4.002	Attend education for parents on newborn developmental issues.	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.4.003	Implement home safety improvements	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.5.003	Conduct developmental surveillance to identify any parental concerns	SNOMED-CT	2.16.840.1.113883.6.96

6.5.5 VS_HPoCActivityEncounter 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.5

3900

This value set holds a list of coded concepts representing plan of care encounters used in a Hearing Plan of Care.

Code	Display Name	Code System Name	Code System OID
IHE-TSC- 7.3.1.1.2.5.5.001	Visit with Primary Care Physician	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.5.002	Follow-up with Primary Care Provider	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.5.003	Referral to audiologist	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.5.004	Referral to Geneticist	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.5.005	Referral to Early Intervention Specialist	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.5.006	Referral to Ear Nose and Throat Specialist	SNOMED-CT	2.16.840.1.113883.6.96

6.5.6 VS_HPoCActivityObservation 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.6

3905 This value set holds a list of coded concepts representing plan of observation (diagnostic test) activities used in a Hearing Plan of Care.

Code	Display Name	Code System Name	Code System OID
91573000	Tympanometry testing (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
277404009	High frequency tympanometry (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
252623004	Oto-acoustic emission test (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
446077009	Automated otoacoustic emission test (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
252626007	Distortion product oto- acoustic emission measurement (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
252624005	Evoked oto-acoustic emission measurement (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
252959008	Programmable oto- acoustic emissions (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
252625006	Spontaneous oto-acoustic emission measurement (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
413083006	Automated auditory brainstem response test (procedure)	SNOMED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
252617009	Auditory brainstem response screening test (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
252618004	Auditory brainstem response threshold test (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
278319009	Electrically evoked auditory brainstem response audiometry (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.6.004	Acoustic Immitance Test	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.6.005	Auditory Brainstem Response with sedation	SNOMED-CT	2.16.840.1.113883.6.96
281010000	Child development checks (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
405824009	Genetic test (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
405825005	Molecular genetic test (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
79841006	Genetic counseling (procedure)	SNOM ED-CT	2.16.840.1.113883.6.96
702597001	Genetic counseling for heritable disorder with patient at risk (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.6.008	Speech and Language Assessment	SNOMED-CT	2.16.840.1.113883.6.96
273697004	Phonological assessment of child speech (assessment scale)	SNOMED-CT	2.16.840.1.113883.6.96
273473000	Fundamental speech skills test (assessment scale)	SNOMED-CT	2.16.840.1.113883.6.96
273870009	Test of language competence (assessment scale	SNOMED-CT	2.16.840.1.113883.6.96
113091000	M agnetic resonance imaging (procedure)	SNOMED-CT	2.16.840.1.113883.6.96

6.5.7 VS_HPoCActivityProcedure 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.7

3910 This value set holds a list of coded concepts representing plan of care procedures (activities to treat a condition and alter the patient's health status) included in a Hearing Plan of Care.

Code	Display Name	Code System Name	Code System OID
359612003	Implantation of cochlear prosthetic device (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
44218004	Implantation of cochlear electrode (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
359608009	Implantation of cochlear prosthetic device, electrode and receiver (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
50676004	Implantation of cochlear prosthetic device, multip le channels (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
43815004	Implantation of cochlear prosthetic device, single channel (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
172732009	Implantation of intracochlear prosthesis (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.7.002	Reconstruction to resolve atresia	SNOMED-CT	2.16.840.1.113883.6.96
84088001	Correction of atresia of external meatus of ear (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.7.003	Treatment for otitis media	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.7.004	Cleft Lip/Palate Repair	SNOMED-CT	2.16.840.1.113883.6.96
234647001	Repair of cleft lip (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
89432003	Lemesurier operation, cleft lip repair (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
248929000	Phary ngorrhap hy for cleft palate (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
315313007	Primary repair of cleft lip (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
234650003	Repair of bilateral cleft lip (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
8616005	Rhinocheiloplasty repair for cleft lip (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
57217008	Thompson operation, cleft lip repair (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
234890003	Repair of cleft palate (procedure)	SNOMED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
450350009	Primary repair of cleft palate (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
12826007	Dorrance operation, push- back operation for cleft palate (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
234891004	Repair of cleft of hard palate (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
234892006	Repair of cleft of soft palate (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
12132004	Langenbeck operation, cleft palate repair (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
68792000	Wardill operation, cleft palate repair (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.7.005	M y ringotomy and PE tube placement	SNOMED-CT	2.16.840.1.113883.6.96
284532000	Myringotomy and insertion of tympanic ventilation tube (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
172679002	M yringotomy and insertion of T tube (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
275001008	M yringotomy and insertion of long-term ventilation tube (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
172676009	M yringotomy and insertion of short-term ty mpanic ventilation tube (procedure)	SNOMED-CT	2.16.840.1.113883.6.96

6.5.8 VS_HPoCActivitySubstanceAdministration 3915 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.8

This value set holds a list of coded concepts representing plan of care substance administration act used in a Hearing Plan of Care.

Code	Display Name	Code System Name	Code System OID
IHE-TSC-	Thy roid Supplement	SNOMED-CT	2.16.840.1.113883.6.96
7.3.1.1.2.5.8.001			
375575006	Thyroid 32mg (product)	SNOMED-CT	2.16.840.1.113883.6.96
375576007	Thyroid 65mg (product)	SNOMED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
87582004	Dessicated animal thyroid preparation (product)	SNOMED-CT	2.16.840.1.113883.6.96
376197009	Thyroid 120mg tablet (product)	SNOMED-CT	2.16.840.1.113883.6.96
375577003	Thyroid 130mg (product)	SNOMED-CT	2.16.840.1.113883.6.96
376198004	Thyroid 180mg tablet (product)	SNOMED-CT	2.16.840.1.113883.6.96
375876000	Thyroid 60mg tablet (product)	SNOMED-CT	2.16.840.1.113883.6.96
226314006	Vitamin supplementation (product)	SNOMED-CT	2.16.840.1.113883.6.96
226317004	Fat soluble vitamin supplementation (product)	SNOMED-CT	2.16.840.1.113883.6.96
226315007	Water soluble vitamin supplementation (product)	SNOMED-CT	2.16.840.1.113883.6.96
27658006	Amoxicillin (product)	SNOMED-CT	2.16.840.1.113883.6.96
350162003	Oral form amoxy cillin (product) - 23 children with different dosage	SNOMED-CT	2.16.840.1.113883.6.96
350163008	Parenteral form amoxycillin (product) - 4 children	SNOMED-CT	2.16.840.1.113883.6.96
255631004	Antibiotic (product)	SNOMED-CT	2.16.840.1.113883.6.96

3920 6.5.9 VS_HPoCActivityNon-MedicinalSupply 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.9

This value set holds a list of coded concepts representing plan of care non-medicinal supply act used in a Hearing Plan of Care. This would cover supply of implantable devices and other medical devices used for patient care.

Code	Display Name	Code System Name	Code System OID
6012004	Hearing aid, device (physical object)	SNOMED-CT	2.16.840.1.113883.6.96
705321004	Air-conduction hearing aid (physical object) - 8 children	SNOMED-CT	2.16.840.1.113883.6.96
705322006	Bone-conduction hearing aid (physical object) - 3 children	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.9.002	Assistive Listening Device	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC-	FM system	SNOMED-CT	2.16.840.1.113883.6.96

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Code	Display Name	Code System Name	Code System OID
7.3.1.1.2.5.9.003			
43252007	Cochlear prosthesis, device (physical object)	SNOMED-CT	2.16.840.1.113883.6.96
360104003	Extracochlear prosthesis (physical object)	SNOMED-CT	2.16.840.1.113883.6.96
360103009	Intracochlear prosthesis (physical object)	SNOMED-CT	2.16.840.1.113883.6.96

3925

6.5.10 VS_HearingScreeningOutcomeObservationValues 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.10

This value set holds a list of coded concepts representing the possible outcome values for a hearing screening panel.

3930

Code	Display Name	Code System Name	Code System OID
164059009	Pass	SNOMED-CT	2.16.840.1.113883.6.96
183924009	Refer	SNOMED-CT	2.16.840.1.113883.6.96
262008008	Not Performed	SNOMED-CT	2.16.840.1.113883.6.96

6.5.11 VS_ReasonNotScreened 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.11

This value set holds a list of coded concepts representing the possible reasons for not performing hearing screening.

3935

Code	Display Name	Code System Name	Code System
410534003	Not performed, medical exclusion - not indicated	SNOMED-CT	2.16.840.1.113883.6.96
183949008	Assessment examination refused (situation)	SNOMED-CT	2.16.840.1.113883.6.96
183945002	Procedure refused - religion (situation)	SNOMED-CT	2.16.840.1.113883.6.96
183948000	Refused procedure - parent's wish (situation)	SNOMED-CT	2.16.840.1.113883.6.96
397709008	Patient died (finding)	SNOMED-CT	2.16.840.1.113883.6.96

6.5.12 VS_HearingScreeningTargetSites 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.12

This value set holds a list of coded concepts representing the possible body sites involved in hearing screening.

3940

Code	Display Name	Code System Name	Code System OID
89644007	Left Ear	SNOMED-CT	2.16.840.1.113883.6.96
25577004	Right Ear	SNOMED-CT	2.16.840.1.113883.6.96

6.5.13 VS_HearingScreeningMethods 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.13

This value set holds a list of coded concepts representing the possible methods for performing hearing screening.

3945

Code	Display Name	Code System Name	Code System OID
LA10387-1	Automated auditory brainstem response (AABR)	LOINC	2.16.840.1.113883.6.1
LA10388-9	Auditory brain stem response (ABR)	LOINC	2.16.840.1.113883.6.1
LA10389-7	Otoacoustic emissions (OAE)	LOINC	2.16.840.1.113883.6.1
LA10390-5	Distortion product otoacoustic emissions (DPOAE)	LOINC	2.16.840.1.113883.6.1
LA10391-3	Transient otoacoustic emissions (TOAE)	LOINC	2.16.840.1.113883.6.1
LA12406-7	Methodology unknown	LOINC	2.16.840.1.113883.6.1

6.5.14 VS_HearingScreeningTestResultValues 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.14

3950

This value set holds a list of coded concepts representing the possible result values produced by a device when performing hearing screening. If a test was not performed by the device, it does not send back a value. The code for "attempted, but unsuccessful-technical fail" indicates that the test was performed, but the value measured by the device could not be determined to be a clear pass or fail (refer).

Code	Display Name	Code System Name	Code System OID
164059009	Pass	SNOMED CT	2.16.840.1.113883.6.96
183924009	Refer	SNOMED CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
103709008	Attempted, but unsuccessful - technical fail	SNOMED CT	2.16.840.1.113883.6.96

3955

Note 1: This value set is designed to be used with a template which uses negationInd to express that an observation was not performed. Thus, this concept is removed from the value set to avoid the possibility of double negation.

6.5.15 VS_RiskFactor 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.15

This value set that holds a list of coded concepts representing concepts indicating that information is a risk factor.

Code	Display Name	Code System Name	Code System OID
80943009	Risk Factor	SNOMED-CT	2.16.840.1.113883.6.96

3960 6.5.16 VS_RiskFactorsForHearing 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.16

This value set holds a list of coded concepts representing the risk factors considered during hearing screening.

Code	Display Name	Code System Name	Code System OID
439750006	Family Hx of Hearing loss	SNOMED-CT	2.16.840.1.113883.6.96
441899004	History of therapy with ototoxic medication (situation)	SNOMED-CT	2.16.840.1.113883.6.96
276687002	Conjugated hyperbilirubinemia in infancy (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
281610001	Neonatal Hyperbilirubinemia (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
281612009	Neonatal conjugated hyperbilirubinemia (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
281611002	Neonatal unconjugated hyperbilirubinemia (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
206331005	Infections specific to perinatal period (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
206005002	Fetus or neonate affected by maternal infection (disorder)	SNOMED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
80690008	Degenerative disease of the central nervous system (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
178280004	Postnatal infection (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
312972009	Neonatal extracranial head trauma (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
161653008	History of - chemotherapy (situation)	SNOMED-CT	2.16.840.1.113883.6.96
LA137-2	None	LOINC	2.16.840.1.113883.6.1
LA12667-4	Caregiver concern about hearing	LOINC	2.16.840.1.113883.6.1
LA12669-0	ICU stay > 5 days	LOINC	2.16.840.1.113883.6.1
LA12670-8	ЕСМО	LOINC	2.16.840.1.113883.6.1
LA12671-6	Assisted ventilation	LOINC	2.16.840.1.113883.6.1
LA12673-2	Exchange transfusion for Hyperbilirubinemia	LOINC	2.16.840.1.113883.6.1
LA12674-0	In utero infection(s)	LOINC	2.16.840.1.113883.6.1
LA12675-7	Craniofacial anomalies	LOINC	2.16.840.1.113883.6.1
LA12681-5	Physical findings of syndromes that include hearing loss	LOINC	2.16.840.1.113883.6.1
LA12676-5	Syndromes associated with hearing loss	LOINC	2.16.840.1.113883.6.1
LA12677-3	Neurodegenerative disorders	LOINC	2.16.840.1.113883.6.1
LA12678-1	Postnatal infections	LOINC	2.16.840.1.113883.6.1

3965 **6.5.17 VS_HPoCProblemObservations 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.17**

This value set holds a list of coded concepts representing the problems considered relevant for hearing care planning. The values below need to include a qualifier that indicates the test produced a "fail", so the total concept is a "failed xyz Test". (Note: this value set is not complete. It is representative of some of the concepts that would be defined for this value set. Before completion of Trial Implementation, the value set will be finalized and entered in a value set

3970 completion of Trial Implementation, the value set will be finalized and entered in a value set repository, then referenced in the EHDI Profile by URL)

Code	Display Name	Code System Name	Code System OID
83330001	Patent ductus arteriosus (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
253686000	Patent ductus arteriosus - persisting type (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
253685001	Patent ductus arteriosus - delay ed closure (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
125963005	Patent ductus arteriosus with left-to-right shunt (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
22033007	Fetal growth retardation (disorder)	SNOM ED-CT	2.16.840.1.113883.6.96
181000119105	Fetal growth retardation, antenatal (disorder)	SNOM ED-CT	2.16.840.1.113883.6.96
276606009	Asymmetrical growth retardation (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
276607000	Symmetrical growth retardation (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
234350007	Neonatal anemia (disorder)	SNOM ED-CT	2.16.840.1.113883.6.96
47100003	Anemia of prematurity (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
359007	Kernicterus due to isoimmunization (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
276579007	Late anemia of newborn (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
276578004	Physiological anemia of infancy (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
387702001	Perinatal anemia (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
67569000	Bronchop ulmonary dysplasia of newborn (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
17190001	Congenital diaphragmatic hernia (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
447821002	Congenital posterolateral diaphragmatic hernia (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
204271000	Preauricular sinus (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
18820007	Preauricular cyst (disorder)	SNOMED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
205616004	Trisomy 21- mitotic nondisjunction mosaicism (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
80281008	Cleft lip (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
304068004	Bilateral cleft lip (disorder)	SNOMED-CT	2.16.840.1.113883.6.96

3975 **6.5.18 VS_HPoCProcedureActivityActs 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.18**

This value set holds a list of coded concepts representing the care activities (those acts not categorized as procedures) considered relevant for hearing care planning.(Note: these acts also are not diagnostic tests. Historical testing is recorded in the Results section.)

Code	Display Name	Code System Name	Code System OID
IHE-TSC- 7.3.1.1.2.5.18.001	Participate in parental support group	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.18.002	Attend education for parents on newborn developmental issues.	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.18.003	Implement home safety improvements	SNOMED-CT	2.16.840.1.113883.6.96

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6.5.19 VS_HPoCProcedureActivityProcedures 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.19

This value set holds a list of coded concepts representing the procedures considered relevant for hearing care planning. (Note: this value set is not complete. It is representative of some of the concepts that would be defined for this value set. Before completion of Trial Implementation, the value set will be finalized and entered in a value set repository, then referenced in the EHDI Profile by URL)

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Code	Display Name	Code System Name	Code System OID
359612003	Implantation of cochlear prosthetic device (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
44218004	Implantation of cochlear electrode (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
359608009	Implantation of cochlear prosthetic device, electrode and receiver (procedure)	SNOMED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
50676004	Implantation of cochlear prosthetic device, multiple channels (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
43815004	Implantation of cochlear prosthetic device, single channel (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
172732009	Implantation of intracochlear prosthesis (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.7.002	Reconstruction to resolve atresia	SNOMED-CT	2.16.840.1.113883.6.96
84088001	Correction of atresia of external meatus of ear (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.7.003	Treatment for otitis media	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.7.004	Cleft Lip/Palate Repair	SNOMED-CT	2.16.840.1.113883.6.96
234647001	Repair of cleft lip (procedure)	SNOM ED-CT	2.16.840.1.113883.6.96
89432003	Lemesurier operation, cleft lip repair (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
248929000	Phary ngorrhaphy for cleft palate (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
315313007	Primary repair of cleft lip (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
234650003	Repair of bilateral cleft lip (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
8616005	Rhinocheiloplasty repair for cleft lip (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
57217008	Thompson operation, cleft lip repair (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
234890003	Repair of cleft palate (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
450350009	Primary repair of cleft palate (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
12826007	Dorrance operation, push- back operation for cleft palate (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
234891004	Repair of cleft of hard palate (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
234892006	Repair of cleft of soft palate (procedure)	SNOM ED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
12132004	Langenbeck operation, cleft palate repair (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
68792000	Wardill operation, cleft palate repair (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC- 7.3.1.1.2.5.7.005	Myringotomy and PE tube placement	SNOMED-CT	2.16.840.1.113883.6.96
284532000	M yringotomy and insertion of tympanic ventilation tube (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
172679002	M yringotomy and insertion of T tube (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
275001008	M yringotomy and insertion of long-term ventilation tube (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
172676009	M yringotomy and insertion of short-term tympanic ventilation tube (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
43252007	Cochlear prosthesis, device (physical object)	SNOMED-CT	2.16.840.1.113883.6.96
360104003	Extracochlear prosthesis (physical object)	SNOMED-CT	2.16.840.1.113883.6.96
360103009	Intracochlear prosthesis (physical object)	SNOMED-CT	2.16.840.1.113883.6.96
233573008	Extracorporeal membrane oxy genation (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
180202002	Neonatal exchange transfusion (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
243155002	High frequency oscillatory ventilation (procedure)	SNOMED-CT	2.16.840.1.113883.6.96
281790008	Intravenous antibiotic therapy (procedure)	SNOMED-CT	2.16.840.1.113883.6.96

6.5.20 VS_NewbornHearingScreeningOutcomeResultsOrganizer 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.20

3990 This value set that holds a list of coded concepts representing concepts indicating that information is a newborn hearing screening outcome result organizer.

Code	Display Name	Code System Name	Code System OID
54111-0	Newborn Hearing Loss Panel	LOINC	2.16.840.1.113883.6.1

6.5.21 VS_HearingScreeningOutcomeObservation-LeftEar 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.21

3995 This value set that holds a list of coded concepts representing concepts indicating that information is a hearing screening outcome observation for the left ear.

Code	Display Name	Code System Name	Code System OID
73741-1	Newborn Hearing screen panel of Ear - left	LOINC	2.16.840.1.113883.6.1

6.5.22 VS_HearingScreeningOutcomeObservation-RightEar 4000 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.22

This value set that holds a list of coded concepts representing concepts indicating that information is a hearing screening outcome observation for the right ear.

Code	Display Name	Code System Name	Code System OID
73744-5	Newborn Hearing screen panel of Ear – right	LOINC	2.16.840.1.113883.6.1

4005 **6.5.23 VS_HearingScreeningResultOrganizer 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.23**

This value set that holds a list of coded concepts representing concepts indicating that information is a hearing screening result organizer.

Code	Display Name	Code System Name	Code System OID
417491009	Neonatal Hearing Test Procedure	SNOMED-CT	2.16.840.1.113883.6.96

4010 6.5.24 VS_NeonatalHearingScreeningTest 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.24

This value set that holds a list of coded concepts representing concepts indicating that information is a neonatal hearing screening test.

Code	Display Name	Code System Name	Code System OID
417491009	Neonatal Hearing Test Procedure	SNOMED-CT	2.16.840.1.113883.6.96

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Appendices

Appendix G – EHDI Profile - Additional Implementer Guidance

G.1 Date Time Precision

Date/time information for hearing screening information needs to be assessed temporally. For example, the hearing screening quality measure that is part of the CMS Meaningful Use incentive program for eligible hospitals needs to be able to compare the date/time of the hearing screening with the date/time of the discharge from the birth encounter. Also, assessment of newborn hearing screening outcomes often requires temporal processing when a newborn's hearing was screened multiple times. The "biologically relevant time" of the hearing screening needs to be captured and exchanged to support the needed data interoperability. The date that screening information was manually entered or shared for exchange is not equivalent to the biologically relevant time of the hearing screening. This requirement needs to be taken into consideration when creating hearing screening messages as well as hearing plan of care documents.

4030 G.2 No Known Information

When the hearing plan of care calls for a section of information in the document, and the system creating the document has no information which would be relevant to populate in that section, then the section should be represented using the patterns established in C-CDA for representing "no known information".

- 4035 Note, the representation of "no known information" is not equivalent to a positive assertion of "none". Thus, if the risk factors section of a hearing plan of care document is coded as "no known information", it cannot be assumed that the newborn has no associated risk factors. It only means the system sending the hearing plan of care document did not have any risk factor information to share.
- 4040 Examples showing how to encode a section with no known information are available from the CDA Examples Task Force. (<u>http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force#No_Information_Problems_Section</u>)

G.3 Representation of Maiden Name

4045 When including the mother's maiden name, the following xml representation is used:

<name use="L">

```
<given>Mary</given>
```

```
<family qualifier="SP">Jones</family>
```

</name>

4050 <name use="SRCH">

<given>Mary</given>

<family qualifier="BR">Smith</family>

</name>