Integrating the Healthcare Enterprise

IHE Quality, Research, and Public Health Technical Framework Supplement

Early Hearing Detection and Intervention (EHDI)

Trial Implementation

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

Foreword

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

This supplement is published on September 5, 2014 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 Quality, Research and Public Health Technical 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.

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.

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

Information about the IHE IT Infrastructure domain can be found at: http://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: http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE IT Infrastructure Technical Framework can be found at: http://ihe.net/Resources/Technical_Frameworks.

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Introduction to this Supplement

This QRPH Technical 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 profiles.

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	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.	This is a template issue. Work with Eric Larson to document this need.
2	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 is a template issue. Work with Eric Larson to document this need.
3	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”	Complete after PCD finished its CP to change the NK1 segment.
4	Request new LOINC Codes for sections specific to HPoC	Complete after Public Comment finishes
5	Add SNOMED CT and LOINC OIDs where currently omitted	Busy work that can be done any time. To do tonight.
6	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.
7	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 Actor.	Review after initial Trial Implementation.
8	Entry templates should be added to the HPoC Section which permits encoding of goals and outcomes from interventions.	Future consideration.

Item Count	Issue Description	Status
9	Add an extension to CDA 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
10	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.
11	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.
12	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.	This issue has been escalated to Alex Lippitt from IHE USA. Lippitt Jr., Alexander (alippitt@himss.org)

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 Otorhinolaryngology 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.
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 Hearing Screening Result Message? **Device Observation Reporter** – The Device Observation Reporter (DOR) Actor 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.	Material is completed

Item Count	Issue Description	Status
7	Tasks to be completed for Vol2-4: 1. Add actor options (if needed) 2. Gather Value Sets for US Realm 3. 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	Completed.
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

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 Actor 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

Transaction	Definition
No new transactions	

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

The EHDI Profile describes the content needed to create a hearing plan of care for a newborn. The HPoC document supports communication and care planning with providers who are a part of the newborn's care team. It helps to standardize care coordination for infants with suspected hearing loss. It also provides interoperability between clinical EMR systems and EHDI systems for increased efficiency and better data quality.

The Hearing Plan of Care (HPoC) 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 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 needed to constrain a message for transmitting device observations from hearing screening devices. The message is used to automate population of hearing screening results in the HPoC document.

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 that data in not available for automated population.

X.1 Actors, Transactions, and Content Modules

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 Hearing Screening Message.

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

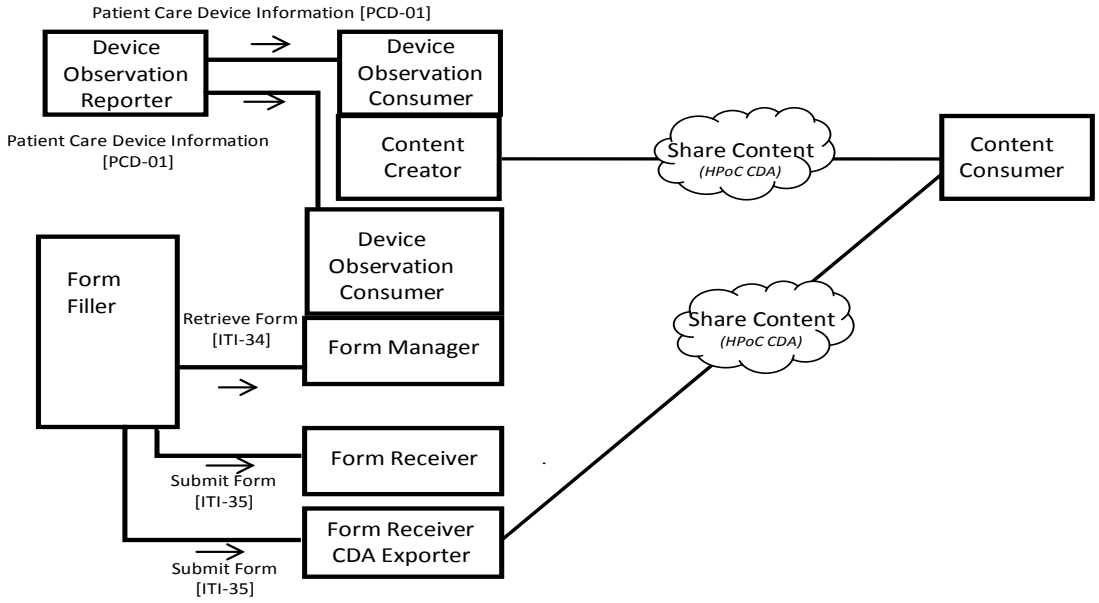

Figure X.1-1: EHDI Actor Diagram

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").

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

Actors	Transactions	Optionality	Section in Vol. 2
Device Observation Reporter	Communicate PCD Data [PCD-01]	R	PCD TF 2: 3.01
Content Creator (with Device Observation Consumer Option)	Communicate PCD Data [PCD-01]	R	PCD TF 2: 3.01
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 TF-2b: 3.34
Form Manager (with Device Observation Consumer Option)	Communicate PCD Data [PCD-01]	R	PCD TF 2: 3.01
Form Receiver	Submit Form [ITI-35]	R	ITI TF-2b: 3.35
Form Receiver CDA Exporter	Submit Form [ITI-35]	R	ITI TF-2b: 3.35

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: HPoC - Actors and Content Modules

Actors	Content Modules	Optionality	Reference
Device Observation Reporter	PCD-01 for Hearing Plan of Care Message Content	R	QRPH EHDI TS V3: 7
Content Creator (with Device Observation Consumer Option)	PCD-01 for Hearing Plan of Care Message Content	R	QRPH EHDI TS V3: 7
	Hearing Plan of Care 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1	R	QRPH EHDI TS V3: 6.3.1.D1
Content Creator (with Device Observation Consumer-US Realm Option)	PCD-01 for Hearing Plan of Care Message Content	R	QRPH EHDI TS V3: 7
	Hearing Plan of Care 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1	R	QRPH EHDI TS V4: 6.3.1.D1
Content Creator	Hearing Plan of Care 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1	R	QRPH EHDI TS V3: 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 EHDI TS V4: 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 EHDI TS V3: 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 EHDI TS V4: 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 R1.1
Form Manager	CCD 2.16.840.1.113883.10.20.22.1.2	R	HL7 C-CDA R1.1
Form Manager (with Device Observation Consumer Option)	PCD-01 for Hearing Plan of Care Message Content	R	QRPH EHDI TS V3: 7
	CCD 2.16.840.1.113883.10.20.22.1.2	R	HL7 C-CDA R1.1
Form Receiver	None	Note 1	
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 EHDI TS V3: 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 EHDI TS V4: 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 Actor or the Form Receiver CDA Exporter are responsible for working directly with implementers of the Form Manager Actor to understand how form data will be formatted.

X.1.1 Actor Descriptions and Actor Profile Requirements

X.1.1.1 Content Creator

The Content Creator SHALL create a valid CDA document which conforms to the IHE HPoC Document template defined in Section QRPH EHDI TS 3:6.3.1.D1.5.

The Content Creator includes the processing logic needed 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 MAY support the US Realm Option which includes structural and vocabulary conformances specific to the US Realm definitions for the HPoC templates.

When implementing the Device Observation Consumer Option, the Content Creator Actor SHALL be grouped with the Device Observation Consumer (DOC) Actor from the Patient Care Device (PCD) Device Enterprise Communication (DEC) Profile. This grouping enables the Content Creator Actor to receive and process PCD-01 transactions from a Device Observation Reporter (DOR) Actor. In the EHDI Profile, the message content of the PCD-01 transaction is constrained for a Hearing Screening Device. The message constraints are documented in QRPH EHDI TS V3:7.

When implementing the Device Observation Consumer Option, the Content Creator Actor SHALL represent information communicated in the next of kin message segment using the recordTarget.guardian structure when the relative is ward over the baby. Representation of the next of kin information in the message is an extension to the base PCD-01 standard.

X.1.1.2 Content Consumer

The Content Consumer SHALL consume a valid CDA document which conforms to the IHE QRPH HPoC document template, and SHALL support the View, Import Document, and Discrete Data Import options defined in PCC TF V2:3.

The Content Consumer MAY support the US Realm Option which includes structural and vocabulary conformances specific to the US Realm definitions for the HPoC templates.

X.1.1.3 Form Filler

The Form Filler SHALL conform to the requirements specified for the Form Filler Actor in the ITI RFD Profile.

The Form Filler SHALL support XHTML Option of the Retrieve Form transaction.

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 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 Manager SHALL conform to the requirements specified for the Form Manager Actor in the ITI RFD Profile.

The Form Manger SHALL support XHTML for the Retrieve Form transaction.

The Form Manager SHALL accept pre-populated data in the form of a CCD, and return a form designed to collect hearing screening information. The pre-populated form SHALL be based on the mapping rules specified in QRPH EHDI TS V3 6.3.1.D1.4 (Data Element Mappings for Form Pre-population). 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 (ITI-34) message.

When implementing the Device Observation Consumer Option, the Form Manager Actor SHALL be grouped with the Device Observation Consumer (DOC) Actor from the Patient Care Device (PCD) Device Enterprise Communication (DEC) Profile. This grouping enables the Content Creator Actor to receive and process PCD-01 transactions from a Device Observation Reporter (DOR) Actor. In the EHDI Profile, the message content of the PCD-01 transaction is constrained for a Hearing Screening Device. The message constraints are documented in QRPH EHDI TS V3:7.

When implementing the Device Observation Consumer Option, the Form Manager Actor SHALL accept information communicated in the next of kin (NK1) message segment. Representation of the next of kin information in the message is an extension to the base PCD-01 standard.

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

X.1.1.5 Form Receiver

The Form Receiver SHALL conform to the requirements specified for the Form Receiver Actor in the ITI RFD Profile.

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

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 Actor or the Form Receiver CDA Exporter are responsible for working directly with implementers of the Form Manager Actor to understand how 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.

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

When the Form Receiver CDA Exporter produces a HPoC, the results received up to that point in time for the patient SHALL be aggregated into the HPoC document based on mapping rules for the Form Receiver CDA Exporter specified in QRPH EHDI TS V3 6.3.1.D.4 (Data Element Mappings for CDA Export).

The Form Receiver CDA Exporter MAY support the US Realm Option which includes structural and vocabulary conformances specific to the US Realm definitions for the HPoC templates.

X.1.1.7 Device Observation Reporter

The Device Observation Reporter SHALL conform to the requirements specified in the PCD DEC Profile for the Device Observation Reporter Actor.

The message content created for the Communicate PCD Information (PCD-01) transaction SHALL meet the specification for a Hearing Screening Device message specified in QRPH EHDI TS V3:7.

X.1.1.8 Device Observation Consumer

The Device Observation Consumer SHALL conform to the requirements specified in the PCD DEC Profile for the Device Observation Consumer Actor.

The Device Observation Consumer only appears in this profile when it is grouped with a Content Creator Actor or Form Manager.

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.

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

Actor	Option Name	Reference
Device Observation Reporter	None	
Content Creator	Device Observation Consumer	QRPH EHDI TS V1:X.2.1
	Device Observation Consumer – US Realm	QRPH EHDI TS V1:X.2.2
	US Realm	QRPH EHDI TS V1:X.2.3

Actor	Option Name	Reference
Content Consumer	US Realm	QRPH EHDI TS V1:X.2.4
Form Filler	CCD Pre-Pop	QRPH EHDI TS V1:X.2.5
Form Manager	Device Observation Consumer	QRPH EHDI TS V1:X.2.6
Form Receiver	None	
Form Receiver CDA Exporter	US Realm	QRPH EHDI TS V1:X.2.7

X.2.1 Content Creator – Device Observation Consumer

In addition to creating a HPoC document, a Content Creator implementing the Device Observation Consumer Option SHALL be grouped with a Device Observation Consumer Actor from the PCD DEC Profile and shall consume messages conforming to the Hearing Screening Device specifications documented in QRPH EHDI TS V3:7.

Table X.2.1-1: HPoC - Actor Groupings

<this Profile Acronym> Actor	Actor to be grouped with	Reference	Content Bindings Reference
Content Creator	Device Observation Consumer	PCD DEC PCD TF V1:2.2.1	QRPH EHDI TS V3:7

X.2.2 Content Creator – Device Observation Consumer – US Realm

In addition to creating a HPoC US Realm document, a Content Creator implementing the Device Observation Consumer-US Realm Option SHALL be grouped with a Device Observation Consumer Actor from the PCD DEC Profile and shall consume messages conforming to the Hearing Screening Device specifications documented in QRPH EHDI TS V3:7.

Table X.2.2-1: HPoC - Actor Groupings

<this Profile Acronym> Actor	Actor to be grouped with	Reference	Content Bindings Reference
Content Creator	Device Observation Consumer	PCD DEC PCD TF V1:2.2.1	QRPH EHDI TS V3:7

X.2.3 Content Creator – US Realm

A Content Creator implementing the US Realm Option SHALL create HPoC documents that conform to the US Realm template specifications.

X.2.4 Content Consumer – US Realm

A Content Consumer implementing the US Realm Option SHALL consume HPoC documents that conform to the US Realm template specifications.

X.2.5 Form Filler – CCD Pre-pop

A Form Filler implementing the CCD Pre-pop Option SHALL supply a CCD document when initiating the Retrieve Form (ITI-34) transaction.

X.2.6 Form Manager – Device Observation Consumer

A Form Manager implementing the Device Observation Consumer Option SHALL be grouped with a Device Observation Consumer Actor from the PCD DEC Profile and shall consume messages conforming to the Hearing Screening Device specifications documented in QRPH EHDI TS V3:7.

Table X.2.6-1: HPoC - Actor Groupings

<this Profile Acronym> Actor	Actor to be grouped with	Reference	Content Bindings Reference
Form Manager	Device Observation Consumer	PCD DEC PCD TF V1:2.2.1	QRPH EHDI TS V3:7

X.2.7 Form Receiver CDA Exporter – US Realm

A Form Receiver CDA Exporter that implements the US Realm Option SHALL create HPoC documents that conform to the US Realm template specifications.

X.3 Required Actor Groupings

This profile does not have any required groupings. It includes a conditional grouping for the Content Consumer Actor defined in X.2.1 and X.2.2, and it includes a conditional grouping for the Form Manager Actor defined in X.2.6.

X.4 Overview

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. 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 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.

X.4.1 Concepts

The Hearing Plan of Care (HPoC) document compiles several types of information relevant to determine a Hearing Plan of Care. It documents the child's active problems, procedures, diagnostic testing/screenings, and relevant risk indicators, and also 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.

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.

X.4.2 Use Cases

X.4.2.1 Use Case #1: HPoC – Simple Case

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

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.

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

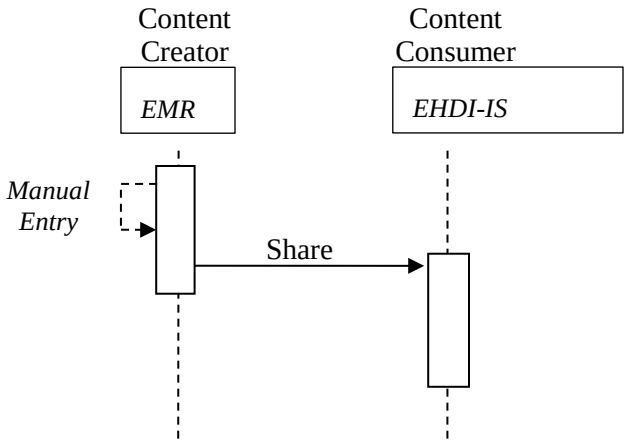

Figure X.4.2.1.3-1: Process Flow Diagram

X.4.2.2 Use Case #2: HPoC – Simple Case with integrated screening device observation reporting

X.4.2.2.1 Use Case Description

A screening device electronically reports the screening result to a system which consumes the result. This system which receives the result generates an 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.

X.4.2.2.2 Processing Steps

X.4.2.2.2.1 Pre-conditions

A Device Observation Reporter Actor is available to populate a Hearing Screening Result Message and initiate a PCD-01 transaction to send that information to a Device Observation Consumer.

X.4.2.2.2.2 Main Flow

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

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

X.4.2.2.2.3 Post-conditions

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

X.4.2.2.3 Process Flow

Device Observation Consumer

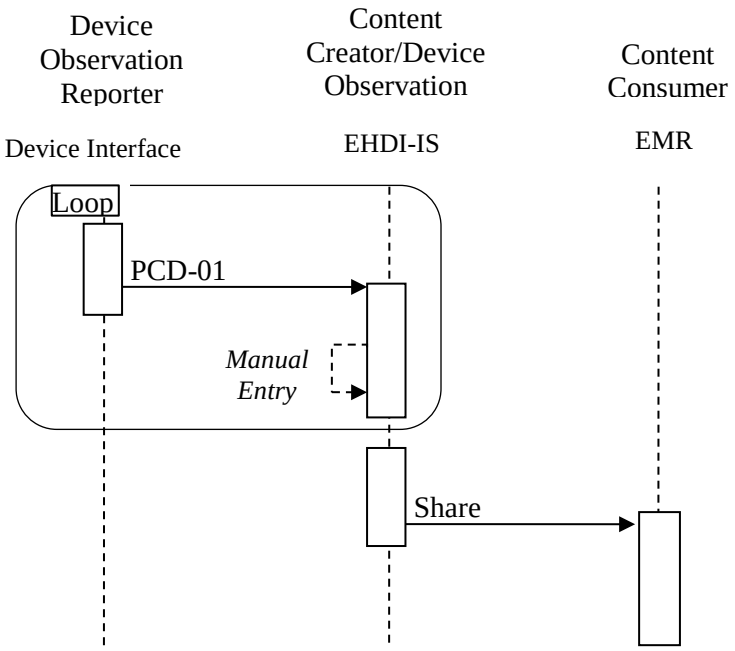

Figure X.4.2.2.3-1: Process Flow Diagram

X.4.2.3 Use Case #3: RFD for Data Capture and CDA Export

X.4.2.3.1 Use Case Description

A system implementing the Form Filler interacts with a system implementing the Form Manager. The Form Manager Actor 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.

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 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 Actor 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

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.

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 and then processes it to create and share an HPoC document.

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

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

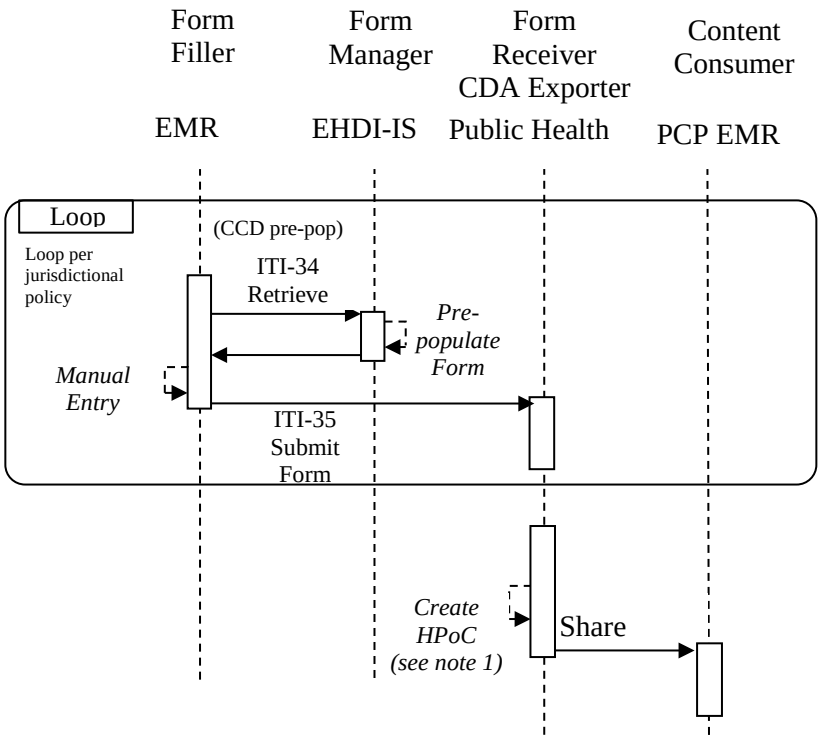

Figure X.4.2.3.3-1: Process Flow Diagram

Note 1: The trigger to initiate the Hearing Plan of Care document is out of scope for this 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.4.2.4 Use Case #4: Combination

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 Actor 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.

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.

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.

X.4.2.4.2 Processing Steps

X.4.2.4.2.1 Pre-conditions

A Device Observation Reporter Actor is available to populate a Hearing Screening Result Message and initiate a PCD-01 transaction to send that information to a Form Manager implementing the Device Observation Consumer Option.

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.

X.4.2.4.3 Process Flow

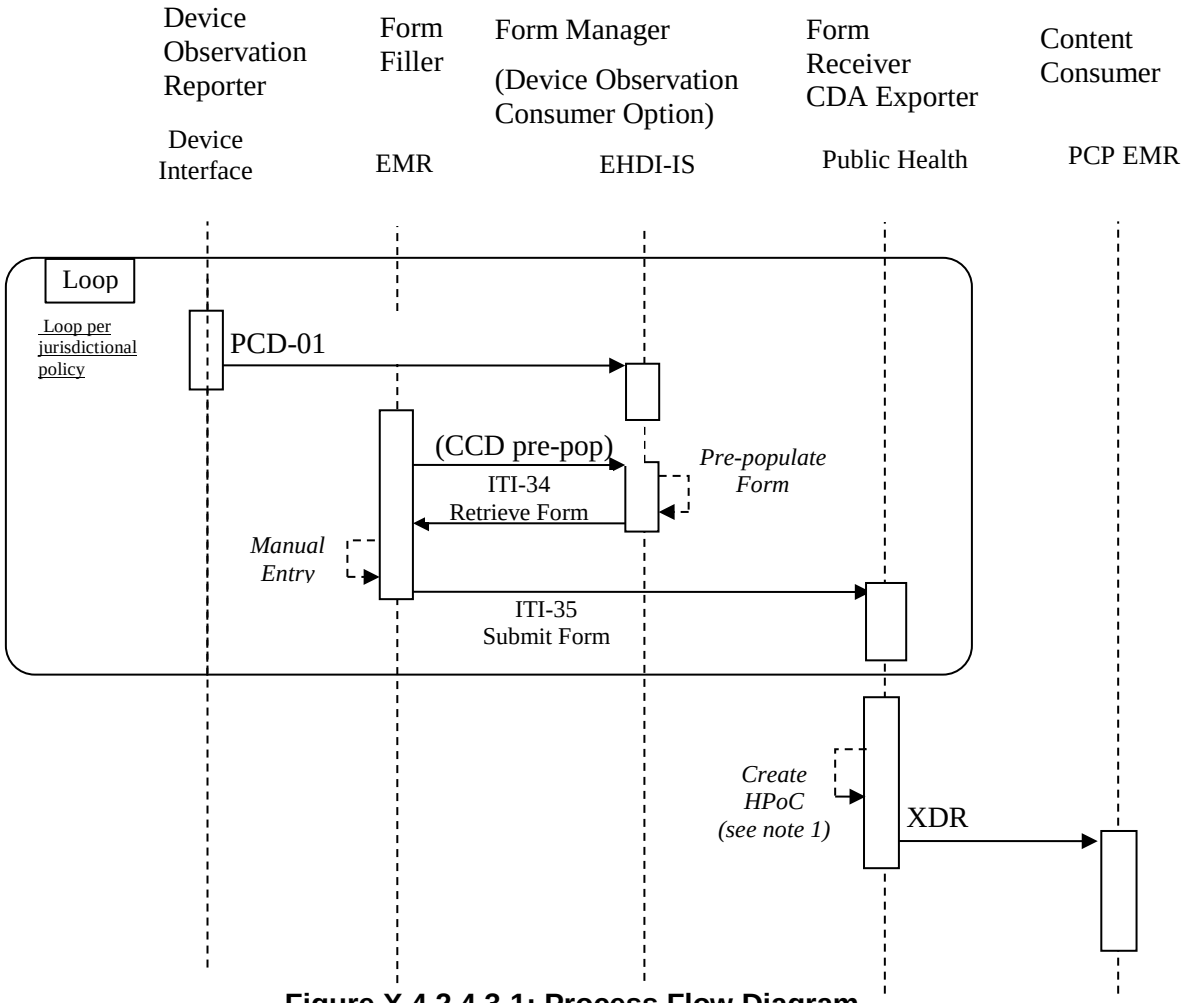

Figure X.4.2.4.3-1: Process Flow Diagram

Note 1: The trigger to initiate the Hearing Plan of Care document is out of scope for this 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

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 ATNA Integration Profile. Other private security mechanisms MAY be used to secure content within enterprise managed systems. 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 ITI DSG 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, XUA and ATNA MAY be utilized to support this implementation.

X.6 Cross Profile Considerations

The following informative narrative is offered as implementation guidance.

X.6.1 Cross Enterprise Document Sharing (XDS.b), Cross Enterprise Document Media Interchange (XDM), or Cross Enterprise Document Reliable Interchange (XDR)

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 1:3.7.1). Below is a summary of recommended IHE transport transactions that MAY be utilized by systems playing the roles of Content Creator or Content Consumer to support the use cases defined in this profile:

- A Document Source in XDS.b, a Portable Media Creator in XDM, or a Document Source in XDR might be grouped with the Content Creator. A Document Consumer in XDS.b, a Portable Media Importer in XDM, or a Document Recipient in XDR might be grouped with the HPoC Content Consumer. A registry/repository-based infrastructure is defined by the IHE Cross Enterprise Document Sharing (XDS.b) that includes profile support that can be leveraged to facilitate retrieval of public health related information from a document sharing infrastructure: Multi-Patient Query (MPQ), Document Metadata Subscription (DSUB) and notification of availability of documents (NAV),
- A media-based infrastructure is defined by the IHE Cross Enterprise Document Media Interchange (XDM) Profile. A Portable Media Creator in XDM might be grouped with the Content Creator. A Portable Media Importer in XDM might be grouped with the Content Consumer,
- A reliable messaging-based infrastructure is defined by the IHE Cross Enterprise Document Reliable Interchange (XDR) Profile. Document Source in XDR might be grouped with the Content Creator. A Document Recipient in XDR might be grouped with the Content Consumer,
- All of these infrastructures support 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 Consumer.

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) Integration Profile in order to use a common uniform managed vocabulary for dynamic management of form mapping rules.

Appendices

Appendix A – New Actors

The EHDI Profile does not define any new actors.

Appendix B – New Transactions

None

Appendix C – Sample Form

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

Appendix D – Header Element Mappings

Appendix D includes an analysis of the use cases to determine their relevance to the information included in the document header. This information helps to explain the meaning associated with the header elements of the CDA document implemented in this profile as they relate to the data elements used in the profile environment..

D.1 Header Participations – Hearing Plan of Care

Participation	Describe how this role pertains to the profiled 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. [We need to think this through further…] 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 – the system that creates the HPoC;
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.
Data Enterer	Maybe reserve this possibility for manual entry. May not be relevant.
Participant	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.

Participation	Describe how this role pertains to the profiled 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 and Public Health was a secondary recipient, or where Public Health is a primary recipient and there is no physician included as a secondary 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 this profile.

D.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 E – Data Elements

Appendix E includes the brief definitions of data elements used in this profile.

E.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.

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.

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 Volume 4, Section 8.7 of this supplement.

E.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.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	
Results.OutcomeAuthor		Who authored the outcomes	AssignedEntity	

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
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?	Entity or 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?	Entity or Device	
RiskFactors. RiskIndicators		Which of the identified Risk Indicators are present?	CD	
Risk Factors Author		Who Authored the Risk Factors?	Entity	
HPoC Problems.Problem List		What is the history of the Active and Inactive Concerns which are relevant for Hearing Care Planning?		

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
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, maybe both?	
HPOC Document Author		Who authored the Hearing Plan of Care Document	Entity or Device, maybe both?	
HPOC Document Custodian		Who is the custodian of the Hearing Plan of Care Document	Jurisdictionally Defined	

Volume 2 – Transactions

None

Volume 3 – Content Modules

5 Namespaces and Vocabularies

Add to Section 5.1.1 Code Systems

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.96	SNOMED 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

Profile	Format Code	Media Type	Template ID
HPoC International Realm	urn:ihe:qrph:hpocUV:2013	Text/XML	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1
HPoC US Realm	urn:ihe:qrph:hpocUS:2013	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

Add to Section 6.3.1.D Document Content Modules

6.3.1.D1 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

The EHDI Profile does not require the use of a particular transactional transport mechanism for sharing an HPoC document.

For implementers who elect to share the HPoC document using transactions from the ITI XDS family of profiles for cross-enterprise document sharing:

- This format code SHALL be used when exchanging a UV Realm HPoC document using transactions from the ITI XDS family of profiles for cross-enterprise document sharing.
- Additionally, XDS transaction bindings for CDA R2 documents specified in the PCC Technical Framework (Volume 2) SHALL be used when exchanging a UV Realm HPoC document using transactions from the ITI XDS family of profiles for cross-enterprise document sharing.

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.

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

Abbreviation	Title	URL
CDA R2	HL7 CDA Release 2.0	https://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
C-CDA R1.1	HL7 Consolidated CDA Release 1.1	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
LOINC©	Logical Observation Identifiers, Names and Codes	https://loinc.org/
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 Volume 4 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

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
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

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.

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Add to Section 6.3.1 Document Content Modules

6.3.1.D1.5 HPoC Document Content Module Specification

Template Name	HearingPlanOfCare
Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1
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	HearingPlanOfCare		1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1
Header	HearingPlanOfCareHeader	[1..1]	n/a
	recordTarget	[1..1]	n/a
	author	[1..*]	n/a
	custodian	[1..1]	n/a
	documentationOf/serviceEvent	[1..1]	n/a
	componentOf/encompassingEncounter	[1..1]	n/a
Section	Hearing Plan of Care	[1..1]	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.1
Section	Hearing Screening	[1..1]	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.2
Section	Risk Indicators for Hearing Loss	[0..1]	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.3
Section	Problems	[0..1]	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.4
Section	Procedures	[0..1]	1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.6

6.3.1.D1.5.1 General Document Constraints

`[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1(open)]`

Template Design Relationships

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 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 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**.
2. **SHALL** contain exactly one [1..1] **typeId**.
    a. This typeId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.1.3".
    b. This typeId **SHALL** contain exactly one [1..1] **@extension**="POCD_HD000040".
3. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contains exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.1".
4. **SHALL** contain exactly one [1..1] **id** such that it
    a. is a globally unique identifier for the document.
5. **SHALL** contain exactly one [1..1] **code** such that it
    a. contains exactly one [1..1] **@code**="34817-7" Hearing Screening Evaluation and Management Note (CodeSystem: LOINC 2.16.840.1.113883.6.1) **STATIC**
6. **SHALL** contain exactly one [1..1] **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 [1..1] **effectiveTime**
8. **SHALL** contain exactly one [1..1] **confidentialityCode**, such that it
    a. is selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 **CNE, STATIC** 2010-04-21.
9. **SHALL** contain exactly one [1..1] **languageCode**, such that it
    a. is selected from ValueSet Language 2.16.840.1.113883.1.11.11526 **CNE, DYNAMIC**.
10. **MAY** contain zero or one [0..1] **setId** such that
    a. **CONDITIONAL** if setId is present versionNumber **SHALL** be present.
11. **MAY** contain zero or one [0..1] **versionNumber** such that
12. **CONDITIONAL** if versionNumber is present setId **SHALL** be present.THE COMPONENT/STRUCTUREDBODY **SHALL** CONFORM TO THE SECTION CONSTRAINTS BELOW.
    a. **SHALL** contain exactly one [1..1] Hearing Plan of Care Section(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.1).
    b. **SHALL** contain exactly one [1..1] Hearing Screening Section (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.2).
    c. **MAY** contain zero or one [0..1] Risk Indicators for Hearing Loss(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.3).

d. **SHOULD** contain zero or one [0..1] Problems Section (`templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.4`).
e. **SHOULD** contain zero or one [0..1] Procedure Section (`templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.6`).

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

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

6.3.2.H1 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.

6.3.2.H1.1 recordTarget

1. **SHALL** contain exactly one [1..1] **`recordTarget`**.
    a. Such recordTargets **SHALL** contain exactly one [1..1] **`patientRole`**.
        i. This patientRole **SHALL** contain at least one [1..*] **`id`**.
        ii. This patientRole **SHALL** contain at least one [1..*] **`addr`**.
        iii. This patientRole **SHALL** contain at least one [1..*] **`telecom`**.
        iv. This patientRole **SHALL** contain exactly one [1..1] **`patient`**.
            1. This patient **SHALL** contain exactly one [1..1] **`name`**.
            2. This patient **SHALL** contain exactly one [1..1] **`administrativeGenderCode`**, which **MAY** be selected from ValueSet `Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1` **DYNAMIC**.
            3. This patient **SHALL** contain exactly one [1..1] **`birthTime`**.

a. **SHALL** be precise to year.
b. **SHOULD** be precise to day.

4. This patient **SHOULD** contain zero or one [0..1] **maritalStatusCode**
5. This patient **MAY** contain zero or one [0..1] **religiousAffiliationCode**
6. This patient **MAY** contain zero or one [0..1] **raceCode**
7. This patient **MAY** contain zero or one [0..1] **ethnicGroupCode**.
8. This patient **SHOULD** contain one or more [1..*] **guardian**.
    a. The guardian, if present, **SHOULD** contain zero or one [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**.
    c. The guardian, if present, **MAY** contain zero or more [0..*] **telecom**.
    d. The guardian, if present, **SHALL** contain exactly one [1..1] **guardianPerson**.
        i. This guardianPerson **SHALL** contain at least one [1..*] **name**.
        ii. This guardianPerson **MAY** contain zero or one [0..1] **birthplace**.
            1. The birthplace, if present, **SHALL** contain exactly one [1..1] **place**.
                1. This place **SHALL** contain exactly one [1..1] **addr**.
                2. This addr **SHOULD** contain zero or one [0..1] **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 [0..1] **postalCode**
9. This patient **MAY** contain zero or one [0..1] **birthplace**.
    a. The birthplace, if present, **SHALL** contain exactly one [1..1] **place**.
        i. This place **SHOULD** contain exactly one [1..1] **addr**.
        1. This addr **SHOULD** contain zero or one [0..1] **country**.
        2. This addr **MAY** contain zero or one [0..1] **postalCode**.

10. This patient **SHOULD** contain zero or more [0..*] **languageCommunication**.
    a. The languageCommunication, if present, **SHALL** contain exactly one [1..1] **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 [0..1] **modeCode**, which **SHALL** be selected from ValueSet LanguageAbilityMode Value Set 2.16.840.1.113883.1.11.12249 **DYNAMIC**.
    c. The languageCommunication, if present, **SHOULD** contain zero or one [0..1] **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 [0..1] **preferenceInd**.
11. This patient MAY contain zero or more [0..*] sdtc:raceCode.

6.3.2.H1.2 author

1. **SHALL** contain at least one [1..*] **author**.
    a. Such authors **SHALL** contain exactly one [1..1] **time**.
    b. Such authors **SHALL** contain exactly one [1..1] **assignedAuthor**.
        i. This assignedAuthor **SHALL** contain exactly one [1..1] **id** such that it
            1. **SHALL** contain exactly one [1..1] **@root**.
        ii. This assignedAuthor **SHOULD** contain zero or one [0..1] **code**.
        iii. This assignedAuthor **SHALL** contain at least one [1..*] **addr**.
        iv. This assignedAuthor **SHALL** contain at least one [1..*] **telecom**.
        v. This assignedAuthor **SHOULD** contain zero or one [0..1] **assignedPerson**.
            1. The assignedPerson, if present, **SHALL** contain at least one [1..*] **name**.
        vi. This assignedAuthor **SHOULD** contain zero or one [0..1] **assignedAuthoringDevice**.
            1. The assignedAuthoringDevice, if present, **SHALL** contain exactly one [1..1] **manufacturerModelName**.
            2. The assignedAuthoringDevice, if present, **SHALL** contain exactly one [1..1] **softwareName**.
        vii. There **SHALL** be exactly one assignedAuthor/assignedPerson, or exactly one assignedAuthor/assignedAuthoringDevice, or exactly one of each.

6.3.2.H1.3 custodian

1. **SHALL** contain exactly one [1..1] **custodian**.
    a. This custodian **SHALL** contain exactly one [1..1] **assignedCustodian**.
        i. This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization**.
            1. This representedCustodianOrganization **SHALL** contain at least one [1..*] **id**.
            2. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **name**.
            3. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **telecom**.
                a. This telecom **SHOULD** contain zero or one [0..1] **@use**
            4. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **addr**.

6.3.2.H1.4 participant

No further constraints specified.

6.3.2.H1.5 informant

No further constraints specified.

6.3.2.H1.6 authenticator

No further constraints specified.

6.3.2.H1.7 legalAuthenticator

No further constraints specified.

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

1. **MAY** contain zero or one [0..1] **componentOf**.
    a. The componentOf, if present, **SHALL** contain exactly one [1..1] **encompassingEncounter**.
        i. This encompassingEncounter **SHALL** contain at least one [1..*] **id**.
        ii. This encompassingEncounter **SHOULD** contain at least one [1..*] **code**

1. This code, if present, **SHALL** be selected from Concept Domain CD_HPoCEncounterType.

iii. This encompassingEncounter **SHALL** contain exactly one [1..1] **effectiveTime**.

iv. This encompassingEncounter **SHALL** contain exactly one [1..1] **location**.

1. This location **SHALL** contain exactly one [1..1] **healthCareFacility**.

a. This healthCareFacility **SHALL** contain exactly one [1..1] **serviceProviderOrganization**.

b. This healthCareFacility **SHALL** contain exactly one [1..1] **location**.

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.

6.3.2.H1.11 documentationOf/ServiceEvent

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

a. The documentationOf, if present, **SHALL** contain exactly one [1..1] **serviceEvent**.

i. This serviceEvent **SHOULD** contain exactly one [1..1] **code**

1. The code, if present, **SHALL** contain exactly one [1..1] **@code**, which **SHOULD** be selected from Concept Domain CD_HPoCServiceEventType.

ii. This serviceEvent **SHALL** contain exactly one [1..1] **effectiveTime**.

1. This effectiveTime **SHALL** contain exactly one [1..1] **low**.

iii. This serviceEvent **SHOULD** contain zero or more [0..*] **performer**.

1. The performer, if present, **SHALL** contain exactly one [1..1] **@typeCode** (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 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, therapists, and counselors.

2. The performer, if present, **MAY** contain zero or one [0..1] **functionCode**.

a. The functionCode, if present, **SHOULD** contain zero or one [0..1] **@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 [1..1] **assignedEntity**.
    a. This assignedEntity **SHALL** contain at least one [1..*] **id**.
    b. This assignedEntity **SHOULD** contain zero or one [0..1] **code**.
        i. The code, if present, **SHALL** contain exactly one [1..1] **@code**, which **SHOULD** be selected from Concept Domain CD_ServiceEventPerformerType.

Implementer Guidance:

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 implementation detail is out of scope for this profile.

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

Add to Section 6.3.3.10 Section Content Modules

6.3.3.S1 Hearing Plan of Care

`[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.1(open)]`

Template Design Relationships

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 R1.1 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

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 @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, 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".
2. **SHALL** contain exactly one [1..1] **code** such that it
    a. contain exactly one [1..1] **@code**="18776-5-HPOC" Plan of Care for Hearing (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 each
    a. contain exactly one [1..1] HPoC Activity Act (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.2).
6. **MAY** contain zero or more [0..*] **entry** such that each
    a. contain exactly one [1..1] HPoC Activity Encounter (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.3).
7. **MAY** contain zero or more [0..*] **entry** such that each
    a. contain exactly one [1..1] 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 [1..1] 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
    a. contain exactly one [1..1] 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 [1..1] HPoC Activity Non-Medicinal Supply (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.7).
11. **MAY** contain zero or more [0..*] **entry** such that each
    a. contain exactly one [1..1] HPoC Instructions (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.1).

6.3.3.S2 Hearing Screening

`[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.2(open)]`

Template Design Relationships

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 R1.1 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.

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.

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"`.
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`).

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.

6.3.3.S3 Risk Indicators for Hearing Loss

`[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.3(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.

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.

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] **code** (CONF:15433) such that it
   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 (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.15).

6.3.3.S4 Problems

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.4(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. 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**="2.16.840.1.113883.10.20.22.2.5.1".
2. **SHALL** contain exactly one [1..1] **templateId** such that it
   a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.4".
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**.
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** Entry(templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.2).

6.3.3.S5 Intentionally blank

6.3.3.S6 Procedures

`[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.3.6(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 R1.1. This template also is an adaptation and generalization of the C-CDA R1.1 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

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 (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 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".
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** (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.18).

6.3.3.S7 Intentionally blank

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)]`

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 R1.1 Instructions template (2.16.840.1.113883.10.20.22.4.20).

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.

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**="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.1".
4. **SHALL** contain exactly one [1..1] **code** such that it
    a. is selected from the Concept Domain CD_HPoCInstructions **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).
6. **SHALL** contain exactly one [1..1] **statusCode** such that it
    a. contains exactly one [1..1] **@code**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**).
7. **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.E2 HPoC Activity Act

`[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 R1.1 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.

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**).
2. **SHALL** contain exactly one [1..1] **@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 [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
    a. is selected from Concept Domain CD_HPoCActivityAct **CWE**.
8. **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).
1. **SHALL** contain exactly one [1..1] **statusCode**.
2. **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.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

The design is an adaptation and generalization of the C-CDA R1.1 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.

1. **SHALL** contain exactly one [1..1] **@classCode**="ENC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**).
2. **SHALL** contain exactly one [1..1] **@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 [0..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.40".
4. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.3".
5. **SHALL** contain at least one [1..*] **id**.
6. **SHALL** contain exactly one [1..1] **code**, such that it
    a. is selected from Concept Domain CD_HPoCActivityEncounter **CWE**.
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
            1. 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**
    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 R1.1 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.

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**, such that it
    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 [0..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.44".
4. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.4".

5. **SHALL** contain at least one [1..*] **id**.
8. **SHALL** contain exactly one [1..1] **code**, such that it
    a. is selected from Concept Domain CD_HPoCActivityObservation **CWE**.
9. **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).
5. **SHALL** contain exactly one [1..1] **statusCode**.
6. **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

`[Procedure: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.5(open)]`

Template Design Relationships

The design is an adaptation and generalization of the C-CDA R1.1 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. **SHALL** contain exactly one [1..1] **@classCode**="PROC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**).
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
    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**="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.5".
5. **SHALL** contain at least one [1..*] **id**.
6. **SHALL** contain exactly one [1..1] **code**, such that it
    a. is selected from Concept Domain CD_HPoCActivityProcedure **CWE**.
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
            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 [1..1] **statusCode**.
8. **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.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 R1.1 Plan of Care Activity 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.

1. **SHALL** contain exactly one [1..1] **@classCode**="SBADM" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**).
2. **SHALL** contain exactly one [1..1] **@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 [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.6".
4. **SHALL** contain at least one [1..*] **id**.
5. **MAY** contain zero or one [0..1] **code** such that it
    a. is selected from Concept Domain CD_HPoCActivitySubstanceAdministrationType **CWE**.
6. **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).
7. **SHALL** contain exactly one [1..1] **statusCode**.
8. **SHALL** contain exactly one [1..1] **effectiveTime** such that it
    a. contain exactly one [1..1] **low**
    b. contain exactly one [1..1] **high**.
9. **SHOULD** contain zero or one [0..1] **effectiveTime** such that it
    a. contain exactly one [1..1] **@operator**="A"
    b. contain exactly one [1..1] @xsi:type=”PIVL_TS” or “EIVL_TS”.
10. **MAY** contain zero or one [0..1] **repeatNumber** such that it
    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.

11. **SHALL** contain exactly one [1..1] **consumable**
12. **SHOULD** include doseQuantity OR rateQuantity.

6.3.4.E7 HPoC Activity Non-Medicinal Supply

`[Supply: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.7(open)]`

Template Design Relationships

The design is an adaptation and generalization of the C-CDA R1.1 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 [1..1] **@classCode**="SPLY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**).
2. **SHALL** contain exactly one [1..1] **@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 [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.7".
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 CD_HPoCActivityNon-MedicinalSupply **CWE**.
6. **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).
7. **SHALL** contain exactly one [1..1] **statusCode**.
8. **SHOULD** contain zero or one [0..1] **effectiveTime** such that it
    a. **CONDITIONAL** if present, contain zero or one [0..1] high.
9. **SHOULD** contain zero or one [0..1] **quantity**.
10. **MAY** contain zero or one [0..1] **participant** such that it
    a. contain exactly one [1..1] **@typeCode**="PRD" Product (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 **STATIC**).
    b. contain exactly one [1..1] **Product Instance** (templateId:2.16.840.1.113883.10.20.22.4.37).

6.3.4.E8 Hearing Screening Organizer

`[Organizer: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.8(open)]`

Template Design Relationships

This design adapts and generalizes the C-CDA R1.1 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

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 gathered. They are a third component and are organized in a Results Organizer.

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 [1..1] **@classCode=** ="CLUSTER" (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**="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.8".
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 CD_HearingScreeningOrganizer **CWE**.
6. **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).
7. **SHALL** contain exactly one [1..1] **statusCode** such that it
    a. contain exactly one [1..1] **@code**, which is selected from ValueSet `Result Status 2.16.840.1.113883.11.20.9.39` **STATIC**.
8. **SHALL** contain exactly one [1..1] **component** such that it
    a. contain exactly one [1..1] Hearing Screening Outcome Observation – Left Ear `templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.9`).
9. **SHALL** contain exactly one [1..1] **component** such that it

a. contain exactly one [1..1] Hearing Screening Outcome Observation – Right Ear `templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.11)`.

10. **SHALL** contain exactly one [1..1] **`component`** such that it
    a. contain exactly one [1..1] Hearing Screening Results Organizer `templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.12)`.

6.3.4.E9 Hearing Screening Outcome Observation – Left

`[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.9(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 pre-coordinated 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 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 [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".
5. **SHALL** contain at least one [1..*] **`id`**.
6. **SHALL** contain exactly one [1..1] **`code`** such that it
    a. is selected from Concept Domain CD_HearingScreeningOutcomeObservation-Left **CWE**.
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
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** such that it
   a. contain exactly one [1..1] **@code**, which is selected from ValueSet `Result Status 2.16.840.1.113883.11.20.9.39` **STATIC**.
9. **SHALL** contain exactly one [1..1] **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 [1..1] **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 [0..1] **methodCode**.
    a. be selected from Concept Domain CD_HearingScreeningMethods **CNE, STATIC**.
12. **SHALL NOT** contain a [1..1] **targetSiteCode**.
13. **MAY** contain zero or one [0..1] **author**.
14. **MAY** contain zero or one [0..1] **entryRelationship**.
    a. **CONDITIONAL** The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode**="RSON" Has Reason (CodeSystem: `HL7ActRelationshipType 2.16.840.1.113883.5.1002` **STATIC**).
    b. **CONDITIONAL** The entryRelationship, if present, **SHALL** contain exactly one [1..1] **Reason Not Screened** (`templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.10`).

6.3.4.E10 Reason Not Screened

`[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.

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).

6.3.4.E11 Hearing Screening Outcome Observation - Right

`[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.11(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

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 pre-coordinated 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 [0..1] **@negationInd**.
4. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.11".
5. **SHALL** contain at least one [1..*] **id**.
6. **SHALL** contain exactly one [1..1] **code** such that it
    a. is selected from Concept Domain CD_HearingScreeningOutcomeObservation-Right **CWE**.

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
            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** such that it
    a. be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 **CNE, STATIC**.
9. **SHALL** contain exactly one [1..1] **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 [1..1] **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 [0..1] **methodCode**.
    a. be selected from Concept Domain CD_HearingScreeningMethods **CNE, STATIC**.
12. **SHALL NOT** contain a [1..1] **targetSiteCode**.
13. **MAY** contain zero or one [0..1] **author**.
14. **MAY** contain zero or one [0..1] **entryRelationship**.
    a. **CONDITIONAL** The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode**="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) **STATIC**.
    b. **CONDITIONAL** The entryRelationship, if present, **SHALL** contain exactly one [1..1] **Reason Not Screened** (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.10).

6.3.4.E12 Hearing Screening Results Organizer

[Organizer: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.12(open)]

Template Design Relationships

The design is an adaptation and generalization of the C-CDA R1.1 Result Organizer (2.16.840.1.113883.10.20.22.4.1). 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.

1. **SHALL** contain exactly one [1..1] **@classCode=** ="CLUSTER" (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] **templateId** such that it
    a. contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.1".
4. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.12".
5. **SHALL** contain at least one [1..*] **id**.
6. **SHALL** contain exactly one [1..1] **code** such that it
    a. is selected from Concept Domain CD_HearingScreeningResultsOrganizer **CWE**.
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
            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** such that it
    a. be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 **CNE, STATIC**.
9. **SHALL** contain zero or more [0..*] **component** such that it
    a. contain exactly one [1..1] Result Observation templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.13).

6.3.4.E13 Hearing Screening Result Observation

[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.13(open)]

Template Design Relationships

This template is an adaptation of the IHE Result Observation template (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 R1.1 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 pre-coordinated 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 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.

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. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.13".
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 CD_HearingScreeningTest **CWE**.
6. **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).
7. **SHALL** contain exactly one [1..1] **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 exactly one [1..1] **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).
9. **SHALL** contain exactly one [1..1] **value**, such that it
    a. be declared as data type xsi:type = “CD”
    b. be selected from Concept Domain CD_HearingScreeningTestResultValues **CNE, STATIC**.
10. **CONDITIONAL: SHALL NOT** contain a value when negationInd=”true”.
11. **SHALL** contain zero or one [0..1] **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 [1..1] **targetSiteCode**, such that it
    a. be selected from Concept Domain CD_HearingScreeningTargetSites **CNE, STATIC**.
14. **MAY** contain zero or one [0..1] **author**.

15. **MAY** contain zero or one [0..1] **performer**.
16. **CONDITIONAL: SHALL** contain exactly one [1..1] **entryRelationship** when negationInd="true", such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. **SHALL** contain exactly one [1..1] **Reason Not Screened** (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.14).
17. **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

[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.15(open)]

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.

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 [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**).
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".
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 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 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**).

8. **SHOULD** contain zero or one [0..1] **effectiveTime**.
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

[Act: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.16(open)]

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

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.

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".

6.3.4.E17 Intentionally blank

6.3.4.E18 Procedure Activity Procedure

[Procedure: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.1.4.18(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 (post-condition) 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.

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.
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".

6.3.4.E19 Intentionally blank

6.3.4.E20 Intentionally blank

6.3.4.E21 Intentionally blank

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Add to sections 6.4 and 6.5 Value Sets

6.4 Section not applicable

This heading is not currently used in a CDA document.

6.5 EHDI Default Value Set Binding for UV Concept Domains

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_HPoCActivitySubstanceAdministration	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
Hearing Screening Section		
CD_HearingScreeningOrganizer	VS_NewbornHearingScreeningOutcomeResultsOrganizer	single code 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.20
CD_HearingScreeningOutcomeObservation-Left	VS_HearingScreeningOutcomeObservation - Left Ear	single code 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.21
CD_HearingScreeningOutcomeObservation-Right	VS_HearingScreeningOutcomeObservation - Right Ear	single code 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.22
CD_HearingScreeningOutcomeObservationValues	VS_HearingScreeningOutcomeObservationValues	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_HearingScreeningResultsOrganizer	VS_HearingScreeningResultsOrganizer	single code 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.23

UV Concept Domain	Default Vocabulary Binding or Single Code Binding	Value Set OID
CD_HearingScreeningTest	VS_NeonatalHearingScreeningTest	single code 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.24
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_HearingScreeningTestResultValues	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		
This section does not use any Concept Domains	VS_HPoCProcedureActivityActs	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.18
This section does not use any Concept Domains	VS_HPoCProcedureActivityProcedures	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.19

7 Device Specialization - Message Content Modules

7.D1 Hearing Screening Device Content Profile for PCD-01

This chapter defines common abstract semantics for hearing screening devices that utilize an HL7 V2 ORU^R01 message to communicate results as constrained by the PCD-01 Transaction. The semantics are based on the ISO/IEEE 11073-10101 nomenclature/terminology and the ISO/IEEE 11073-270 10201 domain information model, with additional semantics systems specified as appropriate (e.g., LOINC or SNOMED-CT) concepts as specified in the HL7 Version 2.6 Implementation Guide: Early Hearing Detection and Intervention (EHDI) Messaging, Release 1, Mappings to ISO/IEEE concepts are provided where known.

7.D1.1 Structural Message Constraints for the EHDI ORU^R01 Message

Below is the full definition of the ORU^R01 message profile. **The segments in gray are not supported in this implementation guide.** The key segments for this implementation guide 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 interpreting the message.

Table 7.D1.1-1: Full Definition of ORU^R01 Message Profile (non-supported segments included)

Segment	Name	Usage	Cardinality	Refer to Base Standard Chapter:	EHDI Reference
MSH	Message Header	R	[1..1]	2	
[{ SFT }]	Software Segment	X		2	
[UAC]	User Authentication Credential	X		2	7.D1.1.1
{	--- PATIENT_RESULT begin				
[	--- PATIENT begin				
PID	Patient Identification	R	[1..1]	3	
[PD1]	Additional Demographics	X		3	
[{NTE}]	Notes and Comments	X		2	
[{NK1}]	Next of Kin/Associated Parties	RE	[0..*]	3	7.D1.1.2
[{OBX}]	Observation (for Patient ID)	X		7	
[	--- VISIT begin				

Segment	Name	Usage	Cardinality	Refer to Base Standard Chapter:	EHDI Reference
PV1	Patient Visit	R	[1..1]	3	
[PV2]	Patient Visit - Additional Info	X		3	
]	--- VISIT end				
]	--- PATIENT end				
{	--- ORDER_OBSERVATION begin				
[ORC]	Order common	X		4	
OBR	Observations Request	R	[1..3]	7	
{[NTE]}	Notes and comments	X		2	
[{ROL}]	Role (for observation)	X		15	7.D1.1.3
[{	--- TIMING_QTY begin	X			
TQ1	Timing/Quantity	X		4	
[{TQ2}]	Timing/Quantity Order Sequence	X		4	
}]	--- TIMING_QTY end	X			
[CTD]	Contact Data	X		11	
[{	--- OBSERVATION begin	RE			
OBX	Observation related to OBR	RE	[0..*]	7	
{[NTE]}	Notes and comments	X		2	7.D1.1.4
}]	--- OBSERVATION end	RE			
[{FT1}]	Financial Transaction	X		6	
{[CTI]}	Clinical Trial Identification	X		7	
[{	--- SPECIMEN begin	X			
SPM	Specimen	X			
[{OBX}]	Observation related to Specimen	X			
}]	--- SPECIMEN end	X			
}	--- ORDER_OBSERVATION end	X			

Segment	Name	Usage	Cardinality	Refer to Base Standard Chapter:	EHDI Reference
}	--- PATIENT_RESULT end	X			
[DSC]	Continuation Pointer	X		2	

7.D1.1.1 Further Constrains on PCD-01

7.D1.1.1.1 Further Constraint for UAC

The usage for the User Authentication Credential segment has been constrained from Optional (O) to Not Permitted (X).

7.D1.1.1.2 Extension for NK1

The usage for the Next of Kin has been segment relaxed from Not Permitted (X) to Required if Available (RE).

7.D1.1.1.3 Further Constraint for ROL

This segment is not mentioned in the PCD-01 Message. In EHDI the Role segment is explicitly Not Permitted (X).

7.D1.1.1.4 Further Constraint for NTE

The usage for Notes and Comments has been constrained from Optional (O) to Not Permitted (X).

7.D1.1.2 Specializations for conveying EHDI Content

The table below shows how specific EHDI content is conveyed in the message Structure.

Table 7.D1.1.2-1: Specification of EHDI ORU^R01 Message

ORU^R01^ORU_R01	Unsolicited Observation Message	Optionality	Cardinality	HL7 V2.6 Chapter	Description

ORU^R01^ORU_R01	Unsolicited Observation Message	Optionality	Cardinality	HL7 V2.6 Chapter	Description
MSH	Message Header	R	1..1	2	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.
{	--- PATIENT_RESULT begin				
	--- PATIENT begin				
PID	Patient Identification	R	1..1	3	The patient identification (PID) segment is used to communicate patient identifying information.
[{NK1}]	Next of Kin/Associated Parties	RE	0..*	3	The Next of Kin segment is used to communicate information on patient contacts.
[	--- VISIT begin				
PV1	Patient Visit	RE	0..1	3	The patient visit segment is used to communicate information on a visit-specific basis.
]	--- VISIT end				
	--- PATIENT end				
{	--- ORDER_OBSERVATION begin				

ORU^R01^ORU_R01	Unsolicited Observation Message	Optionality	Cardinality	HL7 V2.6 Chapter	Description
OBR	Observations Request	R	1..3	7	The observation request (OBR) segment is used to capture information about the hearing screening panel performed. One OBR will report the newborn hearing loss panel. This SHALL be followed by an OBR for the newborn hearing screen panel of the right ear and an OBR for the newborn hearing screen panel of the left ear.
[{	--- OBSERVATION begin				

ORU^R01^ORU_R01	Unsolicited Observation Message	Optionality	Cardinality	HL7 V2.6 Chapter	Description
OBX	Observation related to OBR	R	0..* 1..* (see note)	7	The Observation Result (OBX) segment contains information regarding hearing screening results on the left ear and the right ear. This includes identification of the specific type of observation, the result for the observation, when the observation was made, etc. For newborn hearing screening there is a panel for hearing screening that has been promoted. This hearing screening panel will have 3 OBRs; 1 overarching, 1 for the left ear and 1 for the right ear and this structure resembles the structure used by LOINC in the newborn hearing loss panel. The overarching OBR MAY be supported by OBX segments that carry information on hearing comments/discussion or hearing loss indicators. The Newborn hearing screen panel of ear – right OBR, will be supported by OBX segments for the newborn hearing screening right ear, with the method in OBX-17, the duration, and if appropriate, the reason the screen was not performed. The Newborn hearing screen panel of ear – left, OBR, will be supported by OBX segments for the newborn hearing screening left ear, with the method in OBX-17, the duration, and if

ORU^R01^ORU_R01	Unsolicited Observation Message	Optionality	Cardinality	HL7 V2.6 Chapter	Description
}]	--- OBSERVATION end				
}	--- ORDER_OBSERVATION end				
}	--- PATIENT_RESULT end				

OBX NOTE: For the hearing screening panel OBR, the OBX Cardinality is [0..*], for the right ear and left ear OBRs, the OBX cardinality is [1..*].

7.D1.1.3 Message Transmission

The ORU^R01 message MAY contain a single Observation Request (OBR) for the newborn hearing screening panel, 0 to 1. The Observation Request (OBR) for the newborn hearing loss panel right ear shall be supported by at least 1 OBX. The Observation Request (OBR) newborn hearing loss panel left shall be supported by at least 1 OBX. There MAY be multiple OBX segments associated with OBRs for newborn hearing loss panel right ear and newborn hearing loss panel left ear. Batch messaging SHALL not be supported.

7.D1.1.3.1 ACK^R01^ACK

Guaranteed delivery is required. An ACK message should always be returned to the sender of this message as specified in this guide. All other acknowledgement methods are beyond the scope of this document.

Table 7.D1.1.3-1: ACK^R01^ACK Abstract Message Syntax

Segment	Name	Usage	Cardinality	Comments/Descriptions
MSH	Message Header	R	[1..1]	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	[1..1]	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.

7.D1.2 Device: Hearing Screening Device

7.D1.2.1 Containment tree

Hearing Screening Devices organize their information as follows:

Hearing Screening Device Containment Tree			
MDS: Hearing Screening Device			Proposed term: MDC_DEV_SYS_HEARING_SCREENING_MDS
	VMD: Automated interpretation of hearing screening result		Proposed term: MDC_DEV_SYS_HEARING_SCREENING_VMD
		Channel: Screen Result	n/a

Following public comment, the terms listed above will be proposed to the IEEE nomenclature standard. The QRPH Domain will collaborate with the PCD Domain and IEEE 11073 to work through the process of getting numbers assigned to these codes. This need will remain in the Open Issues for this profile until the code assignments for these terms have been completed.

Containment Tree codes are recorded in OBX-3. They act as a sort of "table of contents" to introduce the contextual structure of the information being communicated by the device. These codes are then used as identifiers in the OBX-4 segments to express the contextual level of the information.

7.D1.2.2 Channels

Channel Parameters				
Name	**Term Code**	**Data Type**	**Units**	**Values**
Screen Result	n/a		N/A	

In this version of the profile, each ear has a pre-coordinated term which is used to distinguish the reported result. Due to the current use of two distinct terms for left ear result and right ear result, separate channels do not need to be established. Adding channels could even be confusing. Note that one single third-level containment tree number will be used, but no additional OBX will be needed to communicate the result.

7.D1.3 Device semantics & controlled terminologies

This part documents specific vocabulary used throughout the message on a segment by segment basis. A table will be established that includes columns to document mapper to ISO/IEEE where known.

7.D1.3.1 Message Header—MSH Segment

The message header (MSH) segment contains information describing how to parse and process the message. The following terminology is used within this segment:

Table 7.D1.3.1-1: MSH Segment and Field Descriptions

Seq	Len	DT	Cardinality	Optionality	Value Set	HL7 Element Name	Comments/Descriptions
15	2	ID	[0..1]	R	HL70155	Accept Acknowledgment Type	This field points out the conditions under which accept acknowledgements that should be returned regarding this message. This is a Required field and is constrained to the value AL, Always. For the sender of the acknowledgement it should always be NE.
16	2	ID	[0..1]	CE	HL70155	Application Acknowledgment Type	The conditions under which application acknowledgements are required in response to this message.
17	3	ID	[0..1]	RE	ISO 3166-1	Country Code	The country of origin is included in this field
19		CWE	[0..1]	RE		Principal Language Of Message	

7.D1.3.2 Patient Identification Segment—PID

This segment is used to communicate patient identification information. This segment contains patient identifying information that is usually permanent and is unlikely to change. The following terminology is used within this segment:

Table 7.D1.3.2-1: Patient Identification Segment (PID)

Seq	Len	DT	Cardinality	Optionality	Value Set	HL7 Element Name	Comments/Descriptions

Seq	Len	DT	Cardinality	Optionality	Value Set	HL7 Element Name	Comments/Descriptions
5		XPN	[1..*]	R	HL70200	Patient Name	This field contains the patient's name or aliases. When the name of the patient is not known, a value must still be placed in this field since the field is required. In that case, |~^^^^^^U| SHALL be used. The "U" for the name type code in the second name indicates that it is unspecified. Since there may be no name components populated, this means there is no legal name, nor is there an alias. This guide will interpret this sequence to mean there is no patient name. Refer to HL7 Table 0200 – Name Type for valid values of the name type code are in HL70200.
8	20	IS	[0..1]	RE	HL70001	Administrative Sex	Patient's sex
10		CWE	[0..*]	RE	HL70005	Race	This field refers to the patient's race.
15		CWE	[0..*]	O	PHVS_Language_ISO_639-2_Alpha3	Primary Language	Need language for communication with the patient (i.e., phone, email, letter, etc.)
22		CWE	[0..1]	RE	HL70189	Ethnic Group	This field further defines patient ancestry. The user MAY use Table HL70189. Other value sets including the Australian Institute of Health and Welfare METeOR identifier 291036 MAY be used.
24	1	ID	[0..1]	O	HL70136	Multiple Birth Indicator	This field indicates if a patient was part of a multiple birth.

7.D1.3.3 Patient Visit Segment – PV1

1960 The PV1 segment is used to communicate information on a visit-specific basis. For EHDI, this is important to indicate if the screening was done as an in-patient, or birth screen, or as an outpatient, follow-up screen. The following terminology is used within this segment:

Table 7.D1.3.3-1: Patient Visit Segment (PV1)

Seq	Len	DT	Cardinality	Optionality	Value Set	HL7 Element Name	Comments/Descriptions

Seq	Len	DT	Cardinality	Optionality	Value Set	HL7 Element Name	Comments/Descriptions
2	1	IS	[1..1]	R	HL70004	Patient Class	This field is used by systems to categorize patients by site. In this message, this field SHALL be used to categorize the patient as an Inpatient or Outpatient.
3	80	PL	[0..1]	RE	HL70302	Assigned Patient location	This field contains the patient's initial location or where the patient is being moved. If a patient is in the Neonatal Intensive Care Unit (NICU) or Special Care Nursery (SCN) this may impact when their hearing screening is performed or how the result is interpreted.

7.D1.3.4 NK1 Segment – Next of Kin Segment

The NK1 segment is used to communicate information on the patient's Next of Kin, or associated parties, most commonly the parent or guardian in newborn screening. For EHDI, this is important if follow-up care or risk monitoring is necessary as a result of the screening. The following terminology is used within this segment:

Table 7.D1.3.4-1: Next of Kin Segment

Seq	Len	DT	Cardinality	Optionality	Value Set	HL7 Element Name	Comments/Descriptions
2	250	XPN	[0..*]	RE	HL0200	Name	This is the name of the next of kin/associated party. Multiple names for the same person are allowed.
3	705	CWE	[0..1]	RE	HL70063	Relationship	This field contains the actual personal relationship that the next of kin/associated party has to the patient. This table has been constrained in this IG.

7.D1.3.5 OBR Segments – Observation Request Segments

In the reporting of hearing screening data there are three possible observation request (OBR) segments that are used to capture information about the hearing screening panel performed. The first OBR will report the newborn hearing loss panel. This SHALL be followed by an OBR for the newborn hearing loss panel of the right ear and an OBR for the newborn hearing panel of the left ear.

7.D1.3.5.1 OBR for the Newborn Hearing Screening Panel

In the reporting of hearing screening data, one OBR is used to report the newborn hearing screening panel. This contains observations relevant to the hearing screening and It MAY be followed by supporting OBX segments that include details on any comments or discussion and/or the hearing loss risk indicators (risk factors). This OBR serves as the report header for the newborn hearing screening panel.

7.D1.3.5.2 OBRs for Newborn Hearing Screen Panel of Ear – Right and Newborn Hearing Screen Panel of Ear - Left

There are two additional OBRs that support the Newborn Hearing Screening Panel; newborn hearing screen panel of ear - right and newborn hearing screen panel of ear - left. These OBRs SHALL be reported for each ear and MAY contain information about the ordering provider and the collector. The OBR for newborn hearing screen panel – right ear and the OBR for newborn hearing screen panel- left ear SHALL be supported by at least one OBX segment that indicates the result of the hearing screen. If a screen is not performed, this result MUST be recorded in the OBX segment. Other data elements relevant to hearing screening recorded in the OBX segment include details on the hearing screening technique, equipment, and screener.

Table 7.D1.3.5.2-1: Observation Request Segments (OBR) for the EHDI ORU^R01 message

Note: the three OBRs have similar structure. The information in OBR-4 identifies whether it is the OBR for the Newborn Hearing Screening panel, the Newborn Hearing Screen panel of Ear – Right or the Newborn Hearing Screen panel of Ear – left.

Seq	Len	DT	Cardinality	Optionality	Value Set	HL7 Element Name	Comments/Descriptions
4		CWE	[1..1]	R	54111-0, 73744-5 and 73741-1	Universal Service Identifier	There may be three OBRs in this message. One OBR is for the newborn hearing screen panel. This will contain the identifier code for the newborn hearing screen panel as a LOINC code, 54111-0. The alternate code to use is a SNOMED-CT code: 417491009, Neonatal Hearing Test procedure There SHALL two other OBRs: One for the newborn hearing screen panel of the right ear and the other for the newborn hearing screen panel of the left ear. These will be identified by their respective LOINC codes 73744-5 and 73741-1.
25	1	ID	[1..1]	R	Table 0123 Result Status Value Set	Result Status	The status of results for this order. C should be used for a Correction to results. F should indicate the Final results; results stored and verified and can only be changed with a corrected result. I should be used to indicate No results are available, if the procedure was incomplete.

7.D1.3.6 OBX Segments – Observation Result Segments

The Observation Result Segment (OBX) contains information regarding a single observation related to a single OBR. The OBR for the newborn hearing screening screen panel, will be supported by optional OBX segments for newborn hearing screen comments or discussion and/or OBX segments for hearing loss risk indicator(s).

The OBR segments for Newborn Hearing Screen panel of ear – right and Newborn Hearing Screen Panel of Ear - left will be supported by OBX segments that include the specific type of observation, the result for the observation, when the observation was made, etc. The newborn hearing screening OBX segments include information on hearing screening technique, equipment, results, reasons, screener and the duration of the screen. For these two OBRS, one OBX is always required. There may be additional OBX segments containing other observations such as percent myogenic, or waveform data that are not specified in this IG. The OBX Universal Service ID values will be drawn from the concept value set that is newborn hearing screening panel. The following terminology is used within this segment:

2030 **Table 7.D1.3.6-1: Observation/Result Segment (OBX)**

Seq	Len	DT	Cardinality	Optionality	Value Set	HL7 Element Name	Comments/Descriptions
2	3	ID	[1..1]	R	HL70125	Value Type	This field identifies the data type used for OBX-5. See *HL7 Table 0125* for the data types that will be supported for this field and OBX-5.
3		CWE	[1..1]	R	Var	Observation Identifier	Unique identifier for the observation for the type of observation. This field provides a code for the type of observation. OBX-3 in conjunction with OBX-4 Observation Sub-ID should uniquely identify this OBX from all other OBXs associated with this OBR. LOINC is used as the coding system for this field.
6		CWE	[0..1]	RE	Unified Code for Units of Measure (UCUM)	Units	UCUM® is an HL7-approved code system and shall be used for units of measure. {} should be used if the measure is unitless.
8	20	IS	[0..*]	RE	HL70078	Abnormal Flags	Indicator of the normalcy of the result found in OBX-5. Null should be used if there is no reference range.
11	1	ID	[1..1]	R	HL70085	Observation Result Status	This field contains the observation result status. F should be used for the final results. C indicates a Correction to Results. P indicates Preliminary Results.
17		CWE	[0..*]	RE	LA10387-1 LA10388-9 LA10389-7 LA10390-5 LA10391-3 LA12406-7	Observation Method	This field can be used to transmit the procedure by which an observation was obtained by the sending system. In hearing screening, this would be the physiological technique. For this OBX field, it should be drawn from the LOINC Value Set 54106-0, EHDI Newborn Hearing Screening Method. The possible values are AABR, ABR, OAE, DPOAE, TOAE, and methodology unknown.
18		EI	[0..*]	RE	Local	Equipment Instance Identifier	This field contains the equipment instance responsible for the production of the observation. In hearing screening the relevant fields to report on a

Seq	Len	DT	Cardinality	Optionality	Value Set	HL7 Element Name	Comments/Descriptions
							piece of equipment are: Brand, model, version, instance data, serial number, local name
20		CWE	[0..1]	RE	Right ear SCT 368570004 Left ear SCT 368592000	Observation Site	This is the body site where the measurement being reported was obtained. This can be either the Right Ear or the Left ear. This is a SNOMED-CT Code.

7.D1.3.6.1 Observation Result Segment (OBX) for Hearing Loss Comments or Discussion

Hearing Screening devices may store comments or discussion on the newborn hearing screen conducted. That information should be included in an OBX segment supporting the Newborn Hearing Loss Panel OBR. This OBX can be used to communicate information on any comments or discussion that may be related to the hearing screening. For example, if the room was noisy or the baby may have atresia, these comments may be included in the device and included in the message transmission to public health or an EHR.

7.D1.3.7 Observation Result Segment (OBX) for Risk Factors of Hearing Loss

Hearing screening devices may store information on risk factors or indicators of hearing loss. Details on the risk factors should be included in an OBX segment(s) supporting the Newborn Hearing Loss Panel OBR. The OBX segments can be used to communicate information on any risk factors for hearing loss the patient may have. For example, the baby was in the NICU for more than 5 days, this is a risk factor that may be of interest to public health. There may be one or many OBX segments for risk factors. SNOMED-CT codes are the preferred codes for these OBX segments. See Risk Factors value set in Chapter 6.5.13 for details.

7.D1.3.8 OBX Segments supporting the Newborn Hearing Screen Panel of Ear - Right OBR and the Newborn Hearing Screen Panel of Ear - Left OBR

In this IG, there is an OBR for the newborn hearing screen panel of the right ear and an OBR for the newborn hearing screen panel of the left ear.

Each panel (OBR) include OBX segments. The OBX segments addressed in this IG are:

- Newborn hearing screen of ear
- Duration of screening right ear and Duration of screening left ear
- Reason not done right ear and reason not done left ear

- There may be additional OBX segments containing other observations such as stimulus parameters used in the screen or waveform data. Processing of these additional optional OBX segments is out of scope for this profile.

7.D1.3.8.1 OBX Segments: Newborn Hearing screen right and Newborn Hearing Screen Left

When a screening has been performed or attempted or not performed, then a result should be communicated in the OBX segment. There should be OBX segment or the result for the newborn hearing screen – right and newborn hearing screen – left, and the method used in the screen should be contained in OBX-17.

7.D1.3.8.2 OBX Segments: Duration of screening of ear – right and Duration of screening of ear - left

If a screening has been performed or attempted, then the duration of the test MAY be communicated in the OBX segment. Some devices capture duration measurements and this OBX is intended to support the communication of that data element. There can be a duration OBX for each screening performed.

7.D1.3.8.3 OBX Segments: Reason Screen Not Done right ear and Reason Screen Not Done left ear

If a hearing screening was not performed that information needs to be shared with public health or the EHR. Reasons can include parental refusal, the screening was attempted but unsuccessful, it was not performed, or it was not performed because of a medical exclusion. The Reason the screen was not done OBX Segment is Required when OBX-5 of the Newborn hearing Screen Right OBX and/or Newborn Hearing Screen Left OBX is Not Performed ; 262008008 SNOMED-CT. The following terminology is used within this segment:

Table 7.D1.3.8.3-1: OBX Identifiers Table

Hearing Screening Supporting OBX Segments	OBX 2 - Value Type	OBX 3 0bservation Identifier	OBX 5 - Observation Value	Code Description	OBX 6 Units	OBX 7 Reference Range	OBX 8 Abnormal Flags
Hearing Loss Comments and Discussion	TX	57700-7	this is text of any comments or discussion	This records any comments or discussion related to the hearing screening	{} should be used if the measure is unitless.	May be populated	May be populated with codes from HL7 Table 0078

Hearing Screening Supporting OBX Segments	OBX 2 - Value Type	OBX 3 0bservation Identifier	OBX 5 - Observation Value	Code Description	OBX 6 Units	OBX 7 Reference Range	OBX 8 Abnormal Flags
Evidence of Hearing Loss Risk Indicators	CWE	58232-0	Coded observation. SNOMED CT codes (Value Set: 1.3.6.1.4.1.19376.1.7.3.1.1.15.2.11 and 1.3.6.1.4.1.19376.1.7.3.1.1.15.2.12) for hearing loss risk factors shall be used when a code exists, otherwise use a LOINC Answer Code (Value Set 58232-0)	Field that documents the specific hearing loss indicator. It is recommended that SNOMED-CT codes be used to report the observation of a risk factor of hearing loss.	{} should be used if the measure is unitless.	May be populated	May be populated with codes from HL7 Table 0078
Newborn hearing screen of Ear - right	CWE	54109-4	Evidence of Hearing Screening Performed Value Set	The OBX segments with the hearing screening result provides coded result values for pass, refer and not performed. The coded values shown are drawn from the value sets for Evidence of Hearing Screening Performed, Pass, Refer and Not Performed. There should be separate OBX segments for each result for the Right Ear and each result for the left ear. SNOMED-CT codes should be used to document the	{} should be used if the measure is unitless.	May be populated	May be populated with codes from HL7 Table 0078

Hearing Screening Supporting OBX Segments	OBX 2 - Value Type	OBX 3 0bservation Identifier	OBX 5 - Observation Value	Code Description	OBX 6 Units	OBX 7 Reference Range	OBX 8 Abnormal Flags
				result of the hearing screening. Please see Chapter 6 for the SNOMED-CT codes for pass, refer, and not performed. If the OBX-5 value is not performed, an OBX segment for the reason screen not performed is required.			
Newborn Hearing Screening Left	CWE	54108-6	Evidence of Hearing Screening Performed Value Set	The OBX segments with the hearing screening result provides coded result values for pass, refer and not performed. The coded values shown are drawn from the value sets for Evidence of Hearing Screening Performed, Pass, Refer and Not Performed. There should be separate OBX segments for each result for the Right Ear and each result for the left ear. SNOMED-CT	{} should be used if the measure is unitless.	May be populated	May be populated with codes from HL7 Table 0078

Hearing Screening Supporting OBX Segments	OBX 2 - Value Type	OBX 3 0bservation Identifier	OBX 5 - Observation Value	Code Description	OBX 6 Units	OBX 7 Reference Range	OBX 8 Abnormal Flags
				codes should be used to document the result of the hearing screening. Please see Chapter 6 for the SNOMED-CT codes for pass, refer, and not performed. If the OBX-5 value is not performed, an OBX segment for the reason screen not performed is required.			
Duration of Screening Right Ear	NM	73740-3	Unit of Time	The observation value is the length of time recorded for the duration of the screen. It is a numeric value.	UCUM units		
Duration of Screening Left Ear	NM	73743-7	Unit of Time	The observation value is the length of time recorded for the duration of the screen. It is a numeric value.	UCUM units	May be populated	May be populated with codes from HL7 Table 0078
Newborn hearing screen reason not performed - right	CWE	73742-9	Screening Result not Performed Value Set	The observation value is the reason the screen was not done. This is a Required OBX segment when the screen is not	{} should be used if the measure is unitless.	May be populated	May be populated with codes from HL7 Table 0078

Hearing Screening Supporting OBX Segments	OBX 2 - Value Type	OBX 3 0bservation Identifier	OBX 5 - Observation Value	Code Description	OBX 6 Units	OBX 7 Reference Range	OBX 8 Abnormal Flags
				performed. The Screening Result not Performed Value Set Shall be used. Please see Chapter 6 for the SNOMED-CT codes.			
Newborn hearing screen reason not performed left	CWE	73739-5	Screening Result not Performed Value Set	The observation value is the reason the screen was not done. This is a Required OBX segment when the screen is not performed. The Screening Result not Performed Value Set Shall be used. Please see Chapter 6 for the SNOMED-CT codes.	{} should be used if the measure is unitless.	May be populated	May be populated with codes from HL7 Table 0078

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7.D1.3.9 MSA Segment

This segment contains information sent while acknowledging another message. The following terminology is used within this segment:

2085 **Table 7.D1.3.9-1: MSA Segment**

Seq	Len	DT	Cardinality	Optionality	Value Set	HL7 Element Name	Comments/Descriptions
1	2	ID	[1..1]	R	HL70008	Acknowledgment Code	This field contains an acknowledgement code. (Refer to *HL7 Table 0008 -*

							Acknowledgment Code for valid values.)

7.D1.3.10 Error Segment—ERR

The ERR segment is used to add error comments to acknowledgment messages. The following terminology is used within this segment:

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Table 7.D1.3.10-1: Error Segment (ERR)

Seq	Len	DT	Cardinality	Optionality	Value Set	HL7 Element Name	Comments/Descriptions
3		CWE	[1..1]	R	HL70357	HL7 Error Code	Identifies the HL7 (communications) error code.
4	1	ID	[1..*]	R	HL70516	Severity	Identifies the severity of an application error. Knowing if something is Error, Warning, or Information is intrinsic to how an application handles the content.

Appendices

None

Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

None

Volume 4 – National Extensions

Add appropriate country section

4 National Extensions

4.R1 National Extensions for US Realm

4.R1.1 Comment Submission

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

IHE USA, Alexander Lippitt Jr.

Email: alippitt@himss.org

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

4.R1.2.1 Hearing Plan of Care – US Realm Specifications

(OPEN ISSUE: This level of the outline is parallel with 6.3.1. What would be an easy way to keep these specifications lined up?)

6 Design Overview

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 chapter 3 below.

Template Type	Template Title	Opt and Card	templateId
Document	HearingPlanOfCare		1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1
Header	HearingPlanOfCareHeader	[1..1]	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.2.1
	recordTarget	[1..1]	n/a
	author	[1..*]	n/a
	custodian	[1..1]	n/a
	documentationOf/serviceEvent	[1..1]	
	componentOf/encompassingEncounter	[1..1]	
Section	Hearing Plan of Care	[1..1]	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	[1..1]	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.2
Entry	Hearing Screening Organizer	[1..1]	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.8
Entry	Hearing Screening Outcome Observation–Left Ear	[1..1]	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.9
Sub-Entry	Reason Not Screened	[0..1]	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.10
Entry	Hearing Screening Outcome Observation–Right Ear	[1..1]	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.11

Template Type	Template Title	Opt and Card	templateId
Sub-Entry	Reason Not Screened	[0..1]	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	[0..1]	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	[0..1]	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	[0..1]	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	[0..1]	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	[0..1]	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	[0..1]	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

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7 Intentionally Blank

8 US Realm

8.4 Document Templates

6.3.1.D1.1 HPoC Document Format Code

Profile	Format Code	Media Type	Template ID
HPoC US Realm	urn:ihe:qrph:hpocUS:2014	Text/XML	1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1

The EHDI Profile does not require the use of a particular transactional transport mechanism for sharing an HPoC document.

For implementers who elect to share the HPoC document using transactions from the ITI XDS family of profiles for cross-enterprise document sharing:

- This format code SHALL be used when exchanging a US Realm HPoC document using transactions from the ITI XDS family of profiles for cross-enterprise document sharing.
- Additionally, XDS transaction bindings for CDA R2 documents specified in the PCC Technical Framework (Volume 2) SHALL be used when exchanging a US Realm HPoC document using transactions from the ITI XDS family of profiles for cross-enterprise document sharing.

6.3.1.D1.5 HPoC Document Template Specification

`[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1(open)]`

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 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 [1..1] **typeId**.
    a. This typeId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.1.3".

b. This typeId **SHALL** contain exactly one [1..1] **@extension**="POCD_HD000040".

3. **SHALL** contain exactly one [1..1] **templateId** such that it
   a. contains exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.1".
4. **SHALL** contain exactly one [1..1] **id** such that it
   a. is a globally unique identifier for the document.
5. **SHALL** contain exactly one [1..1] **code** such that it
   a. contains exactly one [1..1] **@code**="34817-7" Hearing Screening Evaluation and Management Note (CodeSystem: LOINC 2.16.840.1.113883.6.1) **STATIC**
6. **SHALL** contain exactly one [1..1] **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 [1..1] **effectiveTime** such that it
   a. is conformant US Realm Date and Time (DTM.US.FIELDED) (2.16.840.1.113883.10.20.22.5.4).
8. **SHALL** contain exactly one [1..1] **confidentialityCode**, such that it
   a. is selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 **CNE, STATIC** 2010-04-21.
9. **SHALL** contain exactly one [1..1] **languageCode**, such that it
   a. is selected from ValueSet Language 2.16.840.1.113883.1.11.11526 **CNE, DYNAMIC**.
10. **MAY** contain zero or one [0..1] **setId** such that
    a. **CONDITIONAL** if setId is present versionNumber **SHALL** be present.
11. **MAY** contain zero or one [0..1] **versionNumber** such that
    a. **CONDITIONAL** if versionNumber is present setId **SHALL** be present.

6.3.2.H1 HPoC Header Template

`[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.2.1(open)]`

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

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 [1..1] **recordTarget**.
    a. Such recordTargets **SHALL** contain exactly one [1..1] **patientRole**.
        i. This patientRole **SHALL** contain at least one [1..*] **id**.
        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**.
            1. Such telecoms **SHOULD** contain zero or one [0..1] **@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 [1..1] **patient**.
            1. This patient **SHALL** contain exactly one [1..1] **name**.
                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 [1..1] **administrativeGenderCode**, which **SHALL** be selected from ValueSet `Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1` **DYNAMIC**.
            3. This patient **SHALL** contain exactly one [1..1] **birthTime**.
                a. **SHALL** be precise to year.
                b. **SHOULD** be precise to day.
            4. This patient **SHOULD** contain zero or one [0..1] **maritalStatusCode**, which **SHALL** be selected from ValueSet

`Marital Status Value Set` `2.16.840.1.113883.1.11.12212` **DYNAMIC**.

5. This patient **MAY** contain zero or one [0..1] **religiousAffiliationCode**, which **SHALL** be selected from ValueSet `Religious Affiliation Value Set` `2.16.840.1.113883.1.11.19185` **DYNAMIC**.
6. This patient **MAY** contain zero or one [0..1] **raceCode**, which **SHALL** be selected from ValueSet `Race Value Set` `2.16.840.1.113883.1.11.14914` **DYNAMIC**.
7. This patient **MAY** contain zero or one [0..1] **ethnicGroupCode**, which **SHALL** be selected from ValueSet `EthnicityGroup` `2.16.840.1.114222.4.11.837` **DYNAMIC**.
8. This patient **SHOULD** contain one or more [1..*] **guardian**.
    a. The guardian, if present, **SHOULD** contain zero or one [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 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**.
        i. The telecom, if present, **SHOULD** contain zero or one [0..1] **@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 [1..1] **guardianPerson**.
        i. This guardianPerson **SHALL** contain at least one [1..*] **name**.
            1. The content of name **SHALL** be a conformant US Realm Person Name (PN.US.FIELDED) (2.16.840.1.113883.10.20.22.5.1.1).
        ii. This guardianPerson **MAY** contain zero or one [0..1] **birthplace**.
            1. The birthplace, if present, **SHALL** contain exactly one [1..1] **place**.
                1. This place **SHALL** contain exactly one [1..1] **addr**.
                2. This addr **SHOULD** contain zero or one [0..1] **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 [0..1] **postalCode**, which **SHALL** be selected from ValueSet `PostalCodeValueSet 2.16.840.1.113883.3.88.12.80.2` **DYNAMIC**.
4. If country is US, this addr **SHALL** contain exactly one [1..1] state, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.1 StateValueSet **DYNAMIC**.

9. This patient **MAY** contain zero or one [0..1] **birthplace**.
   a. The birthplace, if present, **SHALL** contain exactly one [1..1] **place**.
      i. This place **SHALL** contain exactly one [1..1] **addr**.
         1. This addr **SHOULD** contain zero or one [0..1] **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 [0..1] **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 one [1..1] state, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.1 StateValueSet **DYNAMIC**.
10. This patient **SHOULD** contain zero or more [0..*] **languageCommunication**.
   a. The languageCommunication, if present, **SHALL** contain exactly one [1..1] **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 [0..1] **modeCode**, which **SHALL** be selected from ValueSet `LanguageAbilityMode Value Set 2.16.840.1.113883.1.11.12249` **DYNAMIC**.
   c. The languageCommunication, if present, **SHOULD** contain zero or one [0..1] **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 [0..1] **preferenceInd**.

11. This patient **MAY** contain zero or more [0..*] **sdtc:raceCode**, where the @code **SHALL** be selected from ValueSet `Race Value Set 2.16.840.1.113883.1.11.14914` **DYNAMIC**.

6.3.2.H1.2 author

1. **SHALL** contain at least one [1..*] **author**.
    a. Such authors **SHALL** contain exactly one [1..1] **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 [1..1] **assignedAuthor**.
        i. This assignedAuthor **SHALL** contain exactly one [1..1] **id** such that it
            1. **SHALL** contain exactly one [1..1] **@root**.
                a. If this assignedAuthor is an assignedPerson the assignedAuthor id **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.4.6" National Provider Identifier.
        ii. This assignedAuthor **SHOULD** contain zero or one [0..1] **code**.
            1. The code, if present, **SHALL** contain exactly one [1..1] **@code**, which **SHOULD** be selected from ValueSet `Healthcare Provider Taxonomy (HIPAA) 2.16.840.1.114222.4.11.1066` **DYNAMIC**.
        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 assignedAuthor **SHALL** contain at least one [1..*] **telecom**.
            1. Such telecoms **SHOULD** contain zero or one [0..1] **@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 [0..1] **assignedPerson**.
            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) (2.16.840.1.113883.10.20.22.5.1.1).
        vi. This assignedAuthor **SHOULD** contain zero or one [0..1] **assignedAuthoringDevice**.

1. The assignedAuthoringDevice, if present, **SHALL** contain exactly one [1..1] **manufacturerModelName**.
2. The assignedAuthoringDevice, if present, **SHALL** contain exactly one [1..1] **softwareName**.

vii. There **SHALL** be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice, or exactly one of each.

6.3.2.H1.3 custodian

1. **SHALL** contain exactly one [1..1] **custodian**.
   a. This custodian **SHALL** contain exactly one [1..1] **assignedCustodian**.
      i. This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization**.
         1. This representedCustodianOrganization **SHALL** contain at least one [1..*] **id**.
            a. Such ids **SHOULD** contain zero or one [0..1] **@root**="2.16.840.1.113883.4.6" National Provider Identifier.
         2. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **name**.
         3. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **telecom**.
            a. This telecom **SHOULD** contain zero or one [0..1] **@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 one [1..1] **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

1. **MAY** contain zero or one [0..1] **componentOf**.
   a. The componentOf, if present, **SHALL** contain exactly one [1..1] **encompassingEncounter**.
      i. This encompassingEncounter **SHALL** contain at least one [1..*] **id**.
      ii. This encompassingEncounter **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**.

iii. This encompassingEncounter **SHALL** contain exactly one [1..1] **`effectiveTime`**.

iv. This encompassingEncounter **SHALL** contain exactly one [1..1] **`location`**.

1. This location **SHALL** contain exactly one [1..1] **`healthCareFacility`**.

a. This healthCareFacility **SHALL** contain exactly one [1..1] **`serviceProviderOrganization`**.

b. This healthCareFacility **SHALL** contain exactly one [1..1] **`location`**.

Implementer Guidance:

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

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

a. The documentationOf, if present, **SHALL** contain exactly one [1..1] **`serviceEvent`**.

i. This serviceEvent **SHOULD** contain exactly one [1..1] **`code`**.

1. This code **SHALL** be selected from Value Set `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 [1..1] **`effectiveTime`**.

1. This effectiveTime **SHALL** contain exactly one [1..1] **`low`**.

iii. This serviceEvent **SHOULD** contain zero or more [0..*] **`performer`**.

1. The performer, if present, **SHALL** contain exactly one [1..1] **`@typeCode`** (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 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, therapists, and counselors.

2. The performer, if present, **MAY** contain zero or one [0..1] **functionCode**.
    a. The functionCode, if present, **SHOULD** contain zero or one [0..1] **@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 [1..1] **assignedEntity**.
    a. This assignedEntity **SHALL** contain at least one [1..*] **id**.
        i. Such ids **SHOULD** contain zero or one [0..1] **@root**="2.16.840.1.113883.4.6" National Provider Identifier.
    b. This assignedEntity **SHOULD** contain zero or one [0..1] **code**.
        i. The code, if present, **SHALL** contain exactly one [1..1] **@code**, which **SHOULD** be selected from CodeSystem NUCCProviderTaxonomy (2.16.840.1.113883.6.101) **STATIC**.

Implementer Guidance:

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 implementation detail is out of scope for this profile.

8.4.1 Document Template Structured Body

1. The component/structuredBody **SHALL** conform to the section constraints below.
    a. **SHALL** contain exactly one [1..1] Hearing Plan of Care Section(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.1).
    b. **SHALL** contain exactly one [1..1] Hearing Screening Section (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.2).
    c. **MAY** contain zero or one [0..1] Risk Indicators for Hearing Loss(templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.3).

d. **SHOULD** contain zero or one [0..1] Problems Section (`templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.4`).

e. **SHOULD** contain zero or one [0..1] Procedure Section (`templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.6 `).

8.5 Section Templates

6.3.3.S1 Hearing Plan of Care – Section Template

`[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.1(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 R1.1 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

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 @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, 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".
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".
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
    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).
10. **MAY** contain zero or more [0..*] **entry** such that each
    a. contain exactly one [1..1] HPoC Activity Substance Administration (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.6).
11. **MAY** contain zero or more [0..*] **entry** such that each
    a. contain exactly one [1..1] HPoC Activity Non-Medicinal Supply (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.7).
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).

6.3.3.S2 Hearing Screening – Section Template

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.2(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.

This template adapts the C-CDA R1.1 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.

1. **MAY** contain zero or one [0..1] **templateId** such that it

a. contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.3.1".
2. **SHALL** contain exactly one [1..1] **templateId** such that it
   a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.2".
3. **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**).
4. **SHALL** contain exactly one [1..1] **title**.
5. **SHALL** contain exactly one [1..1] **text**.
6. **SHALL** contain exactly one [1..1] **entry** such that it
   a. contain exactly one [1..1] Hearing Screening Organizer (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.8).

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.

6.3.3.S3 Risk Indicators for Hearing Loss – Section Template

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.3(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.)

1. **SHALL** contain exactly one [1..1] **templateId** such that it
   a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.3".
2. **SHALL** contain exactly one [1..1] **code** (CONF:15433) such that it
   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 (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.15).

6.3.3.S4 Problems – Section Template

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.4(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.

This template adapts the design of the C-CDA R1.1 Problem section template (2.16.840.1.113883.10.20.22.2.5.1) the same entries are used, but an additional optional sub-section is added which can be used to indicate concerns which may be relevant for hearing screening.

Template Purpose

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".
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".
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**.
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] **HPoC Problems section** (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.5).

6.3.3.S5 HPoC Problems – Sub-Section Template

`[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.5(open)]`

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.

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".
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
    a. contain exactly one [1..1] **HPoC Problem Concern** (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.17).

Note: An HPoC Problem Concern does not repeat the full content of a Problem Concern, it only "points to" the Problem Concern us the associated id.

6.3.3.S6 Procedures – Section Template

`[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.6(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.

This template is an adaption of the C-CDA R1.1 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

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 (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 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".
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** (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.18).
6. **MAY** contain zero or more [0..*] **entry** such that it
    a. contain exactly one [1..1] **Procedure Activity Act** (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.19).

6.3.3.S7 HPoC Relevant Procedures – Sub-Section Template

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.3.7(open)]

Template Design Relationships

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.

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".
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**.
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).

8.6 Entry Templates

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.

The design is based on the C-CDA R1.1 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

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
    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 [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).
6. **SHALL** contain exactly one [1..1] **statusCode** such that it
    a. contains exactly one [1..1] **@code**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**).
7. **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.E2 HPoC Activity Act

[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.

The design is a specialization of the C-CDA R1.1 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

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 [1..1] **@classCode**="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**).
2. **SHALL** contain exactly one [1..1] **@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 [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**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.2".
5. **SHALL** contain at least one [1..*] **id**.
6. **SHALL** contain exactly one [1..1] **code**, such that it
    a. is selected from VS_HPoCActivityAct 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.4 **CWE, DYNAMIC**.
8. **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).
9. **SHALL** contain exactly one [1..1] **statusCode**.
10. **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.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

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 R1.1 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.

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 [1..1] **@classCode**="ENC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**).
2. **SHALL** contain exactly one [1..1] **@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 [0..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.40".
4. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.3".

5. **SHALL** contain at least one [1..*] **id**.
6. **SHALL** contain exactly one [1..1] **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 [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).
11. **SHALL** contain exactly one [1..1] **statusCode**.
12. **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.E4 HPoC Activity Observation

`[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.4(open)]`

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.

The design is based on the C-CDA R1.1 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.

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**, such that it
    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 [0..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.44".
4. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.4".
5. **SHALL** contain at least one [1..*] **id**.
6. **SHALL** contain exactly one [1..1] **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 [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).
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

`[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 R1.1 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**).
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
   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

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
         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
   c. contain exactly one [1..1] **`low`**
   d. contain exactly one [1..1] **`high`**.

6.3.4.E6 HPoC Activity SubstanceAdministration

`[SubstanceAdministration: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.6(open)]`

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 R1.1 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.

1. **SHALL** contain exactly one [1..1] **`@classCode`**="SBADM" (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**).
2. **SHALL** contain exactly one [1..1] **`@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 [1..1] **`templateId`** such that it
   a. contain exactly one [1..1] **`@root`**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.6".
4. **SHALL** contain at least one [1..*] **`id`**.
5. **MAY** contain zero or one [0..1] **`code`** such that it
   a. is selected from Value Set VS_HPoCActivitySubstanceAdministrationType 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.8 **CWE**.
6. **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).

7. **SHALL** contain exactly one [1..1] **statusCode**.
8. **SHALL** contain exactly one [1..1] **effectiveTime** such that it
   a. contain exactly one [1..1] **low**
   b. contain exactly one [1..1] **high**.
9. **SHOULD** contain zero or one [0..1] **effectiveTime** such that it
   a. contain exactly one [1..1] **@operator**="A"
   b. contain exactly one [1..1] @xsi:type=”PIVL_TS” or “EIVL_TS”.
10. **MAY** contain zero or one [0..1] **repeatNumber** such that it
    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.
11. **MAY** contain zero or one [0..1] **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**.
12. **MAY** contain zero or one [0..1] **approachSiteCode**, such that it
    a. Is selected from ValueSet Body Site Value Set 2.16.840.1.113883.3.88.12.3221.8.9 **CNE, DYNAMIC**.
13. **SHOULD** contain zero or one [0..1] **doseQuantity**
    a. **CONDITIONAL** The doseQuantity, if present, **SHALL** contain zero or one [0..1] **@unit**, selected from ValueSet UnitsOfMeasureCaseSensitive 2.16.840.1.113883.1.11.12839 **CWE, DYNAMIC**.
    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").
    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.
14. **MAY** contain zero or one [0..1] **rateQuantity**.
    a. **CONDITIONAL** The rateQuantity, if present, **SHALL** contain exactly one [1..1] **@unit**, selected from ValueSet UnitsOfMeasureCaseSensitive 2.16.840.1.113883.1.11.12839 **CWE, DYNAMIC**.
15. **MAY** contain zero or one [0..1] **maxDoseQuantity**.
16. **MAY** contain zero or one [0..1] **administrationUnitCode**, such that it
    a. be selected from ValueSet Medication Product Form Value Set 2.16.840.1.113883.3.88.12.3221.8.11 **CWE, DYNAMIC**.

17. **SHALL** contain exactly one [1..1] **consumable** such that it
    a. contain exactly one [1..1] **Medication Information** (templateId:2.16.840.1.113883.10.20.22.4.23).
18. **MAY** contain zero or one [0..1] **performer**.
19. **MAY** contain zero or more [0..*] **participant** such that it
    a. contain exactly one [1..1] **@typeCode**="CSM" (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) **STATIC**.
    b. contain exactly one [1..1] **Drug Vehicle** (templateId:2.16.840.1.113883.10.20.22.4.24).
20. **MAY** contain zero or more [0..*] **entryRelationship** such that it
    a. contain exactly one [1..1] **@typeCode**="RSON" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) **STATIC**.
    b. contain exactly one [1..1] **Indication** (templateId:2.16.840.1.113883.10.20.22.4.19).
21. **MAY** contain zero or one [0..1] **entryRelationship** such that it
    a. contain exactly one [1..1] **@typeCode**="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. contain exactly one [1..1] **@inversionInd**="true".
    c. contain exactly one [1..1] **Instructions** (templateId:2.16.840.1.113883.10.20.22.4.20).
22. **MAY** contain zero or one [0..1] **entryRelationship** such that it
    a. contain exactly one [1..1] **@typeCode**="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) **STATIC**.
    b. contain exactly one [1..1] **Medication Supply Order** (templateId:2.16.840.1.113883.10.20.22.4.17).
23. **MAY** contain zero or more [0..*] **entryRelationship** such that each
    a. contain exactly one [1..1] **@typeCode**="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) **STATIC**.
    b. contain exactly one [1..1] **Medication Dispense** (templateId:2.16.840.1.113883.10.20.22.4.18).
24. **MAY** contain zero or one [0..1] **entryRelationship** such that it
    a. contain exactly one [1..1] **@typeCode**="CAUS" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) **STATIC**.
    b. contain exactly one [1..1] **Reaction Observation** (templateId:2.16.840.1.113883.10.20.22.4.9).
25. **MAY** contain zero or more [0..*] **precondition** such that it
    a. contain exactly one [1..1] **@typeCode**="PRCN" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) **STATIC**.
    b. contain exactly one [1..1] **Precondition for Substance Administration** (templateId:2.16.840.1.113883.10.20.22.4.25).
26. **SHOULD** include doseQuantity OR rateQuantity.

6.3.4.E7 HPoC Activity Non-medicinal Supply

`[Supply: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.7(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.

The design is based on the C-CDA R1.1 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

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

1. **SHALL** contain exactly one [1..1] **@classCode**="SPLY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**).
2. **SHALL** contain exactly one [1..1] **@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 [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.7".
4. **SHALL** contain at least one [1..*] **id**.
5. **SHALL** contain exactly one [1..1] **code**, such that it
    a. is selected from VS_HPoCActivityNon-MedicinalSupplyType 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.9 **CWE, DYNAMIC**.
6. **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).
7. **SHALL** contain exactly one [1..1] **statusCode**.
8. **SHOULD** contain zero or one [0..1] **effectiveTime** such that it
    a. **CONDITIONAL** if present, contain zero or one [0..1] high.
9. **SHOULD** contain zero or one [0..1] **quantity**.
10. **MAY** contain zero or one [0..1] **participant** such that it
    a. contain exactly one [1..1] **@typeCode**="PRD" Product (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 **STATIC**).
    b. contain exactly one [1..1] **Product Instance** (templateId:2.16.840.1.113883.10.20.22.4.37).

6.3.4.E8 Hearing Screening Organizer

`[Organizer: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.8(open)]`

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 R1.1 Result Organizer template.

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. 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.

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 [1..1] **@classCode=** ="CLUSTER" (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**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.8".
4. **SHALL** contain at least one [1..*] **id**.
5. **SHALL** contain exactly one [1..1] **code** such that it
    a. contain exactly one [1..1] **@code**=" 54111-0" Newborn Hearing Loss Panel (CodeSystem: `LOINC 2.16.840.1.113883.6.1`) **STATIC**.
6. **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).
7. **SHALL** contain exactly one [1..1] **statusCode** such that it
    a. contain exactly one [1..1] **@code**, which is selected from ValueSet `Result Status 2.16.840.1.113883.11.20.9.39` **STATIC**.
8. **SHALL** contain exactly one [1..1] **component** such that it
    a. contain exactly one [1..1] Hearing Screening Outcome Observation – Left Ear `templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.9)`.
9. **SHALL** contain exactly one [1..1] **component** such that it

a. contain exactly one [1..1] Hearing Screening Outcome Observation – Right Ear templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.11).

10. **SHALL** contain exactly one [1..1] **component** such that it
    a. contain exactly one [1..1] Hearing Screening Results Organizer templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.12).

6.3.4.E9 Hearing Screening Outcome Observation-Left

[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.9(open)]

Template Design Relationships

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

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 [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**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.9".
5. **SHALL** contain at least one [1..*] **id**.
6. **SHALL** contain exactly one [1..1] **code** such that it
    a. contain exactly one [1..1] **@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 [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).
8. **SHALL** contain exactly one [1..1] **statusCode** such that it
    a. contain exactly one [1..1] **@code**, which is selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 **STATIC**.
9. **SHALL** contain exactly one [1..1] **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 [1..1] **value**, such that it
    a. be declared as data type xsi:type = "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 [0..1] **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**.
12. **MAY** contain zero or one [0..1] **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 [0..1] **author**.
14. **MAY** contain zero or one [0..1] **entryRelationship**.
    a. **CONDITIONAL** The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode**="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. **CONDITIONAL** The entryRelationship, if present, **SHALL** contain exactly one [1..1] **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

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.

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**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.10".
4. **SHALL** contain exactly one [1..1] **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**.
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).

6.3.4.E11 Hearing Screening Outcome Observation-Right

`[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.11(open)]`

Template Design Relationships

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.

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".
5. **SHALL** contain at least one [1..*] **id**.
6. **SHALL** contain exactly one [1..1] **code** such that it
    a. contain exactly one [1..1] **@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 [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).
8. **SHALL** contain exactly one [1..1] **statusCode** such that it
    a. be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 **CNE**, **STATIC**.
9. **SHALL** contain exactly one [1..1] **effectiveTime**.

3220 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 [1..1] **value**, such that it
    a. be declared as data type xsi:type = "CD"
3225 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 [0..1] **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.**
3230 12. **MAY** contain zero or one [0..1] **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 [0..1] **author**.
14. **MAY** contain zero or one [0..1] **entryRelationship**.
3235 a. **CONDITIONAL** The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode**="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) **STATIC**.
    b. **CONDITIONAL** The entryRelationship, if present, **SHALL** contain exactly one [1..1] **Reason Not Screened** (templateId:
3240 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.10).

6.3.4.E12 Hearing Screening Results Organizer

[Organizer: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.12(open)]

Template Design Relationships

3245 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 R1.1 Result Organizer (2.16.840.1.113883.10.20.22.4.1).

3250 **Template Purpose**

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

1. **SHALL** contain exactly one [1..1] **@classCode=** ="CLUSTER" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) **STATIC.**
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood
3255 2.16.840.1.113883.5.1001) **STATIC.**
3. **MAY** contain zero or one [0..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.1".
4. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.12".

5. **SHALL** contain at least one [1..*] **id**.
6. **SHALL** contain exactly one [1..1] **code** such that it
    a. contain exactly one [1..1] **@code**="417491009" Neonatal Hearing Test (Procedure) (CodeSystem: SNOMED CT 2.16.840.1.113883.6.96) **STATIC**.
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
            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** such that it
    a. be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 **CNE**, **STATIC**.
9. **SHALL** contain zero or more [0..*] **component** such that it
    a. contain exactly one [1..1] 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

[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.13(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.

The design is an adaptation of the C-CDA R1.1 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 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 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.

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. **CONDITIONAL: WHEN THE HEARING SCREENING WAS NOT PERFORMED: SHALL** contain exactly one [1..1] **@negationInd**="true" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) **STATIC**.
4. **MAY** contain zero or one [0..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.2".
5. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.13".
6. **SHALL** contain at least one [1..*] **id**.
7. **SHALL** contain exactly one [1..1] **code** such that it
    a. contain exactly one [1..1] **@code**=" 417491009" Neonatal Hearing Test (Procedure) (CodeSystem: SNOMED CT 2.16.840.1.113883.6.96) **STATIC**.
8. **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).
9. **SHALL** contain exactly one [1..1] **statusCode** such that it
    a. be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39 **CNE, STATIC**.
10. **SHALL** contain exactly one [1..1] **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).
11. **SHALL** contain exactly one [1..1] **value**, such that it
    a. be declared as data type xsi:type = “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**.
12. **CONDITIONAL: SHALL NOT** contain a value when negationInd=”true”.
13. **SHALL** contain zero or one [0..1] **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”.
15. **SHALL** contain zero or one [0..1] **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 [0..1] **author**.

18. **SHOULD** contain zero or one [0..1] **performer**.
19. **CONDITIONAL: SHALL** contain exactly one [1..1] **entryRelationship** when negationInd="true", such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **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".
21. **MAY** contain zero or one [0..1] **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**.
    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 are not to 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 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

[Observation: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.15(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 [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**).
3. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.15".
4. **SHALL** contain at least one [1..*] **id**.
5. **SHALL** contain exactly one [1..1] **code** such that it
    a. contain exactly one [1..1] **@code**=" 80943009" Risk Factor (CodeSystem: SNOMED CT 2.16.840.1.113883.6.96).
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 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**).
8. **SHOULD** contain zero or one [0..1] **effectiveTime**.
9. **SHALL** contain exactly one [1..1] **value** such that it:
    a. be defined as data type @xsi:type="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**.
10. **MAY** contain zero or one [0..1] **entryRelationship**.
    a. **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**.
    b. **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.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 R1.1 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 R1.1 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

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.

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. **MAY** contain zero or one [0..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.3".
4. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.16".
5. **SHALL** contain at least one [1..*] **id**.
6. **SHALL** contain exactly one [1..1] **code** such that it
    a. contain exactly one [1..1] **@code**="CONC" Concern (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**).
7. **SHALL** contain exactly one [1..1] **text** such that
    a. contain exactly one [1..1] **reference** such that it
        i. contain exactly one [1..1] **@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).
8. **SHALL** contain exactly one [1..1] **statusCode**, such that it
    a. be selected from ValueSet ProblemAct statusCode 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.

9. **SHALL** contain exactly one [1..1] **effectiveTime**.
    a. This effectiveTime **SHALL** contain exactly one [1..1] **low**.
    b. This effectiveTime **SHOULD** contain zero or one [0..1] **high**.
10. **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**).
    b. contain exactly one [1..1] **Problem Observation** (templateId:2.16.840.1.113883.10.20.22.4.4).

6.3.4.E17 HPoC Problem Concern

`[Act: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.17(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 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 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 one **Problem Observation** (templateId:2.16.840.1.113883.10.20.22.4.4) 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 [1..1] **@classCode**="ACT" Act (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**).
3. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**).
4. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.3".
5. **SHALL** contain exactly one [1..1] **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.
2. **SHALL** contain exactly one [1..1] **code** such that it
    a. contain exactly one [1..1] **@code**="CONC" Concern (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**).
3. **SHALL** contain exactly one [1..1] **text** such that
    a. contain exactly one [1..1] **reference** such that it
        i. contain exactly one [1..1] **@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).
4. **SHALL** contain exactly one [1..1] **statusCode**, such that it
    a. be selected from ValueSet ProblemAct statusCode 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.

5. **SHALL** contain exactly one [1..1] **effectiveTime**.
    a. This effectiveTime **SHALL** contain exactly one [1..1] **low**.
    b. This effectiveTime **SHOULD** contain zero or one [0..1] **high**.
6. **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**).
    b. contain exactly one [1..1] **Problem Observation** (templateId:2.16.840.1.113883.10.20.22.4.4).

6.3.4.E18 Procedure Activity Procedure

[Procedure: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.18(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 C-CDA R1.1 Procedure Activity Procedure template (2.16.840.1.113883.10.20.22.4.14). It references, by transclusion, other C-CDA R1.1 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 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 (post-condition) 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.

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.
3. **SHALL** contain exactly one [1..1] **templateId** such that it
    a. contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.14".
4. **SHALL** contain at least one [1..*] **id**.
5. **SHALL** contain exactly one [1..1] **code** such that it
    a. contain zero or one [0..1] **originalText**.
        i. **CONDITIONAL** The originalText, if present, **SHALL** contain exactly one [1..1] **reference** such that it
            1. contains exactly one [1..1] **@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).

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 [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).
7. **SHALL** contain exactly one [1..1] **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 [0..1] **effectiveTime**.
9. **MAY** contain zero or one [0..1] **priorityCode**, such that it
   a. be selected from ValueSet `Act Priority Value Set 2.16.840.1.113883.1.11.16866` **CNE, DYNAMIC**.
10. **MAY** contain zero or one [0..1] **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 [1..1] **@code** such that it
       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 [1..1] **specimenRole** such that it
       i. contain zero or more [0..*] **id** 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.
    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 [1..1] **assignedEntity** such that it
       i. contain at least one [1..*] **id**.
       ii. contain exactly one [1..1] **addr**.
       iii. contain exactly one [1..1] **telecom**.
       iv. contain zero or one [0..1] **representedOrganization** 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**

3. **CONDITIONAL** if present, **SHALL** contain exactly one [1..1] **telecom**
4. **CONDITIONAL** if present, **SHALL** contain exactly one [1..1] **addr**

14. **MAY** contain zero or more [0..*] **participant** such that each
    a. contain exactly one [1..1] **@typeCode**="DEV" Device (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. contain exactly one [1..1] **Product Instance** (templateId:2.16.840.1.113883.10.20.22.4.37).
15. **MAY** contain zero or more [0..*] **participant** such that each
    a. contain exactly one [1..1] **@typeCode**="LOC" Location (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 **STATIC**).
    b. contain exactly one [1..1] **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 [1..1] **@typeCode**="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. contain exactly one [1..1] **@inversionInd**="true".
    c. contain exactly one [1..1] **encounter** such that it
        i. This encounter **SHALL** contain exactly one [1..1] **@classCode**="ENC" Encounter (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**).
        ii. This encounter **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**).
        iii. This encounter **SHALL** contain exactly one [1..1] **id**.
            1. Set the encounter ID to the ID of an encounter in another section to signify they are the same encounter.
17. **MAY** contain zero or one [0..1] **entryRelationship** such that it
    a. contain exactly one [1..1] **@typeCode**="SUBJ" Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. contain exactly one [1..1] **@inversionInd**="true" true.
    c. contain exactly one [1..1] **Instructions** (templateId:2.16.840.1.113883.10.20.22.4.20).
18. **MAY** contain zero or more [0..*] **entryRelationship** such that it
    a. contain exactly one [1..1] **@typeCode**="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. contain exactly one [1..1] **Indication** (templateId:2.16.840.1.113883.10.20.22.4.19).
19. **MAY** contain zero or more [0..*] **entryRelationship** such that it
    a. contain exactly one [1..1] **@typeCode**="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. contain exactly one [1..1] **Medication Activity** (templateId:2.16.840.1.113883.10.20.22.4.16).
20. **MAY** contain zero or more [0..*] **entryRelationship** such that it

a. contain exactly one [1..1] **@typeCode**="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
b. contain exactly one [1..1] **Procedure Activity Observation** (templateId: 2.16.840.1.113883.10.20.22.4.13).

6.3.4.E19 Procedure Activity Act

[Act: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.19(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.

This template is an adaptation of the C-CDA R1.1 Procedure Activity Procedure template (2.16.840.1.113883.10.20.22.4.14). It references, by transclusion, other C-CDA R1.1 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 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.

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**, 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 [1..1] **templateId** such that it
   a. contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.12".
4. **SHALL** contain at least one [1..*] **id**.
5. **SHALL** contain exactly one [1..1] **code** such that it
   a. contain zero or one [0..1] **originalText**.
      i. **CONDITIONAL** The originalText, if present, **SHALL** contain exactly one [1..1] **reference** such that it
         1. contain exactly one [1..1] **@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).
   b. be selected from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96).
6. **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).

7. **SHALL** contain exactly one [1..1] **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 [0..1] **effectiveTime**.
9. **MAY** contain zero or one [0..1] **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
    a. **CONDITIONAL** if present **SHALL** contain exactly one [1..1] **assignedEntity** such that it
        i. contain at least one [1..*] **id**.
        ii. contain exactly one [1..1] **addr**.
        iii. contain exactly one [1..1] **telecom**.
        iv. contain zero or one [0..1] **representedOrganization** 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**
            3. **CONDITIONAL** if present, **SHALL** contain exactly one [1..1] **telecom**
            4. **CONDITIONAL** if present, **SHALL** contain exactly one [1..1] **addr**
11. **MAY** contain zero or more [0..*] **participant** such that each
    a. contain exactly one [1..1] **@typeCode**="LOC" Location (CodeSystem: `HL7ParticipationType 2.16.840.1.113883.5.90`) **STATIC**.
    b. contain exactly one [1..1] **Service Delivery Location** (`templateId:2.16.840.1.113883.10.20.22.4.32`).
12. **MAY** contain zero or more [0..*] **entryRelationship** such that each
    a. contain exactly one [1..1] **@typeCode**="COMP" Has Component (CodeSystem: `HL7ActRelationshipType 2.16.840.1.113883.5.1002` **STATIC**).
    b. contain exactly one [1..1] **@inversionInd**="true".
    c. contain exactly one [1..1] **encounter** such that it
        i. This encounter **SHALL** contain exactly one [1..1] **@classCode**="ENC" Encounter (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6` **STATIC**).
        ii. This encounter **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: `ActMood 2.16.840.1.113883.5.1001` **STATIC**).
        iii. This encounter **SHALL** contain exactly one [1..1] **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 [0..1] **entryRelationship** such that it
    a. contain exactly one [1..1] **@typeCode**="SUBJ" Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. contain exactly one [1..1] **@inversionInd**="true" true.
    c. contain exactly one [1..1] **Instructions** (templateId:2.16.840.1.113883.10.20.22.4.20).
14. **MAY** contain zero or more [0..*] **entryRelationship** such that it
    a. contain exactly one [1..1] **@typeCode**="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. contain exactly one [1..1] **Indication** (templateId:2.16.840.1.113883.10.20.22.4.19).
15. **MAY** contain zero or more [0..*] **entryRelationship** such that it
    a. contain exactly one [1..1] **@typeCode**="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. contain exactly one [1..1] **Medication Activity** (templateId:2.16.840.1.113883.10.20.22.4.16).
16. **MAY** contain zero or more [0..*] **entryRelationship** such that it
    a. contain exactly one [1..1] **@typeCode**="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**).
    b. contain exactly one [1..1] **Procedure Activity Observation** (templateId: 2.16.840.1.113883.10.20.22.4.13).

6.3.4.E20 HPoC Procedure Activity Procedure

[Procedure: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.20(open)]

Template Design Relationships

This template is an adaptation of the IHE US Realm Procedure Activity Procedure 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 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

Template Purpose

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

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".
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.
6. **SHALL** contain exactly one [1..1] **code** such that it
    a. contain zero or one [0..1] **originalText**.
        i. **CONDITIONAL** The originalText, if present, **SHALL** contain exactly one [1..1] **reference** such that it
            1. contain exactly one [1..1] **@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).
    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).
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
            1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).

6.3.4.E21 HPoC Procedure Activity Act

[Act: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.21(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

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 [1..1] **@classCode**="ACT" Act (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**="1.3.6.1.4.1.19376.1.7.3.1.1.26.2.4.21".
5. **SHALL** contain exactly one [1..1] **id** such that it
    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.
6. **SHALL** contain exactly one [1..1] **code** such that it
    a. contains zero or one [0..1] **originalText**.
        i. **CONDITIONAL** The originalText, if present, **SHALL** contain exactly one [1..1] **reference** such that it
            1. contains exactly one [1..1] **@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).
    b. be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96)
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
            1. begins with a '#' and points to its corresponding narrative (using the approach defined in CDA Release 2, Section 4.3.5.1).

8.7 Value Set Definitions

6.5.1 VS_HPoCEncounterType 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.1

This value set holds a list of coded encounter types where a hearing plan of care would get created or updated. These are going to be the same concepts as those used in the VS_HPoCActivityEncounters

Code	Display Name	Code System Name	Code System OID
IHE-TSC-	Visit with Primary Care	SNOMED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
7.3.1.1.2.5.1.001	Physician		
IHE-TSC-7.3.1.1.2.5.1.002	Follow-up with Primary Care Provider	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC-7.3.1.1.2.5.1.003	Referral to audiologist	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
IHE-TSC-7.3.1.1.2.5.1.005	Referral to Early Intervention Specialist	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC-7.3.1.1.2.5.1.006	Referral to Ear Nose and Throat Specialist	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

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

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

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 care giver 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

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

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
IHE-TSC-7.3.1.1.2.5.6.001	Tympanogram Test	SNOMED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
IHE-TSC-7.3.1.1.2.5.6.002	Otoacousic emissions Test	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC-7.3.1.1.2.5.6.003	Auditory Brainstem Response Test	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
IHE-TSC-7.3.1.1.2.5.6.006	Developmental assessment	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC-7.3.1.1.2.5.6.007	Genetic Testing and Counseling	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
IHE-TSC-7.3.1.1.2.5.6.009	MRI	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

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
IHE-TSC-7.3.1.1.2.5.7.001	Cochlear implant	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
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
IHE-TSC-7.3.1.1.2.5.7.005	Myringotomy and PE tube placement	SNOMED-CT	2.16.840.1.113883.6.96

6.5.8 VS_HPoCActivitySubstanceAdministration 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-7.3.1.1.2.5.8.001	Thyroid Supplement	SNOMED-CT	2.16.840.1.113883.6.96

IHE-TSC-7.3.1.1.2.5.8.002	Vitamin Supplement	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC-7.3.1.1.2.5.8.003	Amoxicillin	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC-7.3.1.1.2.5.8.004	Antibiotic	SNOMED-CT	2.16.840.1.113883.6.96

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
IHE-TSC-7.3.1.1.2.5.9.001	Hearing Aid	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-7.3.1.1.2.5.9.003	FM system	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC-7.3.1.1.2.5.9.004	Cochlear implant	SNOMED-CT	2.16.840.1.113883.6.96

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.

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.

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	SNOMED-CT	2.16.840.1.113883.6.96

	refused (situation)		
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.

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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.

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

3875

6.5.14 VS_HearingScreeningTestResultValues 1.3.6.1.4.1.19376.1.7.3.1.1.26.2.5.14

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
3880 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
103709008	Attempted, but unsuccessful - technical fail	SNOMED CT	2.16.840.1.113883.6.96
~~262008008 (note 1)~~	~~Not Performed~~	~~SNOMED CT~~	~~2.16.840.1.113883.6.96~~

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.

3885

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

3890

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	SNOMED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
	perinatal period (disorder)		
206005002	Fetus or neonate affected by maternal infection (disorder)	SNOMED-CT	2.16.840.1.113883.6.96
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
~~LA12668-2~~	~~Family Hx of Hearing loss~~	LOINC	2.16.840.1.113883.6.1
LA12669-0	ICU stay > 5 days	LOINC	2.16.840.1.113883.6.1
LA12670-8	ECMO	LOINC	2.16.840.1.113883.6.1
LA12671-6	Assisted ventilation	LOINC	2.16.840.1.113883.6.1
~~LA12672-4~~	~~Ototoxic medication use~~	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
~~LA12679-9~~	~~Head Trauma~~	LOINC	2.16.840.1.113883.6.1
~~LA6172-6~~	~~Chemotherapy~~	LOINC	2.16.840.1.113883.6.1

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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”. (This value set it not a complete set

of codes. The value set needs to be defined in a value set repository and then referenced by URL from this profile.)

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 - delayed 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)	SNOMED-CT	2.16.840.1.113883.6.96
181000119105	Fetal growth retardation, antenatal (disorder)	SNOMED-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)	SNOMED-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	Bronchopulmonary 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	SNOMED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
	(disorder)		
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

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

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. The value set needs to be created and maintained in a value set repository and referenced in this IG by URL.)

Code	Display Name	Code System Name	Code System OID
IHE-TSC-7.3.1.1.2.5.19.001	Cochlear implant	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC-7.3.1.1.2.5.19.002	Reconstruction to resolve atresia	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC-7.3.1.1.2.5.19.003	Treatment for otitis media	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC-7.3.1.1.2.5.19.004	Cleft Lip/Palate Repair	SNOMED-CT	2.16.840.1.113883.6.96
IHE-TSC-7.3.1.1.2.5.19.005	Myringotomy and PE tube placement	SNOMED-CT	2.16.840.1.113883.6.96

Code	Display Name	Code System Name	Code System OID
233573008	Extracorporeal membrane oxygenation (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

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

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 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

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

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

