Integrating the Healthcare Enterprise

IHE Cardiology
Technical Framework Supplement

Cardiac Procedure Note
(CPN)

Rev. 1.0 – Draft for Public Comment

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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 Cardiology Technical Framework V5.0. 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 May 26, 2017 for public comment. Comments are invited and may be submitted at http://www.ihe.net/Cardiology_Public_Comments. In order to be considered in development of the trial implementation version of the supplement, comments must be received by June 25, 2017.

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 www.ihe.net.

Information about the IHE Cardiology domain can be found at 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 Cardiology Technical Framework can be found at http://ihe.net/Technical_Frameworks.

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Introduction to this Supplement

Cardiologists across all subspecialties face an increasing need to exchange reports and discrete clinical procedure data across different care settings and stakeholders with the goals of:

- Enabling cardiac procedure notes to be more easily shared and used between care givers and systems.
- Enabling population-based outcomes-based research on procedure effectiveness.
- Harmonizing data collection for procedural reports with data registries for data exchange.

This supplement provides an Implementation guide consisting of a library of templates to be used for various cardiac subspecialty procedure notes and clinical data exchange. It is based on the HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1 (C-CDA®[1] R2.1).

It consolidates work that has been done in the Cath Report Content (CRC) Profile and the Electrophysiology Report Content Implant/Explant (EPRC IE) supplement, harmonizes templates and value sets defined in those supplements, and updates those templates to the C-CDA R2.1 specification.

Initial focus of this supplement are Cath Lab Reports (including Transcatheter based interventions) and Electrophysiology Implant and Explant Procedure reports intended for adult cardiac procedures. However the aim is to provide an extensible framework to allow for the addition of further report templates in future (e.g., general cardiac imaging procedures like Echocardiography, cardiac CT, MR, or Nuclear Medicine Imaging).

The Report Content for the above procedure is defined based on

- ACC/AHA/SCAI 2014 Health Policy Statement on Structured Reporting for the Cardiac Catheterization Laboratory
- 2016 ACC/ASE/ASNC/HRS/SCAI Health Policy Statement on Integrating the Healthcare Enterprise
- ACC-NCDR ICD dataset and the ACC NCDR ICD version 1.2 and leveraging clinical data standards like ICD9/10, SNOMED, LOINC and IEEE 11073-10103 nomenclature.
- ACC-NCDR Cath/PCI dataset and the ACC NCDR Cath/PCI version 4.4, leveraging clinical data standards like ICD9/10, SNOMED and LOINC.
- STS/ACC TVT Registry dataset version 2.0

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

Open Issues and Questions

190 This section contains a consolidated list of open issues as they have been identified during the development of the Cath Report Content (CRC) Profile and the Electrophysiology Report Content– Implant/Explant (EPRC-IE) Profile. Numbers in brackets reference the item number assigned in the underlying base profile.

#	Open Issue Description
1	Value Set Cardiac Activity Procedures (used in Planned Procedure section) 1.3.6.1.4.1.19376.1.4.1.5.40 does not include a code for the following procedure: 1. Percutaneous replacement of mitral valve using fluoroscopic guidance We are requesting feedback on specific codes to use to represent this procedure.
2	Value Set Complications 1.3.6.1.4.1.19376.1.4.1.5.46: There are no SNOMED codes for the following TVT complications: Device Embolization Left Ventricle, Device Embolization Aorta We are requesting feedback on specific codes to use to represent these complications.
3	Medical History – Cardiac Section: There is codification available for: Hospital admission, transfer from other hospital or health care facility (SNOMED: 4563007) Should we develop codification for patient pre-procedure status to communication status of “transferred from other provider”?
4	In the header element “componentOf/encompassingEncounter/location/healthCareFacility/code” there is no specific code for EP Lab. We are using CVDX as the general code. A request for a new code should be made.
5	Is there a need to document for an EP procedure that the administration of a medication has been held prior to the current procedure?
6	This profile should utilize UDI for representing devices. The goal is to harmonize representation of device serial numbers utilizing UDI. The committee will perform the update as soon as UDI become available for these devices.

#	Open Issue Description
7	We have not included all the templates and value sets referenced by templates that this profile references from the HL7 C-CDA Implementation Guides. If the link is selected an error message is displayed in Art-Décor – "no template (reference) found". We are requesting feedback regarding if this level of template inclusion in this profile supplement is sufficient.
8	There is no "scoping entity" defined for the Procedure Device Organizer template. This is an optional CDA element that can be included to further describe the scope of the playing device in the participant/participantRole. This would typically be the manufacturer of the device. The scoping entity is allowed since this template is "open" and could be extended to include this element. We are seeing feedback if this CDA optional element should be explicitly added to this template.
9	Is this profile based on (and consistent with) ACC NCDR ICD registry version 1.2 or 2.2? There is no valid link for the ACC/NCDR ICD Registry V1.2.
10	There are missing codes for concepts in the following value sets: • Procedure Indications • Rx Recommendations We are requesting feedback for codes which are noted in the Art-Décor values sets with the code specified as "NoCode".
11	Should the name of the value set Cardiac Problems/Concerns be changed to Medical History to reflect the intended use of this set? It is only used in the Problem Observation Medical History – Cardiac template. We are requesting feedback on the name of this value set.
12	In Section 6.3.4.E2.4 Electrophysiology Implant/Explant Observation Constraints, there are no data type or units of measure specified for the following observations: • MDC_IDC_SET_ZONE_TYPE_ATP_1 • "Simultaneous ECG leads" • "P-Wave Duration" • "Epsilon Wave" • "Hx of prolonged QT Interval"

#	Open Issue Description
13	In Section 6.3.4.E2.1 Diagnostic Cath Observation Constraints, there are no codes specified for the Pericardial finding of "size". There is a link to the CIRC Profile value set CARD TF-2: 6.2.2.7.5.1. Is this the appropriate value set to use here?

Closed Issues

The list of closed issues includes issues which have been addressed during the development of the CPN Profile. Issues that have been closed during the development of the CRC and EPRC IE Profile development are not listed in here

8 (EPRC IE 3)	Need to assign EPRC specific conformance IDs, like "CONF:EPRC-xxx". **Answer**: The CPN Profile is developed using the Art-Decor toolkit, which does not use Conformance IDs. Therefore this issue can be closed.

General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A – Actor Summary Definitions

Add the following actors to the IHE Technical Frameworks General Introduction list of actors:

None

Appendix B – Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

None

Glossary

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

None

Volume 1 – Profiles

Copyright Licenses

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

220 N/A

Domain-specific additions

Add new Section X

None.

X Cardiac Procedure Note (CPN) Content Profile

The CPN Profile is a content profile that provides an implementation guide consisting of a library of templates to be used for various cardiac subspecialty reports and clinical data exchange. It defines the structure and the content for a clinical report for various cardiac procedures. Initially supported will be adult procedures in the Electrophysiology (EP) and the Cath Lab; however, the aim is to provide an extensible framework that allows for the addition of further report templates in future (e.g., general cardiac imaging procedures like Echocardiography, cardiac CT, MR, or Nuclear Medicine Imaging).

Initially supported procedures include:

Electrophysiology Procedures:

- Implantable Cardioverter Defibrillator (ICD) Implant
- Permanent Pacemaker (PPM)/Implantable Pulse Generator (IPG) Implant
- Implantable Cardiac Monitor Implant
- Lead Implant
- ICD Explant
- Generator Change
- Lead Explant
- Lead Abandonment
- Imaging associated with Implant/Explant (e.g., Venogram)

Cath Lab Procedures

- Diagnostic Cardiac Catheterizations
- Temporary LV Mechanical Support
- Endomyocardial Biopsy
- Right Heart Catheterization
- Pericardiocentesis
- Percutaneous Coronary Intervention (PCI)
- Transatrial Aortic Valve Replacement (TAVR)
- Transatrial Mitral Valve Replacement (TMVR)
- Mitral Valve Repair (Mitraclip)

The Report Content for the above procedures are defined based on

- ACC/AHA/SCAI 2014 Health Policy Statement on Structured Reporting for the Cardiac Catheterization Laboratory

- 2016 ACC/ASE/ASNC/HRS/SCAI Health Policy Statement on Integrating the Healthcare Enterprise
- ACC-NCDR ICD dataset and the ACC NCDR ICD version 1.2 and leveraging clinical data standards like ICD9/10, SNOMED, LOINC and IEEE 11073-10103 nomenclature.
- ACC-NCDR Cath/PCI dataset and the ACC NCDR Cath/PCI version 4.4, leveraging clinical data standards like ICD9/10, SNOMED and LOINC.
- STS/ACC TVT Registry dataset version 2.0
- HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1 *(C-CDA R2.1).*

X.1 CPN Actors, Transactions, and Content Modules

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

Figure X.1-1 shows the actors directly involved in the CPN Profile and the direction that the content is exchanged.

A product implementation using this profile must group actors from this profile with actors from a workflow or transport profile to be functional. The grouping of the content module described in this profile to specific actors is described in more detail in the "Required Actor Groupings" section below.

Figure X.1-1: CPN Actor Diagram

Note: The primary intended transmission mechanism in the intra-institutional context is the IHE Displayable Reports Profile (DRPT), and in the inter-institutional context the IHE Portable Data for Imaging (PDI) or IHE Cross Enterprise Document Sharing Profiles (XDS, XDM, and XDR). A Report Creator, Document Source or a Portable Media Creator of those profiles may embody the Content Creator. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer.

Table X.1-1 lists the content module(s) defined in the CPN 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").

Table X.1-1: CPN Profile - Actors and Content Modules

Actors	Content Modules	Optionality	Reference
Content Creator	Cardiac Procedure Note (1.3.6.1.4.1.19376.1.4.1.1.4)	R	CARD TF-3: 6.3.1.D
Content Consumer	Cardiac Procedure Note ((1.3.6.1.4.1.19376.1.4.1.1.4)	R	CARD TF-3: 6.3.1.D

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirements on profile's actors.

X.1.1.1 Content Creator

- A Content Creator shall be able to create a Cardiac Procedure Note according to the specifications for that content profile found in CARD TF-3: 6.3.1.D.
- A Content Creator shall support at least one of the options of Table X.2-1: CPN Profile Options.

A Content Creator shall be grouped with the Time Client and shall synchronize its clock with a Time Server.

X.1.1.2 Content Consumer

- A Content Consumer shall be able to consume (receive and process) a Cardiac Procedure Note document.
- A Content Consumer shall implement the View Option or Discrete Data Import Option, or both.
- A Content Consumer that implements the Document Import or Section Import Option shall implement the View Option as well.
- A Content Consumer that implements the View Option shall be able to:
  a. Demonstrate rendering of the document for display.
  b. Print the document.
  c. Display the document with its original style sheet.
  d. Support traversal of any links contained within the document.

A Content Consumer that implements the Document Import Option shall:

a. Store the document.
b. Demonstrate the ability to access the document again from that storage.

A Content Consumer that implements the Section Import Option shall offer a means to import one or more document sections into the patient record as free text.

A Content Consumer that implements the Discrete Data Import Option shall offer a means to import structured data from one or more sections of the document.

X.2 CPN 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: CPN - Actors and Options

Actor	Option Name	Reference
Content Creator (Note 1)	Diagnostic Cath	CARD TF-1 X.2.1.1
	PCI	CARD TF-1 X.2.1.2
	Structural Heart Interventions	CARD TF-1 X.2.1.3
	Electrophysiology Implant/Explant	CARD TF-1 X.2.1.4
Content Consumer	View Option	PCC TF-2: 3.1.1
	Document Import Option	PCC TF-2: 3.1.2
	Section Import Option	PCC TF-2: 3.1.3
	Discrete Data Import Option	PCC TF-2: 3.1.4

Note 1: The Content Creator shall at least support one of the options listed here.

X.2.1 Content Creator Options

Options have been specified for Content Creators based upon the procedure types the Content Creator is able to support. The Content Creator options vary only by procedure type supported. Content requirements and constraints apply to all procedure types unless explicitly stated otherwise. Within this specification the variation in content requirements are expressed in the following ways:

- Result Observation Constraints: Section 6.3.4.E2 defines the specific result observations that may be included within the Procedure Result – Cardiac section. The Content Creator shall select from the following:
  - Diagnostic Cath Observation Constraints
  - PCI Observation Constraints
  - Structural Heart Intervention (StHrtInt) Observation Constraints
  - Electrophysiology Implant/Explant Observation Constraints

X.2.1.1 Diagnostic Cath Option

The Content Creator that supports the Diagnostic Cath Option shall

- create a report that contains a ClinicalDocument/code of (18745-0, LN, Cardiac Catheterization Study) or (34896-1, LN, Cardiology Interventional Procedure Note) and follow the template containment structure defined in Section 6.3.1.D
- support the creation of Diagnostic Cath Observation Constraints in the Procedure Results – Cardiac Section as defined in Section 6.3.4.E2.1
- support the following cardiac procedure types:
  - Diagnostic Catheterization
  - Temporary LV Mechanical Support
  - Endomyocardial Biopsy
  - Right Heart Catheterization
  - Pericardiocentesis

X.2.1.2 PCI Option

The Content Creator that supports the PCI Option shall

- create a report that contains a ClinicalDocument/code of (18745-0, LN, Cardiac Catheterization Study) or (34896-1, LN, Cardiology Interventional Procedure Note) and follow the template containment structure defined in Section 6.3.1.D
- support the creation of PCI Observation Constraints in the Procedure Results – Cardiac Section as defined in Section 6.3.4.E2.2
- support the following procedure types:
  - PCI

X.2.1.3 Structural Heart Interventions Option

The Content Creator that supports the Structural Heart Interventions Option shall

- create a report that contains a ClinicalDocument/code of (18745-0, LN, Cardiac Catheterization Study) or (34896-1, LN, Cardiology Interventional Procedure Note) and follow the template containment structure defined in Section 6.3.1.D
- support the creation of Structural Heart Intervention Observation Constraints in the Procedure Results – Cardiac Section as defined in Section 6.3.4.E2.3
- support the following procedure types:
  - Percutaneous replacement of aortic valve using fluoroscopic guidance
  - Percutaneous replacement of mitral valve using fluoroscopic guidance

- Repair of mitral valve using fluoroscopic guidance (mitral valve clip)

X.2.1.4 Electrophysiology Implant/Explant Option

The Content Creator that supports the Electrophysiology Implant/Explant Option shall

- create a report that contains a ClinicalDocument/code (18750-0, LN, Electrophysiology Study) and follow the template containment structure defined in Section 6.3.1.D.
- support the creation of Electrophysiology Implant/Explant Observation Constraints in the Procedure Results – Cardiac Section as defined in Section 6.3.4.E2.4
- support the following procedure types:
  - ICD Implant
  - ICD Explant
  - ICD Lead Replacement

X.3 CPN Required Actor Groupings

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

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

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

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

Table X.3-1: CPN - Required Actor Groupings

CPN Actor	Actor to be grouped with	Reference	Content Bindings Reference
Content Creator	Time Client in Consistent Time	ITI TF-1:7	--
Content Consumer	None	--	--

X.4 CPN Overview

The Cardiac Procedure Note (CPN) Profile specifies the content structure for a clinical Cardiology Report including Cath Lab procedures as well as Electrophysiology Procedures.

The CPN Profile specifies the use of an HL7®[2] Clinical Document Architecture (CDA) format for the cardiac procedure note. This format supports both the human readable narrative historically used for clinical reports, as well as a substantial set of discrete data elements that may be used for longitudinal or population analysis or other computer processing.

There may be a DICOM®[3] Study associated with the exam. In addition to reference images, the DICOM Study data may include discrete data elements encoded in DICOM Structured Report information objects that may be transcoded into the discrete data elements specified in this Profile. (See the Evidence Documents Profile and its cardiology options in Section 7.)

The CPN Profile does not presume to describe the complete content of an imaging study report. It does provide the framework of high level section titles and a set of discrete data elements. Within that framework reports can be created with the clinical content desired by their authors, including additional discrete data elements. In general, there are no constraints on the narrative text and figures that the cardiologist could include in the report document, although there are requirements on minimum data elements reflecting expert consensus.

X.4.1 Concepts

This profile provides a framework for defining the content for structured reports for cardiology procedures. This framework includes templates and value sets. The templates define the organization of the content for the report and the value sets define the specific codes used to represent concepts for semantic interoperability. These templates have been designed as building blocks that could be utilized within multiple specific structured reports. There are document level templates, section level templates and entry level templates.

Initially the types of reports include cardiology procedure reports for the cardiac catheterization procedures and electrophysiology implant/explant procedures, but it is envisioned that these same templates could be leveraged for additional cardiac structured reports including EP studies and ablation procedures as well as cardiac peripheral vascular interventions and cardiac diagnostic imaging studies.

X.4.2 Use Cases

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

[3] DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

X.4.2.1 Use Case #1: Procedure Report Generation

X.4.2.1.1 Procedure Report Generation Use Case Description

This use case addresses the generation and transfer of a comprehensive set of data acquired in a Cardiology Setting. This could either be in an EP lab or in a Cath Lab. The initial content, structure and coding of the report to support this use case are detailed as part of this profile (see IHE CARD TF-3.6 Content Modules). However various reporting system implementations, institute reporting guidelines and individual Reporting Physician usage may result in some variability in the specific report content provided.

X.4.2.1.2 Procedure Report Generation Process Flow

The systems underlying the data collection and management for the various elements of the cardiac procedure report have all the *mandatory* data elements identified using codes, and are expected to be the source for the information used in creating the *majority* of the cardiac procedure report document.

Main Flow

- Cardiologist reviews and/or records the codified
  - Procedures and protocols used in the procedure
  - Data generated from the various modalities and monitoring equipment used during the procedure so that the key physiological measures, acquired and derived (pre, during and post intervention) are present in line with report specific guidelines.
  - Other relevant patient characteristics
  - Medications documented for the patient both pre and during procedure.
  - Equipment used and implanted in the patient
  - Indications and observations/complications noticed during the procedure.
  - Findings, assessment and plan
- Cardiologist approves the procedure report and this marks it ready for distribution
- The Content Creator system will format the report appropriately (this profile) and send it via one of the IHE mechanisms to a content consumer system (an appropriate workflow profile).

Post conditions

The subsequent clinical stakeholder (system) receives the Document for import, processing and optionally viewing of the data.

X.4.2.2 Use Case #2: Review of Procedure Report

X.4.2.2.1 Review of Procedure Report Use Case Description

A secondary use-case addressed by this profile involves the direct human use of the procedure report. In most practical cases consumers include:

- The referring physician who instigated/ordered the procedure, and other healthcare providers who manage subsequent patient care activities
- Another person involved in downstream clinical or administrative data processing e.g., someone validating/source-checking for QA the original report as part of JCAHO audits
- Pre-submission checking on the original reporting data against the case-data imported in the appropriate cardiac data registry-submission application.
- Device Manufacturer who will receive registration of device information

X.4.2.2.2 Review of Procedure Process Flow

Pre conditions

- The consumer has a system (EMR or other) capable of importing and displaying the received report in a clinically useful format
- The EP Lab Report has been received at this system

Note: This profile does not assume any explicitly specified relationship between the creator and consumer.

Main Flow

- The consumer selects the report of his patient and opens it for review
- The system displays the human readable content for the consumer to review

Post conditions

The consumer has accessed the necessary information from the report.

X.4.2.3 Use Case #3: Analysis of Discrete Data

X.4.2.3.1 Analysis of Discrete Data Use Case Description

The goal of this use case is to assist data collection for comparative and research purposes. Based on a report generated in the previous use cases an advanced medical data analysis system collects discrete data from multiple patients and their procedure, e.g., for cardiac Clinical Decision Support or for advanced lifetime patient records.

X.4.2.3.2 Analysis of Discrete Data Process Flow

Pre conditions

The Content Consumer (e.g., an advanced medical data analysis system) received a Cardiac Procedure Note with coded/structured content as defined in IHE CARD TF-3: 6 CDA Release 2 Content Modules.

Main Flow

The consuming system collects and processes the data from the various reports it receives and extracts those relevant data for either:

- A specific clinical concern for a population e.g., pre-populating a procedure-specific registry; extracting a data subset for a specific research question.
- A more comprehensive longitudinal patient record (e.g., an EMR) which can provide trending over time on an individual patient's key cardiac measures.

Post conditions

The Content Consumer generated new (derived) data for use by others. The type of data generated is out of the scope of this profile.

X.5 CPN Security Considerations

The security considerations for a content module are dependent upon the security provisions defined by the grouped actor(s) provided through the transport mechanisms (e.g., DRPT, XDS)

X.6 CPN Cross Profile Considerations

A Content Creator or Content Consumer should be grouped with appropriate actors from workflow profiles that manage interchange of clinical data. Such groupings are described in this section.

Content profiles may impose additional requirements on the transactions used when grouped with actors from other IHE Profiles. The metadata sent in the document sharing or interchange messages has specific relationships to the content of the clinical document described in the content profile. These mappings between the workflow metadata and the content attributes are described in IHE PCC TF-2:4.

X.6.1 Content Bindings for Displayable Reports (DRPT) Profiles

CDA documents using the CPN content may be exchanged between a Report Creator and a Report Manager, as defined in the Displayable Reports (DRPT) Profile using the Encapsulated Report Submission [CARD-7] transaction. In this case, the CPN Content Creator is grouped with the DRPT Report Creator, and the CPN Content Consumer is grouped with the DRPT Report Manager.

X.6.2 Content Bindings for XDS, XDM, XDR, XDS-I, and XDR-I

It is expected that the transfers of care will occur in an environment where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ) and notification of availability of documents (NAV). An extension for imaging study exchange is Cross Enterprise Document Sharing for Imaging (XDS-I).
- A media-based infrastructure is defined by the IHE Cross Enterprise Document Media Interchange (XDM) Profile.
- A reliable messaging-based infrastructure is defined by the IHE Cross Enterprise Document Reliable Interchange (XDR) Profile. An extension for imaging study exchange is Cross Enterprise Document Reliable Interchange for Imaging (XDR-I).
- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) Profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework, and the IHE Radiology Technical Framework for XDS-I and XDR-I.

Document Source and Document Consumer Actors from the ITI XDS, XDM and XDR Profiles are logically grouped with the CPN Content Creator and Content Consumer Actors, respectively.

X.6.3 Binding for Portable Data for Imaging (PDI)

CDA documents using the CPN content may be exchanged on interchange media in accordance with the Portable Data for Imaging (PDI) Profile. Such documents may be encapsulated within DICOM SOP Instances, or may be native CDA documents, as described in the IHE Radiology Technical Framework. In this case, the CPN Content Creator is grouped with the PDI Portable Media Creator, and the CPN Content Consumer is grouped with the PDI Display or Portable Media Importer Actors.

X.6.4 Content Binding for Retrieve Form for Data Capture (RFD)

A CDA document may be used for pre-population of a data entry form managed by actors of the Retrieve Form for Data Capture (RFD) Profile. In particular, the CPN content, as a carrier of discrete encoded data, may be used to pre-populate data entry forms for cardiovascular data registries. The CPN Profile has been developed with key data elements for the supported procedures for use in common research related data fields. This profile, however, does not provide mapping between procedure specific field content and any specific registry field content. In this case, the CPN Content Consumer is grouped with the RFD Form Manager for the purpose of extracting discrete data from the report to pre-populate the data capture form.

X.6.5 Relationship to Document Digital Signature (DSG)

When a Content Creator needs to digitally sign a document in a submission set, it may support the Digital Signature (DSG) Content Profile as a Document Source. When a Content Consumer needs to verify a Digital Signature, it may retrieve the digital signature document and may perform the verification against the signed document content.

Appendices

None.

Volume 2 – Transactions

There are no transactions in this profile.

Volume 3 – Content Modules

5 Namespaces and Vocabularies

Add to Section 5 Namespaces and Vocabularies

The following code systems are used within this profile. These may have already been defined within the Technical Framework for this domain but are included to support the supplement review.

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.1	LOINC	Logical Observation Identifiers Names and Codes (LOINC)
2.16.840.1.113883.6.96	SNOMED CT	The Systematized Nomenclature of Medicine (SNOMED)
2.16.840.1.113883.6.88	RxNorm	The US National Library of Medicine (NLM) normalized naming system for generic and brand drugs.
2.16.840.1.113883.6.24	IEEE 11073-10103 MDC IDC	The IEEE Medical Device Communication (MDC) for Implantable Device Cardiac (IDC) nomenclature.
2.16.840.1.113883.6.8	UCUM	Unified Code for Units of Measure

The content profile does not include additional IHE Format codes, nor does it define additions to the HL7 ActCode or RoleCode Vocabularies.

6 Content Modules

6.3.1 CDA Document Content Modules

Add to Section 6.3.1.D Document Content Modules

6.3.1.D Cardiac Procedure Note (CPN) Document Content Module

This is the template for a Cardiac Procedure Note for cardiac catheterization diagnostic and interventional procedures as well as electrophysiology implant, explant and lead replacement procedures with support for discrete data elements as described in the following NCDR data dictionaries that are collected just prior to and during the procedure:

- CathPCI Registry version 4.4 Coder's Data Dictionary.
- STS/ACC TVT Registry 2.0 Coder's Data Dictionary for Transcatheter Aortic Valve Replacement procedures, Transcatheter Mitral Valve-in-Valve or Valve-in-Ring procedures, and Transcatheter Mitral Leaflet Clip Valve Procedures
- NCDR ICD Registry version 1.2 and 2.2 Coder's Data Dictionary,

The Template ID for conformance to this template is OID = 1.3.6.1.4.1.19376.1.4.1.1.4.

6.3.1.D.1 Format Code

The XDSDocumentEntry format code for this content is **urn:ihe:card:CPN:2017**

The mapping of CDA header attributes to XDS metadata shall be identical to the XDS-MS mapping specified in PCC TF-2: 4.1.1.

6.3.1.D.2 Parent Template

This CDA document is not a direct specialization of any existing CDA document template ID; however, some parts were based on the IHE Card CIRC document specification and the HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), DSTU Release 2.1 – August 2015 (C-CDA) Procedure Note document specification.

This CPN Profile is inconsistent with the existing Cardiac Imaging Report Content (CIRC) Content Profile that was published for Trial Implementation in 2011.

These inconsistencies include:

- Overall document structure
- This is not based on the IHE PCC section and entry templates but is based on the C-CDA section and entry templates.

6.3.1.D.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.D.3-1: CPN - Referenced Standards

Abbreviation	Title	URL
CathPCI Registry	NCDR CathPCI Registry v4.4 Coder's Data Dictionary.	https://www.ncdr.com/WebNCDR/docs/public-data-collection-documents/cathpci_v4_codersdictionary_4-4.pdf?sfvrsn=2
STS/ACC TVT Registry	STS/ACC TVT Registry™ v2.0 Coder's Data Dictionary	https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/tvt-registry-2_0_coderdatadictionary.pdf?sfvrsn=2
ICD Registry	NCDR ICD Registry v2.2 Coder's Data Dictionary	https://cvquality.acc.org/~/media/QII/NCDR/Data%20Collection%20Forms/ICDv2CodersDataDictionary22.ashx
HL7 CDAR2	HL7 CDA Release 2.0	http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition2010.zip
HL7 C-CDA	HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=408
DICOM	NEMA PS3.16 – DICOM Part 16: Content Mapping Resource	http://dicom.nema.org/standard.html
UCUM	Unified Code for Units of Measure	http://uinitsofmeasure.org/
LOINC	Logical Observation Identifiers Names and Codes	http://loinc.org/
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms	http://www.ihtsdo.org/snomed-ct/
RxNorm	RxNorm - normalized naming system for generic and branded drugs	http://www.nlm.nih.gov/research/umls/rxnorm/
IEEE 11073 10103	IEEE 11073_10103 MDC_IDC Nomenclature	http://standards.ieee.org/downloads/11073/

6.3.1.D.4 Data Element Requirement Mappings to CDA

This section identifies the mapping of data between referenced standards into the CDA implementation guide.

The source for the specification of the clinical content and the organization of the clinical content contained within these reports includes:

- The ACC HPS on Structured Reporting for the Cardiac Catheterization Laboratory – (http://circ.ahajournals.org/content/circulationaha/early/2014/03/26/CIR.0000000000000043.full.pdf)

- Sample reports obtained from cardiac catheterization and electrophysiology laboratories for the clinical reports generated for these procedures

In addition, the definition of the discrete data elements defined and required for clinical data registries for these procedures was reviewed. It is intended that the specific data elements required for submission to these registries that are collected during the clinical procedure would be included in these clinical procedure structured reports as discrete data elements.

The CDA document contains narrative text at the document and section levels. There is no general CDA requirement for the narrative text to completely contain the full coded content of all the elements. However for this profile, IHE recommends that all coded content should be included in the narrative. In any case, there shall be no conflicts between the narrative and the coded content representation.

6.3.1.D.5 Cardiac Procedure Note (CPN) Document Content Module Specification

This section specifies the header, section, and entry content modules which comprise the CPN Document Content Module, using the Template ID as the key identifier.

The CPN document shall include header and section content modules. These content modules will be specified by a set of constraints.

Sections that are used according to the definitions in other specifications are identified with the relevant specification document. Additional constraints on vocabulary value sets, not specifically constrained within the section template, are also identified.

The following table identifies the header and section content modules that may be required, recommended, or allowed to be included in the CPN document. **This table provides direct linked references to the specific templates in the Consolidated-Cardiac Report Content (C-CRC) project in Art-Décor.** These links provide the complete CDA requirements for the CPN Profile including Entry and Value Set information as well as Examples.

As part of Public Comment, the Cardiology Technical Committee is requesting specific comments on this presentation of the CDA Content for the CPN profile.

Table 6.3.1.D.5-1 CPN Document Content Module Specification

Template Title	Opt and Card	Template Type	Template Id	Overview
Cardiac Procedure Note	R[1..1]	document	1.3.6.1.4.1.19376.1.4.1.1.4	
recordTarget - Cardiac	R[1..1]	header	1.3.6.1.4.1.19376.1.4.1.3.7	CARD TF-3 6.3.2.H1
author - Cardiac	R[1..1]	header	1.3.6.1.4.1.19376.1.4.1.3.8	CARD TF-3 6.3.2.H2
custodian - Cardiac	R[1..1]	header	1.3.6.1.4.1.19376.1.4.1.3.9	CARD TF-3 6.3.2.H3
legalAuthenticator - Cardiac	R[1..1]	header	1.3.6.1.4.1.19376.1.4.1.3.10	CARD TF-3 6.3.2.H4

Template Title	Opt and Card	Template Type	Template Id	Overview
authenticator - Cardiac	R[1..1]	header	1.3.6.1.4.1.19376.1.4.1.3.11	CARD TF-3 6.3.2.H5
inFulfillmentOf - Cardiac	R[1..1]	header	1.3.6.1.4.1.19376.1.4.1.3.12	CARD TF-3 6.3.2.H6
authorization - Cardiac	R[1..1]	header	1.3.6.1.4.1.19376.1.4.1.3.13	CARD TF-3 6.3.2.H7
componentOf - Cardiac	R[1..1]	header	1.3.6.1.4.1.19376.1.4.1.3.14	CARD TF-3 6.3.2.H8
documentationOf - Cardiac	R[1..1]	header	1.3.6.1.4.1.19376.1.4.1.3.15	CARD TF-3 6.3.2.H9
Document Summary Section	O[0..1]	section	1.3.6.1.4.1.19376.1.4.1.2.16	CARD TF-3 6.3.3.10.S1
Medical History - Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.17	CARD TF-3: 6.3.3.10.S2
Allergies and Intolerances - Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.27	CARD TF-3: 6.3.3.10.S3
Family History – Cardiac Section	O[0..1]	section	1.3.6.1.4.1.19376.1.4.1.2.31	CARD TF-3: 6.3.3.10.S4
Social History Section	O[0..1]	section	2.16.840.1.113883.10.20.22.2.17	CARD TF-3: 6.3.3.10.S5
Physical Exam Section	R[1..1]	section	2.16.840.1.113883.10.20.2.10	CARD TF-3: 6.3.3.10.S6
Vital Signs – Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.28	CARD TF-3: 6.3.3.10.S7
Pre-Procedure Results – Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.23	CARD TF-3: 6.3.3.10.S8
Planned Procedure – Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.33	CARD TF-3 6.3.3.10.S9
Procedure Indications – Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.29	CARD TF-3 6.3.3.10.S10
Anesthesia Section	O[0..1]	section	2.16.840.1.113883.10.20.22.2.25	CARD TF-3 6.3.3..10.S11
Medications Administered – Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.35	CARD TF-3 6.3.3..10.S12
Procedure Description - Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.19	CARD TF-3 6.3.3.10.S13
Procedure Specimens Taken Section	O[0..1]	section	2.16.840.1.113883.10.20.22.2.31	CARD TF-3 6.3.3.10.S14
Procedure Disposition Section	R[1..1]	section	2.16.840.1.113883.10.20.18.2.12	CARD TF-3 6.3.3.10.S15
Procedure Results - Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.37	CARD TF-3 6.3.3.10.S16
Complications – Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.30	CARD TF-3 6.3.3.10.S17
Postprocedure Diagnosis – Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.32	CARD TF-3 6.3.3.10.S18

Template Title	Opt and Card	Template Type	Template Id	Overview
Plan of Care – Cardiac Section	O[0..1]	section	1.3.6.1.4.1.19376.1.4.1.2.22	CARD TF-3 6.3.3.10.S19
Key Images – Cardiac Section	O[0..1]	section	1.3.6.1.4.1.19376.1.4.1.2.21	CARD TF-3 6.3.3.10.S20
DICOM Object Catalog Section	O[0..1]	section	2.16.840.1.113883.10.20.6.1.1	CARD TF-3 6.3.3.10.S21

6.3.1.D.6 Cardiac Procedure Note (CPN) Conformance and Example

CDA Release 2.0 documents that conform to the requirements of this document content module shall indicate their conformance by the inclusion of the <templateId> XML elements in the header of the document.

The templates and value sets are specified using the Art-Décor tools in the Consolidated-Cardiac Report Content (C-CRC) project. There are valid sample XML snippets for every template included within the Art-Décor C-CRC project.

There are two complete examples of the CPN Document Content Module available on the IHE ftp server at ftp://ftp.ihe.net/TF_Implementation_Material/CARD. There is one example for a cath lab procedure and one example for an EP implant/explant procedure.

Note that these examples are meant to be informative and not normative. These examples show the <templateId (OIDs)> elements for all of the specified templates.

Add to Section 6.3.2 Header Content Modules

6.3.2 CDA Header Content Modules

6.3.2.H1 recordTarget - Cardiac Header Content Module

This is the recordTarget common for cardiac procedure note documents. The recordTarget records the patient whose health information is described by the clinical document.

6.3.2.H2 author - Cardiac Header Content Module

This defines the author common for cardiac procedure note documents. The author element represents the person who created the clinical document. If there are multiple procedures performed, there may be multiple authors for the content of this document.

6.3.2.H3 custodian - Cardiac Header Content Module

This defines the custodian common for cardiac procedure note documents. The custodian is the entity responsible for maintaining the clinical document.

6.3.2.H4 legalAuthenticator - Cardiac Header Content Module

This defines the legal authenticator common for cardiac procedure note documents. The legalAuthenticator identifies the single person legally responsible for the document and must be present if the document has been legally authenticated.

6.3.2.H5 authenticator - Cardiac Header Content Module

This defines the authenticator common for cardiac procedure note documents. The authenticator identifies a participant or participants who attested to the accuracy of the information in the document. There may be one authenticator for the content for each of the Cardiac procedures – e.g., Diagnostic Cath and PCI.

6.3.2.H6 infulfillmentOf - Cardiac Header Content Module

This defines the order the procedure is fulfilling. This is common for cardiac procedure note documents.

6.3.2.H7 authorization - Cardiac Header Content Module

This defines the authorization consents common for cardiac procedure note documents. An authorization consent may be provided for the procedure and an authorization consent may be provided for the anesthesia.

6.3.2.H8 componentOf - Cardiac Header Content Module

This defines the encompassing encounter that this procedure is associated with. This is common for cardiac procedure note documents.

6.3.2.H9 documentationOf - Cardiac Header Content Module

This defines the service event that this procedure is associated with. This may be a DICOM study. This is common for cardiac procedure note documents.

6.3.3 CDA Section Content Modules

Add to Section 6.3.3.10 Section Content Modules

6.3.3.10.S1 Document Summary - Section Content Module

The Document Summary section content module includes a summary of most significant aspects of the procedures in a narrative form. It is a condensed form of the full narrative report whose structure has no constraint.

6.3.3.10.S2 Medical History - Cardiac - Section Content Module

The Medical History – Cardiac section content module describes all aspects of the medical history of the patient even if not pertinent to the current procedure, and may include chief complaint, past medical history, social history, family history, surgical or procedure history, medication history, and other history information. The history may be limited to information pertinent to the current procedure or may be more comprehensive. The history may be reported as a collection of random clinical statements or it may be reported categorically. Social History and Family History are defined as separate section templates. For this Cardiac Procedure Note Content Profile, this Medical History – Cardiac section content module may also contain history about specific relevant problems as problem observations.

In the event that the patient was transferred from another facility where there was a problem indication that the patient was determined to need a cardiac procedure, this will be noted as a problem observation in this medical history section as text in the narrative for now until there is a code representing this.

6.3.3.10.S3 Allergies and Intolerances - Cardiac - Section Content Module

This Allergies section content module lists and describes any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of health care delivery. At a minimum, it should list currently active and any relevant historical allergies and adverse reactions.

6.3.3.10.S4 Family History - Cardiac - Section Content Module

This Family History section content module contains data defining the patient's genetic relatives in terms of possible or relevant health risk factors that have a potential impact on the patient's healthcare risk profile.

6.3.3.10.S5 Social History - Section Content Module

This Social History section content module contains data defining the patient's occupational, personal (e.g., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity and religious affiliation. Social history can have significant influence on a patient's physical, psychological and emotional health and wellbeing so should be considered in the development of a complete record.

To include cocaine misuse behavior, an observation can be included using the code "78267003" from SNOMED CT "Cocaine abuse".

6.3.3.10.S6 Physical Exam - Section Content Module

The Physical Exam section content module includes direct observations made by the clinician. The examination may include the use of simple instruments and may also describe simple maneuvers performed directly on the patient's body. This Physical Exam section includes only

observations made by the examining clinician using inspection, palpation, auscultation, and percussion; it does not include laboratory or imaging findings. The exam may be limited to pertinent body systems based on the patient's chief complaint or it may include a comprehensive examination. The examination may be reported as a collection of random clinical statements or it may be reported categorically.

6.3.3.10.S7 Vital Signs - Cardiac - Section Content Module

The Vital Signs section content module is intended to include vital sign measurements taken at admission and at the time of procedure, if feasible.

6.3.3.10.S8 Pre-procedure Results - Cardiac - Section Content Module

The Pre-Procedure Results – Cardiac section content module contains the results of pre-procedure tests that are required to prepare for the Cath lab and EP lab procedures. Results from prior diagnostic cardiac procedures are included here if they provide indications for the current procedure. There may also be a reference to an optional external document in the result organizer.

Cath Lab Pre-Procedure Results – Cardiac section content module contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes observations such as hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. Any Cath Lab pre-procedure labs that were performed are included here. The section often includes notable results such as abnormal values or relevant trends, and could contain all results for the period of time being documented.

EP Lab Pre-Procedure Results – Cardiac section content module contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes observations such as electrophysiology study, hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. Lab and imaging values affecting ACC-NCDR ICD submission include BUN, Hemoglobin, Sodium, Creatinine, Potassium, BNP, NT-proBNP, 12 lead EKG with associated automated measurements and angiography/echocardiography for associated ejection fraction documentation.

Imaging results are typically generated by a clinician reviewing the output of an imaging procedure, such as where a cardiologist reports the left ventricular ejection fraction based on the review of a cardiac echocardiogram.

6.3.3.10.S9 Planned Procedure - Cardiac - Section Content Module

The Planned Procedure section content module records the procedure(s) that a physician or clinician thought would need to be done based on the preoperative assessment. Procedures include but are not limited to Diagnostic Cath, Angiography, PCI, Structural Heart Intervention (StHrt-Int) and EP implant/explant device procedures.

It may be important to record the procedure(s) that were originally planned for, consented to, and perhaps pre-approved by the payer, particularly if different from the actual procedure(s) and procedure details, to provide evidence to various stakeholders that the providers are aware of the discrepancy and the justification can be found in the procedure details.

6.3.3.10.S10 Procedure Indications - Cardiac - Section Content Module

The Procedure Indications section content module records details about the reason for this cardiac procedure. This Procedure Indications section content module may include the pre-procedure diagnosis or diagnoses as well as one or more symptoms that contribute to the reason the procedure is being performed.

The Indication - Cardiac entry content module documents the rationale for an activity. It can do this with the id element to reference a problem recorded elsewhere in the document or with a code and value to record the problem type and problem within the Indication. For example, the indication for Diagnostic Catheterization might be chest pain.

6.3.3.10.S11 Anesthesia - Section Content Module

The Anesthesia section content module briefly describes the general anesthesia used and may state the actual agent used. The Procedure Activity Procedure entry content module describes the anesthesia procedure. The Medication Activity entry content module may describe the general anesthesia medication used during this procedure.

6.3.3.10.S12 Medications Administered - Cardiac - Section Content Module

The Medications Administered section content module defines medications and fluids administered during the procedure, encounter, or other activity excluding general anesthetic medications.

The set of contrast agents implemented may be limited to a subset of the value set, based on the types of procedures for which the Content Creator creates reports.

6.3.3.10.S13 Procedure Description - Cardiac - Section Content Module

The Procedure Description - Cardiac section records the particulars of the procedure and may include procedure site preparation, surgical site preparation, pertinent details related to sedation/anesthesia, pertinent details related to measurements and markings, procedure times, medications administered, estimated blood loss, specimens removed, implants, instrumentation, sponge counts, tissue manipulation, wound closure, sutures used, vital signs and other monitoring data. Local practice often identifies the level and type of detail required based on the procedure or specialty.

This Procedure Description – Cardiac section content module may include a device organizer to record information about each device used during the procedures. All devices should be defined at this section level within a Procedure Device Organizer – Cardiac entry.

Additional characteristics inherent to these devices, like length and diameter, should be defined using an additional Procedure Device Organizer – Cardiac entry within this section. In addition, dynamic attributes of these devices, like balloon inflation atmospheres, should be recorded in the Procedure Activity Procedure – Cardiac entry within this section content module.

For PCI procedures, individual lesions will be defined in this section as separate lesion observations identified by a unique "lesion ID". Only the location of the lesion will be identified here. Procedures, procedure findings, and results can then reference to the lesion to which it is related by creating an entryRelationship of type="REFR" to the lesion observation based on the "lesion ID" within the Procedure Activity Procedure – Cardiac entry.

For EP procedures the devices and leads are represented as participants in the procedure using enumeration values of IEEE 11073_10103 MDC_IDC Nomenclature (MDC). Parent values of the enumerations can be determined from the MDC standard. In addition, dynamic attributes of these devices, like device interrogation, should be recorded in the Procedure Activity Procedure – Cardiac EPIE entry within this section content module. The various phases in EP procedures being documented can be represented using the Procedure Activity Procedure - Cardiac EPIE entry content module. For each of these phases, devices can be referenced back to the original device inventory. Device measurements and settings may be recorded here. For Lead placements and extractions, individual leads will be defined in this section as separate devices which are identified by a unique id. Procedure findings and results can be recorded in Procedure Results - Cardiac Section.

Procedures that were attempted but not successful should also be included. For example, due to an anatomical constraint discovered during the biventricular implant, the implant of the LV lead did not occur, but this attempted procedure should still be documented.

6.3.3.10.S14 Procedure Specimens Taken - Section Content Module

The Procedure Specimens Taken section records the tissues, objects, or samples taken from the patient during the procedure including biopsies, aspiration fluid, or other samples sent for pathological analysis. The narrative may include a description of the specimens.

6.3.3.10.S15 Procedure Disposition - Section Content Module

The Procedure Disposition Section records the status and condition of the patient at the completion of the procedure or surgery. It often also states where the patient was transferred to for the next level of care.

6.3.3.10.S16 Procedure Results - Cardiac - Section Content Module

This Procedure Results – Cardiac section content module records clinically significant results confirmed or discovered during the procedure. Results include findings, measurements, calculations, and observations.

This Procedure Results – Cardiac section content module should be organized using Procedure Results Organizer – Cardiac entry content modules for specific categories (e.g., right heart cath findings, coronary anatomy findings, left heart cath findings, PCI findings, structural heart

interventional procedure findings, ICD Implant findings, generator change findings, ICD extraction findings, lead implant findings, lead extraction findings, lead abandon findings, lead reuse findings, DFT results, zone VT final device programming, zone VF final device programming, monitor zone settings, and bradycardia parameters). There shall be a Procedure Result Organizer – Cardiac entry content module for one or more of these categories of findings. Procedure Result Observation – Cardiac entries are used to record specific findings (e.g., stenosis, timi flow, lesion characteristics, or wall motion characteristics, induction method, shock impedance, sensing sensitivity, detection interval, ATP) in each category.

6.3.3.10.S17 Complications - Cardiac - Section Content Module

This Complications section content module records problems that occurred during the cardiac procedure. The complications may have been known risks or unanticipated problems.

6.3.3.10.S18 Postprocedure Diagnosis - Cardiac - Section Content Module

The Postprocedure Diagnosis section content module records the diagnosis or diagnoses discovered or confirmed during the procedure. Often it is the same as the pre-procedure diagnosis or indication.

6.3.3.10.S19 Plan of Care - Cardiac - Section Content Module

The Plan of Care - Cardiac section content module contains data that defines pending orders, interventions, encounters, services, and procedures for the patient. 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 information regarding goals and clinical reminders. Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and healthcare quality improvements, including widely accepted performance measures. The plan may also indicate that patient education was given or will be provided.

6.3.3.10.S20 Key Images - Cardiac - Section Content Module

The Key Images section content module contains narrative description of and references to DICOM Image Information Objects that illustrate the findings of the procedure reported.

6.3.3.10.S21 DICOM Object Catalog - Section Content Module

DICOM Object Catalog section content module lists all referenced objects and their parent Series and Studies, plus other DICOM attributes required for retrieving the objects. DICOM Object Catalog sections are not intended for viewing and contain empty section text.

6.3.4 CDA Entry Content Modules

Add to Section 6.3.4.E Entry Content Modules

6.3.4.E1 Pre-procedure Result Observation - Cardiac Entry Content Module

These are results of pre-procedure tests that are required to prepare for the procedure to be performed. These may include results of observations generated by laboratories, imaging procedures, and other procedures.

6.3.4.E1.1 Lab Results Observation Constraints

Lab results may be included as pre-procedure result observations. These will typically be LOINC codes, including those included in the Value Set – Cardiac Lab Results (1.3.6.1.4.1.19376.1.4.1.5.35). The LOINC code for the specific result observation will be specified in the observation/code element.

If the pre-procedure result observation is a physical quantity (type = PQ), the unit of measure will be selected from UCUM (2.16.840.1.113883.6.8).

6.3.4.E1.2 Other Prior Results Observation Constraints

Other results may be selected from LOINC (code system 2.16.840.1.113883.6.1) or SNOMED CT (code system 2.16.840.1.113883.6.96).

6.3.4.E2 Procedure Result Observation - Cardiac Entry Content Module

These are clinically significant results confirmed or discovered during the procedure. Results include findings, measurements, calculations, and observations.

Result observations have been grouped by the type of procedures that are supported:

- Diagnostic Cath
- PCI
- Structural Heart Intervention
- Electrophysiology Implant/Explant

For each procedure type, there is a set of related result observations that may be included in this cardiac procedure note. The constraints for these result observations are defined in the following sections. These constraints may include:

- Cardinality - indicates the minimum and maximum number of these observations that are included for the procedure.
- Procedure Type - indicates the procedure type for which this specific result observation should be included in the entry. This is currently only used for electrophysiology procedures. The procedure types are defined in the Cardiac EP Activity Procedures value set.

  - There is also an indicator if the observation/code is applicable to the Procedure Type – for "R:VT Zone" means that the observation code is required for "VT Zone" procedures.

- Observation/code - defines the code element of this observation. If a code exists, the following are defined:
  - numeric code
  - display name
  - code system name
  - code system identifier

    If no code exists only a display name string is listed.
- Data Type – identifies the HL7 V3 Data Type R1 for the observation value.
- Unit of Measure – if the observation value is of type physical quantity (PQ) then this identifies the unit of measure (from UCUM code system) for the observation value.
- Values – if the observation value is a coded element then this identifies the code(s) allowed.

Using a CDA modeling tool, like Art Décor, provides tremendous advantages in designing profiles, but expressing certain types of complex constraints requires additional explanation and guidance. The Result Observation Entry is a specific case where a specific constraint tables is needed.

The constraint tables are defined for a particular procedure type to define the specific result observations. In some cases that is not always the finest level of granularity that is needed to express relationships between elements. Parent-child relationships are ever present in cardiac procedure noting. A consumer of the report needs to be able to see these relationships, for example, in Diagnostic Cath, findings like Aortic Valve Regurgitation and Aortic Valve Stenosis need to appear under a parent, Aortic Valve Findings. This can be accomplished through nested observations or through additional organizers.

The observation constraint table is not intended to be the exhaustive set of allowed observations and findings for the procedure type, but rather guidelines for known data elements based on clinical experience and registry data dictionary definitions. These tables are also intended to be extended to include other result observations based on specific business needs.

6.3.4.E2.1 Diagnostic Cath Observation Constraints

These are clinically significant results confirmed or discovered during a diagnostic cath procedure.

Cardi-nality	observation/code	Data Type	Unit of Measure	Values
[0..1]	233970002, SNOMED CT, "Stenosis"	PQ	%	
[0..1]	371842003, SNOMED CT, "Fractional flow reserve"	PQ	Ratio	
[0..*]	8583-7, LOINC, "Right atrial A wave amplitude"	PQ	mm[Hg]	
[0..*]	8582-9, LOINC, " Left atrial A wave amplitude"	PQ	mm[Hg]	
[0..*]	8593-6, LOINC, "Right atrial V wave amplitude"	PQ	mm[Hg]	
[0..*]	8592-8, LOINC, "Left atrial V wave amplitude"	PQ	mm[Hg]	
[0..*]	8400-4, LOINC, "Right atrial Intrachamber mean pressure"	PQ	mm[Hg]	
[0..*]	8399-8, LOINC, "Left atrial Intrachamber mean pressure"	PQ	mm[Hg]	
[0..*]	8432-7, LOINC, "Right ventricular Intrachamber systolic pressure"	PQ	mm[Hg]	
[0..*]	8430-1, LOINC," Left ventricular Intrachamber systolic pressure"	PQ	mm[Hg]	
[0..*]	8377-4, LOINC," Right ventricular Intrachamber diastolic pressure"	PQ	mm[Hg]	
[0..*]	8375-8, LOINC," Left ventricular Intrachamber diastolic pressure"	PQ	mm[Hg]	
[0..*]	8392-3, LOINC," Right ventricular End diastolic blood pressure"	PQ	mm[Hg]	
[0..*]	8391-5, LOINC, "Left ventricular End diastolic blood pressure"	PQ	mm[Hg]	
[0..*]	8440-0, LOINC, "Pulmonary Artery Systolic Blood Pressure"	PQ	mm[Hg]	
[0..1]	8414-5, LOINC, "Pulmonary Artery Mean Blood Pressure"	PQ	mm[Hg]	
[0..1]	8393-1, LOINC, "Pulmonary Artery Diastolic Blood Pressure"	PQ	mm[Hg]	
[0..1]	8441-8, LOINC," Pulmonary artery - left Systolic blood pressure"	PQ	mm[Hg]	
[0..*]	8387-3, LOINC, "Pulmonary artery - right Diastolic blood pressure"	PQ	mm[Hg]	
[0..*]	8386-5, LOINC," Pulmonary artery - left Diastolic blood pressure "	PQ	mm[Hg]	
[0..*]	8416-0, LOINC, "Pulmonary artery - right Mean blood pressure"	PQ	mm[Hg]	
[0..*]	8415-2, LOINC, "Pulmonary artery - left Mean blood pressure"	PQ	mm[Hg]	
[0..*]	8584-5, LOINC, "Pulmonary artery wedge A wave amplitude"	PQ	mm[Hg]	

Cardi-nality	observation/code	Data Type	Unit of Measure	Values
[0..*]	8596-9, LOINC, "Pulmonary artery wedge V wave amplitude"	PQ	mm[Hg]	
[0..*]	8368-3, LOINC, "Aorta thoracic ascending Diastolic blood pressure"	PQ	mm[Hg]	
[0..*]	8367-5, LOINC, "Aorta thoracic proximal ascending Diastolic blood pressure"	PQ	mm[Hg]	
[0..*]	8396-4, LOINC, "Aorta thoracic ascending Mean blood pressure"	PQ	mm[Hg]	
[0..*]	8397-2, LOINC, "Aorta thoracic proximal ascending Mean blood pressure"	PQ	mm[Hg]	
[0..*]	8423-6, LOINC, "Ascending thoracic aorta Systolic blood pressure"	PQ	mm[Hg]	
[0..*]	8422-8, LOINC, "Aorta thoracic proximal ascending Systolic blood pressure"	PQ	mm[Hg]	
[0..*]	8840-1, LOINC, " Left atrium Oxygen saturation"	PQ	%	
[0..*]	8841-9, LOINC, "Right atrium Oxygen saturation"	PQ	%	
[0..*]	8842-7, LOINC, " High right atrium Oxygen saturation"	PQ	%	
[0..*]	8843-5, LOINC, " Low right atrium Oxygen saturation"	PQ	%	
[0..*]	8844-3, LOINC, " Mid right atrium Oxygen saturation"	PQ	%	
[0..*]	8845-0, LOINC, " Left ventricular Oxygen saturation"	PQ	%	
[0..*]	8847-6, LOINC, " Right ventricular Oxygen saturation"	PQ	%	
[0..*]	8846-8, LOINC, " Right ventricular outflow tract Oxygen saturation"	PQ	%	
[0..*]	8851-8, LOINC, " Pulmonary artery - left Oxygen saturation"	PQ	%	
[0..*]	8852-6, LOINC, " Main pulmonary artery Oxygen saturation"	PQ	%	
[0..*]	8853-4, LOINC, " Pulmonary artery - right Oxygen saturation"	PQ	%	
[0..*]	8854-2, LOINC, " Pulmonary wedge Oxygen saturation"	PQ	%	
[0..*]	8587-8, LOINC, "Pulmonary artery wedge Mean blood pressure"	PQ	mm[Hg]	
[0..*]	8850-0, LOINC, " Inferior vena cava Oxygen saturation"	PQ	%	

Cardi-nality	observation/code	Data Type	Unit of Measure	Values
[0..*]	8855-9, LOINC, " Superior vena cava Oxygen saturation"	PQ	%	
[0..*]	14775-1, LOINC, " Hemoglobin [Mass/volume] in Arterial blood by Oximetry"	PQ	g/dL	
[0..*]	50188-2, LOINC, " Arterial-venous oxygen saturation difference"	PQ	vol%	
[0..*]	8741-1, LOINC, "Left ventricular Cardiac output"	PQ	L/min	
[0..*]	8736-1, LOINC, "Left ventricular Cardiac output by Fick method"	PQ	L/min	
[0..*]	8733-8, LOINC, " Left ventricular Cardiac output by Angiography single plane"	PQ	L/min	
[0..*]	8732-0, LOINC, "Left ventricular Cardiac output by Angiography biplane"	PQ	L/min	
[0..*]	8750-2, LOINC, " Left ventricular Cardiac index by Fick method"	PQ	L/min/m2	
[0..*]	8747-8, LOINC, "Left ventricular Cardiac index by Angiography single plane"	PQ	L/min/m2	
[0..*]	8746-0, LOINC, "Left ventricular Cardiac index by Angiography biplane"	PQ	L/min/m2	
[0..*]	8743-7, LOINC, "Pulmonary blood flow/Systemic blood flow by Imaging"	PQ	Qp/Qs	
[0..*]	8828-6, LOINC, "Pulmonary vascular Resistance"	PQ	dyn.s/cm5	
[0..*]	8826-0, LOINC, " Pulmonary vascular Resistance by Fick method"	PQ	dyn.s/cm5	
[0..*]	8827-8, LOINC, "Pulmonary vascular Resistance by Indicator dilution"	PQ	dyn.s/cm5	
[0..*]	8831-0, LOINC, ”Systemic vascular Resistance"	PQ	dyn.s/cm5	
[0..*]	8829-4, LOINC, "Systemic vascular Resistance by Fick method"	PQ	dyn.s/cm5	
[0..*]	8830-2, LOINC, "Systemic vascular Resistance by Indicator dilution”	PQ	dyn.s/cm5	
[0..*]	8834-4, LOINC, "Pulmonary vascular Resistance index"	PQ	dyn.s/cm5	
[0..*]	8832-8, LOINC, "Pulmonary vascular Resistance index by Fick method"	PQ	dyn.s/cm5	
[0..*]	8833-6, LOINC, "Pulmonary vascular Resistance index by Indicator dilution"	PQ	dyn.s/cm5	
[0..*]	8837-7, LOINC, "Systemic vascular Resistance index”	PQ	dyn.s/cm5	

Cardi-nality	observation/code	Data Type	Unit of Measure	Values
[0..*]	8835-1, LOINC, "Systemic vascular Resistance index by Fick method"	PQ	dyn.s/cm5	
[0..*]	8836-9, LOINC, "PV Systemic vascular Resistance index by Indicator dilution"	PQ	dyn.s/cm5	
[0..1]	8823-7, LOINC, left ventricle systolic volume	PQ	ml	
[0..1]	8821-1, LOINC, Left ventricle diastolic volume	PQ	ml	
[0..1]	113730, DCM, “Total Fluoro Time”	PQ		
[0..1]	251088005, SNOMED, “Mean aortic value gradient”	PQ	mm[Hg]	
[0..1]	24526-6, LOINC, “Left ventricular cardiac output by US”	PQ	mm[Hg]	
[0..1]	18089-3, LOINC, “Aortic Valve Orifice Area by US”	PQ	cm2	
[1..1]	10230-1, LOINC, “Left ventricular Ejection fraction”	PQ	%	
[0..1]	10230-1, LOINC, “Left ventricular Ejection fraction”	CD		methodCode=258083009, SNOMED CT, “Visual estimation”
[0..1]	10230-1, LOINC, “Left ventricular Ejection fraction”	CD		methodCode=258090004, SNOMED CT, “Calculated”
[0..1]	301123005, SNOMED CT, “Pericardial finding”	CD		35304003, SNOMED CT, “Tamponade”
[0..1]	301123005, SNOMED CT, “Pericardial finding”	CD		373945007, SNOMED CT, “Pericardial effusion”
[0..1]	301123005, SNOMED CT, “Pericardial finding”	CD		Size - see [CARD TF-2: 6.2.2.7.5.1]
[0..1]	301123005, SNOMED CT, “Pericardial finding”	ED text/plain or CD		● Normal
[0..1]	301123005, SNOMED CT, “Pericardial finding”	ED text/plain or CD		● Thickened
[0..1]	301123005, SNOMED CT, “Pericardial finding”	ED text/plain or CD		42653000, SNOMED CT, “Calcified pericardium”
[0..1]	301099004, SNOMED CT, “Aortic valve finding”	CD		60234000, SNOMED CT, Aortic regurgitation
[0..1]	301099004, SNOMED CT, “Aortic valve finding”	CD		301100007, SNOMED CT, “Aortic valve normal”

Cardi-nality	observation/code	Data Type	Unit of Measure	Values
[0..1]	301099004, SNOMED CT, "Aortic valve finding"	CD		84683006, SNOMED CT, "Aortic valve prosthesis"
[0..1]	301099004, SNOMED CT, "Aortic valve finding"	CD		8722008, SNOMED CT, "Aortic valve disorder"
[0..1]	301099004, SNOMED CT, "Aortic valve finding"	CD		253612007, SNOMED CT, aortic valve cusp prolapse
[0..1]	301099004, SNOMED CT, "Aortic valve finding"	CD		301184001, SNOMED CT, aortic valve vegetations
[0..1]	301099004, SNOMED CT, "Aortic valve finding"	CD		13689005, SNOMED CT, congenital anomaly of aortic valve
[0..1]	301099004, SNOMED CT, "Aortic valve finding"	CD		60573004, SNOMED CT, aortic valve stenosis
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		301103009, SNOMED CT, "Mitral valve normal"
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		11851006, SNOMED CT, "Mitral valve disorder"
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		17107009, SNOMED CT, "Mitral valve prosthesis"
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		360063009, SNOMED CT, "Annuloplasty ring"
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		409712001, SNOMED CT, Mitral valve prolapse
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		270906004, SNOMED CT, mitral chordal rupture
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		301185000, SNOMED CT, Mitral valve vegetations
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		79619009, SNOMED CT, Mitral valve stenosis
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		48724000, SNOMED CT, Mitral regurgitation
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		75372006, SNOMED CT, congenital anomaly of Mitral valve
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		301101006, SNOMED CT, "Mitral valve finding"

Cardi-nality	observation/code	Data Type	Unit of Measure	Values
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		251002009, SNOMED CT, mitral valve annular calcification
[0..1]	304522008, SNOMED CT, Pulmonary vein finding	CD		446158009, SNOMED CT, pulmonary venous connections normal
[0..1]	304522008, SNOMED CT, Pulmonary vein finding	CD		variant number of pulmonary veins (usually 3 or 5), but with normal pulmonary venous drainage into left atrium
[0..1]	304522008, SNOMED CT, Pulmonary vein finding	CD		59631007, SNOMED CT, anomalous pulmonary venous drainage
[0..1]	250929008, SNOMED CT, left ventricular cavity size	CD		373124004,SNOMED CT, normal size cardiac chamber
[0..1]	250929008, SNOMED CT, left ventricular cavity size	CD		373125003,SNOMED CT, abnormally small cardiac chamber
[0..1]	250929008, SNOMED CT, left ventricular cavity size	CD		373126002,SNOMED CT, mildly enlarged cardiac chamber
[0..1]	250929008, SNOMED CT, left ventricular cavity size	CD		373127006,SNOMED CT, moderately enlarged cardiac chamber
[0..1]	250929008, SNOMED CT, left ventricular cavity size	CD		373128001,SNOMED CT, markedly enlarged cardiac chamber
[0..1]	250964004, SNOMED CT, right ventricular cavity size	CD		373124004,SNOMED CT, normal size cardiac chamber
[0..1]	250964004, SNOMED CT, right ventricular cavity size	CD		373125003,SNOMED CT, abnormally small cardiac chamber
[0..1]	250964004, SNOMED CT, right ventricular cavity size	CD		373126002,SNOMED CT, mildly enlarged cardiac chamber
[0..1]	250964004, SNOMED CT, right ventricular cavity size	CD		373127006,SNOMED CT, moderately enlarged cardiac chamber
[0..1]	250964004, SNOMED CT, right ventricular cavity size	CD		373128001,SNOMED CT, markedly enlarged cardiac chamber
[0..1]	399121005, SNOMED CT, Left atrium cavity size	CD		373124004,SNOMED CT, normal size cardiac chamber

Cardi-nality	observation/code	Data Type	Unit of Measure	Values
[0..1]	399121005, SNOMED CT, Left atrium cavity size	CD		373125003,SNOMED CT, abnormally small cardiac chamber
[0..1]	399121005, SNOMED CT, Left atrium cavity size	CD		373126002,SNOMED CT, mildly enlarged cardiac chamber
[0..1]	399121005, SNOMED CT, Left atrium cavity size	CD		373127006,SNOMED CT, moderately enlarged cardiac chamber
[0..1]	399121005, SNOMED CT, Left atrium cavity size	CD		373128001,SNOMED CT, markedly enlarged cardiac chamber
[0..*]	442119001, SNOMED CT, “Cardiac shunt finding”	CD		204317008, SNOMED CT, patent foramen ovale
[0..*]	442119001, SNOMED CT, “Cardiac shunt finding”	CD		70142008, SNOMED CT, atrial septal defect
[0..*]	442119001, SNOMED CT, “Cardiac shunt finding”	CD		30288003, SNOMED CT, ventricular septal defect
[0..*]	442119001, SNOMED CT, “Cardiac shunt finding”	CD		83330001, SNOMED CT, patent ductus arteriosus
[0..1]	18087-7, LOINC, Left Ventricle Mass	CD		260395002, SNOMED CT, “normal”
[0..1]	18087-7, LOINC, Left Ventricle Mass	CD		35105006, SNOMED CT, “Increased”
[0..1]	439749006:363698007=73829009, SNOMED CT, Right atrium volume by imaging	CD		373124004,SNOMED CT, normal size cardiac chamber
[0..1]	439749006:363698007=73829009, SNOMED CT, Right atrium volume by imaging	CD		373125003,SNOMED CT, abnormally small cardiac chamber
[0..1]	439749006:363698007=73829009, SNOMED CT, Right atrium volume by imaging	CD		373126002,SNOMED CT, mildly enlarged cardiac chamber
[0..1]	439749006:363698007=73829009, SNOMED CT, Right atrium volume by imaging	CD		373127006,SNOMED CT, moderately enlarged cardiac chamber
[0..1]	439749006:363698007=73829009, SNOMED CT, Right atrium volume by imaging	CD		373128001,SNOMED CT, markedly enlarged cardiac chamber
[0..1]	301104003, SNOMED CT, “Pulmonic valve finding”	CD		91434003, SNOMED CT, Pulmonic regurgitation
[0..1]	404684003, SNOMED CT, “Finding”	CD		308546005, SNOMED CT, “Dissection of aorta”

Cardi-nality	observation/code	Data Type	Unit of Measure	Values
[0..1]	404684003, SNOMED CT, “Finding”	CD		251036003, SNOMED CT, “Aortic root dilation”
[0..1]	404684003, SNOMED CT, “Finding”	CD		2576595010, SNOMED CT, “Bruits – femoral”
[0..1]	2576595010, SNOMED CT, “Finding”	CD		2576593015, SNOMED CT, “Bruits – carotid”
[0..1]	2576595010, SNOMED CT, “Finding”	ED text/plain or CD		Vegetation
[0..1]	2576595010, SNOMED CT, “Finding”	ED text/plain or CD		Thrombus
[0..1]	2576595010, SNOMED CT, “Finding”	ED text/plain or CD		Neoplasm
[0..1]	2576595010, SNOMED CT, “Finding”	CD		Mass of Unknown Etiology
[0..1]	2576595010, SNOMED CT, “Finding”	CD		387842002, SNOMED CT, “neoplasm of heart”
[0..1]	2576595010, SNOMED CT, “Finding”	CD		309519009, SNOMED CT, “LV Thrombus”
[0..1]	"TIMI Flow"	ED text/plain or CD		371867000, SNOMED CT, (TIMI-0)
[0..1]	"TIMI Flow"	ED text/plain or CD		371866009, SNOMED CT, (TIMI-1)
[0..1]	"TIMI Flow"	ED text/plain or CD		371864007, SNOMED CT, (TIMI-2)
[0..1]	"TIMI Flow"	ED text/plain or CD		371865008, SNOMED CT, (TIMI-3)
[0..1]	"Coronary Dominance"	ED text/plain or CD		253729004, SNOMED CT, (Left)
[0..1]	"Coronary Dominance"	ED text/plain or CD		253728007, SNOMED CT, (Right)

Cardi-nality	observation/code	Data Type	Unit of Measure	Values
[0..1]	"Coronary Dominance"	ED text/plain or CD		253730009, SNOMED CT, (Balanced)

6.3.4.E2.2 PCI Observation Constraints

These are clinically significant results confirmed or discovered during a PCI procedure.

Cardi-nality	observation/code	Data Type	Unit of Measure	Values
[0..1]	449389000, SNOMED CT, "Previously Treated Lesion with Stent"	BL		
[0..1]	251030009, SNOMED CT, "In-stent Restenosis"	BL		
[0..1]	421327009, SNOMED CT, "In-stent Thrombosis"	BL		
[0..1]	408716009, SNOMED CT, "Stenotic lesion length"	PQ	cm	
[0..1]	421327009, SNOMED CT, "Thrombus Present"	BL		
[0..1]	371894001, SNOMED CT, "Bifurcation Lesion"	BL		
[0..1]	233970002, SNOMED CT, “Stenosis”	PQ	%	
[0..1]	371842003, SNOMED CT, “Fractional flow reserve”	PQ	Ratio	
[0..1]	70390005, SNOMED CT, "Significant Dissection"	CD		
[0..1]	234010000, SNOMED CT, "Coronary artery perforation"	CD		
[0..1]	113730, DCM, “Total Fluoro Time”	PQ	min	
[0..1]	"TIMI Flow"	CD		371867000, SNOMED CT, (TIMI-0)
[0..1]	"TIMI Flow"	CD		371866009, SNOMED CT, (TIMI-1)
[0..1]	"TIMI Flow"	CD		371864007, SNOMED CT, (TIMI-2)
[0..1]	"TIMI Flow"	CD		371865008, SNOMED CT, (TIMI-3)

6.3.4.E2.3 Structural Heart Intervention Observation Constraints

These are clinically significant results confirmed or discovered during a structural heart intervention procedure.

Cardi-nality	observation/code	Data Type	Unit of Measure	Values
[0..*]	8368-3, LOINC, "Aorta thoracic ascending Diastolic blood pressure"	PQ	mm[Hg]	
[0..*]	8430-1, LOINC," Left ventricular Intrachamber systolic pressure"	PQ	mm[Hg]	
[0..*]	8375-8, LOINC," Left ventricular Intrachamber diastolic pressure"	PQ	mm[Hg]	
[0..*]	8391-5, LOINC, "Left ventricular End diastolic blood pressure"	PQ	mm[Hg]	
[0..*]	8587-8, LOINC, "Pulmonary artery wedge Mean blood pressure"	PQ	mm[Hg]	
[0..*]	8367-5, LOINC, "Aorta thoracic proximal ascending Diastolic blood pressure"	PQ	mm[Hg]	
[0..*]	8396-4, LOINC, "Aorta thoracic ascending Mean blood pressure"	PQ	mm[Hg]	
[0..*]	8397-2, LOINC, "Aorta thoracic proximal ascending Mean blood pressure"	PQ	mm[Hg]	
[0..*]	8423-6, LOINC, "Ascending thoracic aorta Systolic blood pressure"	PQ	mm[Hg]	
[0..*]	8422-8, LOINC, "Aorta thoracic proximal ascending Systolic blood pressure"	PQ	mm[Hg]	
[0..*]	8840-1, LOINC, " Left atrium Oxygen saturation"	PQ	%	
[0..1]	113730, DCM, “Total Fluoro Time”	PQ	min	
[0..1]	251088005, SNOMED, “Mean aortic value gradient”	PQ	mm[Hg]	
[0..*]	24526-6, LOINC, “Left ventricular cardiac output by US”	PQ	mm[Hg]	
[0..*]	18089-3, LOINC, “Aortic Valve Orifice Area by US”	PQ	cm2	
[0..1]	18590009, SNOMED “Cardiac pacing”	PQ	seconds	
[0..1]	301099004, SNOMED CT, “Aortic valve finding”	CD		253612007, SNOMED CT, aortic valve cusp prolapse
[0..1]	301099004, SNOMED CT, “Aortic valve finding”	CD		301184001, SNOMED CT, aortic valve vegetations
[0..1]	301099004, SNOMED CT, “Aortic valve finding”	CD		13689005, SNOMED CT, congenital anomaly of aortic valve
[0..1]	301099004, SNOMED CT, “Aortic valve finding”	CD		60573004, SNOMED CT, aortic valve stenosis

Cardi-nality	observation/code	Data Type	Unit of Measure	Values
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		79619009, SNOMED CT, Mitral valve stenosis
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		48724000, SNOMED CT, Mitral regurgitation
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		301103009, SNOMED CT, "Mitral valve normal"
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		11851006, SNOMED CT, "Mitral valve disorder"
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		17107009, SNOMED CT, "Mitral valve prosthesis"
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		360063009, SNOMED CT, "Annuloplasty ring"
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		409712001, SNOMED CT, Mitral valve prolapse
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		270906004, SNOMED CT, mitral chordae rupture
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		301185000, SNOMED CT, Mitral valve vegetations
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		75372006, SNOMED CT, congenital anomaly of Mitral valve
[0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		251002009, SNOMED CT, mitral valve annular calcification
[0..1]	301104003, SNOMED CT, "Pulmonic valve finding"	CD		91434003, SNOMED CT, Pulmonic regurgitation
[0..1]	301099004, SNOMED CT, "Aortic valve finding"	CD		308546005, SNOMED CT, "Dissection of aorta"
[0..1]	301099004, SNOMED CT, "Aortic valve finding"	CD		251036003, SNOMED CT, "Aortic root dilation"
[0..1]	301099004, SNOMED CT, "Aortic valve finding"	CD		60234000, SNOMED CT, Aortic regurgitation

6.3.4.E2.4 Electrophysiology Implant/Explant Observation Constraints

These are clinically significant results confirmed or discovered during an electrophysiology ICD implant, explant or lead replacement procedure.

Procedure Type	Cardinality	observation/code	Data Type	Unit of Measure	Values
R:ICD Lead	[0..1]	729537, MDC_IDC, MDC_IDC_SET_LEADCHNL_RV_SENSING_SENSITIVITY, “RV Sensing Amplitude”	PQ	mV	
R:ICD Lead	[0..1]	722433, MDC_IDC, MDC_IDC_MSMT_LEADCHNL_RV_IMPEDANCE_VALUE, “RV Impedance”	PQ	ohms	
R:ICD Lead	[0..1]	722177, MDC_IDC, MDC_IDC_MSMT_LEADCHNL_RV_PACING_THRESHOLD_AMPLITUDE,”RV pacing Threshold”	PQ	ohms	
R:ICD Lead	[0..1]	722241, MDC_IDC, MDC_IDC_MSMT_LEADCHNL_RV_PACING_THRESHOLD_PULSEWIDTH, “RV pacing Threshold Pulsewidth”	PQ	ms	
R:ICD DFT Testing	[0..1]	Shock Configuration	Text		
R:ICD DFT Testing	[0..1]	Induction Method	Text		
R:ICD DFT Testing	[0..1]	731648, MDC_IDC, MDC_IDC_SET_ZONE_TYPE-Induced Rhythm, "Induced Rhythm"	CD		
R:ICD DFT Testing	[0..1]	722624, MDC_IDC, MDC_IDC_MSMT_LEADHVCHNL_IMPEDANCE-Shock, ”Shock Impedance”	PQ	ohms	
R:ICD DFT Testing	[0..1]	732225, MDC_IDC, MDC_IDC_SET_ZONE_SHOCK_ENERGY_1,”Shock Energy”	PQ	J	
R:ICD DFT Testing	[0..1]	722051, MDC_IDC_MSMT_LEADCHNL_RV_SENSING_INTR_AMPL_MEAN “RV Sensing INTR Amplitude Mean”	PQ	mV	
R:ICD Bradycardia Parameters	[0..1]	722051, MDC_IDC_MSMT_LEADCHNL_RV_SENSING_INTR_AMPL_MEAN “RV Sensing INTR Amplitude Mean”	PQ	mV	

Procedure Type	Cardinality	observation/code	Data Type	Unit of Measure	Values
R:ICD VT Zone	[0..1]	731840, MDC_IDC, MDC_IDC_SET_ZONE_DETECTION_INTERVAL, “Zone Detection Interval”	PQ	ms	
R:ICD VF Zone	[0..1]	731840, MDC_IDC, MDC_IDC_SET_ZONE_DETECTION_INTERVAL, “Zone Detection Interval”	PQ	ms	
R:ICD Monitor Zone	[0..1]	731840, MDC_IDC, MDC_IDC_SET_ZONE_DETECTION_INTERVAL, “Zone Detection Interval”	PQ	ms	
R:ICD VF Zone	[0..1]	732097, MDC_IDC_SET_ZONE_TYPE_ATP_1, “Therapy”			
R:ICD VT Zone	[0..1]	732097, MDC_IDC_SET_ZONE_TYPE_ATP_1, “Therapy”			
R:ICD VT Zone	[0..1]	732161, MDC_IDC, MDC_IDC_SET_ZONE_NUM_ATP_SEQS_1, “ATP Seqs”	INT		
R:ICD VF Zone	[0..1]	732161, MDC_IDC, MDC_IDC_SET_ZONE_NUM_ATP_SEQS_1, “ATP Seqs”	INT		
R:ICD VT Zone	[0..1]	732225, MDC_IDC, MDC_IDC_SET_ZONE_SHOCK_ENERGY_1, “Shock Energy 1”	PQ	J	
R:ICD VF Zone	[0..1]	732225, MDC_IDC, MDC_IDC_SET_ZONE_SHOCK_ENERGY_1, “Shock Energy 1”	PQ	J	
R:ICD VT Zone	[0..1]	732289, MDC_IDC, MDC_IDC_SET_ZONE_NUM_SHOCKS_1, “Num of Shocks 1”	INT		
R:ICD VF Zone	[0..1]	732289, MDC_IDC, MDC_IDC_SET_ZONE_NUM_SHOCKS_1, “Num of Shocks 1”	INT		
R:ICD VT Zone	[0..1]	732226, MDC_IDC, MDC_IDC_SET_ZONE_SHOCK_ENERGY_2, “Shock Energy 2”	PQ	J	
R:ICD VT Zone	[0..1]	732290, MDC_IDC, MDC_IDC_SET_ZONE_NUM_SHOCKS_2, “Num of Shocks 2”	INT		
R:ICD Bradycardia Parameters	[0..1]	730752, MDC_IDC, MDC_IDC_SET_BRADY_MODE, “Brady Mode”	CD		
R:ICD Bradycardia Parameters	[0..1]	730880, MDC_IDC, MDC_IDC_SET_BRADY_LOWRATE, “Low Rate”	PQ	bpm	
	[0..1]		PQ	V	

Procedure Type	Cardinality	observation/code	Data Type	Unit of Measure	Values
R:ICD Bradycardia Parameters		729985, MDC_IDC, MDC_IDC_SET_LEADCHNL_RV_PACING_AMPLITUDE, “RV Pacing Amplitude”			
R:ICD Bradycardia Parameters	[0..1]	730049, MDC_IDC, MDC_IDC_SET_LEADCHNL_RV_PACING_PULSEWIDTH, “RV Pacing Pulse Width”	PQ	ms	
R:ICD Implant(CRT-D)	[0..1]	100000985, Device Implanted	CD		100001143,ACC NCDR, Implant unsuccessful
R:ICD Implant(CRT-D)	[0..1]	100000985, Device Implanted	CD		100001057,ACC NCDR, Not Attempted
R:ICD Implant(CRT-D)	[0..1]	100000985, Device Implanted	CD		100001107,ACC NCDR, Successfully Implanted
R:ICD Implant(CRT-D)	[0..1]	100000985, Device Implanted	CD		100001084,ACC NCDR, Previously Implanted
R:ICD Implant Biventricular	[0..1]	"LV First"	PQ	ms	
R:ICD Implant Biventricular	[0..1]	"Simultaneous RV first"	PQ	ms	
R:ICD Implant Biventricular	[0..1]	" A-V Pace"	PQ	ms	
R:ICD Implant Biventricular	[0..1]	"A-V (sensed)"	PQ	ms	
R:ECG	[0..1]	"Simultaneous ECG leads"			
R:ECG	[0..1]	"P-Wave Duration"			
R:ECG	[0..1]	100001121, ACC NCDR,Ventricular Paced QRS Duration	PQ	ms	
R:ECG	[0..1]	251208001, SNOMED CT,QRS Duration (Non-Ventricular Paced Complex)	PQ	ms	
R:ECG	[0..1]	"Epsilon Wave"			
R:ECG	[0..1]	"Hx of prolonged QT Interval"			
R:ECG	[0..1]	9651007,SNOMED CT,"Long QT"	CD		
R:ICD Existing Lead	[0..1]	100000989,ACC NCDR,"Existing Lead Status"	CD		100001004,ACC NCDR,"Extracted"
R:ICD Existing Lead	[0..1]	100000989,ACC NCDR,"Existing Lead Status"	CD		100000925,ACC NCDR,"Abandoned"
R:ICD Existing Lead	[0..1]	100000989,ACC NCDR,"Existing Lead Status"	CD		100001099,ACC NCDR,"Reused"
R:ICD Existing Lead	[0..1]	234233007,SNOMED CT,"Placement Issue: Dislodgement"	CD		

Procedure Type	Cardinality	observation/code	Data Type	Unit of Measure	Values
R:ICD	[0..1]	428024001,SNOMED CT ,"Premarket Clinical Trial"	CD		

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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.

970 ## 6.5 CARD Value Sets

All the value sets are defined in Art-Décor and are linked to the templates from which they are referenced.

Appendices

None

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Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

Level (e.g., Section/Document/Entry)	Template id	Name
Document template id	1.3.6.1.4.1.19376.1.4.1.1.4	Cardiac Procedure Note (CPN)
Header template id	1.3.6.1.4.1.19376.1.4.1.3.7	recordTarget - Cardiac
Header template id	1.3.6.1.4.1.19376.1.4.1.3.8	author- Cardiac
Header template id	1.3.6.1.4.1.19376.1.4.1.3.9	custodian- Cardiac
Header template id	1.3.6.1.4.1.19376.1.4.1.3.10	legalAuthenticator- Cardiac
Header template id	1.3.6.1.4.1.19376.1.4.1.3.11	authenticator- Cardiac
Header template id	1.3.6.1.4.1.19376.1.4.1.3.12	inFulfillmentOf- Cardiac
Header template id	1.3.6.1.4.1.19376.1.4.1.3.13	authorization – Cardiac
Header template id	1.3.6.1.4.1.19376.1.4.1.3.14	componentOf– Cardiac
Header template id	1.3.6.1.4.1.19376.1.4.1.3.15	documentationOf– Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.16	Document Summary
Section template id	1.3.6.1.4.1.19376.1.4.1.2.17	Medical History - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.19	Procedure Description - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.21	Key Images - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.22	Plan of Care - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.23	Pre-Procedure Results – Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.27	Allergies and Intolerances - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.28	Vital Signs - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.29	Procedure Indications - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.31	Family History - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.30	Complications - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.32	Postprocedure Diagnosis - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.33	Planned Procedure - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.35	Medications Administered - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.37	Procedure Results - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.10	Lesion Observation
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.11	Pre-procedure Result Organizer – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.12	Procedure Device Organizer – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.13	Device Observation - Cardiac

Level (e.g., Section/Document/Entry)	Template id	Name
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.14	Procedure Activity Procedure - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.17	Plan of Care Activity Act – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.24	Allergy Concern Act – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.25	Allergy - Intolerance Observation – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.26	Vital Sign Observation - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.27	Vital Signs Organizer - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.28	Indication - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.29	Problem Observation - Complication - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.30	Document Summary ObservationMedia
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.31	Family History Observation - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.32	Family History Organizer - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.33	Problem Observation - Postprocedure
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.34	Postprocedure Diagnosis - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.35	Procedure Activity Procedure Medical History - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.36	Procedure Activity Observation Medical History - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.37	Problem Observation Medical History - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.38	Planned Procedure - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.39	
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.40	Medication Information - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.41	Medication Activity - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.42	
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.43	
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.44	Procedure Result Organizer - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.45	Procedure Result Observation - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.46	Pre-procedure Result Observation - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.47	
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.31	Cardiac Problems / Concerns
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.32	Coronary Anatomy
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.33	Cardiovascular Family History
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.34	Contrast Agent Classes for Adverse Reactions
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.35	Cardiac Lab Results
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.36	Vital Signs
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.37	Procedure Indications
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.39	Contrast Agents

Level (e.g., Section/Document/Entry)	Template id	Name
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.40	Cardiac Activity Procedures
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.42	Rx Recommendations
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.44	Cardiac Postprocedure Diagnoses
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.45	Supported File Types
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.46	Complications
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.50	ICD Device Type
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.52	Cardiac EP Activity Procedures
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.64	Cardiac Procedure Results Organizers
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.65	Cardiac Document Type
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.66	Complications – EP
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.67	Cardiac Drug Classes and Specific Drugs - SNOMED
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.68	Cardiac Drug Classes and Specific Drugs - RxNorm

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Volume 4 – National Extensions

Add appropriate Country section

4 National Extensions

None.

