

# Concise Consolidated CDA: *Deploying Encounter Summary and Patient Summary Documents with Clinical Notes*

March 2022

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# Executive Summary

In the Fall of 2017, the independent Carequality and CommonWell Content Work Groups were each attempting to solve a set of similar issues: unacceptably large Consolidated Clinical Document Architecture (C-CDA) documents, an absence of clinical notes in exchanged documents, support for encounter summary documents, and the need for document version management. The initiatives agreed to launch a Joint Document Content Work Group (JDCWG) in January 2018 with participants that included clinicians, vendor representatives, and standards development representatives.

Since its inception, the group has reconvened periodically to address additional scope and revise this document with additional guidance.

This white paper defines a path to improve the content in C-CDA exchange, while acknowledging the realities of present day documentation and exchange practices. The intended audience of this guidance is C-CDA implementers, product development teams, and software developers.

The recommendations resulting from this joint effort are summarized below, with links to the pertinent section.

## Generation and sharing of Patient and Encounter Summary Documents:

- 2.1.1: Implementers SHALL support the ability to generate and send Encounter Summary Documents in addition to current Patient Summary Documents.
- 3: Encounter Summary Documents SHOULD be based upon the C-CDA template for Progress Note (Outpatient/Ambulatory) or Discharge Summary (Inpatient/Hospital).
- 3.2, 3.3, 3.4: Implementers SHOULD incorporate Clinical Notes in C-CDA implementations.
- 3.1: Content in Encounter Summary Documents SHALL only reflect information at the time of the encounter and reflect active: problems, allergies, medications, and immunizations as of the end of the specified encounter.
- 3.1, 2.2.4: Implementers SHALL include a subset of the ONC Common Clinical Data Set / USCDI V1 by default in an Encounter Summary Document, and only if that data was validated during the encounter.
- 4.2: Implementers SHALL include a Section Time Range Observation for each section in Patient Summaries and 3.1: SHOULD in Encounter Summaries.
- 2.6.3.2, 3: Implementers SHALL respond with all applicable encounter summary C-CDA documents when they receive requests that specify a time range that spans multiple encounters.
- 3.5.4: Implementers SHALL support sharing updates to Encounter Summary documents, to include making known that updates are available when queried.
- 4.2: Content in current Patient Summary Documents SHALL reflect active: problems, allergies, medications, and immunizations.

- 4.2.3: Implementers MAY support the ability to populate entries in Patient Summary Documents based on the date range requested.
- Throughout: Additional guidance is provided for implementers to receive and ingest these documents, although it is less prescriptive.

Use of IHE Document Sharing mechanisms:

- 2.3.1, 2.3.2: The foundational IHE Document Sharing concepts are explained clearly: document vs. document entry, metadata, and associations.
- 2.3.2.1, 2.3.4, 2.3.5: Guidance is provided for IHE mechanisms that support dynamic generation of documents such as On-Demand, Delayed Document Assembly, and Deferred Response.
- 2.4: Mappings between the IHE XDS document metadata (which is returned on query) and the content of the CDA document are fully specified.

Interoperable laboratory orders and results:

- 2.5.1: Guidance is provided for sharing laboratory orders and results through their lifecycle, from order to completion, in Encounter and Patient Summary documents.
- 2.5.2: The group captured and analyzed pain points and challenges impacting lab result interoperability, and devised a strategy for identifying actionable work items and working with outside groups to move the bar.
- 2.5.2.6: Guidance is provided for including translations to harmonized codes.

The key words "MUST", "MUST NOT", "REQUIRED", "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT", "RECOMMENDED", "MAY", and "OPTIONAL" in this document are to be interpreted as described in IETF BCP 14.6.<sup>1</sup>

The next steps related to these recommendations are for Carequality and CommonWell representatives to present them to their respective Steering Divisions to determine how to encourage implementation. Additionally, these recommendations have been and will be shared with HL7 for possible inclusion in a future version of C-CDA and/or the C-CDA Companion Guide. The Companion Guide has already incorporated material from a prior version of this guide.

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<sup>1</sup> Best Current Practice 14 - available at: <https://www.rfc-editor.org/info/bcp14>

# Table of Contents

1 Introduction	6
1.1 Purpose and Scope	6
1.2 Audience	6
1.3 Background and Development Approach	7
1.3.1 Sources and Process	8
1.4 How to read this guide	9
1.4.1 Smart Senders and Resilient Receivers	10
2 General Guidance	11
2.1 Moving from just CCDs to a well-factored clinical view of a patient	11
2.1.1 Providing Patient and Encounter Summary Documents	11
2.1.2 Requesting Patient and Encounter Summary Documents	12
2.2 CDA Document Content Guidance	13
2.2.1 Smart Senders: Maintain proper references between coded values and narrative	13
2.2.2 Smart Senders: Maintain act/observation IDs across documents	15
2.2.3 Smart Senders: Reconciliation flag	15
2.2.4 Support for USCDI	16
2.2.5 No Information	16
2.2.6 Section Time Range Observation	16
2.3 Dynamic Generation of Documents (aka On Demand)	18
2.3.1 Basic IHE document sharing	19
2.3.2 Capability: Document Update Sharing	20
2.3.2.1 Capability: Stable Document Update Detection	22
2.3.3 Capability: Delayed Document Assembly Option	23
2.3.3.1 Capability: Delayed Document Assembly with Update Detection	24
2.3.4 Capability: On-Demand Option	25
2.3.4.1 Persistence of Retrieved Documents Option	26
2.3.4.2 Capability: On-Demand with Update Detection	27
2.3.4.3 Capability: On-Demand and Delayed Document Assembly with Update Detection	28
2.3.5 Capability: XCA Deferred Response Option	28
2.4 Mapping between XDS metadata and CDA header	29
2.4.1 Mapping date values to support service date range queries	30
2.4.2 Special Mappings for On-Demand Entries	31
2.5 Laboratory orders and results	31

2.5.1 Laboratory Test Lifecycle	31
2.5.1.1 Initial Lab Order	32
2.5.1.2 Lab Performed	32
2.5.1.3 Lab Cancelled	33
2.5.1.4 Lab Aborted	33
2.5.1.5 Tracking Labs from Order to Results	33
2.5.1.6 Tracking Labs Between Results	34
2.5.1.7 Tracking Lab Result Corrections	34
2.5.2 Interoperable Laboratory Results	34
2.5.2.1 Detailed Problems with Lab Interoperability	34
2.5.2.1.1 Lab values are vendor- or facility- specific codes or free text	34
2.5.2.1.2 Standardized translation available but at different level of abstraction; loss of specificity	35
2.5.2.1.3 Requesting systems have different needs from codes (coarse-grained vs fine-grained)	35
2.5.2.1.4 Reference range received from lab is non-standard	35
2.5.2.1.5 Range/Interpretation received from lab is specific to location of test	35
2.5.2.1.6 Codes, even if standard, can't always be trended together	35
2.5.2.2 Groups Working on Lab Interoperability	35
2.5.2.3 Case Study: Epic / Sutter Health on Types of Code Mappings and Challenges	36
2.5.2.4 Workgroup Strategy	37
2.5.2.5 Creating Mappings	38
2.5.2.6 Performing Translations	39
2.6 Resilient Receivers: Querying, Retrieving and Displaying	40
2.6.1 Document Exchange Workflow Guidance	40
2.6.2 Receive and display any valid CDA document	43
2.6.3 Additional XDS Query Filtering Guidance	43
2.6.3.1 Filtering by coded values	43
2.6.3.2 Filtering by date/time range	45
2.6.3.2.1 Date range search, overlapping	46
2.6.3.2.2 All documents after a set date, overlapping	47
2.6.3.2.3 All documents before a set date, overlapping	47

2.6.3.2.4	Date range search, non-overlapping – missing boundary documents	48
2.6.3.2.5	All documents after a set date, non-overlapping – missing boundary document	48
2.6.3.2.6	All documents before a set date, non-overlapping – missing boundary document	49
3	Encounter Summary Documents	50
3.1	Document Body Guidance	52
3.2	Outpatient/Ambulatory Summary (Progress Note Document)	53
3.3	Inpatient/Hospital Summary (Discharge Summary Document)	54
3.4	Clinical Notes	55
3.4.1	Common Clinical Note Types	56
3.4.2	Sending Clinical Notes in C-CDA	56
3.4.2.1	Note directly attached to the associated act	56
3.4.2.2	Note is in an appropriate section	58
3.4.2.3	Note in stand-alone Notes Section	59
3.4.3	Encounter Linking for Clinical Notes	60
3.4.4	Clinical Note Best Practices	62
3.5	When to Share Encounter Documents Through the Lifecycle	62
3.5.1	Sharing an Encounter that is in Progress	63
3.5.2	Sharing an Encounter that has Ended	63
3.5.3	Sharing Throughout the Encounter Lifecycle	64
3.5.4	Sharing Updates to an Encounter Summary	66
4	Patient Summary Documents	69
4.1	C-CDA Continuity of Care (CCD) Document Type	69
4.2	Generating the Current Patient Summary	70
4.2.1	Service dates for patient summaries in CDA and XDS	71
4.2.2	Populating sections based on default date ranges	72
4.2.3	Populating sections based on query date ranges	73
4.3	Smart Senders: Reducing the clutter of too many generated patient summary documents	75
Appendix A		77
A.1	Additional education material	77
A.2	Future Work	77

## Table of Figures

Figure 1 – A simple IHE XCA Query request, annotated .....	13
Figure 2 – Example id root only .....	15
Figure 3 – Example id root + extension.....	15
Figure 4 – Sample display of Section Time Range.....	17
Figure 5 – Example of Section Time Range Observation .....	18
Figure 6 IHE XDS Document entry and CDA document .....	20
Figure 7 Document Replacement in XDS and CDA .....	21
Figure 8 Delayed Document Assembly in Practice .....	24
Figure 9 On-Demand Basic Functionality.....	25
Figure 10 On-Demand with Persistence of Retrieved Documents .....	26
Figure 11 On-Demand with Persistence and Association Support .....	27
Figure 12 – Translating to a preferred code .....	39
Figure 13 – Document Query.....	40
Figure 14 – Document Retrieval .....	41
Figure 15 - Document Information Available during the IHE Query and in the stored C-CDA.....	42
Figure 16 - Sample Document List Display.....	43
Figure 17 – Filtering on coded values in the IHE XDS Query request .....	43
Figure 18 – Filtering on Timespan Elements in the IHE XDS Query request.....	45
Figure 19 – Progress Note Document Section Requirements .....	54
Figure 20 – Discharge Summary Document Section Requirements .....	55
Figure 21 Example of Note Directly Added to Associated Act.....	57
Figure 22 – Example of Note Attached to an Act.....	58
Figure 23 – Example of Note Added to an Appropriate Section.....	59
Figure 24 – Example of Stand-alone Notes Section .....	60
Figure 25 – Example of Encounter Linking with entryRelationship reference .....	61
Figure 26 – Example of Encounter Linking with encounter nested .....	61
Figure 27 Sharing Throughout the Encounter Lifecycle.....	64
Figure 28 Versioning from Requester's Perspective .....	66
Figure 29 – VA Section Default Timespan Filters .....	73
Figure 30 – VA Section Query-influenced Timespan Filters.....	75

## Version History

Version	Description
2.0 (current)	Added document sharing details, dynamic generation, versioning, labs, pain points, reorganized content. Renamed document from “Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes” to reflect broader scope.
1.1	Clarified use of IHE query parameters, added conformance verbs, moved content to appendix
1.0	Initial release

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# 1 Introduction

Carequality and the CommonWell Health Alliance are two industry initiatives committed to the seamless exchange of healthcare information. This guide is the result of a joint development effort of the Content Workgroups within each initiative to improve the content of Consolidated CDA exchange.

## 1.1 Purpose and Scope

This document provides guidance for generating and sharing Encounter Summary and Patient Summary C-CDA Documents, including Clinical Notes. Because this document targets production exchanges and implementers, **it complements existing content and exchange standards by covering the intersection of CDA content, document sharing mechanisms, and the underlying clinical data used to generate documents.** This guidance describes existing best practices as well as new solutions to “pain points” brought forward by providers, vendors and other implementers.

A **Clinical Note** is narrative text a clinician wrote, dictated, or copied from other portions of the patient’s chart. An Encounter Summary CDA document will include this Clinical Note (required) plus other relevant sections with discrete data as generated by the system and/or included per clinician instructions.

For **guidance pertaining to document content**, this document complements the Health Level Seven (HL7) CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Release 2.1, and the HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R1 Companion Guide Release 2, which primarily supports the requirements of the ONC 2015 Edition Certification Criteria (2015 Edition) Certified Electronic Health Record Technology requirements. The guidance provided here will be considered in future updates to C-CDA and the Companion Guide.

For **guidance pertaining to document sharing**, this document complements the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework, specifically the XCA Query [ITI-38] and XCA Retrieve [ITI-39] transactions that implement the “Pull” mechanism. Although there are other ways of sharing C-CDA content besides Pull (Push, Subscriptions, Direct, FHIR), these sharing mechanisms are out of scope in this version.

See section 1.3.1 for detailed references and links.

## 1.2 Audience

The primary audience of this guide is C-CDA implementers, product development teams, and software developers. This guide provides detailed guidance for placement of clinical information in C-CDA, proper exchange using IHE Document Sharing mechanisms, and best practices for system generators and receivers. Software architects, business analysts, and policy managers can also benefit from

understanding the preferred approach of supporting Encounter Summary documents in addition to Patient Summary documents.

A note on technical detail: we provide best-practice guidance on HL7 C-CDA and IHE XDS/XCA that presumes full knowledge of these technologies. Readers should not expect this guide to provide an introduction to C-CDA or XDS/XCA, although it does try to explain some difficult concepts beyond the source material.

## 1.3 Background and Development Approach

In the fall of 2017, the independent Carequality and CommonWell Content Work Groups were each attempting to solve a set of similar issues: unacceptably large Consolidated Clinical Document Architecture (C-CDA) documents, an absence of clinical notes in exchanged documents, support for encounter summary documents, and the need for document version management. Participants from both content work groups approached the Directors of Carequality and CommonWell to consider a single joint effort to tackle these common issues. The Joint Document Content Work Group launched in January 2018. Participants in the Joint Document Content Work Group included clinicians, vendor representatives and participants involved in standards development.

**The principles of the Joint Document Content Work Group were as follows:**

1. Maintain an initiative agnostic perspective
2. The product of the work group should be a best practices document
  1. Exact format to be determined
  2. Carequality and CommonWell may reference document or incorporate into their material
  3. All final material will have joint branding or none
3. Development will occur in a single content work group
4. Initiatives will independently review and approve guidance
5. Any guidance developed may be transitioned over to HL7 for balloting and maintenance

**The Joint Document Content Work Group set clinical and technical priorities in the first call as follows:**

### ***Clinical***

1. Require Encounter-specific document support
  1. Outpatient/Ambulatory Summary (Progress Note Document) with defined sections
  2. Inpatient/Hospital Summary (Discharge Summary Document) with defined sections
2. Determine most frequently used Clinical Note types<sup>2</sup> - develop examples for each to include in encounter-specific documents
3. Develop guidance on Note placement within documents for generator and consumer
4. Require Patient Summary
  1. Define patient-level (not encounter-specific) sections to always include

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<sup>2</sup> With support from our Argonaut colleagues!

## 2. Future – Define default time ranges for each section

### **Technical**

#### 1. Develop guidance for document versioning

Prior to the launch of the Joint Document Content Work Group, each individual content work group discussed tackling the size of exchanged CCDs by discussing appropriate content restriction by section. It became clear that even improved filtering of a single patient CCD wouldn't solve the information overload for clinicians reviewing documents that could sometimes be over 1,000 pages in length.

The group focused on the importance of providing focused information to the clinician at the time they need it. The group identified encounter-specific document support, including clinical notes, as the top priority. Members felt that the information provided by clinical notes would provide critical supplemental context to the discrete data they were currently getting in Patient Summary CCD documents. They also felt that these notes should not be added to the already long Patient Summary CCD documents they were receiving.

After the Joint Document Content Work Group finalized priorities, weekly calls were scheduled to develop and review design approaches. Decisions were made through discussion and consensus without the implementation of formal voting.

**In its second iteration (for the 2.0 version of the document)**, the Work Group established and prioritized a backlog of new work items, and continued with the same process as before. As items were explored, some were combined and new issues came to light. Key items targeted for this version were:

1. Provide guidance for dynamic generation of documents
2. Provide guidance for sharing laboratory tests throughout the lab order-to-result lifecycle
3. Provide guidance for sharing interoperable laboratory codes, starting with COVID-19
4. Provide guidance for sharing encounters throughout the encounter lifecycle
5. Provide guidance for document versioning
6. Provide guidance for populating Patient Summaries with and without requested date ranges
7. Provide guidance for data provenance<sup>3</sup>
8. Address various pain points

### **1.3.1 Sources and Process**

The Joint Document Content Work Group considered the C-CDA R2.1, C-CDA Companion Guide, and relevant IHE profiles as the baseline for all discussions. As a guiding principle, the Joint Document Content Work Group focused on providing complementary, not conflicting guidance.

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<sup>3</sup> The HL7 Basic Provenance guide had not been balloted in time to incorporate into this guide. Readers may access it [here](#). In addition, the [Sequoia Data Usability Workgroup](#) is addressing provenance.

#### Referenced standards or guides pertaining to document content:

- Health Level Seven (HL7) CDA® R2 IG: C-CDA Templates for Clinical Notes STU [Release 2.1](#)
- HL7 CDA R2 IG: C-CDA Templates for Clinical Notes R1 Companion Guide, [Release 1](#), [Release 2](#) and Release 3 (ballot version only)
- ONC U.S. Core Data for Interoperability [USCDI V1](#) and [USCDI V2](#)

#### Referenced standards or guides pertaining to document sharing:

*Note that these references (and links in this guide) go to the latest versions, as they incorporate errata. However, production exchanges typically depend on fixed versions. Consult the production exchange for the exact versions required.*

- Integrating the Healthcare Enterprise (IHE) IHE IT Infrastructure (ITI) Technical Framework, [Revision 18.0, July 30, 2021 – Final Text](#)
  - [IHE XCA Query: ITI-38](#)
  - [IHE XCA Retrieve: ITI-39](#)
  - Including the following IHE ITI options:
  - [IHE XDS.b Delayed Document Assembly Option](#). This guide extends it for use by IHE XCA as well.
  - [IHE XCA On-Demand Documents Option](#), as defined in IHE XDS.b and XCA.
  - [IHE XCA Deferred Response Option](#), as defined in IHE XDS.b and XCA.

While this guide is complementary to these external guides and standards, it does not actually require them. Organizations or exchanges adopting this guide will need to require them explicitly.

Release 2 of the C-CDA Companion Guide began to incorporate material from earlier versions of this guide. In this version, we have factored out that common content and added references.

Starting in January 2018, the Joint Document Content Work Group met weekly to develop solutions to the identified priorities. The presentations from each week reside in a shared [Google drive folder, resulting in the 1.0 and 1.1 versions of this guide. In February 2020, the group reconvened to create the 2.0 version of the guide. Its materials are available in a different shared Google drive folder.](#)

## 1.4 How to read this guide

This guide is organized into the following sections:

- **1 Introduction** (this section)
- **2 General Guidance** This section explains the major concepts in this guide, including the overall view of a patient consisting of a Patient Summary and a set of Encounter Summaries, IHE document sharing, dynamic generation, and interoperable lab results.
- **3 Encounter Summary Documents** This section provides details on how and when to generate encounter summaries.
- **4 Patient Summary Documents** This section provides details on how and when to generate patient summaries.

- **Appendices** Additional education material, future work.

### 1.4.1 Smart Senders and Resilient Receivers

Successful document exchange relies on layers of rules from CDA document specifications, C-CDA 2.1 specification, and the C-CDA 2.1 Companion Guide. Despite every effort by implementers, and the HL7 community, to document all the important topics for successful exchange, the Joint Document Content Work Group discussed many other areas that would benefit from additional guidance.

Occasionally you will see a callout like this:

**Resilient Receivers:** Of the above attributes, class code is usually the most stable – in other words, a system may have CCDs available that all have the CCD class code but are from different C-CDA versions, i.e. format codes. To avoid missing documents, Requesting Systems SHOULD limit query filtering of this type to class code or none at all, unless the responding system’s use of codes is well understood. Client-side filtering can still be performed of the returned document entries.

The **Smart Senders** and **Resilient Receivers** sections and callouts are not an exhaustive list of best practices, but instead are a list of the best practices that captured the group’s attention. Other topics that would benefit from additional guidance are listed in the future work appendix.

Note that we are using the term “Sender” to mean the sender of CDA documents, and “Receiver” as the receiver of them. In a “Pull” mechanism, the Receiver is the initiating/requesting/consuming system and the Sender is the responding/generating/returning system.

## 2 General Guidance

This section addresses overall issues, pain points and best practices.

### 2.1 Moving from just CCDs to a well-factored clinical view of a patient

With the advent of ONC Certified Electronic Health Record Technology (CEHRT) and the CMS EHR Meaningful Use Program came an increase in the adoption of CDA documents. First, in the form of the HITSP C32 and in later stages, the HL7 Consolidated-CDA (C-CDA). Each new CEHRT rule and C-CDA version added additional data requirements. In the ONC certification rule, the 2015 Edition Health IT Certification Criteria, the requirement to support the Common Clinical Dataset (CCDS) again increased the amount of data reported in these documents, much of it in codified form. While this has been a positive development it has also had some unintended side effects.

In the 2014 and 2015 Editions of the ONC Certification Criteria, patient health summary requirements primarily referenced the CCD (Continuity of Care Document) template within the HL7 C-CDA standard. As data requirements have increased, **many vendors have taken to creating only CCDs and including as much information as possible**. This has led to the issue of unnecessarily large CCDs that may span dozens of pages, which include information of limited value to the document recipient, and which most providers do not have the time to review. This was a driving force behind the efforts of this workgroup to improve the quality and focus of data being included.

*Pain Point: I don't want to receive one document type (CCD) for all clinical situations, when more specific types are available.*

*Pain Point: I don't want to receive bloated documents.*

The primary mechanisms that address these pain points are:

- Express the minimum clinical view of a patient as a [Patient Summary](#) and a series of [Encounter Summaries](#).
- Employ query filtering to reduce both the size and the number of documents that are returned.

The following sections, 2.1.1 and 2.1.2, provide high level guidance for Responding and Requesting systems to accomplish this. Later sections will provide more detailed guidance.

#### 2.1.1 Providing Patient and Encounter Summary Documents

*The Joint Document Content Work Group decided that in order for Responding systems to provide a complete picture of a patient's history, they SHALL provide access to, at a minimum, one Encounter Summary Document for each available*

*encounter and a current Patient Summary Document, if they have control over the documents they generate and/or return.*

Encounter Summary Documents provide information about the patient used or generated during an encounter, complementing the existing [Patient Summary](#) document exchanged by systems today. This guide defines document types for Outpatient/Ambulatory encounters and Inpatient/Hospital encounters. Patient Summary Documents provide the current information about a patient.

The meaning of "one Encounter Summary Document for each available encounter" is fully specified in Section 3, Encounter Summary Documents. The meaning of "a current Patient Summary Document" is fully specified in Section 4, Patient Summary Documents.

To help understand this decision, the Joint Document Content Work Group considered the following scenario:

1. A clinician requests a patient's historical visits from 9/1/2017-12/1/2017.
2. The patient had 3 visits during this time, so the system returns 3 individual Encounter Summary Documents.
3. Each Encounter Summary Document includes the information (e.g. Medication List) at the conclusion of that encounter.

Responding systems MAY share other document types as needed. This guide does not further specify nor constrain them.

This guide assumes an IHE XDS document sharing "Pull" environment using the XCA profile to query and retrieve documents. Responding systems **SHALL** support the FindDocuments query and all its parameters (Note: this is already required by the IHE specifications).

## 2.1.2 Requesting Patient and Encounter Summary Documents

As Responding systems adopt this guidance, Requesting systems will be able to find these documents in queries. Below is a minimal XCA document query request that should return all available document entries for a patient: at least one patient summary and one encounter summary for each known encounter. It may find additional historical documents as well. The requester may then selectively choose which documents to retrieve. See section 2.6.1, Document Exchange Workflow Guidance.

The aspects of approved/deprecated and On-Demand are needed even for a simple query; they will be covered later in section 2.



```
<s:Envelope xmlns:s="http://www.w3.org/2003/05/soap-envelope"
  xmlns:a="http://www.w3.org/2005/08/addressing">
  <s:Header>
    <a:Action s:mustUnderstand="1">urn:ihe:iti:2007:CrossGatewayQuery</a:Action>
    ...
  </s:Header>
  <s:Body>
    <!-- The AdhocQueryRequest supports multiple kinds of queries specified by UUID -->
    <query:AdhocQueryRequest
      xmlns:query="urn:oasis:names:tc:ebxml-regrep:xsd:query:3.0"
      xmlns:rim="urn:oasis:names:tc:ebxml-regrep:xsd:rim:3.0"
      xmlns:rs="urn:oasis:names:tc:ebxml-regrep:xsd:rs:3.0">
      <query:ResponseOption returnType="true" returnClass="LeafClass"/>

      <!-- This constant UUID is for the FindDocuments query, a filter-based search -->
      <rim:AdhocQuery id="urn:uuid:14d4debf-8f97-4251-9a74-a90016b0af0d">

        <!-- This matches documents for one patient -->
        <rim:Slot name="$XSDDocumentEntryPatientId">
          <rim:ValueList>
            <rim:Value>'st3498702^^&1.3.6.1.4.1.21367.2005.3.7&ISO'</rim:Value>
          </rim:ValueList>
        </rim:Slot>

        <!-- This matches documents approved for clinical use (not deprecated) -->
        <rim:Slot name="$XSDDocumentEntryStatus">
          <rim:ValueList>
            <rim:Value>('urn:oasis:names:tc:ebxml-regrep:ResponseStatusType:Approved')</rim:Value>
          </rim:ValueList>
        </rim:Slot>

        <!-- This matches documents of either Stable or On-Demand type (multiple values in
        slot = OR) -->
        <rim:Slot name="$XSDDocumentEntryType">
          <rim:ValueList>
            <!-- Stable document entries -->
            <rim:Value>('urn:uuid:7edca82f-054d-47f2-a032-9b2a5b5186c1')</rim:Value>
            <!-- On-demand document entries -->
            <rim:Value>('urn:uuid:34268e47-fdf5-41a6-ba33-82133c465248')</rim:Value>
          </rim:ValueList>
        </rim:Slot>

      </rim:AdhocQuery>
    </query:AdhocQueryRequest>
  </s:Body>
</s:Envelope>
```

Figure 1 – A simple IHE XCA Query request, annotated

There are additional query parameters which serve to reduce the set of available documents returned. This guide does not require any particular combination of parameters; requesting systems MAY choose which parameters they will support. More comprehensive guidance on query filtering is given in section 2.6.3.

## 2.2 CDA Document Content Guidance

### 2.2.1 Smart Senders: Maintain proper references between coded values and narrative

Narrative text linking is extremely important for processing and validating CDA documents that include machine-processable entries. The narrative text linkages are the mechanism that associate human-

readable information in the narrative text of each section to the entries carrying that information for machine processing. Without proper narrative text linking, it is impossible to accurately validate if the machine-readable entries and the human-readable representation of that information accurately reflect the same semantic meaning.

Resources for more information:

- [How to create narrative text linking in sections that contain machine-processable entries.](#)
- HL7 C-CDA Companion Guide sections 5.1.1 and 5.1.2.
- See narrative reference examples in the [HL7 CDA Examples repository](#). Search on “narrative”.

## 2.2.2 Smart Senders: Maintain act/observation IDs across documents

Many entries in C-CDA require an identifier<sup>4</sup> (ID) on every entry. Maintaining consistent IDs enables receivers who machine-process the documents to de-duplicate the information and accurately identify data that has been previously reported.

The C-CDA Companion Guide recommends using consistent identifiers; this guide requires them. For any entry where an ID is required, systems **SHALL** maintain consistent IDs whether sending the entry in an Encounter Summary Document, a Patient Summary document or any other CDA document types.

When senders don't maintain consistent identifiers, the following example issues may occur:

- The receiving system may not be able to identify a single Allergy sent in both the Patient Summary and Encounter Summary and may present duplicate information to a user.
- Updates to a previously-retrieved entry, such as a retracted lab result, may be listed as two distinct lab results.
- Duplicate or conflicting information may be perceived by clinical users as a failure of the interoperability ecosystem.

When entry IDs are consistently maintained, the receivers who machine-process the data will be more successful and accurate in parsing, de-duplicating, and updating external data; and the clinical user acting on the external information will be more efficient and confident in their workflows.

As a reminder, the HL7 V3 II data type requires these identifiers to be globally unique.

```
<act classCode="ACT" moodCode="EVN">  
  <id root="36e3e930-7b14-11db-9fe1-0800200c9a66"/>  
  ...
```

*Figure 2 – Example id root only*

```
<observation classCode="OBS" moodCode="EVN">  
  <templateId root="2.16.840.1.113883.10.20.22.4.7" extension="2014-06-09" />  
  <id root="2.16.840.1.113883.5555.34567.12" extension="4398764"/>  
  ...
```

*Figure 3 – Example id root + extension*

## 2.2.3 Smart Senders: Reconciliation flag

Sending systems may indicate that a particular list was reconciled prior to sending, as specified by the [IHE PCC RECON Supplement](#). The Reconciliation Act Entry Content Module (1.3.6.1.4.1.19376.1.5.3.1.1.24.3.1) provides the structure to indicate the information in a section has

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<sup>4</sup>C-CDA R2.1 Companion Guide 5.1.4 Use of Consistent Identifiers

been reconciled. Systems SHOULD consider including this act, or a similar indicator, to explicitly state a list has been reconciled, but only if the system is confident a user reconciled the list. This SHOULD NOT be included if a clinician simply reviewed the list and did not reconcile it.

## 2.2.4 Support for USCDI

In 2021, the ONC released the latest [U.S. Core Data for Interoperability \(USCDI V2\)](#), following [USCDI V1](#), which had been released in 2020.

When sharing a newly generated document, Responding systems SHALL support data classes defined in [USCDI V1](#), as required by each document type specification and constrained by this guide, and according to the USCDI V1 definitions for the data, with the following exception: if a requirement in the [USCDI current published version](#) conflicts with USCDI V1, Responding systems MAY conform to the newer requirement.

When sharing a newly generated document, Responding systems SHOULD endeavor to support the [USCDI current published version](#).

Clinical Notes and Provenance are two data elements identified in the USCDI since V1 for immediate inclusion in exchanged documents beyond the required CCDS data elements. These are valuable data elements and should be exchanged to improve patient care. However, participants in the Joint Work Group are concerned systems will dump Clinical Notes in their existing Patient Summary documents making them even larger.

Instead, the Joint Document Content Work Group believes Clinical Notes will serve the clinician best by providing them in the context of the encounter where they were created. When systems add support for Clinical Notes they SHOULD also add support for Encounter Summary documents, and SHOULD include relevant notes to the encounter only inside those documents (i.e. not in Patient Summaries). This guidance is expanded in the document-type-specific sections of this guide.

## 2.2.5 No Information

When sharing a newly generated document, if no information is included for a required section, Responding systems **SHALL** include a 'No information'<sup>5</sup> assertion.

## 2.2.6 Section Time Range Observation

In current exchanges, sending systems include varying amount of information in sections. For example, one sender might include immunizations for the current encounter, while another might include all immunizations on record for the patient. When an end-user reviews a section they may not know what portion of the available data the sender included. HL7 introduced a new observation, the Section Time

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<sup>5</sup>HL7 example for sending '[No Information](#)'. See also the C-CDA Companion Guide section 5.1.6.

Range Observation<sup>6</sup>, to communicate what is included in a section. It was balloted with the C-CDA Companion Guide and is available for use in any existing C-CDA section.

The purpose statement from the Companion Guide: This observation represents the date and time range of the information contained in a section. It is an optional entry and may be used in any section.

The Joint Document Content Work Group recommends all sections include this observation and corresponding text. The text should be included underneath the section header and state either:

- The section includes all information for this encounter
- Or, the section includes information corresponding to a time range with a low and a high value

[-] Procedures for the Encounter					
This section includes all Surgical Procedures and Surgical Procedure Notes associated to the Encounter.					
<b>Surgical Procedures</b>					
This section includes all Surgical Procedures associated to the Encounter.					
Date/Time	Procedure Type	Procedure Qualifiers	Procedure	Provider	Source
Sep 20, 2017	SIMPLE REPAIR OF SUPERFICIAL WOUNDS OF FACE, EARS, EYELIDS, NOSE, LIPS AND/OR MUCOUS MEMBRANES; 2.5 CM OR LESS		RHINOPLASTY (Non-OR)	SULLIVAN,DANIELLE H	CHEYENNE VAMC

*Figure 4 – Sample display of Section Time Range*

<sup>6</sup> C-CDA R2.1 Companion Guide Section Time Range Observation (2.16.840.1.113883.10.20.22.4.201:2016-06-01)

```
<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.7" extension="2014-06-09"/>
  <!-- Procedures section template -->
  <code code="47519-4" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC" displayName="PROCEDURES" />
  <title>Procedures for the Encounter</title>
  <text><!-- This system translated the Section Time Range Observation into text -->
    <paragraph ID="TS_Narrative0">
      The section includes all Surgical Procedures and Surgical Procedure Notes Associated to the
      encounter</paragraph>
    ...
  </text>

  <entry typeCode="DRIV">
    <!-- C-CDA Procedure Activity Procedure entry -->
    <procedure classCode="PROC" moodCode="EVN">
      <templateId extension="2014-06-09" root="2.16.840.1.113883.10.20.22.4.14"/>
      <code code="12011" codeSystem="2.16.840.1.113883.6.12" codeSystemName="CPT-4"
        displayName="SIMPLE REPAIR OF SUPERFICIAL WOUNDS OF FACE, EARS, EYELIDS, NOSE, LIPS
        AND/OR MUCOUS MEMBRANES; 2.5 CM OR LESS">
      ...
    </procedure>
  </entry>

  <entry typeCode="DRIV">
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.201" extension="2016-06-01"/>
      <code code="82607-3" codeSystem="2.16.840.1.113883.6.1"
        displayName="Section Date and Time Range"/>
      <text>
        <reference value="#TS_Narrative0"/>
      </text>
      <statusCode code="completed"/>
      <value xsi:type="IVL_TS">
        <low value="20170920"/>
        <high value="20170920"/>
      </value>
    </observation>
  </entry>
</section>
```

Figure 5 – Example of Section Time Range Observation

## 2.3 Dynamic Generation of Documents (aka On Demand)

There is a great deal of confusion around the term “On-Demand”. Some implementers use the term to refer to the IHE On-Demand mechanism, but others use it to refer to any content that is generated dynamically at the time of query or retrieve. This section is intended to clarify and provide guidance for all such mechanisms, so they may be chosen intelligently. Later sections provide guidance pertaining to specific document types. For clarity, we will use the term “**dynamic**” in this guide to refer to any content that is generated in response to a request. The IHE On-Demand mechanism is one example of this.

Part of the confusion around dynamic documents is that they touch upon many underlying document sharing mechanisms, so we will walk through those first.

### 2.3.1 Basic IHE document sharing

IHE document sharing (described in detail [here](#)) consists of a family of profiles that enable sharing documents and their metadata. This guide references the following:

- XDS, historically called XDS.b. This enables sharing documents in a well-controlled domain, referred to as an “affinity domain”. XDS establishes all the basic mechanisms: document metadata, error reporting, and “Pull” messages for querying and retrieving documents.
- XCA, which leverages XDS to share documents in a “Pull” fashion between different “communities”. XCA is used by both Carequality and CommonWell as the basis for document exchange.

The first key to understanding dynamic generation is understanding **documents** and **document entries**, because all of the complexity has to do with when and how these are created.

- **Document:** A clinical document, related to a single patient. Usually a structured CDA variant, but IHE supports any kind of document.
- **Stable Document Entry:** Information (called metadata) about a single document, for example: the date the document was created, the author, and where the document is stored. For CDAs, this information mostly corresponds to data in the CDA header.
  - An entry has status of Approved (for clinical exchange) or Deprecated.
  - An entry can be stable or on-demand; on-demand will be explained later.

The XCA document sharing **workflow** starts after the requesting system has located a patient it wants clinical information for. It **queries** (using ITI-38) for document entries, **chooses** which documents to retrieve, then **retrieves** (using ITI-39) the documents of interest. Often there is no explicit choice – all available documents are retrieved. Note that in most cases, only Approved status is queried – this allows the Requesting System to avoid the clutter of deprecated documents.

ITI-38, Cross Gateway Query, has multiple kinds of queries for different kinds of metadata. The primary query used is FindDocuments, which supports a handful of filters and returns matching document entries for a patient.

In the simplest case for the responding system, nothing is dynamic. The document is created first, then the entry to describe it. This can be based on a trigger in an EHR, for example, completing an encounter, or based on user action. Here is the state in the responding system at the time of query:



Figure 6 IHE XDS Document entry and CDA document

The key thing to notice is that the document entry includes the size and hash of the document.

Note that the responding system could dynamically create both the document and its entry at the time of the query. Because this doesn't appear any different to the requester, this case is not explored further.

### 2.3.2 Capability: Document Update Sharing

Requesting systems MAY support the Document Update Sharing capability, as specified in this section. Note that while lack of support will not prevent accessing all available documents, it will prevent discovering how documents relate.

Responding systems that dynamically generate documents SHALL support the Document Update Sharing capability, as specified in this section.

*Pain Point: When I discover an updated document, sometimes I need to know how it relates to prior versions, ideally without having to retrieve the documents.*

There are many situations where a document may be updated. For example, receiving a pending lab result or a missing note may trigger an update. The base CDA standard provides a mechanism to replace or append a previous document through the `parentDocument` relationship. The [HL7 C-CDA R2.1 Companion Guide](#) describes this scenario, with examples, in the section: 2.8 Options for Temporarily Unavailable Data.

The document update capability as defined in this section adds to the CDA relationship described above. It consists of the following:

- **A relationship conveyed in the new CDA document's header** that references the prior document. This can be a full replacement of the document or an appendix to it. The `setId` and `versionNumber` elements are not necessary to convey an update, but may be used to convey explicit version numbering.
- **A relationship conveyed in XDS metadata**, where if the update is a replacement the replaced



document entry is marked deprecated, and an association links the document entries of the original and the update.

Document updates use a specific kind of XDS metadata called **associations** that relate other metadata objects. In XCA, support for associations is **optional**. This guide focuses on associations between document entries, for example, where one document replaces another:

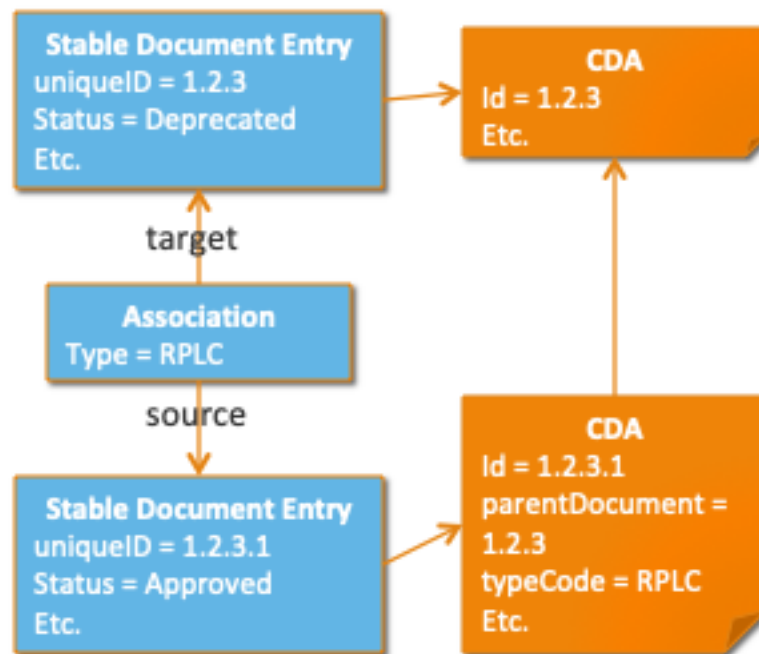


Figure 7 Document Replacement in XDS and CDA

The replaced document entry is marked as **deprecated**.

**Resilient Receivers:** In IHE XCA, association objects are not required to be supported by Responding Gateways (**although this section requires them**). However, Responders that do not support associations typically **will at least reflect replacement by deprecating prior versions** of document entries. Resilient receivers that limit their usual queries to Approved availability status will only see the latest document entries, not prior versions.

Also, note that the replacement association can be discovered in two ways:

- In an association metadata object which may be obtained without retrieving, through other ITI-38 queries: GetAll, GetAssociations, GetDocumentsAndAssociations, and GetRelatedDocuments.
- In the header of the replacement CDA document, which may be examined once the document is retrieved.

To address the pain point, the group decided to **require both of these forms of expressing the**

**relationship.**

Anecdotally, the workgroup learned that replacement is far preferable to appending:

- Few systems reported that they support appending.
- Discussions in the Structured Documents Workgroup and its Implementation-A-Thons revealed much confusion about the right way to structure and version an appending document.
- Understanding an appendix requires the receiver to know about both documents, and this may be difficult to ensure, given the plethora of ways to discover documents (querying, direct push, etc.).

Responding systems that support Document Update Sharing SHALL support document replacement:

- When replacing a document, in the header of the new document, the Responder SHALL populate the relatedDocument element with a typeCode of “RPLC” and identify the prior document id.
- When replacing a document, in the XDS metadata, the Responder SHALL change the AvailabilityStatus attribute of the prior document entry to Deprecated.
- When replacing a document, in the XDS metadata, the Responder SHALL share a “replace” association as defined in [IHE ITI TF-3: 4.2.2.2.3](#).

Responding systems that support Document Update Sharing MAY support document appending:

- When appending a document, in the header of the new document, the Responder SHALL populate the relatedDocument element with a typeCode of “APND” and identify the prior document id.
- When appending a document, in the XDS metadata, the Responder SHALL share an “append” association as defined in [IHE ITI TF-3: 4.2.2.2.1](#).

Responding systems that support Document Update Sharing SHALL support ITI-38 queries as follows:

- The Responder SHALL implement the related XDS queries: GetAll, GetAssociations, GetDocumentsAndAssociations, and GetRelatedDocuments, returning association and document objects.
- The Responder MAY support returning Submission Set and Folder objects in the GetAll query.

### 2.3.2.1 Capability: Stable Document Update Detection

Responding systems that support Document Update Sharing and generate documents dynamically SHOULD support the Stable Document Update Detection capability, as specified in this section.<sup>7</sup>

---

<sup>7</sup> [IHE ITI TF] Vol 1 Section 10.4.11.3, Case 1, says “If errors need to be corrected or updates are needed, they are the responsibility of the source.” Besides IHE, implementers may have legal medical record requirements to make corrections available. This capability handles that responsibility by simple document replacement.

*Pain Point: I need to know if the content of a document has changed.*

*Pain Point: If the content of a document has not changed, I don't want to receive a brand new document if I request it again.*

*Pain Point: I don't want to have to retrieve a document to know whether it's changed.*

With this capability, **requesters can see that updates are available without needing to retrieve the document.**

Each time a Responding system that supports Stable Document Update Detection generates a document that uses this capability, it SHALL track the underlying content for future changes.

If and only if the underlying content of a tracked document changes, if there is an Approved stable document entry corresponding to the previously generated document (i.e. containing its hash and size), the Responding system SHALL replace that document entry with a new one.

This capability MAY be constrained by:

- Establishing what kinds of changes must result in a new version of the document.
- Establishing limits on how long a Responding system must continue tracking updates to a given document.

### 2.3.3 Capability: Delayed Document Assembly Option

Requesting systems MAY support the Delayed Document Assembly Option, as specified in this section. Note that unless requesters intend to check and validate hash and size, use of this option by responders is invisible to requesters.

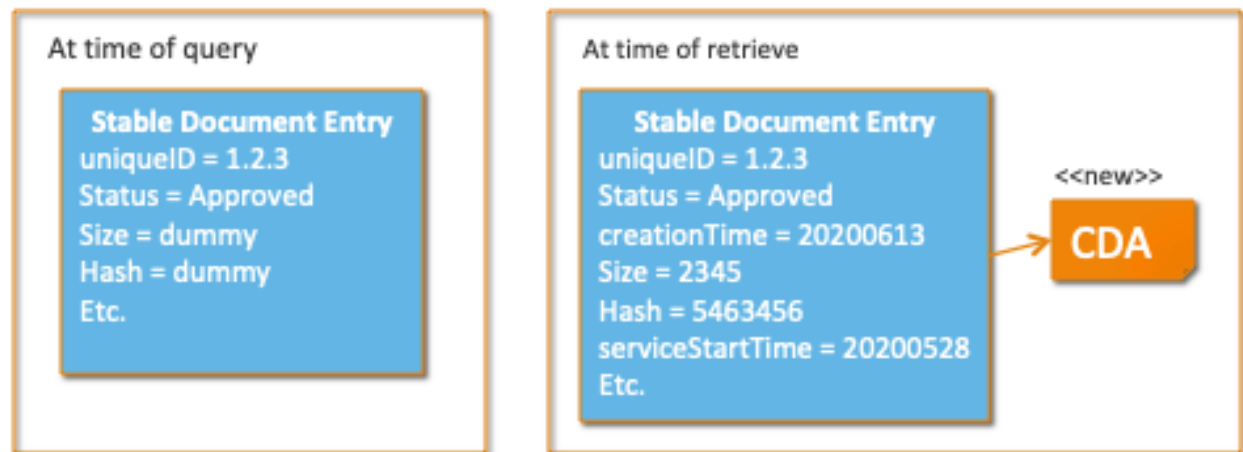
Responding systems MAY support the Delayed Document Assembly Option, as specified in this section. Note: there are more specific requirements to support this elsewhere in this guide.

*Pain Point: I don't want to generate a document unless and until it's requested.*

The [Delayed Document Assembly](#) (DDA) Option is a simple dynamic mechanism: it allows the responder to “lazily” generate the document only if and when it is retrieved.

- At document query, return a stable document entry with size = 0 and hash of a zero length file.
- At document retrieve, generate the document, return it, and update the document entry to reflect the actual size and hash.
- For the most part, this difference is unimportant to the requester. The only exception is if the requester wishes to validate the size and hash. They would just have to re-query for the stable

entry after retrieving.



*Figure 8 Delayed Document Assembly in Practice*

The Delayed Document Assembly Option is defined in this guide as follows:

- The option as defined by the IHE ITI Technical Framework on the XDS.b profile, extended to the XCA profile.<sup>8</sup>
- This option does not require any grouping with XDS.b actors.

Responding systems that support the Delayed Document Assembly Option SHALL:<sup>9</sup>

- Initially set creationTime to the time the document entry was created, or to the time the clinical information was “frozen”.
- Update creationTime with the time of document generation, when updating size and hash.

#### 2.3.3.1 Capability: Delayed Document Assembly with Update Detection<sup>10</sup>

Responding systems that support the Delayed Document Assembly Option SHOULD support the Update Detection capability as specified in this section.

Responding systems that support Delayed Document Assembly with Update Detection SHALL support the Document Update Sharing capability as specified in section 2.3.2.

Responding systems that support Delayed Document Assembly with Update Detection SHALL support the Stable Document Update Detection capability as specified in section 2.3.2.1, constrained as follows:

<sup>8</sup> We have opened Change Proposal [CP-ITI-1271](#) with IHE ITI to add this to XCA.

<sup>9</sup> The Delayed Document Assembly Option in IHE is unclear on the use and meaning of the required creationTime attribute. We have opened Change Proposal [CP-ITI-1272](#) with IHE ITI to clarify this, and the requirement above is our current interpretation.

<sup>10</sup> We have opened a [Change Proposal](#) with IHE to clarify update behavior for DDA.

- When replacing a document entry due to a change in the underlying content of a tracked document, the new document entry MAY utilize Delayed Document Assembly.

Note: The above requirement allows the Responder to return the same new stable document entry in subsequent queries even if content is still changing, as long as the document has not yet been generated.

### 2.3.4 Capability: On-Demand Option

Requesting systems SHALL support the On-Demand Option, as specified in this section. This is needed to prevent loss of information, because On-demand entries are not returned in queries unless asked for. Note that Carequality requires support already.

A requesting system that supports the On-Demand Option SHALL request both On-Demand and Stable document entries (see example in section 2.1.2), unless it is exercising a use case that requires targeted query of only On-Demand or Stable.

Responding systems MAY support the On-Demand Option, as specified in this section. Note: there are more specific requirements to support this elsewhere in this guide.

*Pain Point: I don't want to generate a document unless and until it's requested.*

The [On-Demand Option](#) is a dynamic mechanism addressing the same pain point as Delayed Document Assembly, in that a document isn't created until it is retrieved. What makes On-Demand different is that it introduces the **On-Demand document entry**, which represents the potential document separately from each generated document. In its most basic form, the On-Demand entry is simply a handle that retrieves the latest content. This makes the mechanism a good match for content that is expected to change often, like a current Patient Summary.

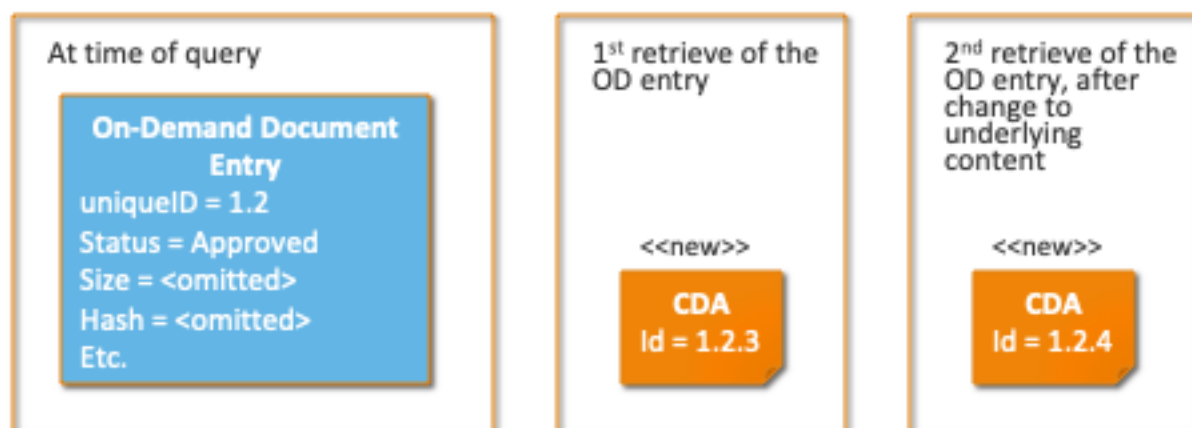


Figure 9 On-Demand Basic Functionality

#### 2.3.4.1 Persistence of Retrieved Documents Option

With the **Persistence of Retrieved Documents Option** (which is required by the Carequality QBDE IG), its behavior gets more complex. This requires generation of a new stable document entry every time a new version of the on-demand document is generated. This is in addition to the on-demand document entry.

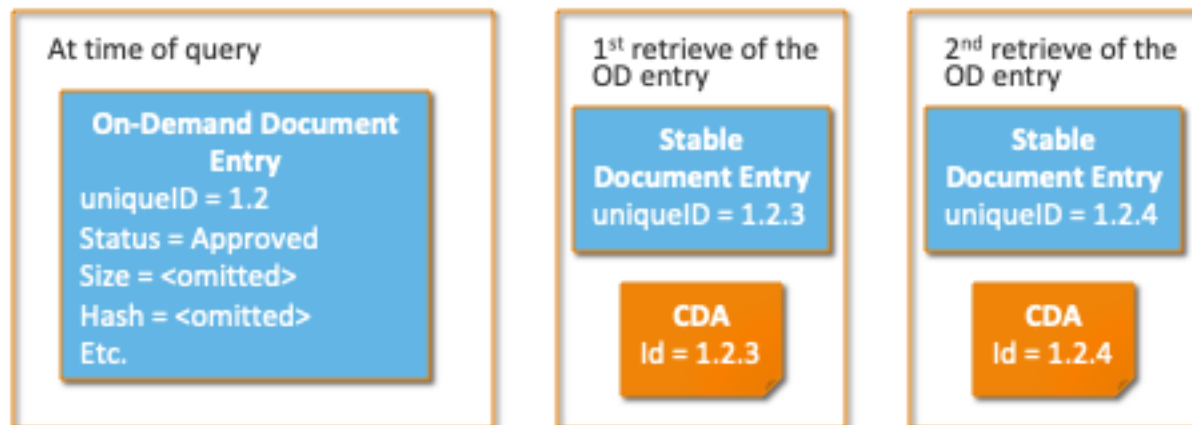


Figure 10 On-Demand with Persistence of Retrieved Documents

Responding systems that support the On-Demand Option with Persistence of Retrieved Documents MAY return the same document in a subsequent retrieve if none of the underlying information has changed, and if doing so, SHALL return the same NewDocumentUniqueid as the prior retrieve.

The On-Demand option can be used with document replacement in the following ways:

- An on-demand entry may itself be replaced if needed. This is more of an edge case.
- With the Persistence of Retrieved Documents option, the newly generated stable document entry MAY replace the prior stable entry. See IHE ITI TF-1: [Figure 18.3.3-2](#): Dynamically created content with persistence.

This guide strengthens the above requirement as follows, in order to reduce clutter of generated documents.

When a Responding system that supports the On-Demand Option with Persistence of Retrieved Documents is generating a new stable document entry, and it had previously generated a prior stable document entry:

- It SHALL mark the prior entry as deprecated.
- If it supports associations, it SHALL create a Replace association between the new and prior stable entry.

If associations are supported by the Responding system, the following figure shows how these stable entries are related, in snapshot associations to the On-Demand entry they were generated from, and in replacement associations to each other:

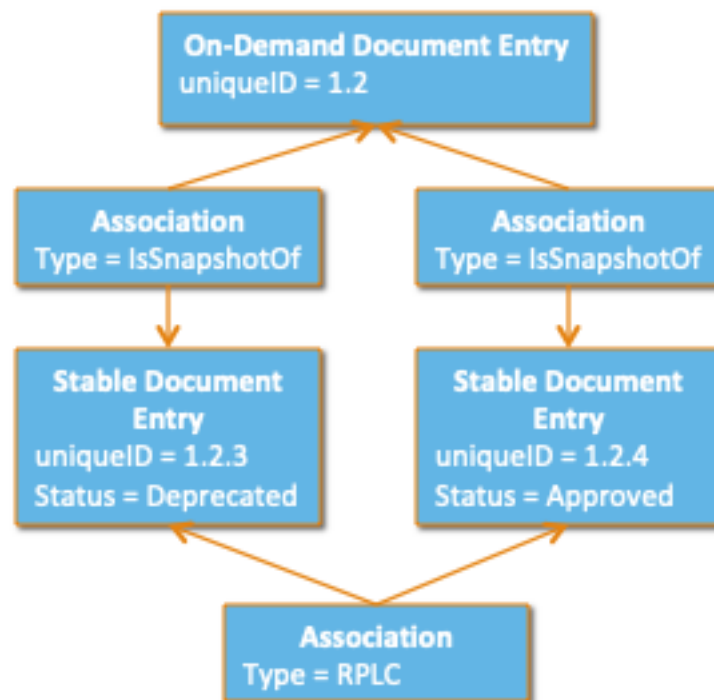


Figure 11 On-Demand with Persistence and Association Support

#### 2.3.4.2 Capability: On-Demand with Update Detection

Responding systems that support the On-Demand Option MAY support the Update Detection capability as specified in this section.

*Pain Point: I need to know if the content of a document has changed.*

*Pain Point: If the content of a document has not changed, I don't want to receive a brand new document if I request it again.*

With this capability, **requesters must retrieve the document to see that it has been updated.**

Each time a Responding system that supports On-Demand with Update Detection generates a document that uses this capability, it SHALL track the underlying content for future changes.

When responding to an XCA Retrieve for the On-Demand entry of a tracked document, if and only if the underlying content has changed, the Responder SHALL return a new NewDocumentUniqueid and document. If the Responding system supports Persistence of Retrieved Documents, it SHALL replace the previous document as well.

This capability MAY be constrained by:

- Establishing what kinds of changes must result in a new version of the document.
- Establishing limits on how long a Responding system must continue tracking updates to a given document.

#### 2.3.4.3 Capability: On-Demand and Delayed Document Assembly with Update Detection<sup>11</sup>

This capability is defined as combining the On-Demand Option (section 2.3.4) with Delayed Document Assembly with Update Detection (section 2.3.3.1).

This combines the benefits of On-Demand, in that there is a persistent handle to the latest content that won't be generated until retrieve, and the benefits of DDA with Update Detection, in that requesters can see that updates are available without needing to retrieve.

### 2.3.5 Capability: XCA Deferred Response Option

Requesting systems MAY support the XCA Deferred Response Option, as specified in this section.

Responding systems MAY support the XCA Deferred Response Option, as specified in this section.

The [XCA Deferred Response Option](#) is a dynamic mechanism that allows responders to take significant time generating document entries or documents, when synchronous transactions would otherwise time out. There are two main use cases:

- A responding system with many clinical documents in paper form or some other format that can't be quickly converted to standard electronic formats - no reason to proactively scan & register unless asked.
- A responding system that often times out when dynamically generating content.

There are other asynchronous mechanisms available in IHE XCA: the WS-Addressing-based Asynchronous and AS4 Asynchronous options. However:

- WS-Addressing-based async is not typically supported in large clinical exchanges due to inconsistent web stack implementations.
- AS4 async is a complete reworking of WS-Addressing and as such is typically deployed as the entire messaging platform.
- XCA Deferred Response allows the delay in responding to be as much as days or weeks.
- XCA Deferred Response allows applications to support recovery of the long-running request and response through system restart.

The mechanism is similar to the IHE XCPD Deferred Option, but there are key differences:

- Deferred XCPD defines a totally separate transaction: deferred request/ack, and deferred response/ack. One request, one response.

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<sup>11</sup> We have opened a [Change Proposal](#) with IHE to suggest this capability.



- Deferred XCA leverages the existing synchronous transaction for the first response, and allows multiple results through a different transaction:
  - Deferred-capable synchronous request
    - Response may include some results, and indicates whether more results coming
  - Zero or more Deferred results transactions: more results
  - Requester knows when they have received the last response.

Note: This supplement is in Trial Implementation, so it would have to be adopted explicitly by Carequality and CommonWell.

## 2.4 Mapping between XDS metadata and CDA header

*Pain Point: There are no normative requirements in Carequality or CommonWell for mapping between what is in the XDS Document Entry and the CDA header.*

*Pain Point: The existing requirements for service dates in XDS and encompassing encounter dates in CDA don't support querying for encounter documents by date range.*

This section fills in the gaps for mapping between XDS metadata and information in the CDA header. Note that stable document entries (see section 2.3.1) correspond directly to a CDA document, as opposed to On-demand entries (see section 2.3.3.1), which can generate multiple documents.

Informative: The optionality of the Document Entry attributes may be found in [IHE ITI TF Vol 3: Table 4.3.2.1-3: Responding Actor Metadata Attribute Optionality](#).

A Responding system SHALL map stable Document Entry attributes to the corresponding CDA header values, as specified in this section.

A Responding system generating a stable Document Entry before creating the document itself SHALL map its attributes based on what the CDA will contain when generated.

A Responding system SHALL map On-demand Document Entry attributes based on what the CDAs will contain when generated, as specified in this section and as constrained in section 2.4.2.

A Responding system SHALL map Document Entry attributes from fields in the CDA header as specified in the [IHE PCC Technical Framework 2016, Volume 2, section 4.1](#), except as constrained by this section.<sup>12</sup>

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<sup>12</sup> There are a few areas where these mappings are unclear or inconsistent. We have opened Change Proposals with IHE ITI and CPP to resolve, and the text in this section reflects our latest understanding of their resolutions.

The term “Affinity Domain” used in the PCC mapping is defined in the context of this guide as the production exchange that systems belong to, e.g. CommonWell. Each exchange MAY define its own rules governing the use of metadata, which MAY include harmonized value sets for coded values such as classCode and practiceSettingCode. Likewise, an individual system MAY define its own metadata rules to harmonize codes for documents it shares, as long as they are compatible with its exchange.

If a harmonized value set is defined for a metadata field, then a Responding system SHALL perform a mapping of the field to the harmonized set as specified by the production exchange.

If no harmonized value set is defined for a metadata field, then a Responding system SHALL perform a direct copy of the field.

A Responding system SHOULD map `DocumentEntry.uniqueId` to `ClinicalDocument/id` as follows:<sup>13</sup>

- If `ClinicalDocument/id` is an OID with no extension, copy directly.
- If `ClinicalDocument/id` is a UUID with no extension, URN encode, i.e. “urn:uuid:<uuid>”.
- If `ClinicalDocument/id` has an extension, encode as “root^extension”.

### 2.4.1 Mapping date values to support service date range queries

To support date range queries for documents, the date range fields in the CDA header need to be mapped to the IHE XDS service date attributes:

When hosting Patient Summary documents, responding systems **SHALL** map

- `DocumentEntry.serviceStartTime` to `ClinicalDocument/serviceEvent/effectiveTime/low`
- `DocumentEntry.serviceStopTime` to `ClinicalDocument/serviceEvent/effectiveTime/high`

Note: The above is already required by the PCC mapping referenced earlier. It is repeated here for clarity.

When hosting Encounter Summary documents, responding systems **SHALL** map<sup>14</sup>

- `DocumentEntry.serviceStartTime` to `encompassingEncounter/effectiveTime/low`
- `DocumentEntry.serviceStopTime` to `encompassingEncounter/effectiveTime/high`

Note that these mappings apply the same way whether responding systems are hosting documents that have already been created or are generating documents when the query is received.

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<sup>13</sup> We have opened Change Proposal [CP-ITI-1269](#) with IHE ITI to address this.

<sup>14</sup> We have opened a [Change Proposal](#) with IHE PCC to address this.

## 2.4.2 Special Mappings for On-Demand Entries

A Responding system that supports the On-Demand Option SHALL map On-demand Document Entry attribute values to the to-be-generated CDA header values in the same way stable entries are mapped in section 2.4, except as follows:

- `uniqueId` SHALL be specific to the On-Demand entry, not mapped to the `ClinicalDocument/id`.
- `creationTime` SHALL NOT be defined.
- `serviceStartTime` and `serviceStopTime` represent “the earliest time(`serviceStartTime`)/most recent time(`serviceStopTime`) health service was rendered for which data is available on-demand.”<sup>15</sup> These SHALL be defined only if each is known and expected to be stable across generated documents. For example:
  - If a patient summary will be generated every time with the patient’s date of birth as `effectiveTime/low` and the time of generation as `effectiveTime/high`, then the corresponding On-demand entry should only define `serviceStartTime` (the stable entries for generated documents will have `serviceStopTime` as well).
  - An On-Demand entry for an encounter summary would have the `serviceStartTime` set to the start of the encounter, and the `serviceStopTime` initially empty, then updated to the end of the encounter once it is known. Alternatively, the Responder may choose not to host an On-demand entry for the encounter until it has concluded.
  - These values could be updated in the rare case they were set incorrectly.
- `formatCode` SHALL be defined and represent the format of all generated documents from this entry. If a Responding system can generate the same content using multiple formats (for example, C-CDA 1.1 or 2.1), it SHALL NOT use a single On-demand entry for this and base generation on the queried `formatCode`; rather it SHALL use an On-Demand entry for each format supported.

## 2.5 Laboratory orders and results

Informative: This section makes use of the C-CDA Results (entries required) section, for processable results. Some C-CDA document types, e.g. Discharge Summary, do not have this section defined currently. We have brought this up to the Structured Documents Workgroup. As the C-CDA templates are open, this guidance presumes use of the Results section.

### 2.5.1 Laboratory Test Lifecycle

*Pain Point: As a requester, I want to be able to track specific labs and results through their lifecycle, from order through result, including pending results and corrections.*

<sup>15</sup> This is documented in [IHE ITI TF] Volume 3, 3.61.4.1.2, and it needs to be moved so that it is clear for XCA On-Demand implementers. We have opened a [Change Proposal](#) with IHE ITI to address this.

*Pain Point: As a responder, I want to be able to indicate that a lab result was on the wrong patient, or it's been cancelled.*

The C-CDA 2.1 Companion Guide has much useful guidance about labs, including examples, in Sections 5.2.5 Order, 5.2.17 Plan of Treatment (for pending orders), and 5.2.11 Result (for pending and completed results). Readers should start there. This guide expands on that guidance by further constraining behavior.

Note that much of this lifecycle guidance would also be appropriate for non-laboratory orders.

#### 2.5.1.1 Initial Lab Order

If a lab is ordered within an encounter, and has not been performed or its status is not known, a responding system SHALL include that lab order in the corresponding encounter summary document, in the Plan of Treatment section.

If a lab is ordered within an encounter, and has not been performed or its status is not known, a responding system SHOULD NOT include that lab order in an encounter summary document for a different encounter, in the Plan of Treatment section.

At the time a responding system generates a patient summary document, if a lab order has not been performed or its status is not known, and the effectiveTime is less than six months prior to the document creationTime, a responding system SHALL include that lab order in the patient summary document, in the Plan of Treatment section.

At the time a responding system generates a patient summary document, if a lab order has not been performed or its status is not known, and the effectiveTime is greater than six months prior to the document creationTime, a responding system SHOULD NOT include that lab order in the patient summary document, in the Plan of Treatment section.

[Example](#) of an order in the Plan of Treatment section.

#### 2.5.1.2 Lab Performed

If a lab is known to have been performed at the time of an encounter, a responding system SHALL NOT include the lab order in the Plan of Treatment section of the corresponding encounter summary document.

If a lab is known to have been performed at the time of an encounter, a responding system SHALL include it in the Results section of the corresponding encounter summary document.

If a lab is known to have been performed at the time a responding system generates a patient summary document, a responding system SHALL NOT include the original lab order in the Plan of Treatment

section of the patient summary document,.

If a lab is known to have been performed at the time a responding system generates a patient summary document, a responding system SHALL include it in the Results section of the patient summary document,.

If a lab has been performed but results are not yet available, a responding system SHALL use the following values for the lab result observation:

- statusCode code="active"
- value nullFlavor="NA"

Example of [pending results](#).

If a lab has been performed and results are available, a responding system SHALL populate results in accordance with existing C-CDA and CDA requirements, and SHALL use the following values for the lab result observation:

- statusCode code="completed"

Example of [completed lab](#).

#### 2.5.1.3 Lab Cancelled

If a lab is known to have been cancelled, a responding system SHALL use the following values for the lab result observation:

- statusCode code="cancelled"
- value nullFlavor="NA"

#### 2.5.1.4 Lab Aborted

If a lab is known to have been aborted, a responding system SHALL use the following values for the lab result observation:

- statusCode code="aborted"
- value nullFlavor="NA"

#### 2.5.1.5 Tracking Labs from Order to Results

The group was not able to create guidance on this topic. This should be addressed in a future workgroup.<sup>16</sup>

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<sup>16</sup> The C-CDA Companion Guide has some guidance in section 5.2.5 about tracking the order to the document for the service event in which the labs were performed using inFulfillmentOf.

#### 2.5.1.6 Tracking Labs Between Results

A responding system SHALL use the same identifier for the same lab result observation, when that observation is returned in multiple documents, including when it changes state.

#### 2.5.1.7 Tracking Lab Result Corrections

The group was not able to create guidance on this topic. This should be addressed in a future workgroup.

### 2.5.2 Interoperable Laboratory Results

*Pain Point: As a receiver, I want to be able to do processing and analysis with lab results, but the values and codes are not in a standardized interoperable format.*

*Pain Point: I want a prioritized list of laboratory results to be shared, similar to how Allergies and Intolerances developed a 'most common allergens' list.*

Some of the most difficult and persistent pain points the group worked on were around standardizing lab results. When results are exchanged in nonstandard formats, valuable actions like analytics and intervention workflows are short-circuited. The group broke this work up into the following activities:

- Enumerate the kinds of problems encountered.
- Examine industry techniques for addressing these problems.
- Devise an overall strategy for addressing these problems.
- Devise guidance for implementers to map results to standard formats.
- "Go deep" and identify codes and identify or develop mappings for a subset of labs related to SARS-CoV-2, for the urgent need as well as to work on a manageable set. Engage outside groups addressing this as well as lab vendors and informatics SMEs.

The group made some progress in each of these areas, but quickly realized that the scale of this work and the different mix of skills required meant that a dedicated follow-on effort would be needed to succeed. See Section 2.5.2.4 for suggested next steps.

#### 2.5.2.1 Detailed Problems with Lab Interoperability

##### 2.5.2.1.1 Lab values are vendor- or facility- specific codes or free text

The primary problem group members reported was that the values they see in test results are often vendor- or facility- specific codes or free text. The primary fields of interest are the test battery (results organizer code), the test itself (result observation code) and the test result value (result observation value).

#### 2.5.2.1.2 Standardized translation available but at different level of abstraction; loss of specificity

The group discussed how the harmonized LOINC code is sometimes at a more abstract level than the original vendor code, resulting in a loss of specificity. When specific examples were discussed, there was tension between two views: providers tended to prefer the more abstract code for trending purposes, while one lab vendor in particular made the point that there is value in more specific kinds of testing, as not all tests are created equal.

As long as the original code is included as a translation, both needs can be met.

#### 2.5.2.1.3 Requesting systems have different needs from codes (coarse-grained vs fine-grained)

The group discussed how codes are often available at different levels of abstraction, and how some consumers (typically systems) would prefer the fine-grained code, while others (typically providers) would prefer coarse-grained.

The group did not come to a decision on this, but one idea would be using the abstract value and adding translations to the fine-grained code as well as the original code.

#### 2.5.2.1.4 Reference range received from lab is non-standard

Although there are standard reference ranges available for various tests, group members reported the ranges sent in CDAs were sometimes different. However, the group decided that it would be inappropriate to try to modify these. Rather, the requesting system could decide how it wants to display the result. Further, the group decided it would be good to identify standard reference ranges informatively.

#### 2.5.2.1.5 Range/Interpretation received from lab is specific to location of test

In some cases, a test interpretation may be subject to the location where the test was performed. For example, a given value might be considered normal at sea level but low at 5000 feet. This would affect the ability to trend values. The group decided that it would be inappropriate to try to modify these. A requesting system wanting to trend this value could double check the interpretation based on its own ranges and flag any deviation for human review.

#### 2.5.2.1.6 Codes, even if standard, can't always be trended together

Providers expressed frustration at the difficulty in trending results for similar, but not identical, codes. This is a problem even if the codes have been translated to LOINC, as reported in the Epic case study in section 2.5.2.3.

### 2.5.2.2 Groups Working on Lab Interoperability

There are multiple groups and organizations working on the problems of lab interoperability:

- LOINC, SNOMED-CT: establish common codes, participate in harmonization initiatives.

- [Systemic Harmonization and Interoperability Enhancement for Lab Data \(SHIELD\) project](#): FDA-run multi stakeholder initiative (CDC, ONC, NIH, CMS, etc.) to create harmonized mappings for lab results.
- HL7 [Orders and Operations Working Group](#): standards body workgroup addressing problems of lab result interoperability.

An important tool used to capture mappings between vendor test codes and LOINC codes is the **LOINC In Vitro Diagnostic (LIVD) Test Code Mapping**. This is an industry standard format (<https://ivdconnectivity.org/livd/>) that can be used to capture the output of harmonization activities. In addition to the specification, this page in the HL7 FHIR R4 standard (<https://build.fhir.org/ig/HL7/livd/>) gives a good overview.

See Section 2.5.2.5 for how to apply this mapping for SARS-CoV-2.

### 2.5.2.3 Case Study: Epic / Sutter Health on Types of Code Mappings and Challenges

*In this section, Epic, working with Sutter Health, describes how it creates mappings it can then apply in real time. This is a labor-intensive process, as differences between facilities require performing analysis at the facility level. The output of this process is a mapping between codes/values at a set of lab facilities and a set of consuming systems. This basic process could be repeated by this or a future workgroup to create common mappings and make them available to a wide audience.*

#### Component/procedure mappings to LOINC

LOINC without a methodology isn't sufficient to trust that two lab results can be trended/compared to each other.

Normal sodium vs. point of care sodium test as an example for one of our lab customers. Those may not be trendable together because the reference ranges are different - what would be normal for one component vs. the equivalent component on the other test would be abnormal. Machine and machine calibration also a factor. Summing it up: Don't have a common set of codes that take all this into account.

How we map: One to one mapping (we use a unique identifier in a custom field).

Decision point: How do you decide when two things trend together? Lab feedback: should be human interaction. Also, only when components are fully mapped - not comfortable as presenting partial results as a finalized lab as part of the native chart.

So how is mapping done? We display to a user:

- reference range
- specimen types (whole blood, breath, etc)



- resulting agency
- unit type (like mg)
- free text name of the procedure

For components: we provide any procedures we've received with that component, we just use LOINC today

For procedures: we provide the linked components from that procedure, CPT, SNOMED, LOINC, name matching to provide suggestions for what looks similar

Outstanding question: Does LOINC specify what is point of care, or whether they share what type of machine resulted the information?

#### 2.5.2.4 Workgroup Strategy

The workgroup quickly realized that the problem of nonstandard results needed to be addressed with a wider strategy than just working on C-CDA interoperability, identifying the following actionable tasks that could be performed by this or any appropriate and interested working group.

**Identify/create preferred value sets for labs:** For a given domain of lab tests, preferred value sets need to be identified that systems will ideally use when exchanging C-CDA documents. In some cases, these may need to be defined in other workgroups such as the SHIELD initiative, which JDCWG members expressed interest in.

**Improve the quality of the data coming from labs:** Ideally, labs would already be sending standardized codes. When workgroup members began to participate in the SHIELD initiative and work with vendors like LabCorp, we found that many labs were already sending standard codes, at least in the SARS-CoV-2 domain, likely due to COVID-19 lab reporting requirements from HHS: <https://www.hhs.gov/sites/default/files/hhs-guidance-implementation.pdf>. So part of the overall strategy would be advocating in all available venues for labs to adopt standard codes.

**Identify/create mappings from lab values/codes to standard codes:** Keep track of which labs are already sending standardized results, and in which domains. When there are LIVD mappings, adopt those. But since lab facilities can vary, to define fully automatable mappings requires analyzing each lab facility explicitly. Harmonization activities can limit scope to a manageable size by choosing a set of result types and a set of lab facilities to analyze. The output of this effort should be a publicly available mapping subset, potentially consumable via API. Over time, these mapping subsets can grow to cover more high-priority results and facilities. Over time, Data Analytics and Machine Learning may be able to create these mappings as well.

**Perform translations from those mappings prior to exchanging data:** Finally, for as many mappings as are defined, systems will translate codes and values using those mappings so that exchanged results are truly interoperable.

**Identify mappings and guidelines for trending dissimilar codes:** As in the Epic example of normal sodium vs. point of care sodium, identify cases where result values can be trendable together, where they cannot, and where they may through some normalization process.

#### 2.5.2.5 Creating Mappings

In this part of the process, we identify and create mappings between vendor-specific values and standard codes, to be applied by systems that receive lab results in HL7 V2 messages or other means and include these results in generated CDA documents.

There are two levels of mappings that can be created for a given input:

- **Automatable mappings**, where exact deterministic translations are specified, **intended to be used by systems** to translate values in real time.
- **Manual mappings, intended to be used by HIMSS teams** to assist in translating values manually and perhaps to guide their creation of automatable mappings.

One important tool in creating mappings is the **LIVD format**. When the workgroup first looked into this, we were hopeful that these mappings were already fully automatable and could simply be adopted as-is by responding systems when generating CDAs. However, we received mixed messages on the efficacy of this when we asked SHIELD directly. So, **at this time we are considering the SARS-CoV-2 LIVD mapping to be a manual mapping**, and not identifying any required automated real-time translations. We hope that a future iteration of the workgroup can pick this task back up, ideally working with HL7 Orders and Observations, and produce such a complete mapping.

The group looked at the preferred value sets and mappings for SARS-CoV-2 related codes, which are maintained by LOINC here: <https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html>. The specific mappings are captured in the spreadsheet “LIVD SARS-CoV-2 Test Codes.xlsx”.

See the [LIVD specification](#) and the HL7 FHIR [LIVD overview page](#) for guidance on using LIVD to perform mappings. At a high level, the process is this:

1. Determine the row(s) in the LOINC Mapping table that this test result maps to. Each row is unique by the combination of the columns: "Manufacturer", "Model", "Vendor Analyte Name", and "LOINC Code". There is also a "Vendor Analyte Code" column that may be populated.
2. Translate the test identifier to the code in the "LOINC Code" column.
3. If the test result value is qualitative and if possible, translate the value to the appropriate SNOMED-CT code in the "Vendor Result Description" column.

As an example, the Abbott “Architect i1000SR” test tool conducting the “CoV-2 IgG” test, identified by

the Abbott-specific code “385”, would be mapped to the preferred LOINC code “94563-4”.

The difficulty is in determining which row, because the V2 message by itself typically lacks the context to determine the manufacturer and model in a deterministic way. This is where lab-specific information comes in, as the Epic/Sutter process shows, to define **automatable mappings for specific lab facilities and specific lab result types**.

The output of this iterative process is a set of defined mappings, manual or automatable.

#### 2.5.2.6 Performing Translations

The manual mappings adopted by this guide are:

- For the domain of SARS-CoV-2: <https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html>. The specific mappings are captured in the spreadsheet “LIVD SARS-CoV-2 Test Codes.xlsx”.

The automatable mappings adopted by this guide are:

- <none>

A Responding system that receives laboratory orders or results and includes them in generated documents SHOULD use the manual mappings adopted by this guide to perform translations to preferred codes. These translations MAY be delayed in generated documents due to their manual nature.

A Responding system that receives laboratory orders or results and includes them in generated documents SHALL use the automatable mappings adopted by this guide to perform translations to preferred codes.

A Responding system that receives laboratory orders or results and includes them in generated documents SHALL maintain the required automatable mappings using one of the following methods:

- Maintain a local copy of the mappings, updated according to the required frequency and schedule established by the production exchange.
- Utilize an API for real-time mapping.

The following example shows a mapping from a local code to a preferred code:

```
<code code="94500-6" displayName="SARS coronavirus 2 RNA"
  codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <translation code="LOCAL-CODE-01D" codeSystem="VENDOR-01D"
    displayName="LOCAL COVID CODE" codeSystemName="LOCAL VENDOR"/>
</code>
```

*Figure 12 – Translating to a preferred code*

When translating a local code to a preferred code, a Responding system SHALL include the original code as a translation element.

When translating a local text value to a preferred code, a Responding system SHALL include the original text as an originalText element.

A Responding system MAY attempt to translate a local code or text value that does not have an exact mapping to a preferred code, and when doing so, SHOULD translate it to the most specific preferred code available.

See the C-CDA Companion Guide section 5.1.2 for additional details and examples of translation and originalText.

## 2.6 Resilient Receivers: Querying, Retrieving and Displaying

### 2.6.1 Document Exchange Workflow Guidance

A clinician determines whether to retrieve or review a document based on a limited set of document metadata (e.g. Date, Title, etc.). The information available to display is slightly different depending on whether the user is reviewing the results of a query or reviewing a document previously retrieved and stored locally.

In a Document Query / Document Retrieve scenario the initial IHE Document Query transaction returns a set of information about the document(s) available from sources associated with the patient. The receiving system then displays this initial information to a user to select which documents to retrieve. Once the user selects which documents are to be retrieved, a subsequent Document Retrieve transaction prompts the document source to deliver the selected documents to be viewed by the user. To optimize performance, some systems pre-fetch a patient's available documents based on an upcoming encounter so the steps in the figures below may be transparent to the user.

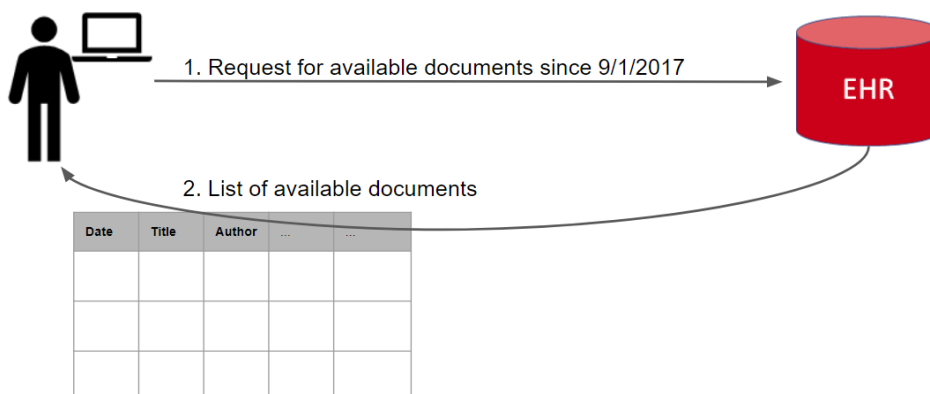


Figure 13 – Document Query

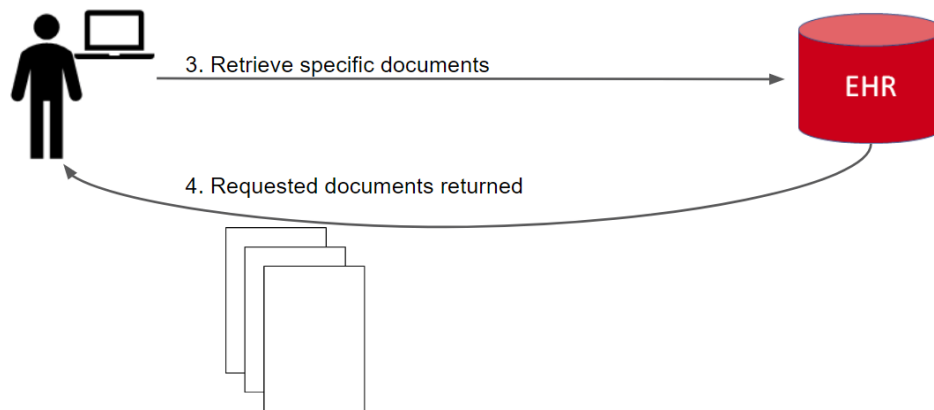


Figure 14 – Document Retrieval

### Document Information display

When displaying available documents for retrieval or retrieved documents, systems should display corresponding document information. This information may be obtained from the IHE query/retrieve transaction (i.e., the same as what was displayed in the “list of available documents” during the query) or may be obtained (parsed) from within the C-CDA document header<sup>17</sup>.

The figure below summarizes the key data elements available in the IHE Query transaction vs the retrieved C-CDA Header<sup>18</sup>:

Document Info	Availability	Location
Date range	IHE Metadata	<code>DocumentEntry.serviceStartTime</code> <code>DocumentEntry.serviceStopTime</code>
	Encounter Summary C-CDA Header	<code>ClinicalDocument/componentOf/encompassingEncounter/effectiveTime/low</code> <code>ClinicalDocument/componentOf/encompassingEncounter/effectiveTime/high</code>
	Patient Summary C-CDA Header	<code>ClinicalDocument/documentationOf/serviceEvent/effectiveTime/low</code> <code>ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high</code>
Title	IHE Metadata	<code>DocumentEntry.title</code>
	C-CDA Header	<code>ClinicalDocument/title</code>

<sup>17</sup> While this section focuses on query/retrieve, documents received via Direct **SHOULD** follow the recommended metadata for display

<sup>18</sup> This list came from The Sequoia Project - [eHealth Exchange Content Testing Program Guide](#) with the additions of Date and Title by the Joint Document Content Work Group. This is an informative mapping only – see section 2.4 for the normative mapping between XDS document metadata attributes and the CDA header.

Document Type	IHE Metadata	<code>DocumentEntry.typeCode</code>
	C-CDA Header	<code>ClinicalDocument/code</code>
Author	IHE Metadata	<code>DocumentEntry.authorPerson</code>
	C-CDA Header	<code>ClinicalDocument/author/assignedAuthor/assignedPerson</code>
Author Organization <sup>19</sup>	IHE Metadata	<code>DocumentEntry.authorInstitution</code>
	C-CDA Header	<code>ClinicalDocument/author/assignedAuthor/representedOrganization/name</code>
List of Services	IHE Metadata	<code>DocumentEntry.eventCodeList</code>
	Encounter Summary C-CDA Header	<code>ClinicalDocument/documentationOf/serviceEvent/code</code>
	Patient Summary C-CDA Header	Not Applicable - the service event information in a patient summary is restricted to "Provision of Care". The document does not contain details about the services provided during the span of time covered by the document.
Practice Type	IHE Metadata	<code>DocumentEntry.practiceSettingCode</code>
	Encounter Summary C-CDA Header	<code>ClinicalDocument/componentOf/encompassingEncounter/location/healthcareFacility</code>
	Patient Summary C-CDA Header	Not Applicable - Patient Summary may multiple practice types
Format Code	IHE Metadata	<code>DocumentEntry.formatCode</code>
	C-CDA Header	Not Applicable - the formatCode is inferred by the templateIDs asserted in the Header

Figure 15 - Document Information Available during the IHE Query and in the stored C-CDA

See below for an example of how data elements from the IHE Query or C-CDA Header might be displayed to improve document selection.

Date	Title	Document Type	Author	Author Institution
4/5/2018	Patient Summary	CCD	Good Health	
4/5/2018	Office Visit Checkout	Progress Note	Dr. Johnson	Good Health Clinic
3/28/2018	Hospital Stay	Discharge Summary	Dr. Smith	Good Health Hospital

<sup>19</sup> eHealth exchange named this Service Location

...				
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Figure 16 - Sample Document List Display

## 2.6.2 Receive and display any valid CDA document

The base CDA standard is designed so that every section's `section.text` element is displayable in a basic browser using the base CDA stylesheet, `cda.xsl`. While receivers are allowed to implement complex processing to apply their own display styles to a section, a system **SHALL** never hide a section if it does not recognize the LOINC section code. Every properly formatted section **SHALL** be displayed, or an option given, to the user to view the full unrestricted document.

## 2.6.3 Additional XDS Query Filtering Guidance

There are two ways to filter documents before retrieving them: server-side, i.e. in the query, and client-side, i.e. with the document entries received, as explained in section 2.6.1. This section offers guidance for Receiving systems to filter XDS queries to reduce the document entries returned.

Each stored query defines a number of available parameters which compare to corresponding attributes of metadata. See IHE ITI TF Vol 2, [Section 3.18.4.1.2](#).

Continuing with the most often used FindDocuments query shown in section 2.1.2, beyond the basic parameters, most of the remaining parameters filter on coded values or dates. Each is described below.

### 2.6.3.1 Filtering by coded values

Below is a snippet of an example query for C-CDA 2.1 progress notes (11506-3) and discharge summaries (11842-5), filtering by two of the coded metadata attributes pertaining to document type, `classCode` and `formatCode`.

```
<rim:Slot name="$XDSDocumentEntryFormatCode">
  <rim:ValueList>
    <rim:Value>('urn:hl7-org:sdwg:ccda-
structuredBody:2.1^1.3.6.1.4.1.19376.1.2.3')</rim:Value>
  </rim:ValueList>
</rim:Slot>
<rim:Slot name="$XDSDocumentEntryClassCode">
  <rim:ValueList>
    <rim:Value>('11506-3^2.16.840.1.113883.6.1', '11842-
5^2.16.840.1.113883.6.1')</rim:Value>
  </rim:ValueList>
</rim:Slot>
```

Figure 17 – Filtering on coded values in the IHE XDS Query request

The example shows the following query parameters (links go to HL7-curated value sets):

- [\\$XSDocumentEntryFormatCode](#): for C-CDA, this chooses the specific family of document formats, for example C-CDA 2.1 documents with a structured body: “urn:hl7-org:sdwg:ccda-structuredBody:2.1”. It gets compared to the document entry formatCode attribute.
- [\\$XSDocumentEntryClassCode](#): for CCD, this chooses the document type directly: “34133-9”. For encounters, this chooses the category, for example: “18842-5” for discharge summary. It gets compared to the document entry classCode attribute.

The query parameters above are **coded value filters**, meaning they have to match the document’s code exactly, including the scheme (aka the code system) the code came from. For example:

- `$XSDocumentEntryClassCode = “34133-9^^2.16.840.1.113883.6.1”` matches documents where the class code of the document is “34133-9” within the scheme “2.16.840.1.113883.6.1”.

Query filters may be combined in AND/OR combinations. Multiple slots mean AND and multiple values in a slot mean OR. In the above example, it means: "Find all documents where format code is C-CDA 2.1 AND (class code is Progress Notes OR Discharge Summary)". See [IHE ITI TF Vol 2, Section 3.18.4.1.2.3.5](#).

Coded values are constrained by adopting **value sets**, which limit the available codes that can be used in a particular field. This guide does not normatively specify value sets, because these are typically defined by the clinical exchange.

**Resilient Receivers:** While it seems simple and straightforward, use filtering on coded values with caution. The reasons for this are twofold. First, filters are additive, meaning the more filters, the fewer documents. Second, without knowing exactly what values the responding system supports (which are usually just an undocumented subset of the value sets adopted by the exchange), there is a real risk of missing documents. False positives (more document entries than you want) are much better than false negatives (missing a document you wanted).

For example, a query could filter on classCode and formatCode, which are fairly well-known and stable, and miss a document with important patient history that is only available as a PDF.

For another example, [\\$XSDocumentEntryTypeCode](#) appears to be a useful filter. This narrows down the document type beyond class code, for example, it could narrow down a discharge summary to “68578-4” for Orthopaedic surgery Discharge summary. However, its implementation is not very consistent, so documents using the general Discharge summary class code would be missed.

When in doubt, filter less on the query (server-side) and more on the query response (client-side) to choose what to retrieve.

**Smart Senders:** We encourage senders to document the value sets they employ for metadata of newly generated and legacy documents.



### 2.6.3.2 Filtering by date/time range

*Pain Point: How do date ranges in XDS Document queries work?*

As stated in [IHE ITI TF Vol 2, section 3.18.4.1.2.3.3](#), document entries returned by a query MUST match the service time parameters passed by the Requesting system.

One of the hardest concepts in XDS for people to get their heads around is date filtering. We'll start with an example and walk through it. Below is an example query using the suggested parameters to indicate the span of time the requestor is interested in.

```
<rim:Slot name="$XDSDocumentEntryServiceStopTimeFrom">
  <rim:ValueList>
    <rim:Value>201501010800</rim:Value>
  </rim:ValueList>
</rim:Slot>
<rim:Slot name="$XDSDocumentEntryServiceStartTimeTo">
  <rim:ValueList>
    <rim:Value>201712310800</rim:Value>
  </rim:ValueList>
</rim:Slot>
```

*Figure 18 – Filtering on Timespan Elements in the IHE XDS Query request*

There are two attributes on each document entry that describe the time range or timespan the document is about, `DocumentEntry.serviceStartTime` and `DocumentEntry.serviceStopTime`. These are mapped to dates in the CDA header in section 2.4.1.

Next, there are four query parameters that filter on these two dates:

- `$XDSDocumentEntryServiceStartTimeFrom`: "I only want documents that start on or later than this time"
- `$XDSDocumentEntryServiceStopTimeFrom`: "I only want documents that end on or later than this time"
- `$XDSDocumentEntryServiceStartTimeTo`: "I only want documents that start earlier than this time"
- `$XDSDocumentEntryServiceStopTimeTo`: "I only want documents that end earlier than this time"
- More succinctly: From parameter  $\leq$  date attribute  $<$  To parameter

Of the four service date parameters, the Work Group recommends two, which are bolded in the list above and used in the example: we are looking for documents where the service stop time is after or equal to January 1, 2015 8AM, AND the service start time is earlier than December 31, 2017 8AM.

The following are the recommended date-related query parameters pertaining to service dates.

- When filtering a query by date range, Initiating systems **SHOULD** send the IHE XDS Query Parameters `$XDSDocumentEntryService`**StopTimeFrom** and

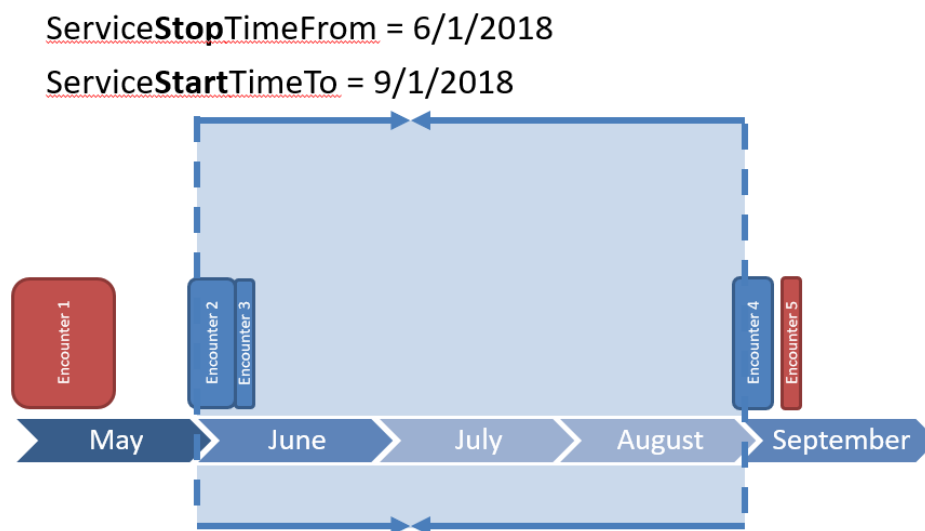
`$XSDDocumentEntryServiceStartTimeTo` to guarantee encounters in progress will be returned. In this guide this is referred to as an “overlapping” date range query, because it pulls in documents that cross the range.

- When filtering a query by date range, Initiating systems **SHOULD NOT**<sup>20</sup> send the IHE XDS Query Parameters `$XSDDocumentEntryServiceStopTimeTo` and `$XSDDocumentEntryServiceStartTimeFrom` since encounters in progress will not be returned. In this guide this is referred to as a “non-overlapping” date range query, because it does not pull in documents that cross the range.

Depending on other filtering, the expected response to this query would typically be a list of encounter summary documents and a patient summary document that fall within this range. The date range may influence the generation of the patient summary. See section 4.2.3 for details.

To understand why the Work Group chose these, let’s look at how they work visually. First, the recommended “overlapping” parameters and their usage examples:

#### 2.6.3.2.1 Date range search, overlapping



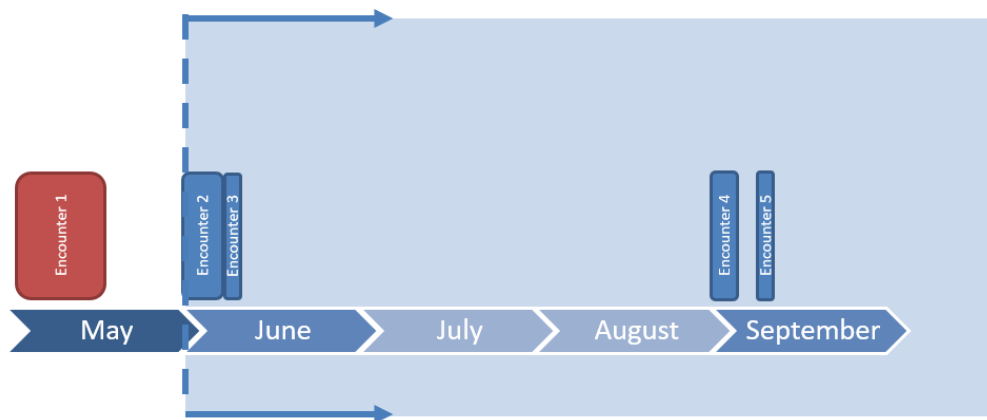
These parameters match encounters where the date range overlaps the range of interest, not just encounters falling entirely within the range of interest.

- `DocumentEntry.serviceStopTime` is greater than or equal to `$XSDDocumentEntryServiceStopTimeFrom`
- `DocumentEntry.serviceStartTime` is less than `$XSDDocumentEntryServiceStartTimeTo`

<sup>20</sup> An initiating system **MAY** use these parameters if they intentionally wish to exclude encounters that didn’t start or end in the query window.

2.6.3.2.2 All documents after a set date, overlapping

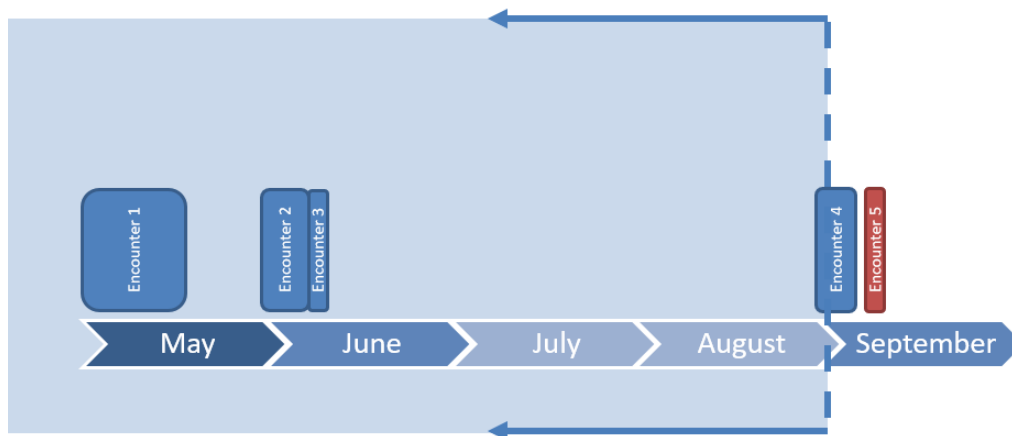
ServiceStopTimeFrom= 6/1/2018



- `DocumentEntry.serviceStopTime` is greater than or equal to `$XDSDocumentEntryServiceStopTimeFrom`

2.6.3.2.3 All documents before a set date, overlapping

ServiceStartTimeTo= 9/1/2018



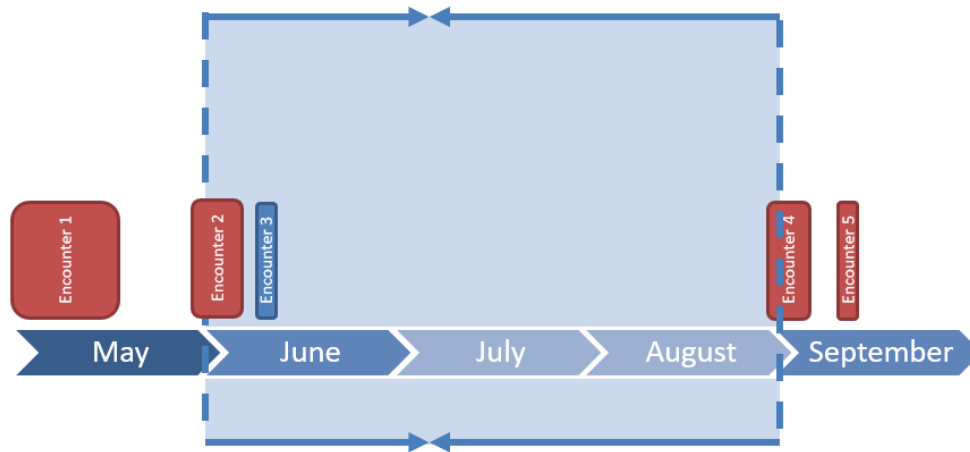
- `DocumentEntry.serviceStartTime` is less than `$XDSDocumentEntryServiceStartTimeTo`

Now, the non-recommended parameters and their usage examples:

2.6.3.2.4 Date range search, non-overlapping – missing boundary documents

ServiceStartTimeFrom = 6/1/2018

ServiceStopTimeTo = 9/1/2018

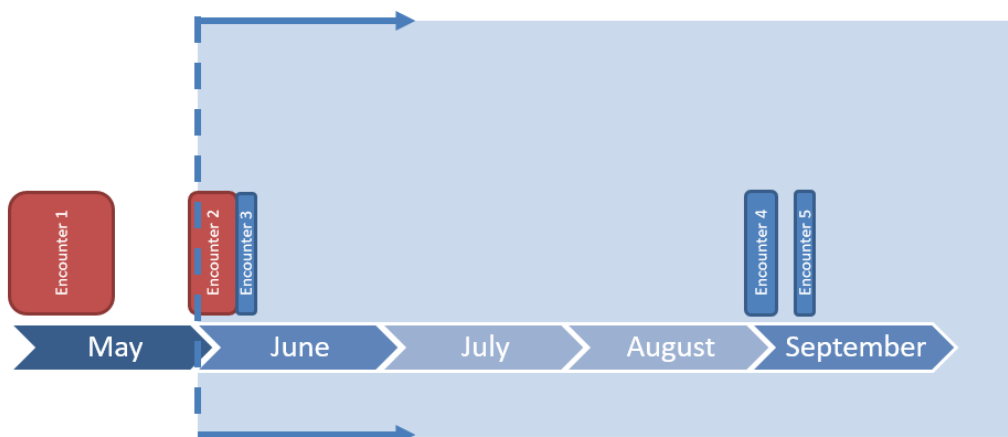


Note that these parameters only match encounters falling entirely within the range of interest, not ones that overlap the range. This approach is not recommended since boundary documents are not returned.

- `DocumentEntry.serviceStartTime` is greater than or equal to `$XDSDocumentEntryServiceStartTimeFrom`
- `DocumentEntry.serviceStopTime` is less than `$XDSDocumentEntryServiceStopTimeTo`

2.6.3.2.5 All documents after a set date, non-overlapping – missing boundary document

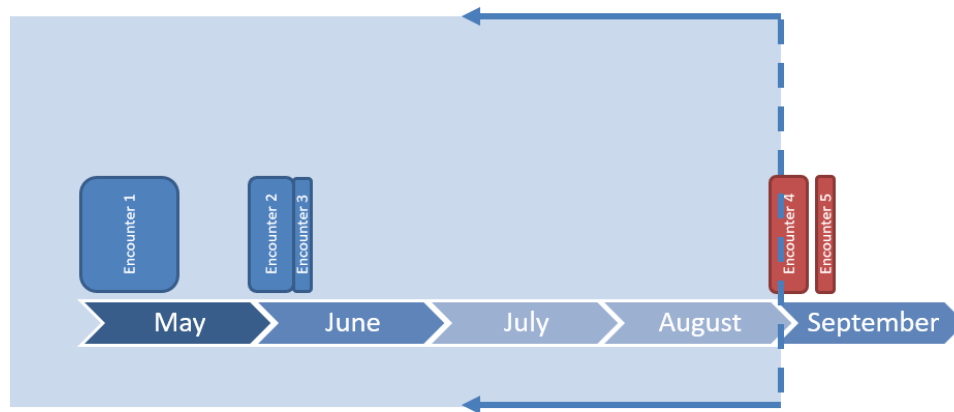
**ServiceStartTimeFrom**= 6/1/2018



- `DocumentEntry.serviceStartTime` is greater than or equal to `$XDSDocumentEntryServiceStartTimeFrom`

2.6.3.2.6 All documents before a set date, non-overlapping – missing boundary document

ServiceStopTimeTo= 9/1/2018



- `DocumentEntry.serviceStopTime` is less than `$XDSDocumentEntryServiceStopTimeTo`

### 3 Encounter Summary Documents

An encounter summary document is primarily a clinician authored collection of information specific to a single patient interaction with a clinician, care team or hospitalization. The document may be provided to a patient immediately upon, or soon after, the conclusion of their visit even if all the information related to that visit is not yet available. For example, an encounter may have pending laboratory results or may lack a finalized clinician note or discharge summary when a patient departs. However, an encounter summary document may be updated when additional encounter specific data is available (i.e. finalized). A complete encounter summary includes any information that may have been updated after the conclusion of the encounter. See the Document Update Sharing section 2.3.2 for guidance on how to manage document versions and updates.

For the purposes of document exchange, this guide focuses on two Encounter Summary Document types:

- Outpatient/Ambulatory Encounter Summary
- Inpatient/Hospital Encounter Summary

It is important to note these two broad categories may not perfectly align with patient billing classes. This guide does not define exact scenarios of when to use each type of encounter summary. The group consensus was to use the outpatient/ambulatory encounter summary for office visits, and use the inpatient/hospital encounter summary for overnight stays in hospitals. For hospital outpatient services (ambulatory surgery, etc.) or inpatient rehabilitation the provider/organization may need to determine which encounter summary document type is most appropriate. For ED visits, the Joint Document Content Work Group recommends systems implement the Inpatient/Hospital Encounter Summary (Discharge Summary).

This supplement provides guidance for generating the C-CDA Progress Note Document to exchange information associated with an Outpatient/Ambulatory Encounter, and the C-CDA Discharge Summary Document to exchange information associated with an Inpatient/Hospital Encounter. The Joint Document Content Work Group selected these information exchange documents because they were designed to support the most generic, encounter level documents currently available. After systems support the Progress Note Document, and the Discharge Summary Document, implementers are encouraged to implement additional document types that support specific use cases, for example Consultation Note or History and Physical Document.

As specified in Section 2.1.1, the Work Group decided that in order for responding systems to provide a complete picture of a patient's history, they SHALL provide access to, at a minimum, one Encounter Summary Document for each available encounter.

Responding systems SHALL share one Encounter Summary Document for each available encounter. The document MAY go through multiple versions.

When sharing a newly generated Encounter Summary Document for an outpatient encounter, Responding systems SHOULD use one of the following C-CDA document types: Progress Note, Consultation Note, or History and Physical. This guide provides guidance for the Progress Note in section 3.2.

When sharing a newly generated Encounter Summary Document for an inpatient encounter, Responding systems SHALL use the C-CDA Discharge Summary document type as specified in section 3.3.

When sharing a previously generated Encounter Summary Document, Responding systems MAY share the document in its original format.

**Resilient Receivers:** Note that historical encounters may not have been generated using encounter-based document types. **Many systems used the CCD document type for all documents until recently.** For this reason, if querying for historical encounters in a date range, either include the CCD class code, or omit class code entirely.

The Joint Document Content Work Group learned systems have different approaches to generate Encounter Summary Documents.

Two common scenarios discussed on the work group for Encounter Summary Documents:

- Generation of the Encounter Summary Document immediately after the visit, or after all information has been filed to visit, and stored for future retrieval
- Generation of the Encounter Summary Document when requested

In both cases, the clinical content must be equivalent. However, some systems that generate when requested are unable to recreate certain items, such as the Medication or Problems at the time of the Encounter.

Systems that are unable to report information that is accurate to the time of the encounter **SHALL NOT** include current information instead. For example, if a system provided the current Medication list with each Encounter Summary, rather than the encounter specific list, all of the documents would have the same information making it impossible for the clinician to determine the state of the patient at the time of the encounter. Thus, systems without the ability to produce a Medication list that accurately reflected the Medications at the end of the encounter, **SHALL NOT** include a Medication list in the Encounter Summary Document. For the most recent encounter, systems **SHALL** always include the current information.

### 3.1 Document Body Guidance

The CDA document body communicates clinical content through sections. C-CDA R2.1 includes robust recommendations for required and optional sections for the C-CDA Progress Note Document and the C-CDA Discharge Document which were determined by the review of thousands of clinical documents. The additional guidance here complements this prior work. When HL7 considers a new ballot, members of the Joint Document Content Work Group will submit these recommendations for inclusion.

The content work group selected sections for the [Progress Note Document](#) and [Discharge Summary Document](#) using these guidelines:

1. **SHALL** include all sections required in the base C-CDA document template.
2. **SHALL** include a priority subset of clinical data drawn from the ONC Common Clinical Data Set (CCDS) and US Core Data for Interoperability (USCDI). (see [Figure 19](#) and [Figure 20](#) for priority subsets for specific encounter document types, and section 2.2.4 for USCDI requirements).
3. Systems **SHOULD** send a 'No information' assertion template if nothing is available<sup>21</sup> for one of the priority subset data elements.
4. Systems **MAY** send additional data elements, beyond the priority subset, if relevant to the encounter. For these additional data elements, systems should not send a 'No information' template if nothing is available.

Many systems include the data required in the Common Clinical Data Set (CCDS) in every C-CDA document even if that data is not updated, or relevant, to an encounter. The participants in the Joint Document Content Work Group recommended that only a priority subset of such data elements always be included (listed below), and only if they were reviewed or reconciled during an encounter. This approach is consistent with ONC's requirement that systems must support sending all CCDS for certification purposes, but also allows the clinician to determine what is relevant for a particular encounter document. The Joint Document Content Work Group recognizes that reconciliation does not occur the same way in every system and provides no guidance on this activity. A goal of the Joint Document Content Work Group is for systems to only include information which is relevant and current at the time of the encounter.

Data elements shown as "Required if Reviewed" in the tables below **SHALL NOT** be included in the Encounter Summary Document if the clinician did not review or reconcile this data at the time of the encounter.

Guidance for key sections:

- Problems - An updated problem list **SHALL** be included if reviewed or reconciled during the encounter and can be recreated as it existed at the time of the encounter. Problems addressed during the encounter **SHOULD** be recorded as Encounter Diagnoses in the encounter section.

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<sup>21</sup> See HL7 Approved C-CDA Example [No Information](#)



- Allergies - An updated allergy list **SHALL** be included if reviewed or reconciled during the encounter and can be recreated as it existed at the time of the encounter.
- Medications - An updated medication list **SHALL** be included if reviewed or reconciled during the encounter and can be recreated as it existed at the time of the encounter.
- Immunizations - Systems **SHALL** include immunizations given during the encounter.

Systems **SHALL NOT** auto-populate the latest information (i.e. current active medications) in a historical Encounter Summary Document.<sup>22</sup> The conditions for allowable updates to Encounter Summaries are listed in section 3.5.4.

Note that requiring historically accurate encounter summaries and a patient summary may represent a change to provider expectations and workflows, so implementers should clearly communicate this change.

Additionally, every section must comply with the following guidance:

- Each section **SHOULD** include the Section Time Range Observation to communicate the date and time range of the information included in the section. See section 2.2.6 Section Time Range Observation for more detail.

## 3.2 Outpatient/Ambulatory Summary (Progress Note Document)

The content work group selected the C-CDA Progress Note document template<sup>23</sup> to support Outpatient/Ambulatory Encounter Summary Document exchange. The Progress Note is a generic document which supports any outpatient visit. It is a first step towards systems exchanging more specific document types per encounter type.

The preferred LOINC document type code is 11506-3, Provider-unspecified Progress note, although systems may send more specific codes from the `ProgressNoteDocumentTypeCode` urn:oid:2.16.840.1.113883.11.20.8.1 value set.

The figure below identifies the priority subset the Joint Document Content Work Group recommends be required for implementations of the Progress Note document type intended to serve as an Outpatient/Ambulatory Summary.

	Required	Required if Reviewed <sup>24</sup>
--	----------	------------------------------------

<sup>22</sup> An exception to this rule is if the last encounter is recent and does contain current information.

<sup>23</sup> C-CDA R2.1 Progress Note templateId: 2.16.840.1.113883.10.20.22.1.9:2015-08-01

<sup>24</sup> Only include if the system is confident a user has reviewed or reconciled the list and is current to the Encounter Summary Document. On generation, systems may include the [IHE Reconciliation](#) template to record an explicit reconciliation act.

Outpatient/Ambulatory Summary (Progress Note Document)	Assessment Section (V2) <sup>25</sup>	Problem Section (entries required) (V3)
	Plan of Treatment Section (V2)	Allergies and Intolerances Section (entries required) (V3)
	Clinical Notes <sup>26</sup> (may include Subjective)	Medications Section (entries required) (V2)
	Encounter Section (V3) with encounter diagnoses for the <u>specific encounter</u> <sup>27</sup>	Immunizations Section (entries required) (V3)

*Figure 19 – Progress Note Document Section Requirements*

The Progress Note Document is not restricted to these sections. Clinicians, or specific sites, may choose to include other sections relevant to the encounter (Results, Vital Signs, etc.). Please consult Section 2.2.4 Support for USCDI for the data elements being prioritized for exchange in federal regulation.

### 3.3 Inpatient/Hospital Summary (Discharge Summary Document)

The content work group selected the C-CDA Discharge Summary document template<sup>28</sup> to support Inpatient/Hospital Encounter Summary Document exchange. The Discharge Summary is a key document for patients transitioning from the hospital to a new care setting.

The preferred LOINC document type code is 18842-5, Discharge Summary note, although systems may send more specific codes from the `DischargeSummaryDocumentTypeCode` value set urn:oid:2.16.840.1.113883.11.20.4.1.

The figure below identifies the priority subset the Joint Document Content Work Group recommends be required for implementations of the Discharge Summary document type intended to serve as an Inpatient/Hospital Summary.

<sup>25</sup>Systems that are unable to send a separate Assessment section, and separate Plan of Treatment section may send a combined Assessment and Plan Section (V2)

<sup>26</sup>C-CDA R2.1 Companion Guide Notes Section 2.16.840.1.113883.10.20.22.2.65:2016-11-01

<sup>27</sup>If the encounter diagnosis is not appropriate for the encounter it may be omitted

<sup>28</sup>C-CDA R2.1 Discharge Summary templateId: 2.16.840.1.113883.10.20.22.1.8:2015-08-01

	Required	Required if Reviewed
Inpatient/Hospital Summary (Discharge Summary Document)	Allergies and Intolerances Section (entries required) (V3)	Problem Section (entries required) (V3)(not covered by Discharge Diagnosis)
	Hospital Course (C-CDA) = Discharge Note <sup>29</sup>	Medications <ul style="list-style-type: none"> <li>- Admission medications list (patient reported/home medications)<sup>30</sup></li> <li>- Facility Administered<sup>31</sup> (Given during admission)</li> <li>- Discharge Medications list<sup>32</sup></li> </ul>
	Clinical Notes <sup>33</sup> (may include Subjective)	Immunizations Section (entries required) (V3)
	Discharge Diagnosis Section (V3)	
	Plan of Treatment Section (V2)	

Figure 20 – Discharge Summary Document Section Requirements

The Discharge Summary Document is not restricted to these sections. Clinicians, or specific sites, MAY choose to include other sections relevant to the encounter (Results, Vital Signs, etc.). Please consult Section 2.2.4 Support for USCDI for the data elements being prioritized for exchange in federal regulation.

### 3.4 Clinical Notes

*Note: some of the guidance the Joint Document Content Work Group originally created around clinical notes in prior versions of this guide has since been incorporated into the HL7 C-CDA Companion Guide. Rather than repeat that content here, we have factored most of it out, leaving guidance that goes beyond the Companion Guide.*

<sup>29</sup> If discharge note summarizes what occurred in the hospital - include Note Activity, label text as 'Discharge Note'. If note is not complete when an external party requests the document, or the acute facility is sending the document immediately to another care provider via Direct, this section may contain the appropriate nullFlavor, commonly NI (no information).

<sup>30</sup> Admission Medications Section (entries optional) (V3) (2.16.840.1.113883.10.20.22.2.44:2015-08-01)

<sup>31</sup> Medications Administered Section (V2) (2.16.840.1.113883.10.20.22.2.38:2014-06-09)

<sup>32</sup> Discharge Medication (V3) (2.16.840.1.113883.10.20.22.4.35:2016-03-01)

<sup>33</sup> HL7 C-CDA R2.1 Companion Guide Notes Section 2.16.840.1.113883.10.20.22.2.65:2016-11-01

This guidance expands on the guidance for Clinical Notes provided in the HL7 C-CDA Companion Guide, section 2.7.

### 3.4.1 Common Clinical Note Types

The HL7 C-CDA Companion Guide, section 2.7.1, describes how clinical note types are identified using LOINC terminology and identifies the most commonly used note types in Table 8. All Responding systems are encouraged to support this list and additional notes from the [Note Types](#) value set. Any future standards publications should not be restricted to this list.

### 3.4.2 Sending Clinical Notes in C-CDA

The HL7 C-CDA Companion Guide provided structure and guidance for sending notes by introducing the Notes Section (Appendix A, Section 2.2) and Notes Activity entry (Appendix A, Section 3.12) . Depending on the clinician workflow, and the discrete information available at time of document creation, the participants agreed on three potential approaches in priority order:

1. Include Note(s) directly attached to the associated act
2. Include Note(s) in an appropriate standard section
3. Include Note(s) in a stand-alone notes section

This priority order is for sending Clinical Notes when information cannot be encoded discretely, or is inappropriate, in an entry.

For further guidance, see the HL7 C-CDA Companion Guide, section 5.2.18 Clinical Note.

#### 3.4.2.1 Note directly attached to the associated act

When a note is specifically about an action a clinician performed, the note should reference that action. For example, a Procedure Note is linked, or nested within, the procedure act it documents. When direct attribution is possible (as an entryRelationship), the clinical note should be included in the appropriate section where the act is included. Receiving systems should be prepared for Clinical Notes directly embedded in an act and provide a control to display, at minimum, and be able to expand or collapse the note. For example, if the Procedure section had 5 procedures, it is preferable to display the 5 procedures in a flat list or table, with an option, possibly a '+' sign, to allow the user to expand and read each individual Procedure note.

```

<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.7" extension="2014-06-09"/>
  <!-- Procedures section template -->
  <code code="47519-4" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC" displayName="PROCEDURES" />
  <title>Procedures</title>
  <text><!-- This system translated the Section Time Range Observation into text -->
    <paragraph ID="TS_Narrative1">
      The section includes all Surgical Procedures Associated to the encounter</paragraph>
    <table>
      <thead><tr><th>Procedure</th><th>Date</th></tr></thead>
      <tbody>
        <tr><td ID="Proc1">Appendectomy</td><td>January 25, 2018</td></tr>
        <tr>
          <td ID="Proc1Note" colspan="2">
            <paragraph>Operative Note - Dr. Surgeon - 01/25/2018</paragraph>
            <paragraph>Patient repositioned with arms extended on arm
              boards...</paragraph>
          </td>
        </tr>
      </tbody>
    </table>
  </text>
  <entry typeCode="DRIV">
    <!-- C-CDA Procedure Activity Procedure entry -->
    <procedure classCode="PROC" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.14"
        extension="2014-06-09"/>
      <templateId root="2.16.840.1.113883.10.20.22.4.14"/>
      <code code="80146002" codeSystem="2.16.840.1.113883.6.96"
        displayName="Appendectomy" />
      ...
      <!-- Start of Note Activity as related to an existing procedure -->
      <entryRelationship typeCode="COMP">
        <act classCode="ACT" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.22.4.202"
            extension="2016-11-01"/>
          <code code="34109-9" codeSystem="2.16.840.1.113883.6.1"
            displayName="Note">
            <translation code="28570-0" codeSystem="2.16.840.1.113883.6.1"
              displayName="Procedure note" />
          </code>
          <text><reference value="#Proc1Note" /></text>
          ...
        </act>
      </entryRelationship>
    </procedure>
  </entry>

```

*Figure 21 Example of Note Directly Added to Associated Act*

```
<entry typeCode="DRIV">
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.201" extension="2016-06-01"/>
    <code code="82607-3" codeSystem="2.16.840.1.113883.6.1"
      displayName="Section Date and Time Range"/>
    <text>
      <reference value="#TS_Narrative1"/>
    </text>
    <statusCode code="completed"/>
    <value xsi:type="IVL_TS">
      <low value="20180125"/>
      <high value="20180125"/>
    </value>
  </observation>
</entry>
</section>
```

*Figure 22 – Example of Note Attached to an Act*

### 3.4.2.2 Note is in an appropriate section

In some situations, the generating system may only be able to place the Note in an appropriate section, and not the specific creation action. For example, when a system is unable to nest the Procedure Note within a procedure act (as an entryRelationship) but is able to place the Note Activity in the Procedure Section. Alternatively, the system may place the Note Activity in an otherwise text-only section, such as the Hospital Course section as demonstrated below in Figure 23.

```
<section>
  <!-- C-CDA Hospital Course Section -->
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.5"/>
  <code code="8648-8" displayName="HOSPITAL COURSE"
    codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>Hospital Course</title>
  <text><!-- This system translated the Section Time Range Observation into text -->
<paragraph ID="TS_Narrative2">
  The section includes Discharge Notes from September 13, 2016</paragraph>
  <list styleCode="TOC">
    <item ID="DischargeSummary">
      <caption>Chung, Anthony - 09/13/2016 2:46 PM CDT</caption>
      <paragraph>The patient was admitted and started on Lovenox and
        nitroglycerin paste...
      </paragraph>
    </item>
  </list>
</text>
<entry>
  <!-- Note Activity Entry -->
  <act classCode="ACT" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.202"
      extension="2016-11-01"/>
    <code code="34109-9" codeSystem="2.16.840.1.113883.6.1"
      displayName="Note">
      <translation code="8648-8" codeSystem="2.16.840.1.113883.6.1"
        displayName="Discharge Summary" />
    </code>
    <text><reference value="#DischargeSummary" /></text>
    ...
  </act>
</entry>
<entry typeCode="DRIV">
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.201" extension="2016-06-01"/>
    <code code="82607-3" codeSystem="2.16.840.1.113883.6.1"
      displayName="Section Date and Time Range"/>
    <text>
      <reference value="#TS_Narrative2"/>
    </text>
    <statusCode code="completed"/>
    <value xsi:type="IVL_TS">
      <low value="20160913"/>
      <high value="20160913"/>
    </value>
  </observation>
</entry>
</section>
```

Figure 23 – Example of Note Added to an Appropriate Section

### 3.4.2.3 Note in stand-alone Notes Section

When a system only knows the Note Type, and the Note Activity doesn't align to an existing C-CDA section, the Note Activity may be sent in the generic Notes Section with an appropriate LOINC code indicating the type of note. Some systems may choose this approach over inserting into existing section and potentially creating clutter for the end user. For example, a system creating an Encounter Summary

for which there are many consultation notes, may choose to put those notes in a standalone Notes Section to avoid cluttering up the Encounter Section.

```
<section>
  <!-- Notes Section -->
  <templateId root="2.16.840.1.113883.10.20.22.2.65" extension="2016-11-01"/>
  <code code="11488-4" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC" displayName="Consultation note"/>
  <title>Consultation Notes</title>
  <text> <!-- This system translated the Section Time Range Observation into text -->
    <paragraph ID="TS_Narrative3">
      The section includes Consultations Notes from September 8, 2016</paragraph>
    <list>
      <item ID="ConsultNote1">
        <paragraph>Dr. Specialist - September 8, 2016</paragraph>
        <paragraph>Dear Dr. Henry Leven: Thank you for referring Ms. Everywoman
          for evaluation. As you know...</paragraph>
      </item>
    </list>
  </text>
  <!-- Note Activity entry -->
  <entry>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.202"
        extension="2016-11-01"/>
      <code code="34109-9" codeSystem="2.16.840.1.113883.6.1"
        displayName="Note">
        <translation code="11488-4" codeSystem="2.16.840.1.113883.6.1"
          displayName="Consultation note"/>
      </code>
      <text><reference value="#ConsultNote1"/></text>
      ...
    </act>
  </entry>
  <entry typeCode="DRIV">
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.201" extension="2016-06-01"/>
      <code code="82607-3" codeSystem="2.16.840.1.113883.6.1"
        displayName="Section Date and Time Range"/>
      <text>
        <reference value="#TS_Narrative3"/>
      </text>
      <statusCode code="completed"/>
      <value xsi:type="IVL_TS">
        <low value="20160908"/>
        <high value="20160908"/>
      </value>
    </observation>
  </entry>
</section>
```

Figure 24 – Example of Stand-alone Notes Section

### 3.4.3 Encounter Linking for Clinical Notes

Clinical Notes are written by a clinician in the context of an encounter. Every Clinical Note **SHALL** have an Author(s) and should be linked to an Encounter, whether a short telephone encounter or a lengthy



Hospital Encounter. Encounter linking is important since some systems parse entries and may not properly retrieve header information.

When the C-CDA is an Encounter Summary the Clinical Note **SHALL** use an `entryRelationship` reference to the ID of an encounter in the Encounters Section or the `encompassingEncounter/id`<sup>34</sup>. The figure below provides an XML example for how this should be done.

```
<!-- Reference to encounter nested within Note Activity -->
...
<entryRelationship typeCode="COMP" inversionInd="true">
  <encounter>
    <!-- Encounter ID matches an encounter in the Encounters Section or
    encompassingEncounter/id -->
    <id root="1.2.3.4" />
  </encounter>
</entryRelationship>
...
```

*Figure 25 – Example of Encounter Linking with entryRelationship reference*

Some existing implementations send Clinical Notes in C-CDA Patient Summary documents. When a C-CDA Patient Summary contains Notes they **SHALL** have explicit encounter reference within the entry. If the document contains an Encounters section with the associated encounter, the Note Activity **SHALL** reference the encounter ID as demonstrated in Figure 25 above. Otherwise, the entire encounter should be included in the Note Activity as demonstrated in Figure 26 below.

If the encounter/id in the `entryRelationship` doesn't match an encounter/id from the Encounters Section, or the `encompassingEncounter/id`, then the contained entry **SHALL** conform to Encounter Activity (V3)

```
<!-- Reference to encounter nested within Note Activity -->
...
<entryRelationship typeCode="COMP" inversionInd="true">
  <encounter>
    <!-- ** If id doesn't match an encounter/id from the Encounters Section,
    then this entry SHALL conform to Encounter Activity (V3) ** -->
    <templateId root="2.16.840.1.113883.10.20.22.4.49" extension="2015-08-01" />
    <id root="1.2.3.4" />
    <code code="99213" codeSystemName="CPT-4" />
    <effectiveTime value="201209271300-0500" />
  </encounter>
</entryRelationship>
...
```

*Figure 26 – Example of Encounter Linking with encounter nested*

<sup>34</sup> The C-CDA Companion Guide [Release 1](#) and [Release 2](#) restricted linking to only encounters in the encounter section. Errata 1522 ([http://www.hl7.org/dstucomments/showdetail\\_comment.cfm?commentid=1522](http://www.hl7.org/dstucomments/showdetail_comment.cfm?commentid=1522)), incorporated into Release 3, additionally allows linking to `encompassingEncounter/id`. This guide adopts the errata.

Systems should prioritize implementing Encounter Summary documents with Clinical Notes over adding Clinical Notes to C-CDA Patient Summary documents.

### 3.4.4 Clinical Note Best Practices

The best practices for clinical note exchange will evolve as exchange of this type of information becomes more common. For a start, these are suggested best practices:

1. Prioritize human authored content. Text generated from structured entries are not considered 'Notes'
2. Notes documenting an act should be associated/nested/linked to the corresponding act (e.g. Procedure Note links to Procedure) and the associated encounter
3. All Note Activity entries **SHALL** have an Author(s) (The author may be inferred from the author of the section) or the corresponding act
4. All Note Activities should link to an encounter
5. Multiple Note Activities, and Note types, can be sent in their appropriate sections in a single C-CDA instance

While this is not an exhaustive list of best practices, it reflects the recurring themes discussed in the Joint Document Content Work Group.

## 3.5 When to Share Encounter Documents Through the Lifecycle

*Pain Point: When, during the lifecycle of an encounter, should an encounter summary document first be shared?*

*Pain Point: When is an encounter done?*

As section 3 indicates, Responding systems SHALL share one Encounter Summary Document for each available encounter. In practice, a document query for a patient can match known encounters in multiple ways, for example:

- The specific filters for document type and date range match the encounters. For example: A Requester queries for Discharge Summaries in March 2019, and the Responding system does have an inpatient encounter that fell during that time.
- The Requester queries with no filters. In this case, the Responder would return document entries for all known encounters for the patient.

Note that at the time of query, there may be no documents or document entries yet created for the encounter. The mechanisms described in section 2.3 and constrained in section [3.5.4](#) allow for dynamic generation.

But when during the lifecycle of the encounter does this requirement kick in? Should an in-progress encounter be shared? In which cases after an encounter has ended SHOULD it be shared or SHALL it be

shared? These seemingly simple questions occupied quite a bit of the group's time. The most common and straightforward answer for when to share is "when the encounter has ended", but providers described multiple special cases, and the definition of when the encounter is "done" is not always clear.

### 3.5.1 Sharing an Encounter that is in Progress

An encounter that is in progress has a start date but no end date. The group agreed that this would not be the typical case for sharing, but discussed the following cases in which such an encounter could be shared:

- The encounter has started.
- The required fields in the encounter summary can be populated.
  - For example: a Progress Note where an assessment has been performed and text is available (Assessment is a required section).
- There is an author known.
- A user explicitly chooses to share a document early for a given purpose.

### 3.5.2 Sharing an Encounter that has Ended

Likewise, the group discussed cases of sharing an encounter on or after its conclusion, i.e. when there is an end date known:

- The encounter has ended.
- There is an expected update to the encounter, for example, the results for labs that were performed during a hospital stay come back.
- The encounter has been authenticated.
- The encounter has been legally authenticated. i.e. "completed".
- There is an unexpected correction to an encounter.

As it turns out, **there isn't a clear definition of "done" for the encounter itself**, although most of the above appear to be candidates. Probably the strongest candidate is legalAuthenticator, about which the HL7 CDA 2.1 standard says "...is serving a medical records function by signing off on the document, moving it into a completed state." However, it's important to remember that **in CDA, a document is a snapshot of information known at some point in time**. So it's perfectly legitimate for a discharge summary to be legally authenticated, even if it will have a later version with the updated lab results.

Adding to the complexity are different ways that legalAuthenticator is used. **In CDA, it is presented as an explicit final step of verification of the content**, of "signing off on" or "completing" the document as a whole. In this view, each document identifies the particular staff member who reviewed it and applied their signature. But in practice, we found inconsistencies in how, or even if, this is done.

Providers reported some sources of clinical documents would either greatly delay legally authenticating, or simply never do so.

Also, some vendors flip the authentication workflow on its head, instead offering the legal authenticator as a single configurable identity which is **implicitly applied to all generated documents**. In practice, this is often set to the HIM manager. At first, this seemed wrong, but in fact, it makes sense if one considers a robust EHR that captures implied signatures and employs protections against errors in data entry at each step of data capture. In this case, the HIM manager is putting her name on the line that she has procured and configured an EHR that does not require an explicit extra step of checking.

The upshot of inconsistent use of legal authenticator is that it can't be taken as a positive trigger that something has changed about the state of the encounter. It is just **an extra assurance as to the correctness of this snapshot**.

We would like to see the HL7 Structured Document Working Group take up the issue of “when an encounter is done” as well as the cases when systems must add legal authenticator.

### 3.5.3 Sharing Throughout the Encounter Lifecycle

The group used the following illustration to discuss these topics, as well as encounter document versioning.

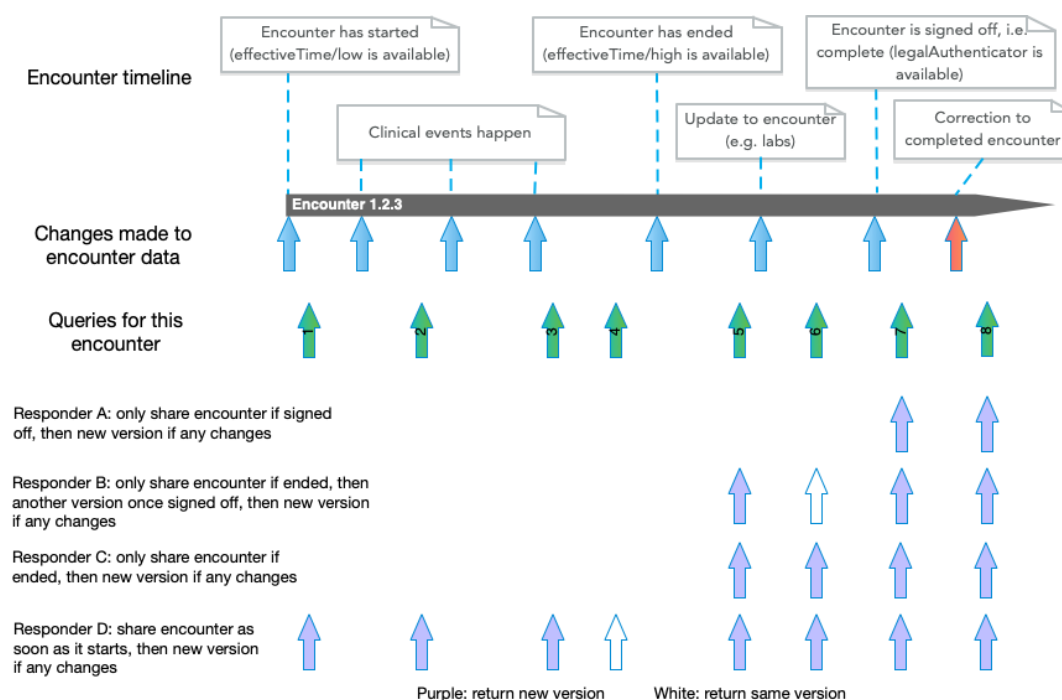


Figure 27 Sharing Throughout the Encounter Lifecycle

Assume a responding system that holds the information about an encounter 1.2.3. The blue arrows with the callouts along the top are events in the encounter's timeline, which runs from left to right. The green arrows represent a requesting system querying for encounter summaries. It may or may not be looking for this specific encounter, but its queries would match encounter 1.2.3. Responders A through

D represent four variations for discussion. The arrows to the right of each responder reflect when they will respond to the query with an encounter summary for encounter 1.2.3. Purple arrows show the responder returning a new version of the encounter summary, while white arrows show it returning the same version as before. **When to share the first version is discussed below**; sharing subsequent versions is discussed in the following section.

**Responder A:** This responder does not share an encounter unless it has been legally authenticated. This practice is followed in the **payment** use case: if subject to the [HL7 Attachments IG](#), a document cannot be shared unless it is legally authenticated. The group **rejected Responder A's variation for the treatment use case**, saying that encounters must be shared even if not legally authenticated. This was due in part to inconsistent use of legal authentication (e.g. physicians who were not timely in signing off on documents).

**Responders B and C:** These responders share an encounter once it has ended. The group decided that this should be a minimum expectation of sharing. The group **allowed Responder C's variation for treatment**. It rejected Responder B because of versioning, which will be discussed in the next section.

**Responder D:** Providers agreed that while it might not be common, they needed the ability to choose to share an in-progress encounter for the purpose of treatment, and that treating doctors at the requesting system would be able to handle the incomplete information, so the group **allowed Responder D's variation for treatment**, even before any clinical events have occurred. The group discussed whether there would be a need to relax any document constraints for this case, and decided against it, the ability to use nullFlavors and "No Known Information" being sufficient. The group decided not to identify any particular points of maturity that would impact sharing.

The following requirements reflect the group's decisions. "Local policy" includes any governance regarding different use cases / purposes of use; the group did not feel there had been sufficient research into use cases to make normative requirements based on them.

If permitted by local policy, a Responder MAY return an encounter summary document for an encounter that is in process.

If permitted by local policy, a Responder SHALL return an encounter summary document if a document query matches an encounter and any of the following is true:

- The end time for the encompassing encounter is defined.
- The encounter has been authenticated.
- The encounter has been legally authenticated.

We would like to see future work look further into differences in sharing based on purpose of use.

### 3.5.4 Sharing Updates to an Encounter Summary

Unlike a “current patient summary”, an encounter summary describes an event that has happened at a specific point in time, so the underlying content should be relatively stable. Still, an encounter summary can go through versions. Any encounter could potentially change in the Responding system after having been shared, for example, due to a correction after it has been completed.

Continuing through the above diagram, recall that purple arrows show the responder returning a new version of the encounter summary, while white arrows show it returning the same version as before.

The group considered the following versioning cases:

- All agreed that **a correction to a completed encounter needed to be shared as a new version**. This is shown as the rightmost purple arrow for all four responders.
- Responder B was proposed as an example of **throttling new versions**, releasing one version on encounter end and another on completion. Other examples discussed were releasing a version a day, or a new version only if a “major” change had occurred. The group discussed all these, but ultimately decided that **any change at all to an encounter that had been shared needed to cause a new version, rejecting Responder B’s variation**.
- Responder D was shown returning the same version in query 4, because nothing about the encounter had changed. The group agreed that this should be required, that **if there were no changes to an encounter, the same version must be returned**.
- In general, versioning encounter summaries was considered **essential, but not anticipated to be frequently needed**, because most encounter summaries would be shared only after the encounter has ended.

The group also discussed encounter summary versioning use cases from the requester’s perspective.

*Pain Point: When I discover an updated document, sometimes I need to know how it relates to prior versions, ideally without having to retrieve the documents.*

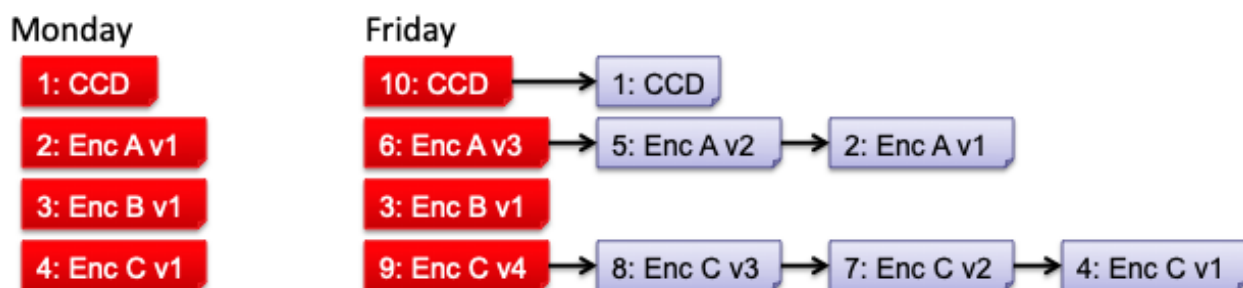


Figure 28 Versioning from Requester's Perspective

In this diagram, approved versions are shown in red, and deprecated in gray. Replacement associations are shown as arrows.

- For most use cases, simply obtaining the latest version of documents is sufficient. In the above example, the queries on Monday and on Friday both return four documents, but three of them have gone through version changes. For these use cases, **requesters can simply query by Approved state, and need not look at associations.**
- Sometimes there is a need to know how versions relate, for example, to know without reading the documents that document 9 was an update to document 4. To meet this use case, **responders would need to support associations, and requesters would need to query associations.** They could also query for Deprecated state if retrieving intermediate versions is needed.

Based on the versioning needs, we require support for sharing updates to encounter summaries, which requires relating both the CDAs and the XDS document entries.

A Responding system SHALL support the Document Update Sharing capability for generating new encounter summaries. See section 2.3.2.

**Resilient Receivers:** Note that historical encounter summary documents that went through multiple versions may not have had support for conveying the relationship between versions in the CDA header or XDS associations. A resilient receiver can also attempt to identify prior versions by matching encompassingEncounter/id.

Based on the pain points from implementers about receiving re-generated but otherwise identical documents, we require update detection logic. Based on the pain points about needing to retrieve to discover changes, we suggest Delayed Document Assembly. Other than that, we are flexible.

A Responding system SHALL support one of the following capabilities for generating new encounter summaries, and SHOULD prefer the options that include Delayed Document Assembly:

- On-Demand Option with Update Detection (see sections 2.3.4, 2.3.4.2)
- Delayed Document Assembly Option with Update Detection (see sections 2.3.3, 2.3.3.1)
- On-Demand and Delayed Document Assembly with Update Detection (see sections 2.3.3, 2.3.4, 2.3.4.3).

A Responding system SHALL consider the following changes a new version of an encounter summary, if one has already been generated:

- Additions to information known at the time of the encounter, e.g. final notes, “signing off” (legally authenticating).
- Corrections to information known at the time of the encounter, i.e. to data “entered in error”.
- Newly available results for labs performed during the encounter (see section 2.5.1.2).
- If an 'in progress' Encounter summary (prior to encounter close) had been generated, then any change to clinical information contributing to the encounter summary.

A Responding system SHALL NOT consider the following changes a new version of an encounter summary, if one has already been generated:

- Configuration settings or clinical content that do not contribute to the generated document.
- Updates to the patient's information unrelated to the encounter (Note: so it would not violate the requirement in section 3.1 that it reflect what is known at the time of the encounter).



## 4 Patient Summary Documents

While an Encounter Summary provides a snapshot of the patient's condition at the time of the encounter as authored by the clinician, a Patient summary provides the most current information available from the sending system across multiple encounters.

As specified in Section 2.1.1, the Work Group decided that in order for responding systems to provide a complete picture of a patient's history, they SHALL provide access to, at a minimum, one current Patient Summary Document for each patient.

There is a great deal of variation in how systems currently implement the current patient summary. This section lays out allowable variations, based on what has been seen in the wild and what the underlying specifications permit. Future work groups may further constrain this behavior to make it more predictable and manageable.

In some cases, Responding systems generate patient summaries specifically to meet the needs of a particular requester, for example to provide more or less data than is typically generated. This guide does not restrict such usage.

### 4.1 C-CDA Continuity of Care (CCD) Document Type

When generating a current Patient Summary Document for a patient, Responding systems SHALL use the C-CDA Continuity of Care (CCD) document type. Note that this is identified by the XDS document entry classCode attribute with LOINC code 34133-9.

When sharing a previously generated Patient Summary Document for a patient, Responding systems MAY share the document in its original format.

Responding systems MAY support generation of the patient summary in multiple formats, for example C-CDA 1.1, C-CDA 2.1, or PDF<sup>35</sup>. When doing so, each supported format SHALL have its own document entries which SHALL be able to be differentiated by the combination of formatCode and mimeType.

Current Patient Summaries are not the only documents that use the CCD document type:

- As mentioned earlier in this guide, many historical documents which would ideally have used encounter summaries or other document types instead were created as CCD documents.
- There may be other legitimate uses of CCD, for example, a comprehensive patient history created for a Transition of Care use case.

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<sup>35</sup> See <https://healthcaresecrecy.blogspot.com/2017/03/multiple-formats-of-same-document.html>

Also, because patient summaries are generated on request, Responding systems can accumulate potentially many of these documents over time.

The following guidance addresses all of the above issues.

**Resilient Receivers:** Note that many systems used the CCD document type for all documents until recently. For this reason, when querying for a current patient summary, be aware that historical CCD document entries may be returned as well. If desired, this can be minimized by filtering on the document type of on-demand, either by query parameter or by choosing which document entries to retrieve.

Also, be aware that some Responding systems may be able to generate patient summaries in multiple formats. If multiple patient summary entries (On-demand entry type with different formatCodes or mimeTypes) are received, rather than retrieving all available document entries, consider adding logic that ranks the preferred formats and only retrieves the most preferred one.

**Smart Senders:** When generating new current Patient Summaries, use the techniques in section 4.3 to reduce the clutter of prior generated documents.

## 4.2 Generating the Current Patient Summary

For a capability to return a “current snapshot”, it must be dynamically generated. Section 2.3 describes multiple ways to generate documents dynamically. This guide requires On-demand.

A Responding system that dynamically generates documents SHALL support the On-Demand capability to generate and share current patient summaries. When doing so, it SHALL host one On-demand entry for each supported format.

When generating a current Patient Summary Document for a patient, Responding systems SHALL at a minimum:

- include active problems, medications, allergies, and immunizations,
- ensure that entries match information from the most recent encounter, which may be a telephone or virtual encounter,
- include the Section Time Range in every section,
- if the section is required it **SHALL** include a ‘No information’<sup>36</sup> assertion if no information is included for a section.

When generating a current Patient Summary Document for a patient, Responding systems SHOULD NOT include Clinical Notes if these notes would be available in Encounter Summary documents. If Responding

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<sup>36</sup>HL7 example for sending ‘[No Information](#)’

systems do include notes, they SHALL follow the encounter linking requirements for Patient Summaries in section 3.4.3 [Encounter Linking for Clinical Notes](#)~~Encounter Linking for Clinical Notes~~.

#### 4.2.1 Service dates for patient summaries in CDA and XDS

Dates in CDA and XDS are interrelated<sup>37</sup>. The dates in the required entries above may relate to section time ranges, and often the overall service date range of the CCD (`ClinicalDocument/serviceEvent/effectiveTime`) encompasses all dates in the entries. This guide does not constrain the population of the CCD service dates beyond what the underlying specifications say.

The mapping between CCD header dates and XDS service times is specified in section 2.4, and the date comparison rules of XDS query are described in section 2.6.3.2.

**If a Requesting system uses service date range parameters in a query for a patient summary, they may impact the generation of the document or prevent it entirely.** For example, we are aware of some systems that generate patient summaries with the patient's date of birth as `effectiveTime/low`, and the time of CCD generation as `effectiveTime/high`. In this case, if the Requesting system were to provide the lower bound of `$XDSDocumentEntryServiceStartTimeFrom` as some time after the patient's DOB (a "non-overlapping" date range query as described in section 2.6.3.2), **it would never receive a current patient summary unless the Responding system ignored date ranges for patient summaries** in a non-compliant way. We have heard of some Responding systems being forgiving with patient summaries in exactly this way, but this can't be expected by Receivers in general.

This guide already recommends against the "non-overlapping" date range query, in favor of the "overlapping" query, which would return the patient summary in the above example.

**Resilient Receivers:** Because Responding systems have leeway in the overall service dates of current patient summaries they generate, yet have to obey the date-related requirements for CDA and XDS, receivers can only guarantee they will receive a current patient summary by either not including date ranges or by using overlapping date range queries as recommended.

Receivers may or may not receive a current patient summary using a non-overlapping date range query.

In addition, receivers need to be aware some senders do not support influencing the content of a patient summary based on date range query parameters.

In the sections below, we will go further into how to populate the sections of the patient summary, depending on whether date ranges are included in the query.

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<sup>37</sup> See <https://blog.aegis.net/its-about-time/>

## 4.2.2 Populating sections based on default date ranges

Generation of a current patient summary with default date ranges is possible in the following cases:

- The requesting system queries with no service date parameters.
- The requesting system queries with service date parameters,
  - AND the Responding system only supports a default current patient summary (i.e. it does not support populating sections based on query date ranges as specified in section 4.2.3),
  - AND the default current patient summary falls within the requested date range. For example, the Responding system only supports a default current patient summary where service dates are the last 12 months, and the Requesting system queries for the last 24 months. The default current patient summary would match the query and should be returned.

Besides the minimum population requirements identified in section 4.2, the Joint Document Content Work Group declined to define default behaviors for each section when date range query parameters aren't provided, as it is impossible to predict the information needs of the requestor. Systems should therefore prioritize support of date range query parameters over implementing new defaults.

The table below summarizes the key sections and corresponding time defaults the VA EHR currently applies when no service date/time parameters are included in the query. While not an endorsement, the Joint Document Content Work Group agreed it is helpful to see an example of the decisions the VA made. Each organization may develop and document/share (think Capability Statement) their own decisions in this area.

Section	Default Time Range
Allergies	All Allergies or “no known allergies” and “no assessment done” when appropriate
Clinical Notes (new USCDI requirement) other notes	<p><b>Discharge Summaries</b> with complete text includes the <b>2</b> most recent summaries within the last <b>18</b> months. <u><b>The data comes from all VA treatment facilities</b></u></p> <p><b>RADIOLOGY STUDIES</b> This section includes the 5 most recent <b>Radiology Reports</b> within the last 24 months. <u><b>The data comes from all VA treatment facilities</b></u></p> <p><b>PATHOLOGY STUDIES</b> This section includes the 5 most recent <b>Pathology Reports</b> within the last 24 months. <u><b>The data comes from all VA treatment facilities</b></u></p> <p><b>SURGICAL PROCEDURE NOTE</b></p>

	<p>Max of 5 <b>Surgery Notes</b> per <b>Surgical Procedure</b>.</p> <p><b>Clinical Procedure Notes</b> the section contains the 10 most recent Clinical Procedure notes, with complete text, that have procedure dates within the last 18 months. <u>The data comes from all VA treatment facilities.</u></p>
Encounters	All <b>Outpatient Encounters</b> within the last 18 months
Immunizations	All Immunizations
Problems	All Problems
Procedures	<b>Surgical Procedures</b> includes the 5 most recent procedures within the last 18 months.
Plan of Care/Treatment	<b>Future Outpatient Appointments</b> with appointment date within the next 6 months, max of 20 appointments
Medications	<p>Outpatient Meds dispensed in the last 15 months</p> <p>All Non-VA Meds on record at VA</p>

*Figure 29 – VA Section Default Timespan Filters*

### 4.2.3 Populating sections based on query date ranges

In this optional capability, a Responding system generates a patient summary that covers, at least in part, the specific date range the Requesting system queries for. The Work Group examined current behavior that has been in production for years, and is considered essential for some Requesting systems to meet their use case.

While the Work Group declined to define specific behaviors for this case, it did acknowledge the following:

- Populating sections based on requested dates is compatible with existing requirements, but represents a new capability. Ideally, it would be specified normatively. The guidance in this section represents the first steps towards doing that.
- It seems acceptable to limit the sections the dates apply to. It may be appropriate to include more than requested in some sections (e.g. allergies) and less in others (e.g. Vitals).
- A future work group should continue refining this topic.

Note that if any sections are not bound by the query parameters, the business logic will not be captured in the service dates for the document, so the responder knows what to generate at retrieve. For example, the requester asks for 18 months, and the responder filters some sections to 18 months and some sections to the life of the patient. The effectiveTime/low in the CCD and serviceTimeStart in the

document entry would be the patient's date of birth. For this reason, the Responder must do one of two things:

- Generate the document and its stable entry fully at the time of query.
- Generate the document entry at the time of query and persist the additional query information with the document entry. In this case, the entry returned at query MAY be an On-demand entry or a stable entry that will be generated using Delayed Document Assembly. This guide does not constrain which mechanism is used.

**Smart Senders:** As it is a best practice to keep queries **idempotent** (i.e. they can be called multiple times without generating client-specific information), Responding systems SHOULD reuse date-bound patient summary documents when possible. For example, if a query comes in for the last 24 months, then another for the last 18 months, as long as there have been no updates to the underlying data, the same document can be returned.

When populating a section based on query date ranges, Responding systems SHOULD apply the date comparisons to entries in the same way as they would apply to the service dates. For example: if the parameter \$XDSDocumentEntryServiceStopTimeFrom is included, choose entries with no effectiveTime/high or an effectiveTime/high after or equal to the parameter.

When populating a section based on query date ranges, Responding systems SHOULD populate the section time range as follows:

- effectiveTime/low: the "...From" query parameter, if provided, otherwise the default.
- effectiveTime/high: the "...To" query parameter, if provided, otherwise the default.
- Section text: indicate the range, including the nature of the range if possible. For example:
  - "Procedures performed between 08/15/2012 and 08/15/2015" for non-overlapping
  - "Procedures performed across 08/15/2012 and 08/15/2015" for overlapping

The VA EHR currently supports populating sections based on query date ranges. The table below summarizes the key sections and corresponding time defaults the VA EHR currently applies when service date/time parameters are included in the query. While not an endorsement, the Joint Document Content Work Group agreed it is helpful to see an example of the decisions the VA made. Each organization may develop and document/share (think Capability Statement) their own decisions in this area.

Section	Default Time Range
Allergies	All Allergies or "no known allergies" and "no assessment done" when appropriate
Clinical Notes (new USCDI requirement) other notes	<b>Discharge Summaries</b> with complete text includes all summaries within the requested date range. <b><u>The data comes from all VA treatment facilities</u></b>

	<p><b>RADIOLOGY STUDIES</b> This section includes all <b>Radiology Reports</b> within the requested date range. <u>The data comes from all VA treatment facilities</u></p> <p><b>PATHOLOGY STUDIES</b> This section includes all <b>Pathology Reports</b> within the requested date range. <u>The data comes from all VA treatment facilities</u></p> <p><b>SURGICAL PROCEDURE NOTE</b> Max of 5 <b>Surgery Notes</b> per <b>Surgical Procedure</b>.  <b>Clinical Procedure Notes</b>, with complete text, that have procedure dates within the requested date range. <u>The data comes from all VA treatment facilities.</u></p>
Encounters	All <b>Outpatient Encounters</b> within the requested date range.
Immunizations	All Immunizations
Problems	All Problems
Procedures	All <b>Surgical Procedures</b> within the requested date range.
Plan of Care/Treatment	<b>Future Outpatient Appointments</b> with appointment date within the next 6 months, max of 20 appointments
Medications	Outpatient Meds dispensed in the last 15 months All Non-VA Meds on record at VA

Figure 30 – VA Section Query-influenced Timespan Filters

### 4.3 Smart Senders: Reducing the clutter of too many generated patient summary documents

Unlike encounter documents, which might go through some versions but eventually stabilize, patient summaries are continuously changing. With potentially many Requesting systems triggering generation, it would be easy for the number of generated documents and document entries to become overwhelming for Requesting systems. There are various techniques, compatible with existing requirements, for Responding systems to reduce the clutter of many generated patient summaries. The group heard of many of these in current practice.

This guide does not constrain these techniques at this time, nor choose a best approach. Perhaps a future workgroup could revisit this.

Responding systems that generate Patient Summaries **SHOULD** employ one of the following techniques to reduce the clutter of generated documents and document entries:

- Use On-Demand without the Persistence of Retrieved Documents Option. Note that this option is not available in Carequality, as the Persistence of Retrieved Documents Option is required.
- Use On-Demand with the Persistence of Retrieved Documents Option, and immediately deprecate returned stable document entries.
- Use versioning of generated stable documents and deprecate all but the current version. This can be done with On-Demand (see section 2.3.4.1) or with stable documents only (see section 2.3.2).



## Appendix A

### A.1 Additional education material

- HL7 C-CDA Companion Guide, Section 7.5 Educational and Support Resources
- [HL7 CDA Example Task Force](#)

### A.2 Future Work

Below is a backlog of remaining tasks the workgroup identified. They may be picked up by a future iteration of this workgroup (resulting in revisions to this guide), or another workgroup with a similar charter, i.e. to consider common operational and best practice guidance beyond the bounds of the underlying HL7 and IHE standards.

As of the 2.0 version of this guide, the Sequoia Data Usability Workgroup had begun their ongoing work by considering this backlog.

#### Backlog:

- Define default time ranges for each section in Patient and Encounter Summaries.
- Create guidance on Tracking Labs from Order to Results (2.5.1.5) and Tracking Lab Result Corrections (2.5.1.7).
- Interoperable laboratory results: identify and perform tasks from section 2.5.2.4, e.g. to identify/create preferred value sets for lab results and to create manual or automatable mappings from custom values/codes to these preferred codes.
- Create guidance on provenance for various use cases.
- Refine guidance on sharing versions of encounter summaries for various use cases (see section 3.5.3).
- Refine guidance on the current patient summary.
- Refine and make normative the guidance on populating sections of Patient Summaries based on query date ranges (section 4.2.3).
- Refine the guidance on reducing the clutter of too many generated patient summary documents (section 4.3).
- Develop best practices for rendering documents - stylesheets
- Provide guidance on sending Referral Notes, or Consultation Notes to complement encounter summaries as an example: Push vs Pull and timing of information
- Develop guidance for populating meaningful narratives.
  - The basic requirement of all CDA documents is they are human-readable. Future efforts may define guidance for the following issues:
  - Discussion about `section.text` is generated vs authored
  - Negative - what are we trying to solve?

- Minimal narrative populated - systems are relying on entries (code information)
- Bloat - generation is including meaningless content clinicians don't want to see -
  - RIM Elements that don't provide additional meaning.
- Importance of narrative-only sections - Clinical Notes, Free Text SIG