Concise Consolidated CDA:

Deploying Encounter Summary and Patient Summary CDA Documents

September 2020

Executive Summary

Joseph Lamy 10/20/2020 8:29 AM
Comment [1]: TODO

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.

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 include the following:

- Implementers should support the ability to generate, send, receive and ingest Encounter Summary Documents in addition to Patient Summary Documents
- Encounter Summary Documents should be based upon the C-CDA template for Progress Note (Outpatient/Ambulatory) or Discharge Summary (Inpatient/Hospital)
- Implementers should incorporate Clinical Notes in C-CDA implementations
- Content in Encounter Summary Documents should 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
- Implementers should only include a subset of the ONC Common Clinical Data Set by default in an Encounter Summary Document, and only if that data was validated during the encounter
- Implementers should include a Section Time Range Observation for each section
- Implementers should respond with all applicable encounter level C-CDA documents when they receive requests that specify a time range that spans multiple encounters

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 will be shared with HL7 for possible inclusion in a future version of C-CDA.

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Version History

Version	Description
2.0 (current)	Add document sharing details, dynamic generation, versioning, labs, pain points, reorganize content
1.1	Clarify use of IHE query parameters, add conformance verbs, move content to appendix
1.0	Initial release

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Comment [2]: TBD if we add provenance

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Primary Editor	Organization
Brett Marquard	Federal Electronic Health Record Modernization (FEHRM) / WaveOne
Ed Donaldson	OneRecord / Ready Computing
Joseph Lamy	SSA / AEGIS

The editors appreciate the collaborative efforts and commitment from all participants to improve the quality of C-CDA documents. Work Group participants included:

Contributor	Organization
Alan Swenson	Kno2
Anand Prabhu	Mediportal
Ava Spetalnick	Athenahealth
Becky Shoemaker	Dignity Health
Benjamin Flessner	Redox
Christopher Dickerson	Carequality
Christopher J. Hills	DoD / VA Interagency Program Office (IPO)
Corey Parker	Greenway Health
Dana Grove	Cerner
Dave Cassel	Carequality
David Camitta MD, MS	Dignity Health
David Parker MD	DoD / VA Interagency Program Office (IPO) / Defined IT
Didi Davis	eHealth Exchange
Elizabeth R. Ames	Sutter Health
Eric Heflin	The Sequoia Project
Farah Saeed	eClinicalWorks
Holly Miller MD, MBA	MedAllies
Jason Goldwater	Cedar Bridge Group
Jitin Asnaani	CommonWell Health Alliance
Joe Wall	MEDITECH

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Comment [3]: Chris, please update to add anyone new

Justin Ware	Epic
Kelly Bundy	Surescripts
Leanna Evans	Cerner
Lisa R. Nelson	MaxMD
Lizz Restat	athenahealth
Luke Doles	NY eHealth Collaborative
Madhav Darji	eClinicalWorks
Margaret Donahue, MD	US Department of Veterans Affairs
Marie Swall	US Department of Veterans Affairs / JP Systems
Marty Prahl	Social Security Administration
Mike Warner	Cerner
Moti Mitteldorf	Womba
Nick Knowlton	Brightree
Rene Cabral-Daniels	Community Care Network of Virginia
Robert “Bo” Fried, MD	Eagle Physicians
Russ Ott	DoD / VA Interagency Program Office (IPO) / Deloitte
Sandi Mitchell	US Department of Veterans Affairs / JP Systems
Steven Lane, MD MPH	Sutter Health
Therasa Bell	Kno2
Virginia Yost	US Department of Veterans Affairs / JP Systems

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 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 IG: C-CDA Templates for Clinical Notes STU Release 2.1, and the C-CDA Templates for Clinical Notes R1 Companion Guide, 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 a future update to C-CDA.

For **guidance pertaining to document sharing**, this document complements the following transactions that implement the "Pull" mechanism. 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.

- IHE XCA Query: ITI-38
- IHE XCA Retrieve: ITI-39

In addition, this guide makes use of the following 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.

Although there are other ways of sharing CDA content besides Pull (Push, Subscriptions, Direct, FHIR), these sharing mechanisms are out of scope in this version.

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 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.

1.3 Background and Development Approach

In the fall of 2017, independent Care*e*quality and CommonWell Content Work Groups were attempting to solve a set of common issues: unacceptably large 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 Care*e*quality 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. Care*e*quality 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 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[1] - 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
    2. Future – Define default time ranges for each section

Technical

[1] With support from our Argonaut colleagues!

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 worked on in this version were:

1. Provide guidance for dynamic generation of documents
2. Provide guidance for sharing laboratory tests through their 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 Data Provenance
6. Provide guidance for document versioning
7. 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. 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.

Other standards or guides referenced through the development:

- 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
- Draft ONC U.S. Core Data for Interoperability (USCDI)

1.4 How to read this guide

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This guide is organized into the following sections:

- Introduction (this section)
- 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, document sharing, and dynamic generation.
- Encounter Summary Documents. This section provides details on how and when to generate encounter summaries.
- Patient Summary Documents. This section provides details on how and when to generate patient summaries.
- USCDI within TEFCA. This section explains the proposed Draft U.S. Core Data for Interoperability (USCDI) within the Trusted Exchange Framework and Common Agreement (TEFCA).
- Document Sharing. This section explains the mechanisms for sharing documents in more detail, including dynamic generation.
- Appendices.

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 query context, the Receiver is the Initiating system and the Sender is the Responding 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.

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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.

2.1.1 Hosting Patient and Encounter Summary Documents

> ***The Joint Document Content Work Group decided that in order for 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.***

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.

Note that the above requirements only apply when the responding system has control over the documents it generates.

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 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

Below is a simple example XCA document query request, passing the required parameters and also choosing both stable and On-demand document entries (which will be explained in section 2.4.4).

```
<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>
    <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 returnComposedObjects="true" returnType="LeafClass"/>

      <!-- This UUID is the FindDocuments query -->
      <rim:AdhocQuery id="urn:uuid:14d4debf-8f97-4251-9a74-a90016b0af0d">

        <rim:Slot name="$XDSDocumentEntryPatientId">
          <rim:ValueList>
            <rim:Value>'st3498702^^^&amp;amp;1.3.6.1.4.1.21367.2005.3.7&amp;amp;ISO'</rim:Value>
          </rim:ValueList>
        </rim:Slot>

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


        <!-- This matches documents of either type (multiple values in slot = OR) -->
        <rim:Slot name="$XDSDocumentEntryType">
          <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

The above request should return all available document entries: 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.

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 TBD.

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
- See narrative reference examples in the General section of HL7 Example Task Force

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Comment [6]: Bad link

2.2.2 Smart Senders: Maintain act/observation IDs across documents

Many entries in C-CDA require an identifier[2] (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.

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.

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

Figure 2 – Example id root only

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```
<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

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2.2.3 Smart Senders: Reconciliation flag

Sending systems may indicate that a particular list was reconciled[3] prior to sending using the IHE Supplement. The Reconciliation Act Entry Content Module (1.3.6.1.4.1.19376.1.5.3.1.1.24.3.1) provides

[2] C-CDA R2.1 Companion 4.1.10 Generating Unique Identifiers

[3] Only include 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.

the structure to indicate the information in a section has been reconciled. While not required, systems should consider including this act, or a similar indicator, to explicitly state a list has been reconciled.

2.3 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 mapping between XDS metadata and information in the CDA header. Note that stable document entries (see section 2.4.1) correspond directly to a CDA document, as opposed to On-demand entries (see section 2.4.4), which can generate multiple documents. This section addresses stable entries only.

A Responding system SHALL map stable 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 guide.

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. 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.

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 SHALL NOT include the caret "^" in the XDS document unique id when there is no extension value in the CDA document id.

- **Note**: This addresses a conflict between PCC and XDS: the PCC mapping includes the caret in all cases, which is in conflict with the XDS metadata definition in IHE ITI Technical Framework Volume 3, Table 4.1-5 Document Metadata Attribute Definition.

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

2.3.1 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 `ClincalDocument/serviceEvent/effectiveTime/low`
- `DocumentEntry.serviceStopTime` to `ClincalDocument/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

- `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.

2.4 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.

2.4.1 Basic IHE document sharing

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IHE document sharing 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 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 4 IHE XDS Document entry and CDA document

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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.

2.4.2 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 SHOULD support the Document Update Sharing capability, as specified in this section.

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> ***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 previously sent document through the `parentDocument` relationship. The HL7 C-CDA R2.1 Companion Guide describes this scenario in the section: 2.8 *Options for Temporarily Unavailable Data*.

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:sdtc="urn:hl7-
org:sdtc" classCode="DOCCLIN" moodCode="EVN" xmlns="urn:hl7-org:v3">
  <realmCode code="US" />
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040" />
  <templateId root="2.16.840.1.113883.10.20.22.1.1" extension="2015-08-01" />
  <templateId root="2.16.840.1.113883.10.20.22.1.8" extension="2015-08-01" />
  <id root="2.16.840.1.113883.19.5.99999.1" extension="20160414014447" />
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" code="18842-5"
    displayName="Discharge Summary" />
  <title>Health Summary</title>
  <effectiveTime value="20160414014447-0500" />
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N" />
  <languageCode code="en-US" />
  <setId extension="20160414014447" root="2.16.840.1.113883.19.5.99999.19" />
  <versionNumber value="1" />
  ...
  <section nullFlavor="NAV">
    <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>Information Not Available</text>
  </section>
  ...
</ClinicalDocument>
```

Figure 5 – Discharge Summary with no Hospital Course information

Joseph Lamy 10/20/2020 8:29 AM
Comment [9]: These examples are a straight lift from the Companion Guide. Necessary?

Joseph Lamy 10/20/2020 7:12 PM
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```
<ClinicalDocument>
  <realmCode code="US">
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <templateId root="2.16.840.1.113883.10.20.22.1.1" extension="2015-08-01">
  <templateId root="2.16.840.1.113883.10.20.22.1.8" extension="2015-08-01">
  <id root="2.16.840.1.113883.19.5.99999.1" extension="20160414145050">
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        code="18842-5" displayName="Discharge Summary" />
  <title>Health Summary</title>
  <effectiveTime value="20160414145050-0500">
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25" code="N">
  <languageCode code="en-US">
  <setId extension="20160414014447" root="2.16.840.1.113883.19.5.99999.19"/>
  <versionNumber value="2">
  <relatedDocument typeCode="RPLC">
    <parentDocument>
      <id root="2.16.840.1.113883.19.5.99999.1" extension="20160414014447">
      <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
            code="18842-5" displayName="Discharge Summary" I>
      <setId extension="20160414014447" root="2.16.840.1.113883.19.5.99999.19">
      <versionNumber value="1">
    </parentDocument>
  </relatedDocument>
  ...
  <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>The patient was admitted and started on Lovenox and nitroglycerin paste. …</text>
  </section>
  ...
</ClinicalDocument>
```

Figure 6 – Replacement Discharge Summary document with Hospital Course Information

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The document update capability as defined in this section is **more than 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.
- A relationship conveyed in XDS metadata, where an association links the document entries of the original and 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:

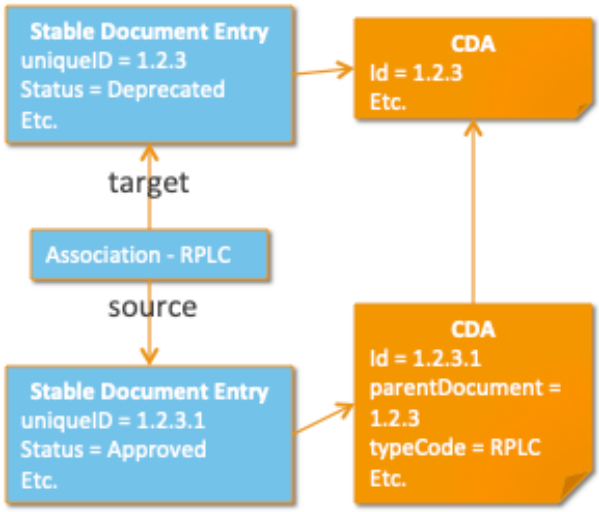

Figure 7 Document Replacement in XDS and CDA

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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.

2.4.3 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 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

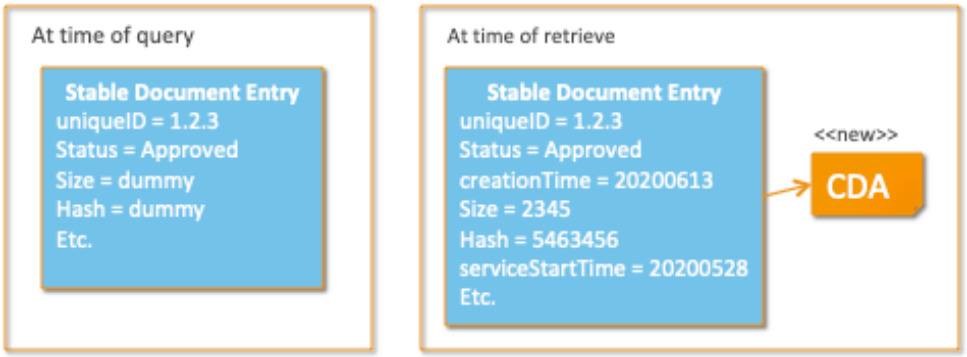

Figure 8 Delayed Document Assembly in Practice

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This guide modifies the option as follows:

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Comment [10]: Consider turning these into conformance requirements.

- The option is only defined on XDS.b. This guide extends it for XCA, and does not require any grouping with XDS.b actors.
- The option is silent on the use and meaning of the creationTime attribute, although this wiki of closed issues from Public Comment has guidance that it reflect the time the content was "frozen". This guide gives implementers a choice below.

Responding systems that support the Delayed Document Assembly Option SHOULD choose from the following:

- Omit creationTime before the document has been generated and update it with the time of document generation.
- Make creationTime the time the clinical information was "frozen". This does not have to be updated when the document is generated.

2.4.4 Capability: On-Demand Option

Requesting systems SHOULD 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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [11]: This should be SHALL, but the group hasn't discussed.

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.

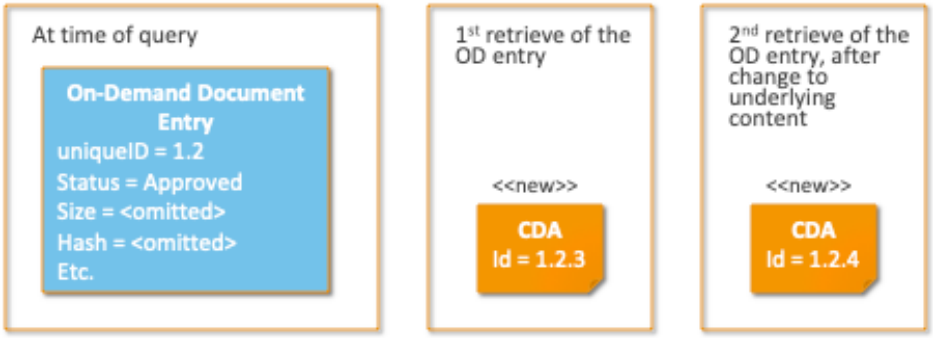

Figure 9 On-Demand Basic Functionality

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A Responding system 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 2.3, except as follows:

- creationTime SHALL not be defined.
- serviceStartTime and serviceStopTime SHOULD be defined only if known and stable. 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.
- 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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [12]: SHALL?

2.4.4.1 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:

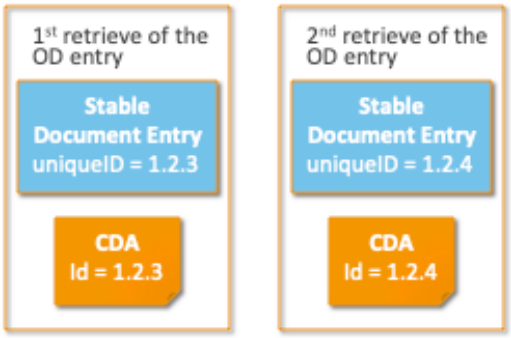

Figure 10 On-Demand with Persistence of Retrieved Documents

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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.

The responder doesn't always have to generate a new document. If the underlying content has not changed, it can return the same document (with the same unique ID) it did last time. **But note that the requesting system has to retrieve the document to find out whether there has been a change.** This makes On-demand less attractive for documents with meaningful versions than the Delayed Document Assembly with Lookahead Updates capability described in section 2.4.5.

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 Document Unique ID as the prior retrieve.

2.4.4.2 On-Demand and Document Replacement

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 assocations, 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:

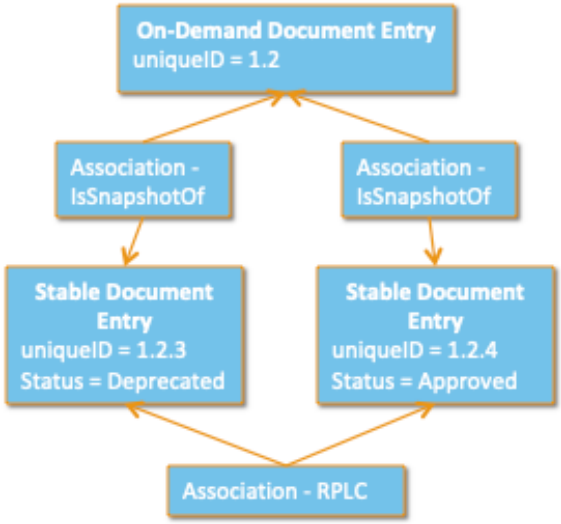

Figure 11 On-Demand with Persistence and Association Support

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2.4.5 Capability: Delayed Document Assembly with Lookahead Updates

Requesting systems MAY support the Delayed Document Assembly with Lookahead Updates capability, as specified in this section.

Responding systems MAY support the Delayed Document Assembly with Lookahead Updates capability, as specified in this section. Note that this is a capability that need not apply to every document type returned by a Responding system. It will be bound to specific document types elsewhere in this guide.

Responding systems that support the Delayed Document Assembly with Lookahead Updates capability SHALL support the Delayed Document Assembly capability as specified in section 2.4.3.

Responding systems that support the Delayed Document Assembly with Lookahead Updates capability SHALL support the Document Update Sharing capability as specified in section 2.4.2.

> ***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.***

The Delayed Document Assembly with Lookahead Updates capability addresses the above pain points by enhancing Delayed Document Assembly to indicate available document updates at the time of query, before generating the document itself. **It is best for documents that relate to a fixed event in time, such as an encounter, yet need to handle updates**.

This is preferable to On-Demand because it is less complex, and because **with On-Demand you only discover that there was an update when you retrieve**.

Each time a Responding system that supports Delayed Document Assembly with Lookahead Updates generates a document that uses this capability, it SHALL track the underlying content for future changes. Other requirements in this guide MAY constrain this capability by:

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

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. it has real hash and size), the Responding system SHALL replace that document entry with a new one with dummy hash and size values in accordance with Delayed Document Assembly.

The above requirement implies the following:

- If none of the data contributing to the document has changed since the last generated document, the Responder will return the same stable document entry.
- If any data contributing to the document has changed since the last generated document, the Responder will return a different stable document entry than the one associated with the generated document.
- The Responder will return the same new stable document entry in subsequent queries even If encounter content is still changing, as long as the document has not yet been generated.

2.4.6 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.
- 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.

2.5 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.***
>
> ***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 Section 4.4.5 Laboratory Tests. Readers should start there. This guide expands on that guidance by further constraining behavior.

Note that much of this lifecycle guidance carries over to 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.

See the C-CDA 2.1 Companion Guide for an example.

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 corresponding encounter summary document, in the Plan of Treatment section.

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

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 patient summary document, in the Plan of Treatment section.

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 patient summary document, in the Results section.

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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [13]: There may be some clarification we can add of existing requirements here (inFulFillmentOf) without breaking any new ground.

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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [14]: Look into this. It may not always be appropriate, for example, if a new result observation is added that replaces the original to reflect a correction.

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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [15]: There may be some clarification we can add of existing requirements here without breaking any new ground.

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 TBD 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 TBD.

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.

The primary 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/general.html) gives a good overview.

See Section TBD 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.

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 participating 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. Over time, these mapping subsets can grow to cover more high-priority results and facilities.

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 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 translate values manually and perhaps to guide their creation of automatable mappings.

When the workgroup first looked into the LIVD format, 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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [16]: This is what we were told, but this doesn't really make sense for mapping, because the receiver of a lab V2 message won't already have the LOINC code.

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

Joseph Lamy 10/20/2020 8:29 AM
Comment [17]: Is there a way to use device identifiers to help with this?

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-OID" codeSystem="VENDOR-OID"
        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.

Joseph Lamy 10/20/2020 7:12 PM
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Joseph Lamy 10/20/2020 8:29 AM
Comment [18]: The workgroup didn't discuss this, but it seems like it should not be controversial. Is it?

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.

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 **Error! Reference source not found.** and **Error! Reference source not found.** may be transparent to the user.

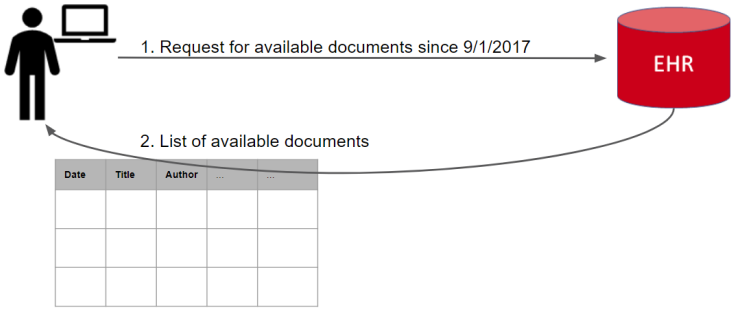

Figure 13 – Document Query

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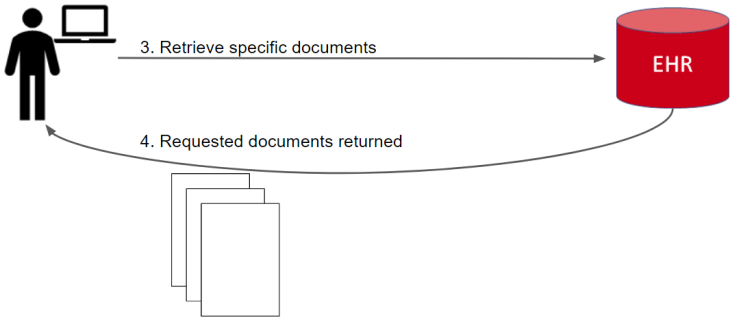

Figure 14 – Document Retrieval

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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[4].

The figure**Error! Reference source not found.** below summarizes the key data elements available in the IHE Query transaction vs the retrieved C-CDA Header[5]:

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

[4] While this section focuses on query/retrieve, documents received via Direct **SHOULD** follow the recommended metadata for display

[5] 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 TBD for the normative mapping between XDS document metadata attributes and the CDA header.

Document Type	IHE Metadata	DocumentEntry.typeCode
	C-CDA Header	ClinicalDocument/code
Author	IHE Metadata	DocumentEntry.authorPerson
	C-CDA Header	ClinicalDocument/author/assignedAuthor/assignedPerson
Author Organization[6]	IHE Metadata	DocumentEntry.authorInstitution
	C-CDA Header	ClinicalDocument/author/assignedAuthor/ representedOrganization/name
List of Services	IHE Metadata	DocumentEntry.eventCodeList
	Encounter Summary C-CDA Header	ClinicalDocument/documentationOf/serviceEvent/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	DocumentEntry.practiceSettingCode
	Encounter Summary C-CDA Header	ClinicalDocument/componentOf/encompassingEncounter/ location/healthcareFacility
	Patient Summary C-CDA Header	Not Applicable – Patient Summary may multiple practice types
Format Code	IHE Metadata	DocumentEntry.formatCode
	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

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See **Error! Reference source not found.** 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

[6] eHealth exchange named this Service Location

...				

Figure 16 - Sample Document List Display

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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 2a, 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','18842-
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):

- $XDSDocumentEntryFormatCode: 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 classCode attribute.
- $XDSDocumentEntryClassCode: 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 formatCode 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:

- $XDSDocumentEntryClassCode = “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 2a, 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 didn't know 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, $XDSDocumentEntryTypeCode appears to be a useful filter. This narrows down the document type beyond class code, for example, it could narrow down a discharge summry 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.

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 Vol 2a, 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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [19]: Fix

Joseph Lamy 10/20/2020 8:29 AM
Comment [20]: Do we want to standardize on metadata value sets in this guide?

Joseph Lamy 10/20/2020 8:29 AM
Comment [21]: Fix

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 2.3.1.

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 <= 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 `$XDSDocumentEntryService`**`StopTimeFrom`** and `$XDSDocumentEntryService`**`StartTimeTo`** 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.

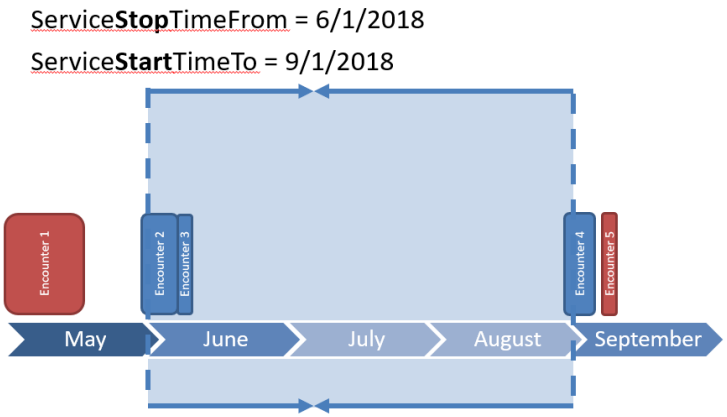
- When filtering a query by date range, Initiating systems **SHOULD NOT**[7] send the IHE XDS Query Parameters `$XDSDocumentEntryServiceStopTimeTo` and `$XDSDocumentEntryServiceStartTimeFrom` since encounters in progress will not be returned. In this guide this is referred to as a "non-overlapping" date 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" paramaters and their usage examples:

Joseph Lamy 10/20/2020 8:29 AM
Comment [22]: Fix

2.6.3.2.1 Date range search, overlapping



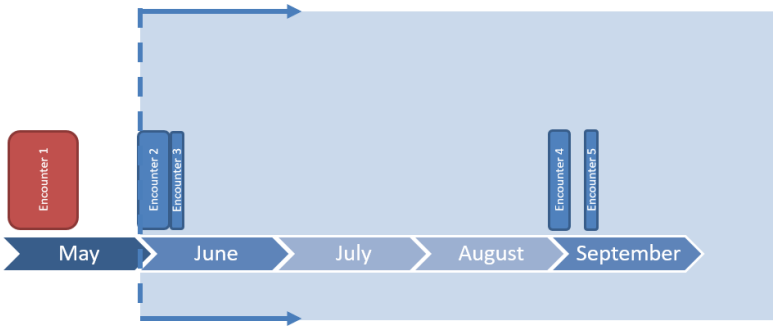
These parameters match encounters where the date range overlaps the range of interest, not just encounters falling entirely within the range of interest.

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

[7] 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

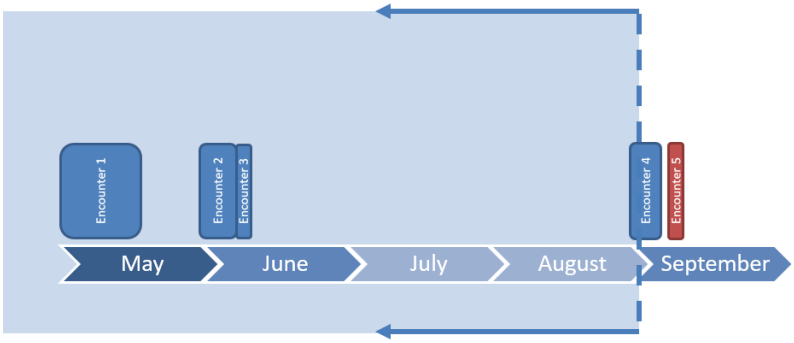
ServiceStopTimeFrom= 6/1/2018



- `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



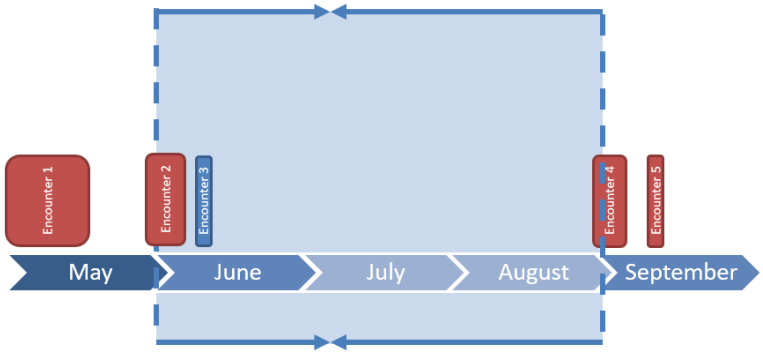
- `DocumentEntry.serviceStartTime` is less than `$XDSDocumentEntryServiceStartTimeTo`

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

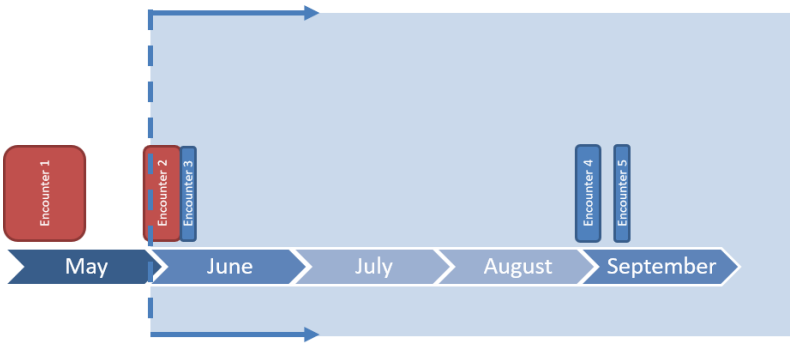


Note that these parameters only match encounters falling entirely within the range of interest, not ones that overlap the range. This is approach is not recommended since boundary documents are not returned.

- `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

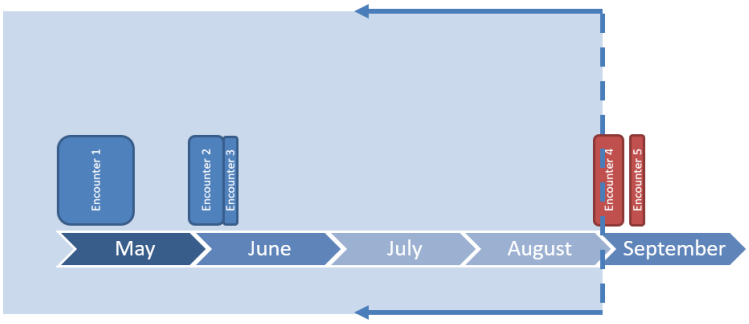
ServiceStartTimeFrom= 6/1/2018



- `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 Document Versioning section for guidance on how to manage documents versions and updates.

Joseph Lamy 10/20/2020 8:29 AM
Comment [23]: Update this reference

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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [24]: This guide doesn't require a minimum of C-CDA 2.1. Should it?

As specified in Section TBD, 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 SHALL use one of the following C-CDA document types: Progress Note, Consultation Note, History and Physical, or Procedure Note.

Joseph Lamy 10/20/2020 8:29 AM
Comment [25]: SHOULD? We are offering guidance about Progress Note, but allow other types. Do we want to allow systems to generate encounter summaries using other document types?

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

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.

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 draft US Core Data for Interoperability (USCDI). (see Figure 21 and Figure 22 for priority subset)

Joseph Lamy 10/20/2020 7:12 PM
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3. Systems **SHOULD** send a 'No information' assertion template if nothing is available[8] 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 that require review **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.
- 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.[9]

Additionally, every section must comply with the following guidance:

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

Joseph Lamy 10/20/2020 8:29 AM
Comment [26]: Need something like this for patient summaries? Seems like it might even be more important than for encounters?

[8] See HL7 Approved C-CDA Example No Information
[9] An exception to this rule is if the last encounter is recent and does contain current information.

- If the section is required (see Progress Note Document and Discharge Summary Document) it **SHALL** include a 'No information'[10] assertion if no information is included for a section.

3.1.1 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 Range Observation[11], 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.

Surgical Procedures

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 19 – Sample display of Section Time Range

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[10] HL7 example for sending 'No Information'
[11] 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 20 – Example of Section Time Range Observation

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Comment [27]: Fix spacing

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3.2 Outpatient/Ambulatory Summary (Progress Note Document)

The content work group selected the C-CDA Progress Note document template[12] 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.

[12] C-CDA R2.1 Progress Note templateId: 2.16.840.1.113883.10.20.22.1.9:2015-08-01

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.

Figure 21 – Progress Note Document Section Requirements, 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.

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	Required	**Required if Reviewed**[13]
Outpatient/Ambulatory Summary (Progress Note Document)	Assessment Section (V2)[14]	Problem Section (entries required) (V3)
	Plan of Treatment Section (V2)	Allergies and Intolerances Section (entries required) (V3)
	Clinical Notes[15] (may include Subjective)	Medications Section (entries required) (V2)
	Encounter Section (V3) with encounter diagnoses for the specific encounter[16]	Immunizations Section (entries required) (V3)

Figure 21 – Progress Note Document Section Requirements

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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 5 USCDI within TEFCA for the data elements being prioritized for exchange in federal regulation.

[13] 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.

[14] 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)

[15] C-CDA R2.1 Companion Guide Notes Section 2.16.840.1.113883.10.20.22.2.65:2016-11-01

[16] If the encounter diagnosis is not appropriate for the encounter it may be omitted

3.3 Inpatient/Hospital Summary (Discharge Summary Document)

The content work group selected the C-CDA Discharge Summary document template[17] 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.

Figure 22 – Discharge Summary Document Section Requirements, 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.

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Deleted: Figure 21 – Discharge Summary Document Section Requirements

	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[18]	Medications - Admission medications list (patient reported/home medications)[19] - Facility Administered[20] (Given during admission) - Discharge Medications list[21]
	Clinical Notes[22] (may include Subjective)	Immunizations Section (entries required) (V3)
	Discharge Diagnosis Section (V3)	

[17] C-CDA R2.1 Discharge Summary templateId: 2.16.840.1.113883.10.20.22.1.8:2015-08-01

[18] 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).

[19] Admission Medications Section (entries optional) (V3) (2.16.840.1.113883.10.20.22.2.44:2015-08-01)

[20] Medications Administered Section (V2) (2.16.840.1.113883.10.20.22.2.38:2014-06-09)

[21] Discharge Medication (V3) (2.16.840.1.113883.10.20.22.4.35:2016-03-01)

[22] C-CDA R2.1 Companion Guide Notes Section 2.16.840.1.113883.10.20.22.2.65:2016-11-01

	Plan of Treatment Section (V2)	

Figure 22 – Discharge Summary Document Section Requirements

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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 5 USCDI within TEFCA for the data elements being prioritized for exchange in federal regulation.

3.4 Clinical Notes

Joseph Lamy 10/20/2020 8:29 AM
Comment [28]: Note that some content from this section has been incorporated into the new version of the C-CDA Companion Guide. We may want to adjust this.

Clinician authored Clinical Notes capture the health story of a patient – this may include their past and current health as well as planned next steps to improve their health. Clinical Notes are a critical part of the patient record. Prior to the formation of the Joint Document Content Work Group the independent Carequality and CommonWell content work groups were discussing methods to exchange Clinical Notes in C-CDA. Additionally, in response to requirements within the 21st Century Cures Act to identify a common set of data for exchange, the Office of the National Coordinator (ONC) proposed the U.S. Core Data for Interoperability (USCDI) include Clinical Notes. The exchange of Clinical Notes is also a high priority for the further development of the Fast Healthcare Interoperability Resources (FHIR) specification as supported through the Argonaut Project. Fortunately, for all activities HL7 drafted an initial approach for exchanging in the HL7 C-CDA companion guide[23] using the new Notes Section[24] and Notes Activity[25]. The HL7 guidance provided a baseline for the additional guidance here.

3.4.1 Common Clinical Note Types

The LOINC terminology includes thousands of different note types. To focus the industry, the Argonaut participants and the Department of Veterans Affairs contributed their most commonly used note types to develop the following list of top notes:

- Discharge summary (18842-5)
- Consultation (11488-4)
- Imaging narrative (18726-0)
- Lab/path narrative
- History & Physical (34117-2)
- Progress note (11506-3)
- Procedures note (28570-0)

The list is not in a priority order, nor does it represent the exclusive list of what systems can and will support. All 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. See the latest C-CDA Companion Guide for more information.

[23] HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2
[24] C-CDA R2.1 Companion Guide Notes Section 2.16.840.1.113883.10.20.22.2.65:2016-11-01
[25] C-CDA R2.1 Companion Guide Note Activity 2.16.840.1.113883.10.20.22.4.202:2016-11-01

3.4.2 Sending Clinical Notes in C-CDA

The introduction of the Notes Section and Notes Activity entry templates in the HL7 C-CDA companion guide provided structure and guidance for sending notes. 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.

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>
```

```
  <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 24 – Example of Note Attached to an Act

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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 25.

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```
<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 25 – Example of Note Added to an Appropriate Section

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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 26 – Example of Stand-alone Notes Section

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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`[26]. Figure 27 below provides an XML example for how this should be done.

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```
<!-- 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 27 – Example of Encounter Linking with entryRelationship reference

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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 27. Otherwise, the entire encounter should be included in the Note Activity as demonstrated in Figure 28 below.

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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 28 – Example of Encounter Linking with encounter nested

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[26] The companion guide published in March 2017 restricted to only encounters in the encounter section. SDWG approved HYPERLINK "http://www.hl7.org/dstucomments/showdetail_comment.cfm?commentid=1522" errata 1522 on 1/29/2018 to additionally allow linking to encompassingEncounter/id.

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

Joseph Lamy 10/20/2020 8:29 AM
Comment [29]: Section 3.5 "Honor time parameters in Query for Documents" moved up to 2.3 .Requesting Patient and Encounter Summary Documents and 2.3.2 .Filtering by date range

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Comment [30]: Fix

> ***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 TBD and constrained in this section 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 Examples of 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 examples in which such an encounter could be shared:

Joseph Lamy 10/20/2020 8:29 AM
Comment [31]: Not really examples

- 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 Examples of Sharing an Encounter that has Ended

Likewise, the group discussed examples 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 their name on the line that they have 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 this topic, as well as encounter document versioning.

Joseph Lamy 10/20/2020 8:29 AM
Comment [32]: Plural

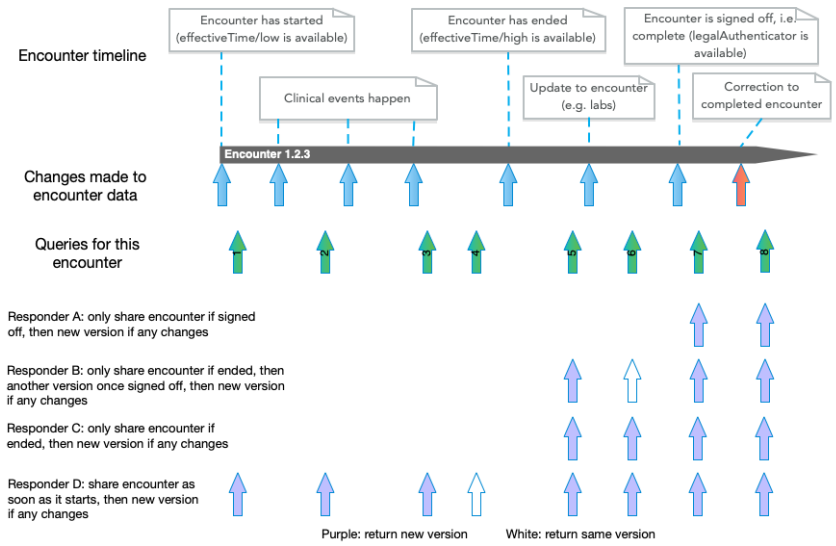

Figure 29 Sharing Throughout the Encounter Lifecycle

Joseph Lamy 10/20/2020 7:12 PM
Deleted: *22*

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 until 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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [33]: Unless

Joseph Lamy 10/20/2020 8:29 AM
Comment [34]: Add link

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 happens at a specific point in time. 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 shown 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.***

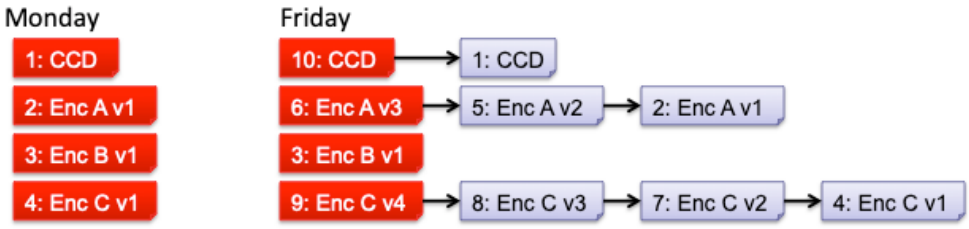

Figure 30 Versioning from Requester's Perspective

Joseph Lamy 10/20/2020 7:12 PM
Deleted: *23*

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. To meet this use case, **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.

Because of these versioning needs, we require support for sharing updates to encounter summaries (which requires relating both the CDAs and the document entries), but offer flexibility in how those updates are represented: via document replacement or document appending.

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

Joseph Lamy 10/20/2020 8:29 AM
Comment [35]: Don't really need this, because it's pulled in by the DDA capability below, but thought it might be clearer.

> **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.

Because the On-Demand mechanism only shows that a document has been updated upon a retrieve, the group opted instead to require the new lookahead capability on stable documents.

A Responding system SHALL support the Delayed Document Assembly with Lookahead Updates capability to share updates to encounter summaries. See section TBD. When implementing this capability for encounter summaries, the term “underlying content”, used to refer to the information being tracked for changes, SHALL correspond to all clinical information contributing to the encounter summary. If there are configuration settings or clinical content that do not contribute to the generated document, they MAY be changed without generating a new version.

4 Patient Summary Documents

Joseph Lamy 10/20/2020 8:29 AM
Comment [36]: A note about this section: The workgroup did not have time to talk much about patient summaries, which is unfortunate because it was one of the big backlog items from the V1.1 guide. However, the primary authors were able to discuss this topic at length after the workgroup had ceased meeting, both at the "pure spec" level and with current implementers. The new content does not add any breaking requirements that were not discussed in the workgroup, but it does explain some of the difficult concepts and make suggestions that future workgroups could hopefully pick up and advance.

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.

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. 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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [37]: Note that this is not adding anything new, just describing known behavior in the wild that is legal.

Joseph Lamy 10/20/2020 8:29 AM
Comment [38]: There is a helpful blog on this topic. Should we link to it? https://healthcaresecprivacy.blogspot.com/2017/03/multiple-formats-of-same-document.html

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.

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 paramater 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 retreiving all available document entries, consider adding logic that ranks the preferred formats and only retreives the most preferred one.

Joseph Lamy 10/20/2020 8:29 AM
Comment [39]: fix

Joseph Lamy 10/20/2020 8:29 AM
Comment [40]: fix

Smart Senders: When generating new current Patient Summaries, use the techniques in section TBD 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 2.4 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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [41]: This is a new requirement for v2.0, but was discussed in the workgroup.

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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [42]: Note that this is not a change from V1.1 of this guide, just a restructuring into bullets. Added "at a minimum" because more can be included.

Smart Senders: The Joint Document Content Work Group recommends Responding systems SHOULD include the Section Time Range in every section. Including this observation will help receiving systems be confident in the range of information received.

4.2.1 Service dates for patient summaries in CDA and XDS

Dates in CDA and XDS are interrelated. The dates in the required entries above may relate to section time ranges, and often the overall service date range of the CCD (`ClincalDocument/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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [43]: I have a blog on this, and some of the difficulties: https://blog.aegis.net/its-about-time/. Should we link to it?

The mapping between CCD header dates and XDS service times is specified in section 2.3.1 for stable entries and section 2.4.4 for On-demand entries, and the date comparison rules of XDS query are described in section 2.6.3.2,

Joseph Lamy 10/20/2020 8:29 AM
Comment [44]: fix
Joseph Lamy 10/20/2020 7:12 PM
Deleted: 2.1.2.2

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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [45]: fix
Joseph Lamy 10/20/2020 7:12 PM
Deleted: 2.1.2.2

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.

4.2.2 Populating sections based on default date ranges

Joseph Lamy 10/20/2020 8:29 AM
Comment [46]: This content was revised from v1.1 appendix "Missing Time Parameters". No breaking changes were made. The VA info was brought up to date.

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.

Joseph Lamy 10/20/2020 8:29 AM
Comment [47]: Is this still our suggestion?

The table**Error! Reference source not found.** 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 Capabilities Statement) their own decisions in this area.

Joseph Lamy 10/20/2020 8:29 AM
Comment [48]: fix

Section	Default Time Range
Allergies	All Allergies or "no known allergies" and "no assessment done" when appropriate
Clinical Notes (new USCDI requirement) other notes	**Discharge Summaries** with complete text includes the **2** most recent summaries within the last **18** months. **The data comes from all VA treatment facilities** **RADIOLOGY STUDIES** This section includes the 5 most recent **Radiology Reports** within the last 24 months. **The data comes from all VA treatment facilities** **PATHOLOGY STUDIES** This section includes the 5 most recent **Pathology Reports** within the last 24 months. **The data comes from all VA treatment facilities** **SURGICAL PROCEDURE NOTE** Max of 5 **Surgery Notes** per **Surgical Procedure**. **Clinical Procedure Notes** the section contains the 10 most recent Clinical Procedure notes, with complete text, that have procedure dates within the last 18 months. **The data comes from all VA treatment facilities**.
Encounters	All **Outpatient Encounters** within the last 18 months
Immunizations	All Immunizations

Problems	All Problems
Procedures	**Surgical Procedures** includes the 5 most recent procedures within the last 18 months.
Plan of Care/Treatment	**Future Outpatient Appointments** 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 31 – VA Section Default Timespan Filters

Joseph Lamy 10/20/2020 7:12 PM
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4.2.3 Populating sections based on query date ranges

Joseph Lamy 10/20/2020 8:29 AM
Comment [49]: This content was revised from v1.1 appendix "Missing Time Parameters" and added to to reflect current practice and underlying requirements. No breaking changes were made. The VA info was brought up to date.

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. 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:

Joseph Lamy 10/20/2020 8:29 AM
Comment [50]: Explain – so the responder remembers what to generate

- 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

Joseph Lamy 10/20/2020 8:29 AM
Comment [51]: I received a bit of pushback from some REST purists about keeping this idempotent. However, the guidance does limit the usefulness if requesters don't want more than they asked for.

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 paramater, if provided, otherwise the default.
- effectiveTime/high: the "…To" query paramater, 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**Error! Reference source not found.** 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 Capabilities 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	**Discharge Summaries** with complete text includes all summaries within the requested date range. **The data comes from all VA treatment facilities** **RADIOLOGY STUDIES** This section includes all **Radiology Reports** within the requested date range. **The data comes from all VA treatment facilities** **PATHOLOGY STUDIES** This section includes all **Pathology Reports** within the requested date range. **The data comes from all VA treatment facilities** **SURGICAL PROCEDURE NOTE** Max of 5 **Surgery Notes** per **Surgical Procedure**.

Joseph Lamy 10/20/2020 8:29 AM
Comment [52]: This is the key requirement for populating entries based on query date range. If/when we want to make it a normative capability, turn this into a SHALL. Maybe add a diagram as well.

Joseph Lamy 10/20/2020 8:29 AM
Comment [53]: Change to SHALL when we make this normative.

Joseph Lamy 10/20/2020 8:29 AM
Comment [54]: fix x 2

Joseph Lamy 10/20/2020 8:29 AM
Comment [55]: This needs analysis by HL7 Structured Documents.

Joseph Lamy 10/20/2020 8:29 AM
Comment [56]: fix or remove

	Clinical Procedure Notes, with complete text, that have procedure dates within the requested date range. **The data comes from all VA treatment facilities**.
Encounters	All **Outpatient Encounters** within the requested date range.
Immunizations	All Immunizations
Problems	All Problems
Procedures	All **Surgical Procedures** within the requested date range.
Plan of Care/Treatment	**Future Outpatient Appointments** 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 32 – VA Section Query-influenced Timespan Filters

Joseph Lamy 10/20/2020 7:12 PM
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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 stablize, 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 document entries, both on-demand and stable.
- Use versioning of generated stable documents and deprecate all but the current version. This can be done with On-Demand (see section 2.4.4.2) or with stable documents only (see section 2.4.2).

5 USCDI within TEFCA

Joseph Lamy 10/20/2020 8:29 AM
Comment [57]: Update this and reference new USCDI

A recent proposed change in federal requirements is the proposed Draft U.S. Core Data for Interoperability (USCDI) within the Trusted Exchange Framework and Common Agreement (TEFCA). Clinical Notes and Provenance are two data elements identified in the Draft USCDI 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. 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.

A future Joint Document Content Work Group will consider data provenance when ONC provides more guidance on which elements they are consider important. More guidance on representing Care Team Members also is needed.

Data classes outlined in red represent the current ONC CEHRT- Common Clinical Data Set (CCDS).

Draft USCDI Version 1 Data Classes	
1. Patient name	2. Sex (birth sex)
3. Date of Birth	4. Preferred Language
5. Race	6. Ethnicity
7. Smoking Status	8. Laboratory tests
9. Laboratory values/results	10. Vital signs
11. Problems	12. Medications
13. Medication Allergies	14. Health concerns
15. Care Team members	16. Assessment and plan of treatment
17. Immunizations	18. Procedures
19. Unique device identifier(s) for a patient's implantable device(s)	20. Goals
21. Provenance	22. Clinical Notes

Figure 33 – ONC Draft USCDI

Joseph Lamy 10/20/2020 7:12 PM
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Appendix A

A.1 Additional education material

- Refer to Section 5 in *Companion Guide to HL7 Consolidated CDA R2.1*
- HL7 CDA Example Task Force

A.2 Future Work

Joseph Lamy 10/20/2020 8:29 AM
Comment [58]: Update this to reflect new backlog and priorities

- Develop a prioritized list of laboratory results to be shared, similar to how Allergies and Intolerances developed a 'most common allergens' list.
- 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
    -