Data Usability Workgroup Implementation Guide

Version 1.0

December 14, 2022

Executive Summary

The Sequoia Project Interoperability Matters Initiative is a public-private cooperative solving discrete health information exchange challenges. Launched by The Sequoia Project in 2018, Interoperability Matters engages experts from across the healthcare and health IT communities to identify, prioritize, and collaborate on the most pressing, discrete challenges to nationwide health information sharing.

In October 2020, the Interoperability Matters: Data Usability Workgroup was launched by The Sequoia Project to develop specific and pragmatic implementation guidance on clinical content for healthcare stakeholders in order to facilitate health information exchange. This workgroup is open to all industry stakeholders and the roster includes over 260 organizations and over 350 participants following this work effort through 2022. The industry stakeholders engaged represent:

- healthcare providers
- health IT developers
- health information networks and exchanges
- federal, state, and local governments
- health plans and payers
- consumers and patients
- standards developers, public health and others

This implementation guide covers specific priority use cases that can be readily adopted by health information exchange vendors, implementers, networks, governance frameworks (i.e., TEFCA, Carequality, eHealth Exchange, Commonwell, etc.), and testing programs. Our primary charge as a workgroup is to improve the *usability of data* received by end users within their workflows. In this setting, data usability may include timeliness, completeness, clinical context, provenance, and semantics. These and many other dimensions can enable receiving systems to more directly **incorporate** shared data into the workflow of a clinician and make it more **computable** (e.g., for clinical decision support) and **actionable**. This Implementation Guide will build on existing work, including, but not limited to, C-CDA Implementation Guides, C-CDA Templates, ONC programs and other standards such as USCDI V1 and V2, the recommendations of the Carequality-CommonWell Joint Document Content Workgroup and in coordination with related standards development organizations and industry initiatives. Our intent is *not* to create new standards, but to serve as a point of convergence and community for existing and future standards and methods. From this intention, our task is to identify priority areas of focus for vendors and implementers alike that will be most valuable in improving data usability. Future work efforts will incorporate guidance for Electronic Health Information Exchange of data leveraging USCDI V2, FHIR Implementation Guides and other industry publications. The following key deliverables, in the form of high-level use cases will be the scope for this and may be expanded for future versions of this implementation guide:

- Provider-to-provider health information exchange
- Provider-to-public health agency information exchange
- Healthcare entity-to-consumer information exchange

The above use cases are agnostic to technology that is acting as a data source and a provider to anyone providing care to a patient. The guidance within this document will be agnostic to the technical infrastructure that comprises the C-CDA Data/Document Source. The content source system could be an EHR, HIE, or some other platform technology.

The Interoperability Matters Leadership Council chartered the Data Usability Workgroup to work in the following phases:

Phase 1 Administration and Prioritization

Phase 1 activities of the Data Usability Workgroup focused on Administration and Prioritization of priority elements that resulted in identification of 34 "pain points" submitted by workgroup members documented here. These problem topics were grouped into 6 topic categories and workgroup members voted to put them in the following priority order:

1. Data Provenance and Traceability of changes
2. Effective Use of Codes in Shared Information
3. Reduce Impact of Duplicates
4. Data Integrity/Trust
5. Data Tagging/Searchability
6. Effective Use of Narrative for Usability

Phase 2 Implementation Guide Development

Phase 2 began in April 2021 with weekly workgroup meetings to scope the guidance to be included in the initial draft of the implementation guide. In June 2021, The Sequoia Project convened a clinician workshop to review the prioritization that was established in phase 1 and to further refine the scope. The workgroup continued a regular cadence of meetings through August 18, 2022 where this initial draft implementation guide was developed for public comment.

Phase 3 Implementation Guide Public Comment

The Public Comment period began on August 29, 2022 with a press release announcing the publication followed by a public webinar on August 30th that reviewed the public comment process and timeline that ended after 45 days on October 14, 2022. The Sequoia Project socialized the work with a wide group of industry partners during these

45 days to encourage comments from users of digital health technology and the vendors and/or developers of these technologies.

Phase 4 Finalizing Implementation Guide for Publication

The leadership team reviewed and disposed of comments to finalize the development of Version 1 (2022) of this implementation guide. The 2022 Version 1 Implementation guide will be published on December 14, 2022 in conjunction with the Sequoia Project Annual Member meeting.

All meeting materials and recordings can be found here.

Version History

Version	Description
0.1	Initial release for Public Comment
1.0	126 Public Comments were resolved from 19 organizations for this Final publication of Implementation Guide on December 14, 2022.

Acknowledgements

Primary Editors	Organization
Adam Davis, M.D.	Sutter Health
David Camitta, M.D.	CommonSpirit Health
Bill Gregg, M.D.	HCA Healthcare
Didi Davis	The Sequoia Project
Data Usability Workgroup Members	Roster

The editors appreciate the collaborative efforts, comments, edits and commitment from all participants of the Data Usability Workgroup to improve the quality and usability of clinical data exchanged.

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Statement of Intent

The Sequoia Project Data Usability Workgroup was chartered to assemble specific and pragmatic guidance around sharing clinical content for healthcare stakeholders in order to facilitate the usability of the shared data. This guidance, in the form of an implementation guide covering identified priority use cases, can be readily adopted by EHR and health information exchange vendors, implementers, networks, governance frameworks (i.e., ONC Trusted Exchange Framework and Common Agreement (TEFCA), Carequality, eHealth Exchange, Commonwell, etc.), and testing programs. This guidance includes data systems and processes from the originating EHR through intermediaries to the end user.

Usable data is data that facilitates users providing optimal care for a patient. On a pragmatic level, the goal of the Data Usability Workgroup (DUWG) is to foster an ongoing process to identify and prioritize important use cases from the perspective of the consumers of exchanged clinical content. Barriers to this "last mile" of exchange often involve very specific, but simple issues that present challenges to clinicians and other users of this data to complete their tasks – whether it is missing or inconsistent information, a lack of semantic content or simply missing narratives from a clinical care summary.

The first product of our process is this Implementation Guide. By design it is built on existing work; including, but not limited to, C-CDA Implementation Guides, C-CDA Templates, ONC and other standards such as USCDI V1 and the Joint Carequality/Commonwell Document Content Workgroup (JDCWG). Because of its widespread use, our initial focus is on C-CDA, but will expand to FHIR as market utilization increases. Input from all relevant stakeholders including both providers of healthcare and vendors developing HIT tools will be balanced to ensure the IG is both useful and implementable in a reasonable time frame by industry. The primary audience for this guide is HIT implementers, product development teams, software developers and groups who provide content testing.

Our most proximal foundation is the Carequality/Commonwell Joint Document Content Workgroup (JDCWG) C-CDA Whitepaper. The JDCWG first identified many important usability issues and focused on the improvement of C-CDA documents to improve information sharing. With the release of the TEFCA Common Agreement and the QHIN Technical Framework (QTF) in January 2022 there was an opportunity to create an ongoing process of identification, information gathering and recommendations around data usability under the umbrella of the Sequoia Project and in coordination with related standards development organizations and industry initiatives.

This Implementation Guide will serve as the template for that process and path forward. The recommendations in this first draft are modest, but in the context of the recent release of the JDCWG C-CDA Whitepaper in March 2022, our goal was to identify the important use cases, add recommendations, but not to burden developers and

implementers with too many changes, too quickly. By design, the work of the DUWG is intentionally iterative. As standards, systems, and vendors mature, we will continue to focus on identifying valuable combinations of testable changes that lead to improved, practical data usability. It is also anticipated that this Implementation Guide will stage requirements over time using SHALL, SHOULD, MAY – enabling the goal of practical, real world conformance testing. For example, certain topic category guidance may be designated SHALL now with others SHOULD or MAY. In future releases of this implementation guidance , some SHOULDs will become SHALLs and MAYs will become SHOULDs. Our future work will make the process of identification of issues and recommendations more predictable for all of the stakeholders. This Guide follows the same Section/Chapter structure for each of the six topic categories as follows:

- Problem statement
- Use Cases
- Existing Work
- Guidance
- Future Efforts
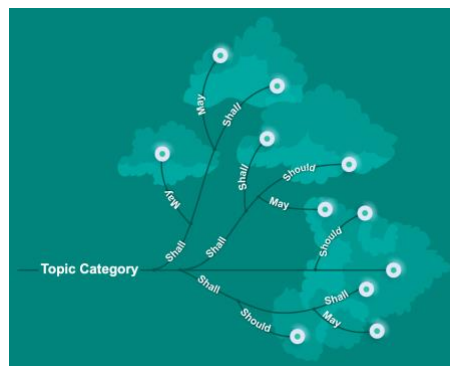
The phased process for next iterations of this Implementation Guide will begin in February 2023 and may include:

- Advice on interpretation of guidance in different contexts beyond the following:
  - Provider to/from Provider
  - Provider to/from Public Health
  - Provider to Consumer
- Refined Structure of the document ("How to read this implementation guide."):
  - Definitions for Human, Machine, and Inter-organization Usability
    - Human Usability: How can we structure data to make it more useful, readable, and interpretable, for end users. ⇒ Narrative
    - Machine Usability: How can we make data we send out easier for machines to parse, sort, index, etc. ⇒ Discrete/machine information
    - Inter-organization Usability: How can we send data in a way that is easy for the receiving party to accurately interpret and derive value from.

This guide evaluates usability from both human and machine perspectives. Within the context of CDA document exchange, human usability typically refers to the narratives shown to an end-user/clinician, while the machine usability refers to the discrete elements or metadata sent along with documents to be reconciled or otherwise morphed into a patient's chart.

1. Data Provenance & Traceability of Changes

Guidance for
**Data Provenance
& Traceability
of Changes**

Problem statement

There are many things that can happen between a clinician documenting a piece of clinical data in one system, and a downstream user seeing that data in their own system. "Provenance" refers to the origination or modification (update) of a piece of data and what has happened to it as it has been transmitted between systems, which may include the name of the clinician who originated a piece of data, their organization, or modifications that have been made to the data. Provenance can convey metadata that typically comprises the who, what, when, where and why of the origination or update event. Provenance may pertain to a composite dataset (e.g., CDA/C-CDA document or section) and/or to individual data elements (attributes). Provenance may be inextricably bound to data content (e.g., with digital signature), or may be asserted by association with particular documents, datasets or data elements. Data usability can be impacted when data content/context is ambiguous. The Data Usability Workgroup notes that while the issue is complex, incremental changes to improve provenance can be expanded with future versions.

The problem today is multi-dimensional:

1. The data provenance detail is often not shown to users in receiving systems.
2. Data provenance elements are not always populated in sending systems.
   NOTE that USCDI v1/v2 only include two provenance elements: author's organization and timestamp.
3. Data exchange leveraging C-CDA in production today does not yet typically include provenance attributes.
4. Intermediary data transformations may occur as a result of translational processes, (e.g., a medication intolerance could mutate into an allergy), provenance may help in tracking through intermediary systems.
5. Provenance metadata alone does not *ensure reliability of information*, but is one important dimension in the trust framework. e.g., changes to data from the original entry may also be corrections or meaningful updates to inaccurate historical information.

Use Cases

Provenance meta-data guidance will focus on **Allergies and Intolerances, Immunizations, Medications and Problems Data Class Elements Only**. This focus will give time to create a template for making Data Provenance more usable and enable future expansion to other data classes.

1.2.1 Provider to Provider - Example use case:

1.2.1.1. When viewing Problem list data received from another institution, *preserving and displaying* the original timestamp of capture (as opposed to date of data transfer/receipt) is important to understanding the relative time frame of a diagnosis (without creating a cluttered view with multiple discordant dates). Consistency in display across systems helps with the usability of such provenance data.

1.2.2. Provider to Public Health - Differentiate between original documentation and reconciliation of externally sourced data:

1.2.2.1. A public health organization wishes to leverage provenance to distinguish administered vaccines from a later recording of an externally sourced vaccine in another record. Patient history of vaccinations is sometimes recorded in the official immunization section of the EHR to satisfy gaps in care/CDS, but can be done inconsistently or inaccurately. Immunization registries, regional HIEs (as aggregators) and individual EHRs all may share vaccine information, making duplication a bigger problem. The original administration is the most valuable but the later recording is error prone. Loss of provenance would make reconciliation difficult.

Existing Work

1.3.1. USCDI v1 & v2

1.3.1.1. [HL7 CDA R2.1 IG: Consolidated CDA Templates for Clinical Note (US Realm), DSTU R2.1—Vol. 2: Templates](#)

1.3.1.2. [C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2](#) documents USCDI V1 requirements.

1.3.1.3. [C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3](#) documents USCDI V2 requirements.

1.3.1.4. Exchange of provenance elements is required as part of [ONC's USCDI v2](#) data set. This effort covers allergies, medications, problems, and immunizations, as well as data types outside of the three discussed in this section. [Guidance for the implementation of provenance](#) as specified by USCDI has been assembled by HL7 workgroups. Instead of drafting new guidance on this effort, we will follow HL7's guidance to ensure standard exchange of provenance data. The HL7 guide includes recommendations for implementation of provenance in the discrete entries in CCDA documents. In addition, HL7 developed some resources to guide

development to display this standardized provenance information received to end users. These resources are linked here for reference.

1.3.1.5. In section 2.2.4 of the JDCWG C-CDA Whitepaper it states: When sharing a newly generated document, Responding Systems SHOULD endeavor to support the USCDI current published version.

1.3.2. Incorporating CLIA Requirements

1.3.2.1. Certain provenance-related data elements are required for laboratories performing testing on people. This includes the name and address of the testing laboratory, test report date, and the test performed, under CLIA § 493.1291. Since this information is required, it establishes a good basis for the provenance of individual elements linked to said lab result. While not required to be retransmitted if the specific result is included in a C-CDA document, retaining this information in an organization's EHR system would allow for an adequate chain to be followed to the original source of result data.

1.3.3. HL7 Guidance: Basic Provenance for C-CDA and FHIR, Release 1 - US Realm

1.3.3.1. When considering provenance, it's often easy for the history of a piece of data to grow much larger than the data itself. Without a standardized approach for determining relevant provenance information for a given data point, organizations will likely send inconsistent information, obscuring the actual meaning of provenance received from different sources. It's crucial that any approach to provenance be simple and focus on easily tracked information. For this reason, the approach suggested here is to focus on only the core information representing the most recent "link" in the "chain" of provenance for individual data elements. Fortunately, a lot of effort and thought has been put into this topic already. Groups such as the Argonauts Data Provenance Workgroup have made excellent recommendations on the implementation of provenance. The guidance in this document largely summarizes their suggestions. We recommend implementers refer to their work.

Guidance (Focus on Allergies, Immunizations Medications & Problem Lists ONLY – at this time)

1.4.1. This first version of the guide focuses on guidance for provenance for allergies, immunizations, medications and problem sections and specific entries within those sections exchanged via CDA documents only – this allows implementers and developers to focus on consistency and presentation of provenance metadata starting with these sections with the goal of raising the bar for other documents, sections, and entries in the future.

1.4.2. The workgroup acknowledges the complexity of the provenance space, particularly providing the full chain of trust for healthcare data. Our aim is to keep this end in mind, while incrementally improving the content and manner that provenance data is shared. As the industry progresses to FHIR based TEFCA exchange, options for a more thorough chain of trust may evolve.

1.4.3. A sending system SHALL include provenance information, when available, at the entry level for allergies, immunizations, medications and problems as specified by USCDI v1 or the most current version when a companion guide specification is published by HL7. This information SHALL include author organization and time stamp.

1.4.4. Sharing Author Person for USCDI Data

1.4.4.1. The Data Usability workgroup endorses the elevation of author person from a Level 2 data element to full USCDI inclusion. This will require specification on who the author should be for data elements edited by multiple users.

1.4.4.2. Prior to that change, provenance entries MAY include the author person for a data item when known. While author person is not required by USCDI it provides valuable context for receivers on where the data originated. The HL7 implementation guide linked in section 1.3 includes guidance for how to share author person.

Future Efforts

1.5.1. JDCWG C-CDA Whitepaper

1.5.1.1. As Appendix A highlights, this workgroup whitepaper deliverables will build upon the reference to USCDI (most current version) in this original guide to document testable guidance for future implementers.

1.5.2. Guidance for Data Provenance

1.5.2.1. Additional data elements and staged requirements over time using SHALL, SHOULD, MAY will be considered. It is expected this will be aligned with the USCDI future versions as ONC releases these.

1.5.2.2. Additional attributes will be considered such as Medication Prescriber information and others.

1.5.2.3. Guidance beyond HL7 C-CDA to include HL7 FHIR will be added to align with HL7 mapping work currently underway.

1.5.2.4. Support and promotion for the addition of Credential and Role information for Author to the USCDI future versions.

1.5.2.5. Guidance will be considered for other data formats for other standards organizations, (i.e., HL7 v2.x and HL7 FHIR Public Health standards and published implementation guides).

1.5.3. Consequential Data Update

1.5.3.1. From the end user perspective, it is often difficult to discern the point of origin or "source of truth" for a particular dataset or data item. This is particularly true, as data finds its way traversing multiple exchange hops distant from its point of origination, as data content and context may be transformed multiple times, e.g., to/from exchange artifacts (HL7 v2 messages, CDA documents, FHIR resources). Data provenance information can support improvements to deduplication of data and engender trust in the data exchanged. Future versions will likely build and add data provenance elements to better communicate the appropriate provenance attributes to support the Who, What, When, Where, How and Why.

1.5.4. US Realm Header - Legal Authenticator Guidance

1.5.4.1. The industry needs guidance for who the most appropriate person is to include as a document's legalAuthenticator? In particular, there is evidence of some organizations who set it to a generic background user representing the organization's HIM director while others reference a system only. Ideally there should be some guidance for best practice guidance for legalAuthenticator handling as required by the C-CDA Specifications.

1.5.5. Create guidance on provenance for various use cases

1.5.5.1. Other use cases such as Healthcare Entity to Consumer / Patient Access will be considered to support the initial focus for TEFCA.

1.5.5.2. Consider guidance for remote patient monitoring sensors/devices and how to document provenance.

2. Effective Use of Codes

Problem Statement

When a system sends clinical data to another system, discrete data usually references standardized sets of codes, such as LOINC, CPT, or CVX. This potentially allows the receiving system to map data elements to standard codesets, such as a medication, to the local representation of that element, which in turn allows the data to be "understood" by the receiving system. Coded data can be more easily incorporated into clinical decision support and may make reconciliation easier. This coded data may be found in the structured section of the XML as a translational field, depending on the receiving system, the translational field may or may not be consumed or displayed.

A core issue for health care providers is the mapping of common 'concepts' to one or more coded terms. The granularity of these concepts depends upon the use case. In multi-hierarchical terminologies such as SNOMED CT, the parent child relationships can sometimes be used to group similar terms, though referencing relationships across different hierarchies can be challenging (i.e., identifying interceptive parents and siblings in the hierarchies). Some clinical content may require the curation and use of logical value sets with multiple terminologies (i.e., LOINC used with SNOMED CT) to represent the full meaning of lab data. Work between these terminologies, EHR-data developers and other stakeholders can help create and maintain methods, metadata and value sets to help providers and other technology implementers effectively and safely USE externally mapped data in the care of patients. As the world moves toward FHIR based queries and exchange, effectively using these relationships will enable the appropriate level of abstraction when requesting information. Enabling Clinical Decision Support (CDS), concept-based search and other techniques helps clinicians sift through the noise of available data.

Use Cases

2.2.1. Provider to Provider - Example Scenarios:

2.2.1.1. Electronic Health Record (EHR) converts and shares lab results (lab priorities only) in CDA documents with other EHRs and HIEs. Providers wish to graph or trend lab data requiring normalization of data and enable clinical decision support.

2.2.1.2. Electronic Health Information Exchange (HIE) converts and shares lab results (lab priorities only) in CDA documents with other EHRs and HIEs. Providers

wish to graph or trend lab data requiring normalization of data and enable clinical decision support.

2.2.1.3. Laboratories can be considered a Provider of information when they share lab results (lab priorities only) with EHRs and HIEs. Providers graph or trend lab data requiring normalization of data and enable clinical decision support.

2.2.1.4. Conversion and sharing of allergy information (allergens priority list).

2.2.1.3.1.In the Electronic Health Record (EHR).

2.2.1.3.2. In the Electronic Health Information Exchange (HIE).

2.2.1.5. Conversion and sharing of immunization information (COVID only).

2.2.1.4.1. In the Electronic Health Record (EHR).

2.2.1.4.2. In the Electronic Health Information Exchange (HIE).

2.2.2. Provider to Public Health Agency - Example Scenarios:

2.2.2.1. A provider receives lab results into their EHR from a laboratory (or now with COVID, consumer performed testing), and is required to report to public health by law using Electronic Case Reporting specifications.

2.2.2.2. COVID administered vaccines, externally sourced data, EHR, HIE, Registry

2.2.2.2.1. Patient history in the Individual Medical Management System (IMMS) or Vaccine Action Command and Coordination System (VACCS) is sometimes recorded in the official vaccination section of Electronic Health Record (EHR) to satisfy care gaps in the Clinical Decision Support System (CDSS) , but may be done inconsistently or inaccurately.

2.2.2.3. Guidance for mapping to SARS-CoV-2 LOINC terms: COVID results

2.2.2.4. Facilities are required to report Healthcare Associated Infections (HAIs) to National Healthcare Safety Network (NHSN) Public Health (state and/or federal requirements).

Existing Work

2.3.1 ISA Recommendations

2.3.2. CVX Codeset

2.3.3. RxNorm and SNOMED-CT

2.3.4. CDC Immunization Basics: Definition of Terms

2.3.4.1. **Vaccine:** A preparation that is used to stimulate the body's immune response against diseases. Vaccines are usually administered through need injections, but some can be administered by mouth or sprayed into the nose

2.3.4.2. **Vaccination:** The act of introducing a vaccine into the body to produce protection from a specific disease

2.3.4.3. **Immunization:** A process by which a person becomes protected against a disease through vaccination. This term is often used interchangeably with vaccination or inoculation.

2.3.5. HL7 C-CDA Online: A navigation website for C-CDA 2.1

2.3.5.1. C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 documents USCDI V1 requirements.

2.3.5.2. C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3 documents USCDI v2 requirements.

Guidance

2.4.1. General Guidance for COVID-19 Immunization Related Codes

2.4.1.1. Data Originator (source) Organizations SHALL include the relevant CVX code for COVID-related immunizations. There is a list of the CVX codes for COVID-19 immunizations here.

2.4.1.2. If an organization has information about the dose and dose unit of an immunization, the organization SHALL include that information when generating documents along with the CVX code for the immunization. In the case of some COVID booster shots, the dose and dose unit are necessary to differentiate between the immunization and the booster.

2.4.2. General Guidance for CVX -- Immunizations Administered

2.4.2.1. Organizations SHALL include the relevant CVX code for all immunizations administered, when a valid code exists. The full list of CVX codes is here.

2.4.2.2. Important clarification – the Data Usability Workgroup recommends that exchange of primary immunization information (from the performing provider) is made clearly distinct from patient or other party reports. This is achievable in C-CDA through the author participation node: Author Participation [author, 2.16.840.1.113883.10.20.22.4.119, open] - C-CDA Online (hl7.org)

2.4.2.3. Organizations SHALL include the immunization lot number and appropriate CVX codes when available. They SHOULD include dose, dose unit and expiration date information.

2.4.2.4. USCDI specifies both active immunization administration records *AND* externally sourced immunization records. The Level 2 USCDI candidate data elements include 'Vaccine Event Record Type" with candidate specs (https://phinvads.cdc.gov/vads/ViewCodeSystem.action?id=2.16.840.1.114222.4.5.293). While this remains in limited use, the Data Usability Workgroup recommends continued development and SHOULD include delineation from primary or from secondary immunization information.

2.4.2.5. Organizations MAY send externally sourced immunization information, but if they choose to do so they SHALL appropriately mark these immunizations such as externally sourced. Sending of externally sourced immunizations are Optional, but it is critical for a system to appropriately mark these as Secondary.

2.4.2.5.1. Patient Reported Vaccines SHALL Conform to the published HL7 Example: https://cdasearch.hl7.org/examples/view/Immunizations/Influenza%20Vaccination%20-%20Patient%20Reported

2.4.3. Allergies and Intolerances

2.4.3.1. Organizations SHOULD send either RxNorm (active pharmaceutical ingredient) or UNII (non-pharmacological substances) and SNOMED-CT (reaction and class) codes for all allergies and intolerance observations, when available. These observations are more useful if coded (CDS, e.g.), so organizations SHOULD include the correct codes per ISA Recommendations if possible. Even if un-coded, all documented allergies and intolerance observations SHALL be sent.

2.4.3.1.1. Representing Patient Allergies and Intolerances; Medications

2.4.3.1.2. Also, refer to the ONC Advisory re: ISA.

2.4.4. Documenting and Sending "No Known Allergies"

2.4.4.1. If the allergies have been reviewed with the patient and the patient and clinician have confirmed the patient has no allergies, organizations SHALL send notice that there are "No Known Allergies". Organizations SHALL NOT send a "No Known Allergies" notice before allergies have been reviewed with the patient.

2.4.4.1.1. Guidance for best practices to exchange "No Known Allergies" is available here.

2.4.4.2. Organizations SHOULD send variants of No Known Allergies (i.e., "No Known Medication Allergies") only if allergies for that category have been reviewed with the patient.

2.4.4.2.1. Guidance for best practices to exchange "No Known Medication Allergies" is available here.

2.4.4.3. Representing Patient Allergies and Intolerances; Medications

2.4.5. Priority Code List for Lab Results

2.4.5.1. The JDCWG C-CDA Whitepaper effectively identified the challenges in lab interoperability in their recently published draft CCDA document (Section 2.5.2 - Interoperable Laboratory results and 2.5.2.4 Workgroup Strategy).

2.4.5.1.1. The Aim of this workgroup is to take the next steps based on the issues identified by JDCWG. Our plan is to work with the stakeholders listed below (and others) to build out the best practices and requirements at each step using a focused set of generally useful labs as the example.

2.4.5.2. To facilitate moving forward in this process, the Data Usability Workgroup suggests utilizing this list of priority labs (developed with inputs from multiple health systems) (see appendix A) as a *minimum* set of exchanged *and* mapped/interoperable lab results. Feedback on the contents of the list is welcome and encouraged.

2.4.5.3. The mappings for these results SHOULD be completed at the most granular applicable level.

2.4.5.4**. Initial receiving EHR:** Downstream, manual mappings SHOULD NOT be replaced in downstream systems EXCEPT by updates from the originating system.

2.4.5.5. **Downstream receiving and consuming system:** Utilize value sets as a tool for consuming systems to identify less granular groupings of different lab codes depending on use case.

Future Efforts

2.5.1. Prioritized list of laboratory results to be shared

2.5.1.1. This version of the IG highlighted priority labs as shown in Appendix A, but it is expected that discussions with other lab subject matter experts and groups such as Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) will inform future guidance. SHIELD is working on a national laboratory strategy now, which has engaged many stakeholders (IVD test vendors, EHR/LIS vendors, laboratories, federal agencies like CDC, FDA(CDRH, CDER, CBER), ONC, NLM/NIH, HHS/CMS, IICC, LOINC/Regenstrief, SNOMED, etc.) for all work on laboratory data interoperability and usability.

2.5.1.2. Expand guidance for Laboratory Test Lifecycle: JDCWG C-CDA Whitepaper section 2.5.1

2.5.1.2.1. Consider creating guidance on Tracking Labs from Order to Results JDCWG (2.5.1.5) and Tracking Lab Result Corrections JDCWG (2.5.1.7).Tracking Labs from Order to Results (across documents) guidance for HL7 V2 messaging.

2.5.1.3. Interoperable Laboratory Results: JDCWG C-CDA Whitepaper section 2.5.2

2.5.1.3.1. Interoperable laboratory results: identify and perform tasks from section 2.5.2.4, e.g., to identify/create preferred value sets for lab results and to create manual or automatable mappings from custom values/codes to these preferred codes.

2.5.1.3.2. Guidance on formatting translations. Reference HL7 Orders and Observations WG and LOINC SHIELD group.

2.5.1.3.3. Guidance on formatting translations.

2.5.1.4. Additional use cases will also be considered for incorporation.

2.5.1.4.1 Consider transmission of results from a Laboratory to a Public Health Agency

2.5.1.5. Investigate the differences among vendors for consumption and display of translational fields.

2.5.2. Guidance for the translation of lab result codes and nomenclature

2.5.2.1. Consider providing guidance for issues that arise when any down or upstream information system (i.e., EHR) uses a different naming convention than determined by the performing laboratory.

2.5.2.2. **Performing laboratories:** Initial responsibility for mapping a proprietary/local term for a lab result to LOINC rests with the performing lab. Continued development of value sets for lab results (e.g., https://vsac.nlm.nih.gov/) is encouraged to allow receiving systems to logically 'lump' lab types together for ease of consumption and clinical decision support as appropriate. The workgroup will start with reviewing this work: https://www.harmonization.net/measurands/

2.5.3. Guidance for codes in discrete data elements

2.5.3.1. In support of the continued development of logical groupings of codes/terms into value sets or other types of hierarchies, focused effort should be made on facilitating and coordinating work to develop these groupings.

2.5.3.2. These efforts should be consistent among all stakeholders for at least a core set of logical groupings, maintained by a convener (e.g., VSAC).

2.5.3.3. The Data Usability Workgroup will focus on recommendations for the coordination of this work and consolidation of different effort streams, built upon the Interoperability Standards Advisory. (https://www.healthit.gov/isa/sites/isa/files/inline-files/2022-ISA-Reference-Edition.pdf)

2.5.4. Guidance will go beyond content exchanged for HL7 C-CDA to include HL7 v2.x and HL7 FHIR.

2.5.4.1. The 1.5 Implementation Guide references https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf

2.5.5. Create guidance for various use cases.

2.5.5.1. Descriptions/codes for document/data types are desired to filter (i.e., Radiology Reports from Lab Data) to allow indexing or filtering by date).

2.5.6 Detailed Lab Result fields (e.g., reference ranges, Priority, etc.) will be addressed in a future implementation guide.

2.5.7 Investigate the consumption and display of translational fields across vendors

2.5.8 Consider guidance on chart correction workflows and how to propagate data edited during chart corrections downstream.

3. Reducing the Impact of Duplicates

Problem Statement

When clinical data is exchanged between multiple systems duplicate information is a frequent occurrence. Commonly this is the result of receiving the same information from more than one external organization or multiple times from a single trading partner. Unidentified duplicate information takes clinician time to filter and reconcile and can make it harder to find the most up to date information about a patient.

Use Cases

Duplicates should be easily identifiable on a receiving system when the sending system has sent the data previously. This guide focuses specifically on **problems, allergies, medications, and immunizations** exchanged within CDA documents.

3.2.1. Provider to Provider: Identical clinical items are represented by the same underlying data structure for documents generated by the same organization

> 3.2.1.1. Known duplicates should be identifiable between documents: If an organization generates CDA Document A for a patient documenting an entry corresponding to a unique occurrence of angina in the problem list and then generates CDA Document B later containing that same instance of angina, the entry for angina should contain the same identifier so that a receiving system can recognize that the entries correspond to the same problem.

> 3.2.1.2. Additional information should link to the same underlying data: If an organization generates CDA Document A with an entry for an immunization and more information becomes available later (such as lot number or administration site), further documents should be generated with this additional information but should still be identifiable as the same immunization from CDA Document A.

Existing Work

3.3.1. Whitepaper published by the Joint Content Document Workgroup Whitepaper v2.0

3.3.2. HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1 - Section 2.6

3.3.3. HL7 CDA R2 IG: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3 - US Realm

3.3.4. HL7 C-CDA Online: A navigation website for C-CDA 2.1

Guidance

3.4.1. Methods of identifying duplicate data

3.4.1.1. In the guide published by the Joint Document Content Workgroup (v2.0)

Section 2.2.2: The C-CDA Companion Guide recommends using consistent identifiers; this guide requires them. For any entry where an ID is required, systems SHALL maintain consistent IDs whether sending the entry in an Encounter Summary Document, a Patient Summary document or any other CDA document types.

3.4.2. Use reliable identifiers between documents and over time

3.4.2.1. Organizations SHOULD send the same ID for a piece of clinical data which has not changed. If a document is generated twice for a single encounter, at least one ID per discrete element SHOULD be consistent within the document for entries that correspond to the same piece of clinical data.

3.4.2.2. C-CDA documents are typically allowed to send multiple IDs per data element, and these can be used for versioning of a single data element.

3.4.2.2.1. Example: When a result observation is updated, while a new ID may reflect that this data has been updated, the original result ID shall still be sent along with this new ID.

3.4.2.3. Organizations SHOULD record and share the consistent IDs for entries across documents that refer to the same piece of clinical data. This consistency in identifiers will enable the receiving system to safely de-duplicate repeat clinical data – and perform as a 'resilient receiver' as described by the JDCWG C-CDA Whitepaper.

3.4.3. Use sequencing identifiers for immunizations

3.4.3.1. Organizations SHALL send an appropriate sequence number for an immunization that is administered as part of a series, if known. This improves the guidance documented in the C-CDA Companion Guide and JDCWG C-CDA Whitepaper.

3.4.4. Sharing External Imported (as opposed to simply viewing) Data (incl data shown in patient portals)

3.4.4.1. Any externally sourced discrete data imported automatically or manually into the patient's record MAY be shown in patient portals as guided by the [21st Century Cures Act (Cures Act)](#) and applicable State laws.

3.4.4.2. Externally sourced discrete data for Allergies, Immunizations & Problem Lists imported into a chart SHOULD be coded to the same level of specificity as internally produced data, to enable high quality and usable data to be sent to other systems. ([See effective use of codes guidance](#))

3.4.4.3. For additional data types an important distinction exists- consider two different types of patient data:

3.4.4.3.1*. Patient attributes* – e.g., diagnoses, allergies

3.4.4.3.1.1. Reconciliation/incorporation often involves a new assessment of diagnosis or other attribute and the new reconciled item SHOULD be coded to the highest degree of known specificity.

3.4.4.3.2*. Patient testing and results* (actions taken by an outside organization) *See [JDCWG C-CDA Whitepaper](#) 2.5.2.6 - Translations* - e.g. labs, radiology results, immunizations

3.4.4.3.2.1. Unmapped results SHOULD be mapped (to standard terminologies) and those codes provided when sharing results.

Future Efforts

3.5.1. [Reduce Impact of Duplicates](#)

3.5.1.1. Expand guidance beyond Allergies, Immunizations & Problem Lists

3.5.1.2. Expand potential guidance, clarifying how to identify duplicates within systems, including data elements that make it a duplicate.

3.5.2. [List Reconciliation](#)

3.5.2.1. Consider best practice guidance for receiving systems to optimize and speed reconciliation of lists, including deduplication strategies and auto-reconciliation thresholds.

3.5.2.2. Expand Healthcare Entity to Consumer use case from Documents/data imported into a system or Portal. The current guide provides guidance for primary information only.

3.5.3. Problem Oriented Health Record functional requirements are in the process of being balloted by HL7. Future versions of this implementation guide will consider referencing guidance once published.

4. Data Integrity, Format and Trust

Problem Statement

Different types of documents are exchanged between Providers depending on the clinical scenario. These different documents contain different types and quantities of information. For instance, in a clinical summary lab, data may be included in what was produced within a certain time frame.

While a number of factors can influence data integrity format and trust, including provenance and other topics addressed elsewhere in this IG, the Data Usability Workgroup will focus our IG on a core aspect of data integrity – accurate patient matching. This core function underlies all other aspects of data integrity and in the era of TEFCA, has become one of the central challenges in information sharing at scale. Future work by the Data Usability Workgroup will likely involve other aspects of Data Integrity, but the initial scope will be focused on patient matching, specifically encouraging broader use and adoption of Project US@ recommendations as a simple, but effective means of improving patient matching.

Use Cases

4.2.1. Provider to Provider - Example Scenario

4.2.1.1. Person names may be exchanged in a variety of ways, and they should remain consistent where possible. Patient Matching is critical for patient safety and individuals with the same name and identifying attributes.

4.2.1.2. Inconsistencies in patient addresses can lead to difficulties in patient matching. For instance, systems may not be able to match "Lane" with "Ln" or "Circle" with "Cir." When these matches fail, patient records cannot be adequately linked to documents and patient care may suffer.

4.2.1.3. Clinicians desire a complete picture of a patient's history rather than just the current Encounter Summary, which can somewhat be conveyed by a Patient Summary Document.

Existing Work

4.3.1. Project US@ Guidance for patient addresses

4.3.1.1. The ONC has collaborated with standards development organizations to release version 1.0 of the Project US@ technical specification. This guide establishes an industry-wide approach to representing patient addresses in order to improve accuracy of patient matching. The scope of this work includes only United States domestic and military patient addresses.

4.3.2. American Health Information Management Association (AHIMA) Guides

4.3.2.1. AHIMA's Recommended Data Elements for Capture in the Master Patient Index guide contains guidance for exchanging patient demographics in order to create a standard naming convention policy and facilitate accurate patient matching.

4.3.2.2. Project US@ ONC-AHIMA Companion Guide

4.3.3. Patient Summary Documents Guidance in C-CDA as published in the JDCWG C-CDA Whitepaper in section 4.

Guidance

4.4.1. Project US@

4.4.1.1. Data for address fields used for patient discovery query SHOULD conform to Project US@ Technical Standards. This guidance SHOULD be applied to both the transport meta-data attributes and within the C-CDA demographics.

4.4.1.2. Data for address fields used in Patient Discovery Queries SHALL be converted, if needed to conform to Project US@ Technical Specifications, by the Initiating Gateway prior to being transmitted to any Responding Gateways.

4.4.2. General formatting recommendations

4.4.2.1. The JDCWG C-CDA Whitepaper provides a foundation for formatting and data integrity that this group also recognizes:

4.4.2.1.1 **Section 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.

4.4.2.1.2. **Section 4.2: Generating a current Patient Summary**

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4.4.2.1.2.1 A Responding system that dynamically generates documents SHALL support the On-Demand capability to generate and share current patient summaries

4.4.2.1.2.2 When generating a current Patient Summary Document for a patient, Responding systems SHALL at a minimum:
- include active problems, medications, allergies, and immunizations
- ensure that entries match information from the most recent encounter, which may be a telephone or virtual encounter
- include the Section Time Range in every section
- if the section is required it SHALL include a 'No information' assertion if no information is included for a section.

4.4.2.1.3. Section 3.0: Encounter Summary Documents

4.4.2.1.3.1 Responding system, in order to provide a complete picture of a patient's history, SHALL provide access to, at minimum, one Encounter Summary Document for each available encounter

4.4.2.2. An additional dimension of formatting C-CDA documents is the inclusion of the human generated narratives (e.g., discharge summary). See Section 6.4.1 of this document for guidance on narrative information.

Future Efforts

4.5.1. Data Accountability/Binding Content and Authorship

4.5.1.1. Future work will consider how to ensure content and authorship binding is intact and verifiable when data is exchanged. Digital signatures could be considered along with guidance for governance requirements. This is an important issue to tackle over time. Including guidance for data attestation includes various trust and medical/legal implications which demand further review by the workgroup.

4.5.2. Data Integration or Data Insulation

4.5.2.1. Guidance will be considered to establish best practices for how receivers import and incorporate external data into a clinical workflow to avoid having a provider have to navigate among multiple user interfaces.

4.5.2.2. Consider guidance for remote patient monitoring sensors/devices as sources of important data.

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4.5.2.3. Consider guidance from AHIMA's Recommended Data Elements for Capture in the Master Patient Index (MPI). This will inform data captured for individuals in an EHR, including, but not limited to patients, guarantors, clinicians, and all contributors to the health record.

4.5.3. Data Transformation from Source

4.5.3.1. Consideration for how data may be transformed from its original source representation (i.e., C-CDA to FHIR) may result in additional guidance to avoid loss or distortion of data exchanged.

4.5.4. Temporal Parameters - Consider additional temporal parameters to improve C-CDA

4.5.4.1. Decision: It seems like this was scratched due to the complexity component, and will need to check on later recordings or notes.

4.5.4.2. Explicitly called out as a future topic.

4.5.5. Consider referencing 360X Project – Closed Loop Referral IG

4.5.5.1. Decision: not with this IG unless we can find a specific reason it relates to usability. While this provides a nice feature set, there's not much directly tied to this IG/section.

4.5.6. Consider derived work from HL7 EHR Reducing Clinician Burden Project referenced in Proposed Data Usability Characteristics.

4.5.6.1. Data Definition Consistency.

4.5.7. Consider how to improve data granularity in a groupable hierarchy.

Guidance for
**Data Tagging /
Searchability**

5. Data Tagging / Searchability

Problem Statement

For years, organizations have developed individual definitions of which CDA documents are sent as part of a patient's record, with most sending a minimum of a current patient summary and a summary of relevant encounters. Recently, the Joint Document Content Workgroup introduced a more comprehensive and standardized view of the patient, labeled the Longitudinal Record, which includes at minimum a current patient summary along with an encounter summary for *each* encounter. While an excellent wealth of information, this exchange can contain more than is applicable to the clinical goals of the requestor. The quantity of content can make it difficult to understand the context around particular pieces of data that are of interest and the connection between pieces of information in different sections of the document.

Use Cases

5.2.1. Provider to Provider and Provider to Public Health - Example Scenario

5.2.1.1. A provider searches by C-CDA document titles to only request documents which pertain to certain criteria, such as diagnosis code.

5.2.2. Healthcare Entity to Consumer - Example Scenario

5.2.2.1. A consumer seeks to see all C-CDA documents related to certain criteria, such as those with diagnosis codes related to COVID.

Existing Work

5.3.1. HL7 C-CDA Companion Guide provided structure and guidance for sending notes by introducing the Notes Section (Appendix A, Section 2.2) and Notes Activity entry (Appendix A, Section 3.12).

5.3.2. Methods of Sending Clinical Notes in C-CDA in the JDCWG C-CDA Whitepaper in section 3.4.2.

5.3.3. Encounter Linking for Clinical Notes in C-CDA in the JDCWG C-CDA Whitepaper in section 3.4.3.

Guidance

5.4.1. Sending Clinical Notes in C-CDA - All appropriate notes as identified by the source document system SHALL be included. Below is the priority order for how to include Clinical Notes in a document sent electronically.

> 5.4.1.1. Document Source Systems SHOULD reference guidance found in *HL7 C-CDA Companion Guide, section 5.2.18 for Clinical Notes*
>
> 5.4.1.2. Document Source Systems SHOULD include Note(s) directly attached to the associated act, if not possible;
>
> 5.4.1.3. Document Source Systems SHOULD include Note(s) in an appropriate standard section, if not possible;
>
> 5.4.1.4. Document Source Systems SHOULD include Note(s) in a stand-alone notes section

5.4.2. Note directly attached to the associated act

> 5.4.2.1. When a note is specifically about an action a clinician performed, the note SHOULD reference that action.
>
> > 5.4.2.1.1. For example, a Procedure Note is linked, or nested within, the procedure act it documents.
>
> 5.4.2.2. When direct attribution is possible (as an entryRelationship), the clinical note SHOULD be included in the appropriate section where the act is included.
>
> 5.4.2.3. 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.
>
> > 5.4.2.3.1. 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.

5.4.3. Note in stand-alone Notes Section

> 5.4.3.1. 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 dependent on appropriate LOINC code being attached, indicating the type of note.

5.4.4. Document Narrative Linking

5.4.4.1. Organizations SHOULD provide links to other sections within clinically related concepts. For instance, linking a procedure in the Procedures Section to its related results within the Results Section.

5.4.4.1.1. Examples for how to provide links to other sections can be found [here](#).

5.4.5. Laboratory Orders and Results

5.4.5.1. Informative: This guidance 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. Since the C-CDA templates are open, and any other templates can be included within any document type, this guidance constrains the use of the Results section to SHALL be included in Patient Level and Encounter Based Documents as appropriate.

5.4.5.2. Provider Organizations SHALL implement the requirements outlined in Section 2.5.1 of the [JDCWG C-CDA Whitepaper](#) Guidance, where the Laboratory test lifecycle is described in detail both as a specific example, but also as a template for other order types.

5.4.5.2.1. The HL7 [C-CDA 2.1 Companion Guide](#) also has useful guidance about labs, including examples, in Sections 5.2.5 Order, 5.2.17 Plan of Treatment (for pending orders), and 5.2.11 Result (for pending and completed results).

Future Efforts

5.5.1. [Data in Context](#)

5.5.1.1. Specific elements of context – e.g., BP. Physical location, patient positioning, method, performer, author, circumstances (supine, standing, sitting, post exercise, etc.) is very EHR dependent, but future work may provide additional guidance geared to FHIR exchange.

5.5.2. [Guidance for longitudinal view](#) – For a resilient receiver, providing robust search and filtering capabilities helps the end user to quickly find relevant information in what are

often complex, lengthy documents. The DUWG will explore identifying and codifying best practices for EHRs with the goal of reducing clinician burden.

5.5.3. Receiving system filtering and search within Received Documents

5.5.3.1. While the version of this document focused on sending systems, future work will consider the entire data exchange ecosystem. Optimally, usable data requires that every player in the chain contribute. In addition to the sending system transmitting things properly, the receiving systems need to present the data in usable fashion. While no clear standard for searching and filtering of documents exists, such capabilities are important to clinical users often tasked with finding specific data in large documents. In future efforts the DUWG will explore industry best practices and consider recommendations for resilient receivers to enable such functions.

5.5.4. Industry and government has an interest in an interchange system that will allow advanced algorithms to parse, search and distribute data sets and digital documents based on pre-ordained data rules. Collaboration and work with groups such as the HL7 Structured Documents Work Group can create business cases for further experimentation with tagging in support of advanced governance technologies.

5.5.5. Consideration for Orders and results for diagnostic Imaging will be discussed with delineation of advanced imaging for example: MRI, CT, PET, Nuclear Imaging, Ultrasound, Echo, Venous Doppler and Interventional Radiology.

6. Effective Use of Narrative for Usability

Problem Statement

Current document formats and general practice in the industry often prioritizes 'discrete' data elements that are easy to store and understand individually over longer format narrative information that better captures the 'story' of the patient. Auto-generated documents made of discrete elements are useful, but are an incomplete 'patient story' for the busy clinician. Consistently providing and linking these valuable clinical narratives to the discrete data can help clinicians validate and understand the context of shared data. Robust sharing of clinical narrative information in ways that are easily digestible by receiving organizations and clinicians can significantly improve patient care.

Use Cases

6.2.1. Provider to Provider

6.2.1.1. While discrete elements such as discharge diagnosis and instructions are useful, for the busy clinical provider, the narrative discharge summary and ED provider note and other high value narrative documents may provide valuable insights into patient assessment and summarization, clinical decision making, and other thoughts from the authoring provider.

6.2.2. Healthcare Entity to Consumer

6.2.2.1. The narrative discharge summary provides value to the patient/healthcare consumer by including them in the clinical reasoning and thoughts of the authoring provider.

Existing Work

6.3.1. [Health Level Seven (HL7) CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Release 2.1](#)

6.3.2. HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R1 Companion Guide Release 2

6.3.3. [HL7 CCDA Companion Guide](#) sections 5.1.1 and 5.1.2

6.3.4. Examples - Search on "narrative".

6.3.5. CDA Document Content Guidance in C-CDA as published in the JDCWG C-CDA Whitepaper in section 2.2.

6.3.6. CDA Document Content Guidance for Clinical Notes as published in the JDCWG C-CDA Whitepaper in section 3.4.

6.3.7. The THSA (Texas Health Services Authority), via consensus, created a suggested hierarchy of narrative note and other elements value for receiving clinical users. This is not intended as a definitive list, but is a potential example to help implementers prioritize documents/data types in their CDA Documents. See Appendix B.

Guidance

6.4.1. Implementers SHALL, at minimum, include available narrative discharge summaries and ED provider notes at time of document creation. Processes that make these narrative summaries available as soon as possible are strongly encouraged.

> 6.4.1.1. Following guidance in the HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Companion Guide Release 3, section 5.2.18.1, Implementers SHOULD use a Note Activity Entry for narrative notes to improve machine processing on the receiving system side

6.4.2. Implementers (MAY) consider including additional high value/priority narrative and other data types in their CDA Document payload.

6.4.3. Implementers SHALL follow the CDA Document Content Guidance in C-CDA as published in the JDCWG C-CDA Whitepaper in section 2.2.

6.4.4. Implementers SHALL follow the CDA Document Content Guidance for Clinical Notes as published in the JDCWG C-CDA Whitepaper in section 3.4.

6.4.5. Narrative Availability

> 6.4.5.1 Organization SHOULD provide mechanisms for clinicians to view received document narratives.

Future Efforts

6.5.1. Continue to help define and encourage the use of standard narrative inclusions in various exchange use cases. Currently, there is little standardization in what is actually shared and further developing rational guidance may help consistency in the industry.

References

1. American Health Information Management Association

   1. [Project US@ ONC-AHIMA Companion Guide](#)
   2. [Recommended Data Elements for Capture in the Master Patient Index (MPI)](#)

2. Carequality & Commonwell
   1. Concise Consolidated CDA: Deploying Encounter Summary Patient Summary and Documents with Clinical Notes Whitepaper published March 2022 - referenced as [JDCWG C-CDA Whitepaper](#)

2. Centers for Disease Control and Prevention (CDC)
   1. [Immunization Information Systems (IIS): Current HL7 Standard Code Set](#) - CVX
   2. [CDC Immunization Basics: Definition of Terms](#)
   3. [COVID-19 Vaccines Administered](#)
   4. [COVID-19 Vaccine Codes](#)
   5. Healthcare Associated Infections (HAI)
      1. [State-based Requirements](#)
      2. [Federal-based Requirements](#)
   6. [Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS)](#)

3. Health Level Seven (HL7)
   1. [HL7 CDA R2.1 IG: Consolidated CDA Templates for Clinical Note (US Realm), DSTU R2.1—Vol. 2: Templates](#)
   2. HL7 [C-CDA 2.1 Companion Guide](#)
   3. HL7 Guidance: [Basic Provenance for C-CDA and FHIR, Release 1 - US Realm September 2019](#)
   4. [HL7 Provenance Domain](#) Mapping Documents
   5. [C-CDA Examples Repository](#)

4. International Consortium for Harmonization of Clinical Laboratory Results
   1. [Measurands](#)

5. LOINC COVID-19
   1. Guidance for mapping to SARS-CoV-2 LOINC terms: [COVID results](#)

6. National Archives Code of Federal Regulations

      1. CLIA Requirements - CLIA § 493.1291

7. National Library of Medicine (NLM)
      1. Value Set Authority Center (VSAC)

8. Office of the National Coordinator (ONC)
      1. 21st Century Cures Act (Cures Act)
      2. Clinical Decision Support
      3. Interoperability Standards Advisory (ISA)
            i. 2021 Interoperability Standards Advisory Reference Edition
            ii. 2022 Interoperability Standards Advisory Reference Edition
            iii. Table of Contents of ISA Sections
      4. Project US@ Unified Specification for Address in Healthcare
            i. AHIMA Companion Guide
            ii. Version 1.0 of the Technical Specification released January 7, 2022
      5. US Core Data for Interoperability USCDI current published version
            i. https://github.com/HL7/cda-core-xsl/tree/features/USCDI

9. Sequoia Project Interoperability Matters Data Usability Workgroup
      1. 2020 - 2021 Phase I Work Items Prioritization Survey (Responses)
      2. 2020 - 2022 Proposed Work Items
      3. Charter
      4. Leadership Council
      5. Roster
      6. Website

10. U.S. Department of Health and Human Services
      1. Office of the Assistant Secretary for Planning and Evaluation (ASPE)
      2. SHIELD - Standardization of Lab Data to Enhance Patient-Centered Outcome Research Ad Value-Based Care

Appendix A – High Priority Lab Results

The current state of lab results interoperability across the health care community is poor. The lack of this interoperability affects the ability for clinicians to provide safe, high-quality, low-cost care. A broad community of clinical experts and stakeholders developed a preliminary list of lab results that are most valuable for care management, clinical decision support and quality measures across the care continuum. Thus, their providence and mapping for interoperability should be a high priority focus with their use across information systems to preserve clinical intent and meaning and prevent patient safety and data quality issues.

There are initiatives such as SHIELD, working on national laboratory interoperability needs. Meanwhile, health systems and vendors can work with their partners providing or exchanging laboratory data to help ensure the following steps are taken to improve interoperability of laboratory data. Ensure laboratory data are:

1. **Electronic.** Paper doesn't cut it anymore.
2. **Discrete.** PDF and text blobs are physician readable, but not very computer readable and usable.
3. **Encoded.** Laboratory orders and results SHALL be LOINC encoded, while specimen types, sources, qualitative result values, and organisms SHOULD be SNOMED CT encoded. Encoding helps facilitate computer usability and semantic meaning.
4. **Messaged.** Typically, the performing laboratory (and laboratory community) exchanges laboratory data in various HL7 v2.x messaging formats. LIS/LIMS do not currently have FHIR functionality for daily reporting needs and in CLIA compliant format. Although HL7 FHIR is utilized for laboratory data in downstream systems and apps, many may not be complete with all laboratory data elements needed for the complete meaning of a test such as specimen, test name, etc. FHIR users may wish to proceed with caution and clinically validate applications with laboratory data to ensure they are complete and clinically accurate.
5. **Maintained.** Whether it is a new test like COVID introduced for clinical use or updates in code systems or messaging standards, all systems should be maintained. When one information system uses newer codes and downstream systems do not, errors may occur and interoperability is impeded, and clinical meaning lost.

In future versions of this implementation guide, lab interoperability will be a prioritized item, partnering with national lab interoperability initiatives to push semantic lab interoperability. As standards are being developed EHR platform and lab systems may

Interoperability MATTERS

focus on mapping and maintaining codes for this preliminary high clinical impact list (for reference only):

Blood Chemistry: Chemistry Results
- Albumin
- Alkaline Phosphatase
- ALT
- AST
- Bilirubin, Total
- Calcium
- Chloride
- Creatinine
- eGFR
- Glucose
- Hemoglobin A1c
- Lead Screening
- Potassium
- Protein, Total
- Sodium
- T4
- Urea Nitrogen (BUN)
- BNP
- Troponin
- Vitamin B1
- Vitamin B12
- Vitamin D 25,OH

Urine Chemistry:
- Microalbumin Urine
- Microalbumin/Creat Ratio

Coagulation:
- INR
- Protime

Endocrinology:
- Pregnancy Test Urine
- Beta HCG, QT
- Pregnancy Test Serum
- PSA
- TSH

Hematology:
- Hematocrit
- Hemoglobin
- Platelet Count
- White Blood Cell count (blood)

Infectious Disease:
- Hepatitis C Ab
- HIV1/HIV2
- Quantiferon Gold
- RPR
- FTA-ABS

Lipids:
- Cholesterol, Total
- CHOL/HDL Ratio
- HDL Cholesterol
- LDL Cholesterol
- Non-HDL Cholesterol
- Triglycerides
- VLDL

Additional Prenatal labs:
- Blood Type (ABO/Rh)
- Blood antibody screen (coombs)
- Hep B Surface Antigen
- Hep B Surface Ab
- Hep B Core Ab
- Rubella IgG
- Gonorrhea probe
- Chlamydia probe

Additional high priority results for discrete exchange:
- Pap smear
- Group B strep
- Urine culture

Appendix B – A Priority list of documents for information sharing

A consensus statement from THSA (Texas Health Services Authority) in Fall 2022 adds an example of the view from providers on the relative value of different documents. Included for reference as submitted by THSA:

"Although C-CDA was implemented to make data transfer between various EMR/EHR easier, that is not always the case. C-CDA data received by the clinical community is inconsistent creating frustration with the community and lack of trust in the data received. Clinicians have vocalized that data transfer between different EMR / EHR vendors and organizations is inconsistent. When sending patient information from one group to another, fax or printed papers are still used. Even if the electronic method of the transfer is used, topics/parts that are filled may differ between organizations. There are policy requirements for C-CDA and transitions of care but the application is inconsistent across the ecosystem as such not optimally supporting transitions of care between various healthcare providers.

The feedback from providers is that all too often the content of the data currently being exchanged has too little or too much information. This leads to lack of trust and will lead to lower utilization. Too much information is as much a problem as too little information – providers today struggle with cognitive overload from electronic health records. It is very important to have succinct and relevant information presented to healthcare providers. Future capabilities, like FHIR, may enable the best of both worlds – a succinct summary with the ability to drill down to further details if needed.

It is recognized that this is not perfect but a beginning. Clinicians can query for additional information when needed – this recommendation is to meet the majority of clinician needs. The list is organized by priority of content. Each organization is asked to work with their EHR vendor and information technology teams to send and receive the Discharge C-CDA Content."

Discharge C-CDA Minimum Data-Set Content

1. Discharge Summary Narrative (aka Hospital Course)
2. Discharge Medications
3. Allergies
4. Admission Diagnosis
5. Discharge Diagnosis
6. Procedures: including Interventional Radiology, Cardiac Cath, operative procedures
7. Diagnostic Imaging – Advanced imaging for example: MRI, CT, PET, Nuclear Imaging, Ultrasound, Echo, & Venous Doppler

8.   Laboratory – Recommend first and last laboratory result for every test. On rare tests – they are only done once so would be included (ANA Rheumatoid)

9.   Consultations

10.   Assessment & Plan (includes future orders for follow-up with PCP and diagnostic tests)

11.   Problem List