Interoperability MATTERS
an initiative of The Sequoia Project

# Data Usability Workgroup Implementation Guide Version 2.0

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the sequoia project

# 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 (DUWG) 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 373 organizations and 509 participants following this work effort through 2024. 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/QHINs, Carequality, eHealth Exchange, Commonwell, HIEs, 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 data quality (timeliness, completeness), knowledge work (clinical context), data lifecycle (provenance), and interoperability (semantics, syntax, and physical mechanism or transport to move data). These and other dimensions can enable receiving systems to integrate the data into their records and make them available and actionable as appropriate for viewing and/or including reconciled discrete data into relevant workflows. This Version 2.0 Implementation Guide will build on the prior Version 1.0 Implementation Guide and other existing work, including, but not limited to: C-CDA Implementation Guides, C-CDA Templates, FHIR Implementation Guides, ONC programs and other standards such as USCDI V1, V2, and V3, the recommendations of the Carequality-CommonWell Joint Document Content Workgroup (JDCWG) 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 move beyond the baseline set for this publication of USCDI V3 to incorporate guidance for Electronic Health Information Exchange of data leveraging USCDI V4 and beyond, 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/from) provider health information exchange
- Provider (to/from) public health agency information exchange
- Healthcare entity (to/from) consumer information exchange

The above use cases are agnostic to the technology acting as the data source and include any entity providing care to a patient. The guidance within this document will also be agnostic to the technical infrastructure that comprises the technical transport (e.g. HL7 V2 transaction, FHIR App or C-CDA to focus on sending and receiving systems). The content data source or receiving system could be an EHR, HIE, LIS, or some other HIT system or 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 scoping and identification of new “pain points” and review of the prior parking lot items not addressed in the Version 1.0 by workgroup members documented here. These problem topics were grouped into 7 topic categories:

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
7. Laboratory Data Interoperability

## Phase 2: Implementation Guide Development

Phase 2 began in July 2023 with monthly workgroup meetings to scope the guidance and gather feedback to be included in the initial draft of the implementation guide. The

workgroup continued a regular cadence of meetings through July 11, 2024 where this initial draft implementation guide was developed for public comment.

An open call for Laboratory Subject Matter Experts in August 2023 resulted in the formation of a Tiger Team that helped scope the problem statement and use cases included in this second version of implementation guidance. The Lab Tiger Team began monthly meetings in October 2023 and started a hiatus with their last meeting on July 11, 2024. The Tiger Team members are encouraged to join the full workgroup to participate in future phases of work and continue with incremental improvements to Laboratory Data Interoperability.

In addition, feedback received from implementers and supporters from July 2023-2024 of the Data Usability Taking Root Movement community of practice were incorporated. To learn more about how you can join this movement, please consider pledging your support. Be part of a cross-industry community of practice co-sponsored by AHIMA to support and implement data usability guidance published by The Sequoia Project. Working together, we can improve the completeness and usability of data.

The DUWG leadership team worked together to resolve all workgroup comments and suggested edits received from workgroup members and the community of practice currently deploying version 1.0 guidance to inform the publication of this Final Version 2.0.

## Phase 3: Implementation Guide Public Comment

The Public Comment period began on July 23, 2024 with a press release announcing the publication and video recording to review the public comment process and timeline that ended after 33 days on August 23, 2024. The Sequoia Project socialized with a wide group of industry partners during these 30+ days to encourage comments from users of digital health technology and the vendors and/or HIT developers of these technologies.

## Phase 4: Finalizing Implementation Guide for Publication

The leadership team reviewed and resolved the 179 comments received between August - December 2024 to finalize the development of Version 2.0 (2024) of this implementation guide. The 2024 Version 2.0 Implementation guide will be published on December 11, 2024 in conjunction with the Sequoia Project Annual Member meeting.

All past and future meeting materials and recordings for the workgroup can be found here.

## Version History

*Data Usability Workgroup Implementation Guide 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. |
| 1.1 | First Draft of Cycle 2 Efforts for Implementation Guide Version 2.0 for Public Comment |
| 2.0 | 179 Public comments were resolved for this Final publication of Implementation Guide on December 11, 2024. |

## Acknowledgments


| Primary Editors | Organization |
|---|---|
| Adam Davis, M.D. | Sutter Health |
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# Statement of Intent

The Sequoia Project Data Usability Workgroup (DUWG) was chartered to assemble specific and pragmatic guidance for the capture and sharing of clinical content among healthcare stakeholders in order to facilitate the usability of the shared data while still maintaining trust in the shared data. This guidance, in the form of an implementation guide covering identified priority use cases, can be readily adopted (within 18 months) by EHR and health information technology (HIT) vendors, implementers, networks, governance frameworks (i.e., ONC Trusted Exchange Framework and Common Agreement (TEFCA), Carequality, eHealth Exchange, Commonwell, HIEs, etc.), and testing programs. This guidance includes maintaining high quality and usable data to support trust among data systems and processes from the originating EHR through intermediaries to the end user.

Usable data is data that enables users to provide optimal care for a patient along a journey from data source (data origination) to data use. Usable data can also involve other stakeholders including public health and patients/consumers. Consideration needs to be given to maintaining proper data management at each step on the journey. On a pragmatic level, the goal of the 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 timely, complete, contains missing or inconsistent information, a lack of semantic content or simply missing narratives from a clinical care summary.

Our most proximal foundation is alignment with existing standards and guidance that are referenced by the United States Core Data for Interoperability (USCDI) and further refined by the Standards Version Advancement Process (SVAP) that permits health IT developers to voluntarily update health IT products certified under the ONC Health IT Certification Program (Certification Program) to a newer version of adopted standards as part of the “Real World Testing” Condition and Maintenance of Certification requirement (§ 170.405) of the 21st Century Cures Act.

This Implementation Guide is the second publication from the DUWG, expanding on the guidance given in version 1.0 of this document; new content includes alignment with USCDI V3 for more data types, extended constraints, and new guidance on Laboratory Data, as well as addressing data shared beyond document-based sharing, e.g., HL7 v2 and HL7 FHIR. Input from all relevant stakeholders including both providers of healthcare and vendors developing HIT tools was 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 developers or implementers, product development teams, software developers and groups who can provide content testing.

This Implementation Guide will serve as the template for that process and path forward. The recommendations in this second version are modest, but our goal is to identify 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.

The key words “SHALL”, “SHALL NOT”, “SHOULD”, “SHOULD NOT”, “RECOMMENDED”, “NOT RECOMMENDED”, “MAY” in this document are to be interpreted as described in BCP 14 [RFC2119] [RFC8174] when, and only when they appear in all capitals, as shown here.

An implementation is not compliant if it fails to satisfy one or more of the SHALL REQUIRED level requirements for the sections it implements. An implementation that satisfies all the SHALL or REQUIRED level and all the SHOULD level requirements for its protocols is said to be "unconditionally compliant"; one that satisfies all the SHALL level requirements but not all the SHOULD level requirements for its protocols is said to be "conditionally compliant."

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, SHOULD NOT 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 the stakeholders. This Guide follows the same Section/Chapter structure for each of the seven topic categories as follows:

- Problem statement
- Use Cases
- Existing Work
- Guidance
- Future Efforts

The Third Cycle with its four phased process for the next iteration of this Implementation Guide will begin later in 2025 and include lessons learned from real world implementations from the Sequoia Data Usability Taking Root Movement:

- Advice on interpretation of guidance in different contexts beyond the following:
    - Provider to/from Provider
    - Provider to/from Public Health
    - Provider to/from 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. (e.g. including narrative information in addition to discrete data provides more usable and useful information)
        - **Machine Usability:** How can we make data we send out easier for machines to parse, sort, index, etc. (e.g. inclusion of appropriate value sets or codes will enable semantic interoperability of 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 HL7 CDA document exchange, HL7 V2.x, or HL7 FHIR, human usability typically refers to the narratives shown to an end-user/clinician, while machine usability refers to the use of discrete elements or metadata sent along with documents to be reconciled or otherwise incorporated into a patient's chart.

# 1. Data Provenance & Traceability of Changes

## 1.1. 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 documentation of the origination or modification (update) to provide history of a piece of data and what has happened to it as it has been modified or transmitted within or between systems. Provenance provides details about the creation, modification, and ownership of health information. This includes who created the data, when it was created, how it was created, and any subsequent changes made to the data.

Provenance data, where applicable includes the name and role of the clinician who originated a piece of data, their organization, the legal authenticator or authenticator who made modifications to the data on the journey from data source (data origination) to data use, as well as important date//time stamps and identifiers or codes. Provenance conveys essential data and metadata that typically comprises the who, what, when, where and why of the origination or update event of the data of interest.

Provenance must be maintained both within a single internal system and across multiple systems and must persist when communicated using any transmitting formats (e.g., HL7 CDA/C-CDA, HL7 V2 message or HL7 FHIR resource, document or section) and with their corresponding vocabulary in the appropriate 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/uniqueness is ambiguous. Provenance data enables the ability to disambiguate content, context, and uniqueness. 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. Data provenance elements are not always populated in sending systems and this impacts the receiving system and stakeholders trust in the information
    a. *NOTE that USCDI v1/v2/v3/v4 requires inclusion of two provenance elements: author's organization and timestamp.*
2. Data exchange leveraging HL7 C-CDA, HL7 FHIR, HL7 v2.x in production today does not include or capture the provenance attributes necessary during typical healthcare workflows.

3. Intermediary data transformations may occur as a result of translational processes, (e.g., a medication intolerance could mutate into an allergy) where provenance of that transformation event may help in tracking through intermediary systems.

4. Provenance data 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.

5. Legal Authenticator is a desired attribute and the U.S. Realm Header requirements for C-CDA includes this attribute, however, guidance is necessary to define who should/can be a Legal Authenticator and who should/can be Authenticators.

6. The data provenance detail is often not shown to users in receiving systems.

## 1.2. Use Cases

Provenance data guidance is applicable to all USCDI v3 Data Class Elements and appropriate USCDI v4 Data Class Elements specific to the Laboratory data found in the Laboratory Guidance in section 7.0 in this document.

### 1.2.1. Provider to Provider – Example use case:

This guidance is scoped to focus on clinicians reviewing provenance data during care in four workflows:

**1. "Fax" - Direct transmission of information from one provider to another provider**: This transmission could be sent by a DIRECT message, web services-based exchange/PUSH, or FHIR REST call directly to a single FHIR server.

(The most basic provenance scenario is the direct transmission of information from one provider to another provider. This transmission could be sent by a DIRECT message, web services-based exchange, or a FHIR REST call directly to a single FHIR server. While it is important to know which system passed you the information, the primary concern of the clinician end-user is the author of the content, the author organization, and a timestamp on the information.

**2. Health Information Exchange (HIE) Redistribution**: A Health Information Exchange (HIE) is an organization and technology to facilitate exchange from one-to-many partners. In certain HIE scenarios they only redistribute information, while in others they store, transform, and redistribute information. This use case focuses on storage and redistribution only, no transformation of content is done. When the HIE is only redistributing content, the HIE must keep fidelity of the clinical content,

including original author, author organization, and timestamp. The HIE must keep track of who sent them the information for auditing, however, they are not required to include the original transmitter when redistributing content. This transmitter isn't relevant to the clinician end-user; however, it may be important when data transformation issues are the source of identified loss in data fidelity.

**3. HIE Transformation:** HIE Redistribution includes transformation of data. Information is received (e.g., v2 lab, other C-CDAs) and transformed by an HIE, stored, and then passed in a new format (e.g. CCD or FHIR Resource). Source data is not manipulated beyond transforming into a new format. Transformation of data from one format to another does not change the authorship of the information. The HIE is only the author/author organization if they produce and include new information.

**4. Clinical Information Reconciliation and Incorporation (CIRI)** Clinical Information Reconciliation and Incorporation (CIRI) is a process where a user reviews and updates, or accepts, information into their system. The information could come from a Health Information Exchange (HIE), a 3rd-party FHIR server, or a patient providing information.

These four use cases increase in complexity and help take the abstract concept of 'Provenance' into concrete guidance. The use cases are agnostic to any content or transmission standards.

***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. This original creation timestamp of capture can assist a provider in making clinical decisions regarding incorporation of active problems, allergies, or diagnosis. This is especially important when conflicting status is received from different sources. The timestamp enables a provider and the EHR system to accurately classify and present active information in a manner that is actionable. (e.g., This would help with a recipient not reconciling a diagnosis (URI or UTI) that is 10 years old when a clinician has not appropriately maintained the patient's chart. Another useful component of Provenance, beyond the actual author of the data, is the proximate source of the data - the data holder who had the data and sent it to the recipient, which may well be different than the author. This is particularly relevant, as the restrictions on the use of an element of received data is typically determined by the source, not the original author.

***1.2.1.2.*** Disability Evaluation Under Social Security: Most Social Security disability claims are initially processed through a network of local Social Security Administration (SSA) field offices and State agencies (usually called Disability Determination Services or DDSs). Usually, the DDS tries to obtain evidence from the claimant's own medical sources first. If that evidence is unavailable or insufficient to make a determination, the DDS will arrange for a consultative examination (CE) to obtain the additional information needed. The claimant's treating source is the preferred source for the CE, but the DDS may obtain the CE from an independent source. After completing its development of the evidence, trained staff at the DDS makes the initial disability determination. All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided (legal authenticator), consistent with hospital policies and procedures.

***1.2.1.3.*** Use Case: Provider A receives a data item from an HIE who received the data item from Provider B. Under current standards, Provider A is unable to contact Provider B since the provenance author information is not exchanged.

SSA cannot accept electronic medical records submitted by applicants because the integrity of those records cannot be verified without knowing the **author and without (cryptographic) digital signatures of the content**. In a patient medical record, the legalAuthenticator identifies the single person legally responsible for the document and must be present if the document has been legally authenticated. The industry needs guidance for who the most appropriate person is to include as a document's legalAuthenticator. There is evidence of some organizations who set it to a generic background user representing the org's HIM director. Ideally there should be some guidance for best practice guidance for legalAuthenticator handling.

### 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.

**1.2.3.** Healthcare Entity to Consumer/Patient – A patient is seeing a new primary care provider (PCP) who is reconciling the chart with information received from an external system. It is imperative that the discrete problems from the problem list are pulled into the chart information regarding the clinician that originally made the diagnosis including the original date of diagnosis. It is critical as external data is reconciled in the recipient chart that provenance characteristics (metadata) are maintained in the recipient system regarding the clinician that originally made the dx as well as the original date of diagnosis are maintained. One challenge is that it is difficult to assess the actual diagnostician who made the diagnosis and someone who just recorded it later.

## 1.3. Existing Work

**1.3.1.** United States Core Data for Interoperability (USCDI) v1, v2, v3, v4, and v5

***1.3.1.1.*** HealthIT.gov USCDI Data Class - Provenance

1.3.1.1.1. USCDI V5 - Author and Author Role were added

1.3.1.1.2. USCDI Level 1 - Source

1.3.1.1.3. USCDI Level 0 - Author Credential, Signature, Physical Location, etc.

1.3.1.1.4. 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 which at the time of publication of the Whitepaper (2020) was USCDI v1. The guidance here further constrains this to recommend that newly generated documents SHALL support USCDI v3 in accordance with the HTI-1 legislation in place at the time of publication of this document.

1.3.1.1.5. Trusted Exchange and Common Agreement (TEFCA) Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 2.0

The Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) Facilitated FHIR exchange model provides the opportunity for QHINs to make available selected network services to enhance Participants' and Subparticipants' use of FHIR Application Programming Interface (APIs) among themselves. This QTF is accompanied by the Facilitated FHIR Implementation SOP, which describes the roadmap and requirements for adoption of network wide Facilitated FHIR Exchange. The SOP references HL7® FHIR® specifications for Facilitated FHIR exchange between QHINs, Participants, and Subparticipants, including the use of the **FHIR Provenance Resource** to track data transformation to and from FHIR resources.

*1.3.1.2.* HL7 FHIR U.S. Core Implementation Guide - Basic Provenance

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

1.3.1.3.1. US Realm Health V4

**Heading: legalAuthenticator**
The legalAuthenticator identifies the single person legally responsible for the document and must be present if the document has been legally authenticated. A clinical document that does not contain this element has not been legally authenticated. **Note that the legal authenticator, if present, must be a person.**

**Heading: authenticator**
The authenticator identifies a participant or participants who attest to the accuracy of the information in the document. legalAuthenticator Example

*1.3.1.4.* HL7 CDA R2.1 IG: Consolidated CDA Templates for Clinical Note (US Realm), DSTU R2.1—Vol. 2: Templates

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

*1.3.1.6.* C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3 documents USCDI V2 requirements.

*1.3.1.7.* C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - documents USCDI V3 requirements.

Exchange of provenance elements is required as part of ONC's USCDI v3 data set. 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 C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1, which documents USCDI V3 guidance to ensure standard exchange of provenance data. The HL7 guide includes recommendations for implementation of provenance in the discrete entries in C-CDA documents in section 5.2.1. 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.

*1.3.1.8.* Data Quality - Electronic Health Records

1.3.1.8.1. Data Quality - Information Flow Example with Record Lifecycle/Provenance Events

1.3.1.8.2. Data Quality - Foundations of Accountability

1.3.1.8.3. Data Quality - Chain of Trust

***1.3.1.9.*** EHRS Functional Model - Record Lifecycle Events

1.3.1.9.1 EHRS Functional Model - Record Lifecycle Events - Provenance

1.3.1.9.2. EHRS Functional Model - Record Lifecycle Events - AuditEvent

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

***1.3.2.1.*** 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.

**1.3.3.** HL7 v2 to FHIR Mapping - HL7 v2 has very little provenance information built into common use of the specification. This is not to say that there isn't provenance. In theory, one knows the sender of the message, but as a message, this sender information is usually discarded.

**1.3.4.** HL7 CDA to FHIR Mapping - CDA - has a well implemented CDA header that holds Provenance. While the CDA header is not described as Provenance, however, it does describe: (a) Who authored the document, (b) What organization is the custodian of the document, (c) When was this document authored, and (d) Why was this document authored. Given that a CDA document is a document, and not a transport, it does not include to whom it is being sent, and from where it is being sent. These are gaps overall, but gaps that one should expect the transport to fill as appropriate.

**1.3.5.** Incorporating Guidance on Legal Authenticator

***1.3.5.1.*** Code of Federal Regulations - Title 42 Public Health

Chapter IV - Centers for Medicare & Medicaid Services, Department of Health and Human Services

Subchapter G - Standards and Certification

Part 482 Conditions of Participation for Hospitals

Subpart C - Basic Hospital Functions

§ 482.24 Condition of participation: Medical record services.

***1.3.5.2.*** Center for Medicare and Medicaid Services Medicare Learning Network "Complying with Medicare Signature Requirements"

**1.3.6.** The DIRECT Standard - Implementation Guide for Direct Edge Protocols

## 1.4. Guidance

**1.4.1.** This second version of the guide focuses on requiring provenance attributes to be included in health data exchange transactions for ALL USCDI V3 data classes or elements exchanged via HL7 C-CDA, HL7 v2.x or HL7 FHIR.

***1.4.1.1.*** The workgroup acknowledges the complexity of the provenance space, particularly recording and sharing 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. Note this Guidance includes laboratory data. Note additional requirements per the Clinical Laboratory Improvement Amendments (CLIA), those states (New York and Washington) which are CLIA exempt, accreditation agencies, and public health reporting laws, etc. may apply to laboratory data depending on the types of data transactions. A number of these requirements apply to a variety of health information technologies (e.g. electronic health records, interface engines, public health systems) and not just the clinical Laboratory Information System (LIS) or public health Laboratory Information Management System (LIMS). Please see Section 7.4, for more details on laboratory data

***1.4.1.2.*** A sending system SHALL include provenance information, when available, for all transactions as specified by USCDI v3. This information SHALL include author organization and time stamp.

1.4.1.2.1. A sending system SHALL conform to the U.S. Core Implementation Guide - Basic Provenance requirements.

1.4.1.2.2. FHIR Transactions: A sending system SHALL record Provenance records on all Create, Update and Delete actions on any resource other than Provenance or AuditEvent.

1.4.1.2.3. FHIR Transactions: A sending system SHALL record Audit Event records on all Create, Update and Delete actions as well as all GET operations (read, search, etc.).

1.4.1.2.4. C-CDA 2.1 Documents:Provenance - Author Participation: A sending system SHALL use this template at any place C-CDA allows an author. For example, at the CDA Header, CDA Section, CDA Entry, or within a CDA entry (e.g. Organizer and contained Observation(s)). This template is used to identify primary authorship for an entry.

An entry may have many authors, but recipients need a single authoritative point of contact for resolving issues. This is typically the last provider to make substantive changes to the entry. If two providers are simultaneously involved in that activity, the implementer must choose one, ideally in a repeatable way.

***1.4.1.3.*** Sending systems SHALL develop a timeline for replacing FAX related workflows with electronic PUSH transactions leveraging the DIRECT Standards.

### **1.4.2.** Sharing Author for USCDI Data

***1.4.2.1.*** The Data Usability workgroup endorses the data element inclusion of the author in USCDI v5. This will require specification on who the author should be for data elements edited by multiple users in the future when adopted by regulation.

***1.4.2.2.*** Prior to that change, provenance entries SHOULD include the author for a data item when known. Including the author provides valuable context for receivers on where the data originated. The HL7 Guidance: Basic Provenance for C-CDA and FHIR, Release 1 - US Realm September 2019 includes guidance for how to share author information.

### **1.4.3.** Sharing Legal Authenticator in CDA documents and FHIR

***1.4.3.1.*** A sending system MAY include information about the Legal Authenticator of the data item when known. This information SHALL include, at minimum, a timestamp and the identity of the Legal Authenticator. This information MAY contain a signature element.

***1.4.3.2.*** The Legal Authenticator SHOULD be a provider responsible for the care of the patient.

## 1.5. 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.*** This workgroup supports the inclusion of "Author Role" (https://www.healthit.gov/isp/taxonomy/term/2201/uscdi-v5) into USCDIv5 as well as the promotion of "Author Credential(s)" https://www.healthit.gov/isp/taxonomy/term/2206/level-0" into future versions of the USCDI.

**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 to include multiple transport methods to be technology agnostic.

**1.5.4.** Create guidance on provenance for various use cases

***1.5.4.1.*** Other use cases such as Healthcare Entity to Consumer / Patient Access will be considered to support the patient provenance use case(s) relative to error identification and correction and ultimately pushed to all "relevant" providers. This could include a person that would be the authenticator for documents, e.g., POLST, DNR, Consents in addition to flagging and tracking error corrections particularly for medications.

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

***1.5.4.3.*** Consider guidance for consumer-directed health information exchange that is becoming more prevalent, verifying the integrity of patient-supplied medical information will become an imperative. When EHI obtained by a patient that is digitally signed is provided to a third party along with the chain of trust from its origin, that third party can have confidence in the integrity of that EHI. As Consumer apps facilitate the submission of sports physicals and immunization records to schools driving patient-driven care coordination, consumers will demand this access to their data, and providers receiving that data will need to know it is unaltered.

**1.5.5.** Transformation of data edge cases to be considered and further definition of what is meant by translation for each data standard including HL7 V2 and HL7 FHIR.

# 2. Effective Use of Codes

## 2.1. Problem Statement

Codes are useful at various levels of data exchange. For C-CDA Document exchange, codes allow systems to request and respond with codes for specific documents with the right type of information. Codes are also used at the section and entry levels within C-CDA documents. In addition, when a system sends clinical data to another system, discrete data usually references standardized sets of codes, such as LOINC, CPT, or CVX. In many cases this allows the receiving system to map data elements (e.g. a medication) from a standard codeset to the local code for that element, which in turn allows the data to be "understood" by the receiving system. Among other benefits, coded data can be more easily incorporated into clinical decision support (CDS) 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 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, concept-based search and other techniques helps clinicians sift through the noise of available data.

## 2.2. Use Cases

**2.2.1.** Provider to Provider:

***2.2.1.1.*** Conversion and sharing of USCDI v3 data classes and attributes.

2.2.1.1.1. In the Electronic Health Record (EHR).

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

***2.2.1.2.*** Conversion and sharing of diagnosis information

2.2.1.2.1. In the Electronic Health Record (EHR)

2.2.1.2.2. In the Electronic Health Information Exchange (HIE)

2.2.1.2.3. In the Hospital Billing Systems

***2.2.1.3.*** The term “clinical note” can be used to mean different things, depending on the context of use. For example, the term “clinical note” can refer to an entire C-CDA document. A C-CDA document is a clinical note in that it includes all the clinical information that is relevant and pertinent to a care encounter, a span of time when care services have been delivered, or a point in time when clinical information about a patient needs to be shared across systems. C-CDA, in fact, was developed to exchange clinical notes in this sense of the term.

Additionally, the term clinical note is often used to describe a document authored by a clinician to 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) has included Clinical Notes in U.S. Core Data for Interoperability (USCDI).

***2.2.1.4.*** 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.

**2.2.2.** Provider to Public Health Agency - Example Scenarios:

***2.2.2.1.*** USCDI V3 data classes and attribute, externally sourced data, EHR, HIE, Registry

2.2.2.1.1. 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.

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

## 2.3. Existing Work

**2.3.1.** ISA Recommendations

**2.3.2.** CVX Codeset

**2.3.3.** NDC Codeset

**2.3.4.** RxNorm

**2.3.5.** SNOMED-CT

**2.3.6.** LOINC

**2.3.7.** ICD-10

**2.3.8.** CDC Immunization Basics: Definition of Terms

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

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

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

**2.3.9.** USCDI v1, v2, & v3

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

***2.3.9.2.*** HL7 CDA R2.1 IG: Consolidated CDA Templates for Clinical Note (US Realm), DSTU R2.1—Vol. 2: Templates

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

***2.3.9.4.*** C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3 documents USCDI V2 requirements.

***2.3.9.5.*** C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 documents USCDI V3 requirements.

***2.3.9.6.*** USCDI V3

***2.3.9.7.*** FHIR version 4

***2.3.9.8.*** HL7 Version 2.5.1 Implementation Guide: Immunization Messaging (Release 1.5)

## 2.4. Guidance

**2.4.1.** General Guidance for CVX -- Immunizations Administered

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

2.4.1.1.1. Organizations MAY include the relevant NDC code in addition to the required CVX code. The full list of NDC codes is here.

***2.4.1.2.*** 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 SHOULD be documented as follows:

2.4.1.2.1. 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)

2.4.1.2.2. In FHIR as performer/actor

2.4.1.2.3. In HL7 v2 in RXA-10 (Administering Provider) on Page 268 of the HL7 v2 Implementation Guide

***2.4.1.3.*** Organizations SHALL include the immunization dose, dose unit, expiration date, lot number, and appropriate CVX codes when available.

***2.4.1.4.*** USCDI specifies both active immunization administration records *AND* externally sourced immunization records. The Level 3 USCDI candidate data elements include 'Vaccine Event Record Type" with candidate concepts (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.

***2.4.1.5.*** 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.

2.4.1.5.1. For Patient Reported Vaccines - alignment with the published HL7 Example is RECOMMENDED.

**2.4.2.** Allergies and Intolerances

***2.4.2.1.*** 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.

***2.4.2.2.*** Organizations SHOULD send RxNorm for active pharmaceutical ingredient or UNII for non-pharmacological substances and non-medication allergens including excipients (e.g., yellow dye #5, latex, pollen, shellfish). Organizations SHOULD send SNOMED-CT codes for reaction and class for all allergies and intolerance observations, when available.

2.4.2.2.1. Representing Patient Allergies and Intolerances; Medications

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

**2.4.3.** Documenting and Sending "No Known Allergies"

***2.4.3.1.*** 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.

2.4.3.1.1. Guidance for best practices to exchange "No Known Allergies" using CDA is available here.

2.4.3.1.2 Guidance for best practices to exchange "No Known Allergies using FHIR is available here.

***2.4.3.2.*** 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 at the time of encounter.

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

2.4.3.2.2 Guidance for best practices to exchange Medication Allergies using FHIR is available here.

***2.4.3.3.*** Representing Patient Allergies and Intolerances; Medications

**2.4.4.** Diagnosis

***2.4.4.1.*** Organizations SHOULD send ICD-10 codes and/or SNOMED-CT codes for all diagnosis information when available.

***2.4.4.2.*** If both are used, value sets SHOULD be inclusive of both terminologies.

***2.4.4.3.*** If mapping is done, the original value SHALL be maintained along with the new value.

**2.4.5.** Document Level Clinical Notes

***2.4.5.1.*** The HL7 C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1, section 2.7.1, describes how clinical note types are identified using LOINC terminology and identifies the most commonly used note types in Table 8. C-CDA Content Creators SHOULD support creation of C-CDA documents.

2.4.5.1.1. Document Level Clinical Notes SHOULD use the most general LOINC code from C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1, section 2.7.1, Table 8 as document type code.

2.4.5.1.2. Document Level Clinical Notes SHOULD include a more specific LOINC code from the Complete Note Type Value Set in C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1, section 2.7.1 Table 8 as a translation of the main code.

***2.4.5.2.*** C-CDA Content Creators SHOULD support inclusion of narrative clinical note information in structured sections of C-CDA documents.

The LOINC terminology includes thousands of different clinical note types. These codes can be used at the document, section, or entry level to categorize the type of clinical note information being shared. 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 most frequently created clinical note documents.

In addition, please note additional clinical note narrative guidance in section 6.

## 2.5. Future Efforts

**2.5.1.** Guidance for codes in discrete data elements

***2.5.1.1.*** 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.

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

***2.5.1.3.*** 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 Reference Guide.

**2.5.2.** Create guidance for various use cases.

***2.5.2.1.*** Further guidance on descriptions/codes for document/data types that are desired to filter (i.e., Radiology Reports from Lab Data) to allow indexing or filtering by date.

**2.5.3.** Investigate the consumption and display of translational fields across vendors.

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

**2.5.5.** Guidance will be extended to include the expanded data types being developed by USCDI+ domains.

**2.5.6.** Guidance for Immunizations

***2.5.4.1.*** 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.

***2.5.4.2.*** This workgroup supports the inclusion of “Lot Number” and "Performer" (https://build.fhir.org/ig/HL7/US-Core/StructureDefinition-us-core-immunization.html) into US Core v8.0.0 as well as the inclusion of these fields into future versions of the USCDI.

# 3. Reducing the Impact of Duplicates

## 3.1. 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.

## 3.2. Use Cases

Duplicates should be easily identifiable on a receiving system when the sending system has sent the data previously. This guide focuses on the resources contained within USCDI v3.

**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 payloads: 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.

## 3.3. Existing Work

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

**3.3.2.** USCDI v1, v2, & v3

> ***3.3.2.1.*** HL7 C-CDA Online: A navigation website for C-CDA 2.1

***3.3.2.2.*** HL7 CDA R2.1 IG: Consolidated CDA Templates for Clinical Note (US Realm), DSTU R2.1—Vol. 2: Templates

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

***3.3.2.4.*** C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3 documents USCDI V2 requirements.

***3.3.2.5.*** C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 documents USCDI V3 requirements.

***3.3.2.6.*** USCDI V3

***3.3.2.7***. *FHIR version 4*

***3.3.2.8.*** 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 which at the time of publication of the Whitepaper (2020) was USCDI v1. The guidance here further constrains this to recommend that newly generated documents SHALL support the USCDI v3 in accordance with the HTI-1 legislation in place at the time of publication of this document current published version.

**3.3.3.** FHIR to CDA mapping

## 3.4. 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 unique IDs within their scope and shall be consistently re-used as the same data appears in different documents, messages, and/or other exchange context.

3.4.1.1.1 When transforming CDA data to FHIR or vice versa, the processes listed in the FHIR to CDA mapping Section 4.2 SHOULD be followed to maintain consistency. .

**3.4.2.** Use reliable identifiers between documents and over time

***3.4.2.1.*** Organizations SHALL send the same ID for clinical data which has not changed. Identifiers can only change when another instance of the concept is documented. 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 and FHIR resources are typically allowed to send multiple identifiers 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 identifier may reflect that this data has been updated, the original result identifier shall still be sent along with this new identifier.

***3.4.2.3.*** Organizations SHOULD record and share the consistent identifiers for entries across data elements 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.** Sharing External Imported (as opposed to simply viewing) Data (incl data shown in patient portals)

***3.4.3.1.*** Externally sourced discrete data for all data classes of USCDI V3 imported into a chart SHOULD be coded to the same level of specificity as internally produced data when sent out or "re-served", to enable high quality and usable data to be sent to other systems. (See effective use of codes guidance)

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

3.4.3.2.1. *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

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

## 3.5. Future Efforts

### 3.5.1. Reduce Impact of Duplicates

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

***3.5.1.2.*** Guidance will be extended to include the expanded data types being developed by USCDI+ domains.

### 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 has been balloted by HL7. Future versions of this implementation guide will consider referencing this guidance.

**3.5.4.** Patient Contributed Data work is in process at HL7. Future versions of this implementation guide will consider referencing guidance from that work when complete.

# 4. Data Integrity, Format and Trust

## 4.1. 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 several factors can influence data integrity format and trust, including provenance and other topics addressed elsewhere in this IG, the Data Usability Workgroup's IG will focus 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, including encouraging broader use and adoption of Project US@ recommendations as a simple, but effective means of improving patient matching.

## 4.2. 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. Clinicians benefit when meaningful and usable clinical data is exchanged. "No Data Available" does not meet the clinician's needs. This causes a waste of time for clinicians to sort through documents with no meaningful or useful information.

## 4.3. 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 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.

## 4.4. Guidance

**4.4.1.** Project US@

***4.4.1.1.*** Data for address fields used for patient discovery query SHALL conform to Project US@ Technical Standards. This guidance SHALL be applied to both the transport meta-data attributes and within the payload that contains the discrete data elements, (e.g. C-CDA document, FHIR Document Bundle, or other HL7 v2.x transactions) that include demographics.

**4.4.2.** Patient Identity and Patient Matching

***4.4.2.1.*** Patient Identity data used for patient discovery and patient matching SHALL conform to the guidance in AHIMA's Recommended Data Elements for Capture in the Master Patient Index.

**4.4.3.** General formatting recommendations

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

4.4.3.1.1. When generating a current Patient Summary Document for a patient in response to an on-demand document query, responding systems SHALL use the C-CDA Continuity of Care (CCD) document type as stated in Section 4.1: 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.

4.4.3.1.2. When generating a "current snapshot" Patient Summary document Responding Systems SHALL conform to the following guidance from Section 4.2: Generating a current Patient Summary

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

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

- SHALL include ALL USCDI v3 data classes and elements as required by regulation as available.
- SHALL ensure that entries includes information from the most recent encounter with a provider who directly documented that encounter in the Responding system, not a received/copied encounter that may even be more currently represented in the Responding system, which may be a telephone or virtual encounter.
- SHALL 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.

4.4.3.1.3. Section 3.0: Encounter Summary Documents

*4.4.3.1.3.1.* 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 that contains ALL USCDI v3 data classes and elements required by regulation as available. Note that this is identified by the XDS document entry classCode attribute with LOINC code 11506-3.

***4.4.3.2.*** 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.

## 4.5. Guidance

### 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.

**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 and FHIR payloads.

**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.

# 5. Data Tagging / Searchability

## 5.1. 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.

In addition, from the end use/end user perspective, it is important to know if data pertains to an activity and the data tense (is in the past, in the present, or in the future). Also, the likely state/status of the data.

## 5.2. 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. Providers can benefit from having a complete patient story if notes can be easily found for a specific patient encounter within a progress note. Providers can also benefit from having discharge instructions and medications for a transition of care.

***5.2.1.2.*** From the end use/end user perspective, it is important to know if data pertains to an activity (action) that is in the past, in the present, or in the future. Another way to consider what data needs to be recorded and exchanged would include: has the event happened or is it planned, when documented, and when reviewed by the user. In addition, the state/status (complete/final, partial/incomplete/subject to change, or pending) of the data is important for certain workflows. (Example: tetanus shot) When did it happen? When was it recorded? When did it get pulled into the system?

***5.2.1.3.*** A provider working on a research project searches for a C-CDA document for the particular diagnosis code relevant to their research. When the document is received, the provider is alerted that there are sections of the document that are

marked with privacy tags indicating the patient involved does not consent to their data being used in research. The provider removes this document from their research pool.

**5.2.2.** Healthcare Entity to Consumer - Example Scenario

***5.2.2.1.*** A consumer seeks to see all relevant health data related to certain criteria, such as those with diagnosis codes related to Cardiac Care or Cancer encounter.

***5.2.2.2.*** A consumer seeks to see all relevant health encounter data for radiology or laboratory procedures.

## 5.3. 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.

**5.3.4.** USCDI v1, v2, & v3

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

***5.3.4.2.*** HL7 CDA R2.1 IG: Consolidated CDA Templates for Clinical Note (US Realm), DSTU R2.1—Vol. 2: Templates

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

***5.3.4.4.*** C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3 documents USCDI V2 requirements.

***5.3.4.5.*** C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 documents USCDI V3 requirements.
***5.3.4.6.*** Consolidated CDA R3.0

**5.3.5.** HL7 Data Segmentation for Privacy, Release 1

## 5.4. 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 ensure the embedded notes are easily discoverable and visible to the consumer.

5.4.2.3.1. If the Procedure section had 5 procedures, it is preferable to display the 5 procedures in a flat list or table, with an option, such as 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.** Use of Subsections in Procedures and Results sections.

C-CDA Section templates are open templates. This allows for the inclusion of subsections to enhance the organization of narrative content.

***5.4.5.1.*** If a subsection for laboratory procedures within the Procedure Section, or laboratory results within the Results Section is specified the code element SHOULD contain LOINC code 11502-2 “Laboratory report”

***5.4.5.2.*** If a subsection for imaging procedures within the Procedure Section, or imaging results within the Results Section is specified the code element SHOULD contain LOINC code 18748-4 “Imaging report”

**5.4.6.** Data Segmentation for Privacy - Document Source Systems MAY include information detailing privacy protections that apply to some or all of the information in the document. If such information is included, it SHALL be encoded to comply with HL7 Data Segmentation for Privacy, Release 1.

***5.4.6.1.*** Documents containing such privacy information SHALL contain a templateId identifying it as a Privacy Segmented Document

***5.4.6.2.*** Documents containing such privacy information SHALL contain at least one author.

5.4.6.2.1. At least one of those authors SHALL contain exactly one Mandatory Document Provenance

***5.4.6.3.*** Document Source Systems MAY apply different privacy protections to different sections of the document. In this case, sections with privacy information attached SHALL contain a templateID identifying it as a Privacy Segmented Section.

5.4.6.3.1. If no sections of the document are identified as Privacy Segmented Sections, Document Source Systems SHALL apply the top-level guidance to the whole document.

## 5.5. 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.

***5.5.1.2.*** Consideration will be given for how to leverage tagging to improve the searchability to enable the ability to find the relevant documents of interest by the clinician or patient. This would require alignment on document type encoding/classification and search parameter/method guidance to increase the probability of receiving the right, expected documents.

Today it is entirely possible to query for documents, get zero results, even though it is known there are records of interest. Either the document type classification used by requester and responder are not in sync, and/or the method of searching is not aligned. Clarity and alignment can help reduce frustration of not finding documents.

***5.5.1.3.*** Consideration will be given to add searchability based on the documenter's role, e.g., to search all notes from a (e.g., respiratory therapist, or a speech and language pathologist, etc. Also, by physician specialty, (e.g. oncologist or orthopedist, PCP, etc.).

**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 have 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.

**5.5.6.** Guidance will be extended to include the expanded data types being developed by USCDI+ domains.

**5.5.7.** FHIR Data Segmentation for Privacy - Expand DS4P guidance to include FHIR resources.

# 6. Effective Use of Narrative for Usability

## 6.1. Problem Statement

Clinical narrative notes are critical components of health data exchange, providing essential context and insights beyond the discrete data elements typically prioritized in electronic health records. The ability to easily locate and parse these narrative notes is vital to the usability and effectiveness of health data exchange for clinicians.

However, current nomenclature and documentation standards create significant challenges. For instance, the term "Physician Discharge Summary" can refer either to the clinical narrative note itself or to a Continuity of Care Document (CCD) that includes discrete data elements alongside the narrative note. Adding to the confusion, the same narrative note might also be found within the "Summary of Episode Note"—a CCD document that contains much more than just the clinical note. This overlap in terminology, combined with the large number of CCD document types that serve overlapping purposes, has led to variability in how different systems deliver these critical documents.

This heterogeneity poses significant challenges for inter-vendor health data exchange. For example, LOINC codes like 11490-0 (Physician Discharge Summary) and 34133-9 (Summary of Episode Note) are often used inconsistently, blurring the distinction between narrative notes and CCD documents. Such inconsistencies make it difficult for receiving systems and clinicians to reliably identify and utilize the information they need.

To address these issues, it is essential to establish clear and consistent guidelines for linking clinical narrative notes to discrete data elements. This ensures that clinicians can validate and understand the context of shared data effectively. Furthermore, robust and standardized sharing of clinical narratives in formats that are easily digestible by receiving organizations and clinicians can significantly enhance the quality of care.

By resolving ambiguities in nomenclature and document structure and improving the standardization of narrative note exchange, we can improve usability and advance the goals of interoperable, patient-centered care.

## 6.2. 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. Providers wish to pull a document or data set by diagnosis/ICD-10. One example includes the desire to see data related to a COVID ER Visit, bipolar or dementia diagnosis. Consider three (3) types of tags: 1) setting (ER, hospital, ICU, SNF, outpatient) 2) important transitions (ER

visit, hospital admission, ICU admission, ICU discharge, death, hospital discharge, SNF or Rehab admission, SNF or Rehab discharge, outpatient new patient visit) and 3) problem or diagnosis for both narrative and structured elements

**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.

**6.2.3.** Provider to Public Health

***6.2.3.1.*** Public Health officials would like to have the capability to query or have data pushed based on a diagnosis/ICD-10 related to TB, HIV or Syphilis. Both narrative and structured elements.

## 6.3. Existing Work

**6.3.1.** USCDI v1, v2, & v3

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

***6.3.1.2.*** HL7 CDA R2.1 IG: Consolidated CDA Templates for Clinical Note (US Realm), DSTU R2.1—Vol. 2: Templates

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

***6.3.1.4.*** C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3 documents USCDI V2 requirements.

***6.3.1.5.*** C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 documents USCDI V3 requirements.

***6.3.1.6.*** FHIR version 4

***6.3.1.7.*** 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 which at the time of publication of the Whitepaper (2020) was USCDI v1. The guidance here further constrains this to recommend that newly generated documents SHALL support the USCDI v3 in accordance with the HTI-1 legislation in place at the time of publication of this document current published version.

**6.3.2.** C-CDA Examples - Search on “narrative”.

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

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

**6.3.5.** 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.

## 6.4. Guidance

**6.4.1.** Implementers SHALL, at minimum, include available narrative discharge summaries and ED provider notes at time of document creation and SHOULD include relevant discrete data as appropriate. 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 4.1, 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 SHOULD 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.

**6.4.6.** Narrative Text Linking

***6.4.6.1.*** Following guidance in the HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Companion Guide Release 4.1, section 5.1.1, Implementers SHOULD use a reference element to link data elements to the appropriate part of the narrative text.

## 6.5. 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 shared and further developing rational guidance may help consistency in the industry.

# 7. Laboratory Interoperability

## 7.1. Problem Statement

The current state of laboratory results interoperability across the health care community is highly variable. Different levels of standards adoption by clinical laboratories and facilities coupled with a loss of information during transmission of discrete health data across health information technology platforms within and between institutions are contributing factors. This lack of interoperability affects the ability of clinicians to provide safe, high-quality, low-cost care. A broad community of clinical experts and stakeholders developed a preliminary list of laboratory orders and results that are most valuable for care management, clinical decision support and quality measures across the care continuum. Mapping these high value laboratory tests for interoperability should be a high priority focus.

Clinical laboratory data are impacted by one or more regulatory, accreditation, public health and health information technology related requirements. These entities include the Clinical Laboratory Improvement Amendments (CLIA), and those states (New York and Washington) which are CLIA exempt and who may have more stringent requirements, CLIA deemed accreditation agencies who support CLIA at a minimum and may have additional requirements, and multiple public health reporting laws, which may have different reporting requirements for the same data elements depending on where they occur (e.g. ELR versus eCR, versus HAI). A number of these are included in this guide; however some may not be mentioned here. As such implementers are advised to confirm which requirements apply to them and may include requirements not in this guide. Be advised even though a few HL7 Implementation Guides list CLIA information, many other IGs, artifacts, and examples may not be compliant with these regulations currently.

These clinical laboratory regulatory requirements include overlap with aspects of provenance. For example CLIA 42 CFR 493.1291(c)(2) indicates , the “test report must indicate the following:” “(2) The name and address of the laboratory location where the test was performed,” and “The test report date.,” among others. This is in addition to the USCDI v3 Provenance elements of “Author Timestamp” and “Author “Organization.” Note USCDI “Author Timestamp” is more stringent than CLIA’s ‘test report date” as USCDI also includes the time. Accreditation requirements include interface checks whereby data sent by the performing laboratory’s LIS to the first downstream entity, which can be an EHR, LIS, HIE, or Public Health System, are checked to ensure data are not missing, modified, truncated, etc. in the receiving system. Further downstream exchanges may or may not have the requirements outlined here, but with the need for quality, accurate, and complete information about laboratory test data for those users that need them, warrants including the required elements in this guide and regulations including by intermediaries to avoid

blocking their availability and/or usability in any systems where they are needed. Adoption of the provenance data requirements indicated in section 1 will be one of these key requirements.

Initiatives such as the Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) Collaborative Community and FDA's SHIELD Program, are working on national laboratory interoperability needs and preservation of information for the complete meaning of laboratory results across the care continuum. Meanwhile, health systems and vendors can work with their partners providing or exchanging laboratory data to improve interoperability of laboratory data by utilizing the following paradigm:

1. **Electronic.** Paper doesn't cut it anymore. Increased adoption of EHRs and Health IT was influenced by Meaningful Use (MU) and public health reporting requirements. However, adoption of standards and technology, especially by laboratories has been highly variable as the MU program put minimal requirements on clinical laboratories. For example, placing electronic orders via Computerized Provider Order Entry (CPOE) was required, but transmission of orders did not have to occur electronically and so many practices continue to print paper based orders and send them with the specimen to the performing laboratories. This burdens laboratories who have data technicians hand enter orders into their Laboratory Information Systems (LIS). Typos, delays, and other negative impacts to patient care may occur as a result. Other entities use fax and other non-discrete modalities. In order to have any lab interoperability, electronic interfaces should be implemented, including between laboratory LISs, EHRs, HIEs, and Public Health to facilitate electronic exchanges of data.

2. **Discrete.** PDF and text blobs are physician readable, but not easily digested by computers. Facilities are encouraged to review how laboratory data are stored, exchanged, and used within their Health IT Platforms. Are reports stored as pdf or media files, or is time taken to map laboratory results received (whether CDA, HL7 V2.5.1, FHIR, fax, etc.) into discrete data elements that can be stored and encoded with standardized terminologies to provide computer usable data and meaning? Increasing the percentage of results that are stored and messaged discreetly can greatly improve interoperability. Beginning the effort with common chemistry and hematology labs but continuing to more challenging results of microbiology, genomics and pathology is a good strategy to prioritize the most common high volume laboratory results to realize benefits quickly.

3. **Encoded.** Proper and consistent encoding of laboratory orders and resulting tests, and qualitative results helps facilitate computer usability and increases semantic meaning. Leveraging standardized computerized processes also reduces clinical burden, and potential for errors, misinterpretations and biases.

4. **Messaged.** Typically, the performing laboratory exchanges laboratory data in various HL7 v2.x messaging formats. When the LIS and EHR within the organization are from the same vendor, interfaces may not be utilized depending on the level of integration between these capabilities, e.g., data may be shared between the laboratory LIS module and the EHR and possibly other modules such as for public health reporting. Currently LIS solutions do not currently have FHIR functionality for daily reporting needs and in a CLIA compliant format. A few laboratories may in other information systems transform HL7 v2.x messages into HL7 FHIR for use in exchanges. Although HL7 FHIR is utilized for laboratory data in downstream systems and apps, many may not contain all laboratory data elements needed for the complete meaning of a test such as the specimen type, test name or units. Users deploying HL7 FHIR based solutions may wish to proceed with caution and clinically validate applications with laboratory data to ensure they are complete for the purpose of use.

Messaging of laboratory data may occur from an EHR to another entity via HL7 CDA document format, HL7 FHIR or other HL7 interface. No matter how laboratory data is exchanged, the content and discrete encoding should be preserved so they are available to all users in the health ecosystem.

If using CDA documents to transmit lab results, since most providers rely on direct consumption from the CDA rather than parsing of the individual data elements, the results should be arranged intuitively within the document for the end user (e.g., hematology tests and chemistry tests should each be grouped together and panels should be maintained).

It's important as laboratory data are exchanged, that the receiving system, whether interfaced or internally, maintain structure and meaning of laboratory tests in every place they are utilized. For example, while it technically makes sense to have a single hemoglobin test result stored in database of patients results and values, the specimen type, units, reference range/interval, and the order in which it is associated are all important details for the complete meaning and use of the result in the appropriate clinical context. It is important for receivers to be able to keep panel elements and structure together in downstream systems to know if a hemoglobin was a single orderable and resultable versus as part of a Complete Blood Count (CBC) or another panel.

5. **Maintained.** Whether it is a new test, like COVID, introduced for clinical use or updates in code systems or messaging standards, all systems must be maintained and kept up to date. When one information system uses newer codes and downstream systems do not, errors may occur and interoperability is impeded, and clinical meaning lost.

## 7.2. Use Cases

**7.2.1.** Clinical Laboratory utilizing a Laboratory Information System (LIS) to send results to the Provider's EHR

***7.2.1.1.*** Laboratories can be considered a provider of information (sending system) when they share lab results with provider and hospital EHRs, HIEs, Public Health, and other laboratory LISs directly. Laboratory results received from "outside referral laboratories" are typically via HL7 v2 transactions to LISs and EHRs. Referral laboratory testing may be received directly into a provider's EHR or indirectly, if referral results are part of a referring laboratory's test report. That is the referring laboratory receives results from the outside laboratory and references them in their report sent to the ordering provider. Discrete data such as specimen type (e.g. nasopharyngeal swab, serum, urine, wound swab) or source may not be transmitted with lab results, or lab results may not be discrete and thus encoded, as seen with many genomics reports.

**7.2.2.** Provider to Provider Exchanges - Example Scenarios:

***7.2.2.1.*** A provider shares laboratory results to another provider's EHR via an interface directly, Health Information Exchange (HIE), or Health Information Network (HIN) network to network exchanges like TEFCA.

***7.2.2.2.*** Laboratory results in FHIR Resources or CDA documents are shared from EHRs with other EHRs and HIEs. Receiving systems need to ensure laboratory orders and results are assembled/structured appropriately in receiving systems. New laboratory build elements may be needed for outside results to ensure they are not commingled with internally performed results or patient performed testing. Technology implementers will need to determine which result values are clinically equivalent to graph or trend lab data and may need to determine which result values are clinically equivalent to enable accurate clinical decision support and artificial intelligence applications.

**7.2.2.3.** Additionally, the general usefulness of direct viewing of laboratory results in CDA documents shared from EHRs and HIEs is an important factor. Most provider systems do NOT parse lab results out of the CDA document but provide them for direct viewing within the document. Consideration, by the sending system, of the format and readability of the lab results provided in a CDA document is critical to usability for the receiving consumer. Human readable/viewable results may not be very computer processable/usable as discrete data elements in receiving system applications.

**7.2.3.** Provider to Public Health Agency - Example Scenarios:

***7.2.3.1.*** A provider receives lab results into their EHR from a laboratory, and is required to report to public health by law using Electronic Case Reporting specifications.

## 7.3. Existing Work

**7.3.1.** USCDI V3 (Test, Values/Results, Specimen Type, Results Status).

**7.3.2.** USCDI V4 (Adds Result Reference Range, Result Unit of Measure, Result Interpretation, Specimen Source Site, Specimen Identifier, and Specimen Condition Acceptability).

**7.3.3.** USCDI V5 (Adds Laboratory Order, Procedure Order, and Provenance Author and Author Role).

**7.3.4.** HL7 Version 2 Laboratory Value Set Companion Guide, Release 2 - US Realm

**7.3.5.** HL7 Version 2.5.1 Laboratory Orders Interface (LOI)

**7.3.6.** HL7 Version 2.5.1 Laboratory Test Compendium Framework (eDOS) aka Electronic Directory of Service provides a v2 specification to initially populate a laboratory test compendium in a receiving system (EHR), as well as receive updates for new tests, encoding, and other compendium details.

**7.3.7.** HL7 Version 2.5.1 Laboratory Results Interface (LRI), Edition 5

This guide provides guidance on how to communicate laboratory results in general from a (reference) Laboratory's LIS to a system interested in lab results, e.g., EHR, Public Health, other Laboratory. It covers general lab results, as well as specifications focused on microbiology, newborn dried bloodspot screening, and clinical genomics. The guide includes particular guidance that can be pre-adopted with any ORU^R01 message version to support pandemic response reporting to public health and references preliminary guidance to include SOGI/Gender Harmony data.

**7.3.8.** HL7 Version 2.5.1 Electronic Lab Reporting (ELR) to Public Health (R1 and Clarification Document)

- CDC How to Implement ELR

**7.3.9.** Incorporating CLIA Requirements. Some HL7 Implementation Guides (e.g. LOI, LRI) include information pertaining to CLIA requirements in those exchanges. However, other Implementation Guides, examples, or artifacts may not have been reviewed in light of CLIA and additional requirements may be needed to be in compliance.

***7.3.9.1.*** Part 493 - Laboratory Requirements

***7.3.9.2.*** 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**.**

**7.3.10.** System Safety within Laboratory Data Exchanges Report

## 7.4. Guidance

**7.4.1.** Performing Laboratory to EHR - Sending System: Sending System SHALL exchange Clinical Laboratory and/or Pathology Data available in electronic form with discrete data elements. The discrete data elements SHALL conform to the HL7 Version 2.5.1 Laboratory Results Interface (LRI), Edition 5 Implementation Guide. At a minimum the base profiles should be supported, with additional profiles as applicable. For example, laboratories performing testing that may be reportable to public health should support the ELR profile.

***7.4.1.1.*** The performing laboratory (sender) currently sharing data electronically to provider EHRs (receiving system), SHALL include LOINC test mapping at most appropriate detailed granularity from the originating Lab Information System - Test (the applicable value set SHALL be LOINC with Attribute Order vs. Observation = 'obs only' or 'both' and Class = 'Lab').

***7.4.1.2.*** Results

7.4.1.2.1. Result Status SHALL be included.

7.4.1.2.2. Result Value SHALL be included. Organisms SHALL be encoded with SNOMED CT Organism hierarchy codes, where available. Qualitative Result Values Shall be encoded with SNOMED CT Qualifier hierarchy codes, where available.

7.4.1.2.3. Units of Measure SHALL be included, where applicable. Units of Measure SHALL be encoded using The Unified Code for Units of Measure (UCUM).

7.4.1.2.4. Reference Range SHALL be supported where applicable.

7.4.1.2.5. Result Interpretation SHALL be supported where applicable. If included, Result Interpretation SHOULD be encoded using SNOMED-CT, where available, or HL7 Observation Interpretation Table HL70078 codes.

7.4.1.2.6 Result Date SHALL be included, and Result Time SHOULD be included.

***7.4.1.3.*** Specimen

7.4.1.3.1. Specimen Identifier SHALL be included.

7.4.1.3.2. Specimen Type SHALL be included and SHOULD be encoded using SNOMED CT Specimen Hierarchy Codes.

7.4.1.3.3. Specimen Type Qualifiers SHOULD be included as applicable and SHOULD be encoded using SNOMED CT Qualifier Hierarchy Codes.

7.4.1.3.4. Specimen Source Site SHOULD be included and SHOULD be encoded using SNOMED CT Anatomic Body Site Hierarchy Codes.

7.4.1.3.5. Specimen Source Site Qualifiers SHOULD be included as applicable and SHOULD be encoded using SNOMED CT Qualifier Hierarchy Codes.

7.4.1.3.6. Specimen Collection Method SHOULD be included and SHOULD be encoded using SNOMED CT Procedure Hierarchy Codes.

7.4.1.3.7. Specimen Condition SHALL be included where applicable; if included it SHOULD be encoded using SNOMED CT codes where available, or HL7 Specimen Condition Table HL70490 codes.

***7.4.1.4.*** Sending System SHALL include provenance information in accordance with CLIA Mandatory Reporting requirements as detailed in HL7 Version 2.5.1 Laboratory Results Interface (LRI) Implementation Guide, Section 14 (R1 STU R4 and Edition 5).

**7.4.2.** EHR/HIE/Public Health - Receiving systems **-** When sending out laboratory data received from other organizations, receiving systems SHALL retain original discrete data and the associated encoding received from the sending system.

***7.4.2.1.*** Laboratory (Tests) Results SHALL be included, and SHOULD be coded to LOINC, where available, to conform to USCDI V1. The Laboratory Test Name SHALL be included.

***7.4.2.2.*** LOINC test mapping SHOULD be coded to conform to USCDI V3 at the most appropriate detailed granularity from the originating Laboratory Information System.

7.4.2.2.1. Sending systems, when sending lab data received from an external organization (i.e. re-serving), SHOULD maintain and send the same mapped codes that were received. Received codes can be utilized in downstream systems where pre-coordinated codes may be needed for reporting requirements of laboratory data (e.g. Healthcare Associated Infection (HAI) Reporting). Codesystem mappings should not be replaced in downstream systems EXCEPT for updates from the originating system or correcting errors. Transforming post coordinated coding into pre-coordinated coding may occur to meet reporting requirements, but the original coding should be available.

When a mapping error is detected, best practice is to contact the performing laboratory who can confirm whether an error has occurred or if it is the best map as they best know their tests and nuances that may not be reflected in health information technology (such as manufacturer's instructions for reporting that must be followed). It also allows for updates at the source, so all other consumers of the test are notified and can benefit.

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

### *7.4.2.2.* Results

7.4.2.2.1. Result Status SHOULD be included and SHOULD conform to USCDI V3 using the HL7 Observation Result Status value set as defined in LRI Edition 5 in version 2 messages, in Consolidated CDA when using CDA, or in the US Core Lab Observation Profile when using FHIR.

*7.4.2.2.1.1.* When the Receiving System is transmitting this result to another, the original value for Result Status SHOULD be included, where possible.

7.4.2.2.3. Result Value SHOULD be included and, when included, SHOULD be coded to conform to USCDI V3

*7.4.2.2.3.1.* Organisms, where included SHALL be coded with SNOMED CT Organism hierarchy codes, where available.

*7.4.2.2.3.2.* Qualitative Result Values where included SHALL be coded with SNOMED CT Qualifier hierarchy codes, where available.

*7.4.2.2.3.3.* Numeric Result Values where included and as applicable SHALL include Units of Measure.

*7.4.2.2.3.4.* Units of Measure SHALL be included, where applicable. Units of Measure SHALL be encoded using The Unified Code for Units of Measure (UCUM).

7.4.2.2.4. Result Reference Range SHALL be included, if applicable and, when included, SHOULD be coded to conform to USCDI V4.

7.4.2.2.5. Result Interpretation MAY be included and, when included, SHOULD be coded to conform to USCDI V4.

***7.4.2.3.*** Specimen

7.4.2.3.1. Specimen Type SHOULD be included and, when included, SHOULD conform to USCDI V3. Specimen Type SHOULD be encoded with SNOMED CT Specimen Hierarchy Codes.

7.4.2.3.2. Specimen Type Qualifiers SHOULD be included as applicable and SHOULD be encoded using SNOMED CT Qualifier Hierarchy Codes.

7.4.2.3.3. Specimen Source Site MAY be included and, when included, SHOULD conform to USCDI V4. Specimen Source Site when included SHOULD be encoded with SNOMED CT Body Site Hierarchy Codes.

7.4.2.3.4. Specimen Source Site Qualifiers SHOULD be included as applicable and SHOULD be encoded using SNOMED CT Qualifier Hierarchy Codes.

7.4.2.3.5. Specimen Collection Method SHOULD be included and, when included SHOULD be encoded using the SNOMED CT Procedure Hierarchy Codes and conform to USCDI V3.

7.4.2.3.6. Specimen Identifier SHOULD be included and, when included, SHOULD conform to USCDI V4. The Organization assigning the Specimen Identifier SHALL be included.

7.4.2.3.7. Specimen Condition Acceptability MAY be included and, when included, SHOULD conform to USCDI V4.

*7.4.2.3.7.1.* When the Receiving System is transmitting this result to another, the original value for Specimen Condition Acceptability SHOULD be included.

***7.4.2.4.*** Provenance (Please reference the Provenance guidance requirements in section 1.4.)

7.4.2.4.1. Sending systems SHALL send Provenance elements.

7.4.2.4.2. Receiving systems SHALL retain Provenance of the Sending

System for Clinical Laboratory and/or Pathology Data. Original performing laboratory location in conformance with USCDI V3.

This Provenance SHALL be taken from the values specified by the Sending System in accordance with CLIA Mandatory Reporting requirements as detailed in HL7 Version 2.5.1 Laboratory Results Interface (LRI) Implementation Guide, Section 13.

***7.4.2.5.*** Sending or Provider Organizations SHALL implement the requirements outlined in Section 2.5.1 of the JDCWG C-CDA Whitepaper Guidance, as applicable, where the laboratory test lifecycle is described in detail both as a specific example, but also as a template for other order types.

7.4.2.5.1. The HL7 C-CDA 2.1 Companion Guide also has useful guidance about laboratory tests, 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).

## 7.5. Future Efforts

**7.5.1.** Test Method - work in progress - This item may be reflected in the laboratory order or result name, LOINC code mapped to the laboratory order or result, included in some laboratory test compendium details, indicated in the In Vitro Diagnostics (IVD) device package insert, or implied by other test details (e.g., a differential performed on a hematology analyzer is an automated method and not manual). Test methods are not typically collected discreetly in the LIS or EHR and thus not able to be exchanged as such.

However, where there are multiple distinct test methods utilized in Health Information Technology, whether a LIS, or in an EHR, care should be taken to represent the lab results by different methods distinctly. This may entail building a separate result component from in house performed test results, as reference ranges and other test details will likely differ. Different methods which result in clinically significantly different result values should not be commingled in decision support, algorithms, displays, calculations and other uses as doing so may result in data quality and patient safety issues. Trends may be misinterpreted as due to patient disease or treatment effect, when in reality they are due to test method differences.

**7.5.2.** Device and Test Kit Device Identifiers - Although proposed in USCDI v5, they were excluded from the final version. See ONC's comments for further details. LIS and EHR functionality to send or receive these elements is currently lacking. However, with the continued interest in distinctive test details, these identifiers may become a future requirement.

**7.5.3.** Proposed New Use Cases

***7.5.3.1.*** EHR to Reference Lab messaging for Laboratory Orders

7.5.3.1.1. Laboratory orders should be exchanged utilizing the HL7 Version 2.5.1 Implementation Guide: Laboratory Orders from EHR (LOI) Edition 5 - US Realm.

7.5.3.1.2. USCDI v5 lists Laboratory Orders, but a code system is not yet specified. However, LOINC is the code system for laboratory orders in LOI, LRI, FHIR, and CCDA exchanges.

***7.5.3.2.*** Healthcare Entity to Consumer

7.5.3.2.1. Establish best practices for receiving EHR or portal systems to display data from Laboratory Information Systems AND minimum for sharing data via HL7 C-CDA or HL7 FHIR. (Note: these are primarily in EHR to EHR and HIE sharing.)

***7.5.3.3.*** Provider to Public Health

7.5.3.3.1. Clinical Laboratories should target structuring their laboratory test results as discrete data elements, especially from historic text or pdf based reports like pathology and genomics. It will facilitate encoding of the discrete elements so they are more computer usable such as infectious disease testing for use in public health, and cancer pathology results for registries and precision medicine.

**7.5.4.** Advance a minimum set of labs (e.g., CBC and BMP) for compliance but the goal is compliance for full discrete labs.

**7.5.5.** Development of recommended value sets for grouping labs (target VSAC and lab standard bodies) - this is something that providers should be able to access and NOT reinvent themselves.

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

***7.5.6.1.*** 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.

***7.5.6.2.*** Consider specific CLIA and accreditation requirements for how corrected laboratory result items are handled. CLIA requires laboratories to maintain duplicates (original and corrected report). "Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test

results." Based on the Synensys research, specimen information is dropped as laboratory data travel from EHR to EHR, so it's likely correction details may as well. This would have more important implications on patient safety as clinicians may have made decisions on incorrect information.

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

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

**7.5.7.2.** Continue investigating ways to improve searchability and readability of laboratory data exchanged in CCDA documents with a goal of reducing the number of pages in a CCDA document and/or leveraging filtering or searching to quickly locate pertinent data needed to provide care.

7.5.7.2.1. Provider and Consumer Use Case: As a Veteran, my personal CCD document is 54 pages long. When my provider needs to quickly locate a recent A1c, or H/H, or PT/INR, it is very difficult and time consuming to search through 54 pages to get this information.

**7.5.8.** Guidance for the translation of lab result codes and nomenclature

***7.5.8.1.*** 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.

***7.5.8.2.*** Performing laboratories: Initial responsibility for mapping their lab result terms 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/.

# 8. 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. Carequality
    3. Commonwell Health Alliance
3. 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. CDC How to Implement ELR
    7. Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS)
4. Center for Medicare and Medicaid Services Medicare
    1. Learning Network “Complying with Medicare Signature Requirements”
5. Direct Trust
    1. The DIRECT Standard - Implementation Guide for Direct Edge Protocols
6. eHealth Exchange
7. U.S. Food and Drug Administration
    1. NDC Codeset
8. Health Level Seven (HL7)
    1. HL7 V2.X
        1. HL7 Version 2.5.1 Laboratory Orders Interface (LOI)
        2. HL7 Version 2.5.1 Laboratory Results Interface (LRI), Edition 5

3. HL7 Version 2.5.1 Laboratory Test Compendium Framework (eDOS) aka Electronic Directory of Service
4. L7 Version 2.5.1 Electronic Lab Reporting (ELR) to Public Health
5. HL7 Version 2 Laboratory Value Set Companion Guide, Release 2 - US RealmHL7 Provenance Domain Mapping Documents
6. HL7 Version 2.5.1 Implementation Guide: Immunization Messaging (Release 1.5)

2. HL7 C-CDA
    1. HL7 C-CDA Online: A navigation website for C-CDA 2.1
    2. HL7 CDA R2.1 IG: Consolidated CDA Templates for Clinical Note (US Realm), DSTU R2.1—Vol. 2: Templates
    3. C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2
    4. C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 3
    5. C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1
    6. HL7 C-CDA 2.1 Companion Guide
    7. HL7 Data Segmentation for Privacy, Release 1
    8. HL7 Guidance: Basic Provenance for C-CDA and FHIR, Release 1 - US Realm September 2019
    9. C-CDA Examples Repository
3. HL7 FHIR
    1. FHIR version 4
    2. FHIR Data Segmentation for Privacy
    3. FHIR Allergies and Intolerances
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    5. HL7 Guidance: Basic Provenance for C-CDA and FHIR, Release 1 - US Realm
4. HL7 EHR Workgroup
    1. EHR Work Group - Data Quality
    2. EHRS Functional Model - Record Lifecycle Events
    3. HL7 Problem Oriented Health Record functional requirements
    4. Data Quality - Information Flow Example with Record Lifecycle/Provenance Events
    5. Data Quality - Foundations of Accountability

6. Data Quality - Chain of Trust
5. HL7 Other
    1. HL7 Patient Contributed Data
    2. HL7 v2 to FHIR Mapping
    3. HL7 CDA to FHIR Mapping
    4. U.S. Core Implementation Guide - Basic Provenance
9. International Consortium for Harmonization of Clinical Laboratory Results
    1. Measurands
10. LOINC
    1. LOINC Terminology
    2. Guidance for mapping to SARS-CoV-2 LOINC terms: COVID results
11. National Archives Code of Federal Regulations
    1. CLIA Requirements - CLIA § 493.1291
        1. 42 CFR 493.1291(a)(3)
    2. CLIA Requirements  CLIA § 493.1299
    3. Legal Authenticator - § 482.24 Condition of participation: Medical record services.
12. National Library of Medicine (NLM)
    1. Value Set Authority Center (VSAC)
    2. RxNorm
13. Office of the National Coordinator (ONC)
    1. 21st Century Cures Act (Cures Act)
    2. Clinical Decision Support
    3. Computerized Provider Order Entry
    4. Interoperability Standards Advisory (ISA)
    5. Standards Version Advancement Process
    6. Project US@ Unified Specification for Address in Healthcare
        1. Version 1.0 of the Technical Specification released January 7, 2022
    7. US Core Data for Interoperability USCDI current published version
        1. https://github.com/HL7/cda-core-xsl/tree/features/USCDI
    8. ONC Standards Bulletin July 2024
14. Sequoia Project
    1. Recognized Coordinating Entity for QHINs
        1. Trusted Exchange and Common Agreement (TEFCA) Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 2.0

2. Interoperability Matters Initiative
3. Interoperability Matters Data Usability Workgroup
    1. 2023 - 2024 Proposed Work Items
    2. Charter
    3. Leadership Council
    4. Roster
    5. Website
4. Data Usability Taking Root Movement

15. SNOMED-CT
    1. SNOMED-CT
16. Synensys
    1. System Safety within Laboratory Data Exchanges Report
17. 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
18. World Health Organization
    1. ICD-10

# Appendix A – High Priority Lab Results

The Data Usability Workgroup membership identified Laboratory Interoperability as an area that needed significant improvement during the first cycle (2020 - 2022) that concluded with the publication of the Data Usability Implementation Guide Version 1.0. In Version 1.0, this Appendix A was included to allow HIT Developers, EHR platforms and lab systems to focus on mapping and maintaining codes for this list of 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

In October 2023, the Data Usability Workgroup launched a Laboratory Tiger Team to convene industry experts to identify, prioritize and scope next steps to be included in this Version 2.0 guidance. The task and goal for the Tiger Team was to identify ways to raise the bar for laboratory data exchange with guidance that can be implemented in the next 18-24 months.

In addition, the US Core Data for Interoperability (USCDI) data classes have expanded to include more data elements specific to Laboratory with the associated vocabularies and value sets.

USCDI Version 3:

Laboratory Data Class Includes: Tests, Values/Results, Specimen Type and Result Status

USCDI Version 4 and USCDI Version 5:

Laboratory Data Class Includes: Tests, Values/Results, Specimen Type, Result Status, Result Unit of Measure, Result Reference Range, Result Interpretation, Specimen Source Site, Specimen Identifier, and Specimen Condition Acceptability

In January 2024, the Laboratory Tiger Team had a presentation from the Massachusetts Institute of Technology and Synensys highlighting their report that was completed for the U.S. Food and Drug Administration (FDA) under FDA Contract #75F40122C0012.

The report identified some items that can have some impact such as Specimen type or Source not being transmitted with lab results. Some have reported missing units or reference ranges or interpretations or flags. Many have reported missing LOINCs or SCT codes.

To help raise the bar for data quality and usability, the Tiger Team identified 5 aspects to focus upon:

1. Getting electronic data. Paper doesn't cut it anymore (including fax).
2. Getting discrete data. PDFs and text blobs are human readable, but not very machine processable. Are there lab results that are not discrete that you are sending or receiving?
3. Is data encoded?
4. Are data exchangeable?
5. Are data configurations and the latest standards maintained? Are folks 3-5 releases behind on terminology updates or other standards?

While developing Version 2.0 guidance (2023 - 2024), it was proposed that additional education and guidance be considered for each of the individual high priority labs in the list above. Many of the HIT Systems in production today configured the EHR or HIT Systems in the early days of Meaningful Use and many systems have not reviewed these original configurations to ensure the most appropriate information is exchanged during the Laboratory workflows.

The Data Usability Workgroup would like comments and input on whether providing additional detail for the high priority labs above would be useful to the industry? The Workgroup began drafting a spreadsheet for these Lab that can be found here.

Using Albumin as an example (see rows 3 - 8) in the spreadsheet linked above, many (incorrectly) use the high level LOINC Result code to group Albumins by other methods. There are more suitable LOINC codes for Methods as shown in Column I and J. Clinical values can differ significantly with different methods.

| | |
|---|---|
| BCG | Albumin [Mass/volume] in Serum or Plasma by Bromocresol green (BCG) dye binding method |
| BCP | Albumin [Mass/volume] in Serum or Plasma by Bromocresol purple (BCP) dye binding method |
| Nephelometry | Albumin [Mass/volume] in Serum or Plasma by Nephelometry |
| Electrophoresis | Albumin [Mass/volume] in Serum or Plasma by Electrophoresis |
| BCP | Albumin [Mass/volume] in Blood by Bromocresol purple (BCP) dye binding method |

As referenced by Recommendation 13 in the Synensys report: “Develop formal processes for inclusion of laboratorians in the multidisciplinary teams responsible for decisions about laboratory data needs, representations, and interfaces at care facilities.

For example, medical practitioners are responsible for ordering tests to monitor and diagnose patients, but at the same time have a huge range of responsibilities and could benefit from better communication with laboratories. Laboratorians have up-to-date information on changes to the diagnostic testing environment, including new test options or how test results should be interpreted. However, due to the way many interfaces are set up, laboratorians may not receive sufficient data to fully support practitioners.

To assist the industry with HL7 FHIR, CCDA and V2 Laboratory data mapping, the Data Usability workgroup leadership team worked with HL7 to create this mapping resource. The table attempts to highlight the USCDI Laboratory related Class/elements across various specifications, fields, value sets and coding requirements for HL7 V2.5.1., HL7 FHIR, HL7 C-CDA and CLIA. This table is non-normative and provided as reference only.

# 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 sections within 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