



HL7 Clinical Document Architecture

An Introduction

Toolkit for Planning an EHR-based Surveillance Program | www.phii.org/EHRtoolkit





Presentation Outline

- Brief description of HL7
- Brief history of CDA
- Description of Document Paradigm
- CDA levels
- CDA components
- Examples

Disclaimer: This presentation is not a comprehensive training in the HL7 standard. The HL7 organization offers many training courses that provide more in-depth training.

This presentation gives context to Clinical Document Architecture (CDA) by describing the HL7 organization and how CDA was developed. It explains the concept of an electronic document, and after illustrating the CDA levels, describes the components of a CDA.



Standards: Critical to Achieving Interoperability

- Semantic interoperability
 - Do we speak the same language?
 - Grammar
 - Vocabulary
- Syntactic interoperability
 - Is the data structure compatible?
- Technical interoperability
 - Can we connect to each other?

First, some important background, which may be familiar to you already.

Semantic interoperability: ensures that the sender and receiver systems use the same meaning for the data—in other words, that the systems “speak the same language”.

Syntactic interoperability: enables business processes at the sender and receiver systems to work together by ensuring their data structure is compatible.

Technical interoperability: ensures that the sender and the receiver systems can connect to each other when moving data from one system to the other.

A successful interoperability standard is characterized by:

- Using a standard format for packaging the data that defines:
 - The required data
 - The framework that holds the data
- Using mostly structured data (a standard code represents a given concept)



Organizational History of HL7

- Founded as an international standards development organization in 1987 to promote communication between hospital data systems
- Stated a goal of creating a platform independent method of moving data between different systems
- Developed grammar for messaging and a standardized vocabulary

HL7 is an international standards development organization (SDO) that was established to enable interoperability of health care information. Initially it focused on interoperability among information systems within large hospitals. Later, the organization began focusing on interoperability among systems in disparate organizations, including public health.

Early initiatives of the organization included developing grammar for messaging and a standardized vocabulary

It is not the only standard that is used for transmitting health related data. Others include:

- NCPDP (National Council for Prescription Drug Programs) for ordering medications
- EM TEP (OASIS Emergency Management Tracking of Emergency Patients) for tracking health information for patients in transport

While both NCPDP and EM TEP are specialized standards, they can be mapped to HL7 concepts.



HL7: The Primary Standard for Communicating Health Data

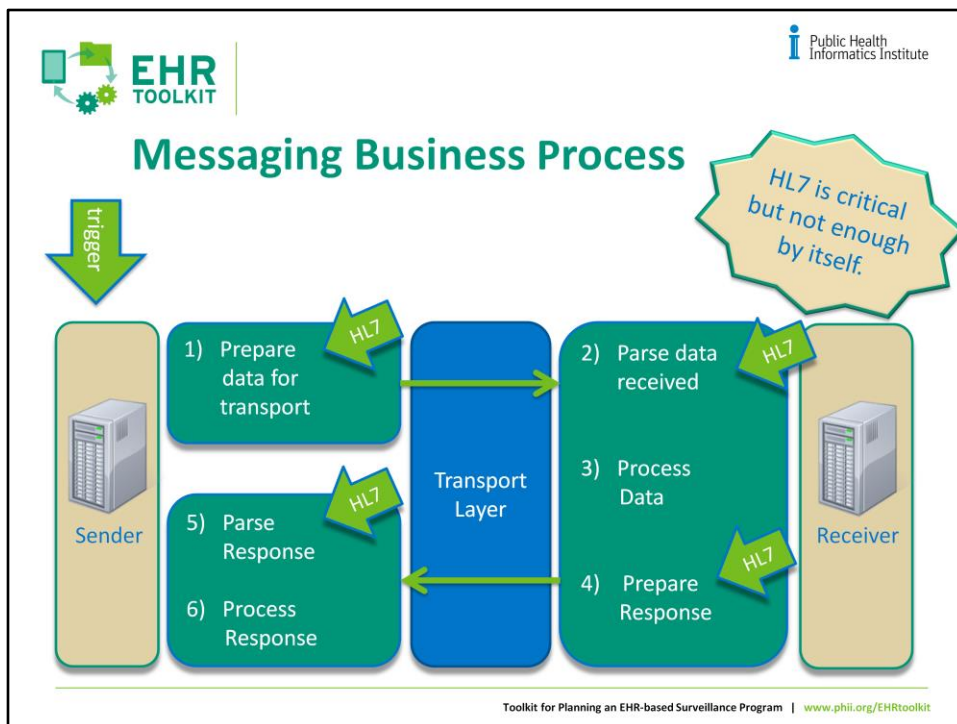
- ANSI standard for clinical interoperability
- The standards continue to evolve and are widely adopted
- Meaningful Use has identified a number of HL7 standards to support sharing data between systems
- HL7 website: <http://www.hl7.org/>

HL7 is considered *the* standard for communicating health data.

As an ANSI-approved standard, it has gone through rigorous validation and approval process.

HL7 standards for the exchange, management and integration of electronic health care information continue to evolve.

The use of HL7 received a big boost with the enactment of the “Meaningful Use” program. This included use of specific HL7 implementation guides developed by public health for lab results, cancers, syndromes and immunizations.



This picture provides a simplified graphical overview of what interoperability entails, showing the possible connection between sender and receiver systems. Interoperability can be more complex—for example, when one system talks to another through a health information exchange, or HIE.

And as noted on this slide, HL7 is critical to sharing messages between sender and receiver systems, but is *not* enough on its own.

HL7 is responsible for both semantic and syntactic interoperability (see the tools under the Analyzing Technical Options section of this presentation). Semantic standards refer to the vocabularies used to denote data elements such as events, lab results, and conditions. Syntactic standards refer to how the sender system packages those data and associated vocabularies before sending.

In addition, the transport layer refers to the protocol for connecting one system to another. Transport standards are different than semantic and syntactic standards, and the transport layer is “agnostic” to the semantics and syntax (the content and format) of the data being transported.

In looking at the **seven** steps depicted in this slide, you see where HL7 contributes and where it doesn't.

In addition, the transport layer refers to the protocol for connecting one system to another. Transport standards differ from, and are content and format agnostic to, the semantic and syntactic standards of the data being transported.

The steps depicted in this graphic point out where HL7 does and does not contribute:

0) Something in the real world causes the process to start. It is called a *trigger* event. The trigger could be any number of activities, such as a person clicking a button on the sending system that requests a query of another system, or entering a new immunization into the system.

- 1) First, the sender prepares the data for transport. This means that they extract the needed data and package it for transport. They apply the specified HL7 standard to create this package of data in a specific and predictable way.
- 2) Next, the sender connects to the receiver through the transport layer. This step includes authenticating that the sender may send data.
- 3) Third, the receiver gets the package of data and parses it (translates it from HL7 to an internal format).
- 4) In the fourth step, the receiver processes the data, applying local business rules and data hygiene. While this is not a part of the standard used, it is an important part of the process and can cause issues if not clearly documented by the receiver and communicated to the sender.
- 5) Then, the receiver acknowledges the receipt of the package of data and indicates whether it was successful or not.
- 6) Finally, and crucially, regardless of the number of **steps** between sender and receiver, the response must return to the sender. For instance, if the data pass through an HIE, the receiver must return the acknowledgement through the HIE to the initiating system. This allows the sender to be informed of the outcome, and is especially important for helping detect problems on the receiving side.



HL7 Versions

- HL7 Version 2.x messaging
- HL7 Version 3 messaging
- HL7 Clinical Document Architecture (CDA)
- HL7 Fast Healthcare Interoperability Resources (FHIR)

Because HL7 continually evolves with use and experience, multiple HL7 versions now exist as you can see by this list.

This presentation focuses on CDA. HL7 version 2 messaging is presented in another EHR Toolkit presentation.

The HL7 organization released version 2 messaging decades ago. This version is still being updated and improved and is widely implemented in the U.S. In addition to the current Meaningful Use requirements around version 2 messaging, version 2.x supports unsolicited updates such as new information sent to be added to a case report. Version 2.x also supports query and response—for example, an EHR system requesting and receiving an immunization history from a registry.

HL7 Version 3 messaging has been implemented widely internationally, but not in the U.S.

CDA is widely adopted in the U.S. and is in use with Consolidated-Clinical Document Architecture (C-CDA)

A key distinction between HL7 messages and HL7 CDA documents is that messages are packets of data sent from one system to another, generally for incorporation into the receiving system. In comparison, documents are basically electronic versions of physical documents.

Public health largely relies on version 2.x messages, although CDA has been piloted in some areas, including reporting for cancer, fetal birth and deaths.

FHIR (pronounced “fire”) is just emerging, but appears to be easily implemented and may be the wave of the future. It can support Version 2, Version 3, and CDA paradigms.



Clinical Document Architecture - CDA

- An electronic equivalent of a paper document
- Has an author/attester
- Represents a point in time view of data
- Persists as an artifact over time
- Supports simple to very complex document types

While messages are very good at transferring data from one system to another, the Health IT community identified a need to support the electronic exchange of data in a way analogous to sending a document. This led to the creation of the Clinical Document Architecture standards by HL7. The CDA became a standard in 2000.

HL7 built the CDA on the data framework of HL7 Version 3.

CDA provides a foundation for developing electronic documents; there are many varieties of CDA.

Profiles constrain or specify CDA to accomplish specific tasks.

CDA was developed incrementally, starting as a “simple envelope” for data, and evolving to today’s varieties of CDA.

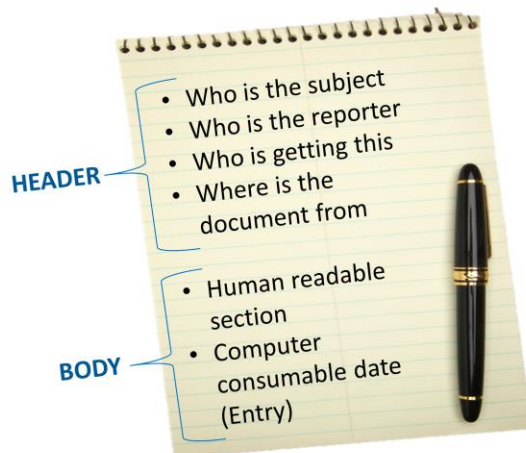
While messages are streams of structured information that one system sends to another, documents are electronic equivalents of paper documents:

- They are owned and attested to
- They are persistent and versioned
- They contain human readable representation of the content (essentially viewable on a browser)

- Their structure and contents can be based on the HL7 version 3 information model, known as the Reference Information Model or RIM

It is important to understand that CDA is a broad class of artifacts. A CDA may be as simple as an electronic envelope, containing an image, or it may be as complex as a complete Transfer of Care Summary that contains the data in a format that can be displayed, but also in a computer readable format. You often hear specific CDA profiles referred to simply as "CDA". For example, a consolidated CDA may be referred to as "CDA" instead of its complete reference "C-CDA".

Clinical Document Architecture (CDA)



The structure of a basic, simple document includes both a *header* and the *body*.

Document components may be nested. Documents are “written” in Extensible Markup Language (XML), a language that supports both human and machine readable formats.

The header component provides information about:

- The type of CDA and the basic structure
- Who the document is about
- Who “wrote” it
- Where it came from
- Where it is going
- When it was created

The body contains the information about the person who is subject of the document. In a simple document, it may be a basic piece of information such as an X-ray image or a PDF document. Such basic pieces of information are called a non-XML body.

CDA - Structured Body

The CDA body is composed of a Narrative block and an Entry block

- Narrative block. A text section that a browser can render so that it is readable by a human
- Entry block. The data formatted in a way that facilitates computer consumption of the structured data and represents the same information as the data in the Narrative block

In the more complex and common structures seen today, the body section of a document is composed of the Narrative block information, which is text that a human can read in a browser. The Entry block then contains the same data described in the Narrative block, but in a format that a computer can consume.

To recap, a CDA document includes both human-readable narrative content in the Narrative block and computable content in the Entry block.



Profiles Constrain the HL7 Base Standard

- Base standard is designed to meet many needs from many countries
- To be useful, the standard must be constrained to meet a specific need in a specific realm

It is possible to create either HL7 Version 2 messages or documents that meet the standard exactly, but that differ from the same artifact created by another entity. The base standard is intended to support a wide range of needs in a wide range of countries. By definition, this means that they must have lots of options.

But having many options is the enemy of interoperability. The solution to this problem of having many options is creating profiles on the base standard that constrain most or all of the options. This provides the specification necessary for implementing with consistent structure and content.

Profiles have been called implementation guides. They bind specific vocabularies to the message or document.

CDA Profiles Building Blocks

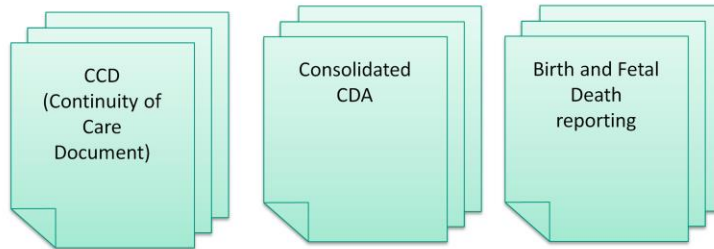
- Profiles are built from components
 - Patient
 - Medication List
 - Immunization Record
- Profiles specify which components *must* be included and which *may* be included

Like other profiles, CDA profiles define the contents of the data package. They specify the requirements for each component and sub-component. For example, a patient is a person. A person has a name. The profile may specify that the name is required. The name is composed of subcomponents (last name, first name, middle name, etc.). The components will have documented requirements. For example, every person must have a name. Every name must have a last name and first name, but middle name may be optional.

Profiles are difficult to read by a human.



Example Clinical Document Architecture (CDA) Profiles



CDA is a foundation for developing electronic documents, and as noted earlier, many varieties of CDA currently exist. The Continuity of Care Document (CCD) is a CDA that is a major focus in healthcare interoperability today.

Recall that CDA is a broad class of artifacts, ranging from an electronic envelope that contains an image to a complex complete transfer of care summary that contains the data in a format that can be read by a human in a browser, but also contains data in a computer readable format.

The Consolidated Templated implementation (C-CDA) guide contains a library of CDA templates, incorporating and harmonizing previous efforts from the Health Level Seven (HL7) organization, Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP). It represents harmonization of the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and Continuity of Care (CCD).



CDA Public Health Examples

- Consolidated CDA (Continuity of Care Document)
- Cancer reporting
- Vital records fetal birth and death
- Quality Reporting Document Architecture (QRDA)

There are many CDA examples for public health, including:

- Consolidated CDA, including the Continuity of Care documentation. These CDAs are most likely to be used in local health departments that deliver care services and need to interoperate with healthcare providers.
- Cancer reporting.
- Vital records data for fetal birth and death records (piloted only).
- Quality Reporting Document Architecture (QRDA), which, like other healthcare quality reporting measures, can be used as part of a population health assessment.



When to Use CDA Documents

- The focus is on persistence of the artifact
- Need tight control over authenticated content
- When human readability across platforms is desirable

One aspect of a CDA document is that it persists, intact, until it is deleted. While the data may be extracted to be incorporated into a database, the document may be retrieved in the condition it was originally sent.

The CDA standard supports tighter control over the content of the document because the content is not intended to be edited once received. In addition, the document is signed in the same way that a nursing note in a chart is signed.

The design of the message permits it to be viewed in a standard browser, where the reader may easily read the authenticated content.



When to Avoid Using CDA Documents

- Need for workflow
 - Decision support
 - Request - response
- Data are dynamic
 - Want view of data now, not when authored
 - Multiple contributors over time
- Data from disparate systems need to be integrated

CDA documents may not be the most appropriate standard for your particular use case, as in the following examples:

- When the workflow requires rapid back-and-forth exchanges, such as requesting information from a decision support engine or service or evoking a request-response query.
- When the data are more dynamic, and persistence is not required—for example, when you only want to see how the data look in the moment, or when more than one person or entity will be contributing data over time.
- When the data need to be acquired from multiple sources and integrated, in which case HL7 messages may be simpler or otherwise more appropriate.



Additional Resources

- HL7 (hl7.org) has a variety of materials including tutorials where you can get the specifics for each of its standards.
- HL7's website is at: <http://www.hl7.org/>
- CDC's Vocabulary Access and Distribution Systems (PHIN VADS) can be found at <https://phinvads.cdc.gov/>

This presentation addressed these aspects of HL7 at an introductory level. For additional information, HL7 has a very robust website with many free offerings. For example, they have an Education Portal with free webinar recordings (<http://www.hl7.org/implement/courseList.cfm>). Some of these recordings include an introductory webinar for HL7 and an overview of the healthcare connection with HL7. These and other resources, such as tutorials where you can get the specifics for each of the standards, are available as well.

You can also get information from the CDC Public Health Information Network (PHIN) web site, which includes vocabulary and other standards related to public health CDAs

We encourage you to check out these and other HL7 resources!