Clinical Documentation 2

Clinical documentation is used throughout healthcare to describe care provided to a patient, communicate essential information between healthcare providers and to maintain a patient medical record. What is a clinical document? The simple and easy answer is that a clinical document is anything that you might find in a patient's medical record or anywhere else that documents the care given to that patient.

The definition used by CDA™ for a clinical document is "documentation of clinical observations and services" [§1.1]. This allows just about anything that could appear in a patient's medical record to be a clinical document, but it also allows for other uses. Other documents are also "clinical documents" by this definition, and they need not appear within a patient's medical record. Examples of these include personal health records, public health case reports [1] and quality reports [2] used to track operational activities within a healthcare organization.

Rule #1: My favorite saying among health information management professionals is "If it isn't documented, it didn't happen."

Its corollary is that almost every healthcare activity is documented.

There are other kinds of patients and subjects for which clinical documentation is relevant. Your family pet may have a medical record, and that could contain several different kinds of clinical documents. A friend of mine has a small herd of miniature ponies. That herd could also have a medical record containing several clinical documents. The water in my local pond could also be the subject of clinical observations and services (e.g., number of bacteria of a particular type, and a record of the recent treatment of it). However, CDA Release 2.0 was designed to support clinical documents for human patients, and does not readily support non-human (my cat or my friend's herd) or non-living subjects (the creek in my back yard). CDA Release 3.0 will support clinical documents for non-human patients and non-living subjects. After several years of implementation HL7 has determined that most of the features of CDA Release 2.0 are more than adequate to support these other subjects.

2.1 Properties of Clinical Documents

Clinical documents have two key functions. They **communicate** relevant clinical information between healthcare providers separated by time or distance and support **compliance** with local policy, regulation and law. Key features supporting these functions are **credibility** and **completeness**.

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A clinical document must be credible to be effective. This means that it is often produced by a trusted authority and is itself a trusted record of care that was provided.

Clinical documents should also be complete records of care that do not leave out important details. The judgment of what is relevant or important within a clinical document at the time it was written is left to the trusted authorities that produce them. As we learn more, what was important yesterday may no longer be relevant now, but information that seemed irrelevant then might be important today.

These functions and features are intertwined. It would be difficult to provide credible and compliant documentation of care if the documentation were not complete. Similarly an incomplete or non-credible document may result in communication failures that could result in harm to a patient.

2.2 The Six Characteristics of Clinical Documents

These features and functions lead to the six characteristics of a clinical document defined by the CDA standard. These characteristics are *persistence, stewardship, potential for authentication, context, wholeness and human readability* [§1.1].

Persistence

According to the CDA standard, persistence is a characteristic of a clinical document in that it "… continues to exist in an unaltered state, for a time period defined by local and regulatory requirements." [§1.1]. Healthcare providers and provider organizations are required by local policy, regulation and law to retain documentation of care that has been provided for specific time periods. These time periods can be rather long, for example, patient life plus seven years. One of the reasons for using a standard format for clinical documents is the need to comply with these policies. One need only recall difficulties reading older word processing formats in newer software to understand why a well-documented standard format is needed.

As a result of this characteristic, the CDA standard requires the use of specific versions of the HL7 Reference Information Model, Data Types, Vocabulary and XML Implementation Technology Specification (ITS) be used with the CDA standard. These standards are all subject to updates and maintenance as our understanding of requirements changes over time. Structuring the CDA standard so that specific versions of these standards are used provides a stable foundation. This enables interpretation of the clinical documents conforming to the CDA standard to remain consistent.

The material in this book describes the versions of the foundational standards required by the CDA standard rather than the most current versions of these standards. The foundational standards of the CDA standard are provided in the CDA Release 2.0 Normative Edition, which is available from HL7 International. In large part, the changes which have been made to these foundational standards have been relatively minor in the years since the

CDA Release 2.0 standard was approved. There have been some changes that would have modified the interpretation of a CDA document.

Stewardship

Clinical documents are "maintained by an organization entrusted with its care" [§1.1]. This means that an organization must be able to produce the original of a clinical document, sometimes years after it was created (see Sect. 2.2.1 above). The ability of an organization to produce the original of a document long after it was written aids with compliance and credibility, and ensures that communication can occur long after the patient has left the facility.

The CDA format requires that the name of the steward organization be recorded as of the time the document was created. Over time, organizations may merge with other organizations, may be split off or sold to other organizations. CDA does not require that the history of organizational changes be recorded and maintained after the fact in the document. Instead, it assumes that knowledge of the original steward should be sufficient to locate any subsequent organization that would retain the original copy of the document. The steward of a CDA document is known as its custodian.

The CDA standard does not allow for individual persons to be stewards of documents, only organizations. This would appear to cause difficulty in using the CDA to support clinical documents created by a patient as part of his or her own personal health record. Pragmatically, most of these documents will be stored for the individual by another organization, so this difficulty is readily overcome. Furthermore, nothing prevents an individual person from being represented as an organization in the CDA format. In fact, many single physician practices are sole proprietorships. The legal distinction between the healthcare provider as a person and the organization that they operate is virtually nonexistent. The technical details of the CDA standard are not intended to prevent these providers from creating CDA documents, nor should they prevent patients from creating their own clinical documents using the standard.

Potential for Authentication

The potential for authentication of a clinical document refers to its ability to record or attest to the signature of the legally responsible provider. This legal authentication attests to the completeness and accuracy of the clinical information, and lends credibility to its content.

Clinical documents are often signed by a clinician who takes legal responsibility not only for the content of the document, but also for the acts recorded in that clinical document. The act of legally signing the document does not imply that the signer authored or created the document. For example, an ECG device can create a document containing a patient's ECG readings. The signing clinician may do little more than press a button and enter a password to "sign" the document. There is little authorship involved in this scenario, yet a great deal of responsibility entailed in the signature the clinician attached to the document.

There may be different kinds of "signers" of a clinical document. Some signers are simply attesting that the content of the document is appears as they wrote it. Others are signing the document to assert that not only is it true, correct and complete, but also that that they accept legally responsible for the care described in it. In some jurisdictions, a resident may sign a clinical document to indicate that it documents the care that they provided, but the signature of the patient's attending physician is required to assert legal responsibility for the care.

The CDA standard supports the ability of different types of authenticators to be recorded in the CDA document. It distinguishes between the legal authenticator (the person taking legal responsibility for the document content), and other authenticators.

Legal authentication is recorded in a CDA document a form that supports **electronic signatures** rather than **digital signatures**. An electronic signature is an indelible mark on the bits of the document that assert that the signer did sign the document. A digital signature is a type of electronic signature that uses cryptographic techniques to prove that only the signer could have applied their signature to a document. It is also possible to digitally sign a CDA document, but the standard remains silent on how to accomplish this.

When a paper document is signed, it is very clear that what is being signed is the information that appears on the paper. When a CDA document records the signature of an authenticator, the standard does not make clear that it is the human readable content being authenticated. This is left to local policy for implementation. Other standards and frameworks for electronic and digital signatures indicate that only that which is "seen" should be signed [3].

Organizations using CDA and providing "signed" CDA documents should establish policies on rendering the portions of the document attested to by the signature. The policies on what is attested by a signature may vary between organizations. Healthcare information systems may receive CDA documents from multiple organizations with varying policies with respect to signatures.

Often, organizations will have policies that permit only those documents which have been "legally authenticated" to be accessed by anyone other than the document creator. In these organizations, the act of "signing" the document completes it and makes it available in the patient's electronic medical record. This prevents documents which are still in the process of being written from being used for care before the information in them has been verified by the person legally responsible for the patient's care.

As more health information systems are developed that automatically produce clinical documents, this restriction on release is often relaxed for those automatically produced documents.

Just as organizations do not sign contracts or checks, they also do not sign documents. The authority to sign a document rests with individual people who have been assigned that responsibility by the organization. The CDA standard indicates that the signers of a document are persons, and records the information about the person or persons who signed a document. It also allows for the organizations those persons represent to be communicated. The semantics of the communication make it clear that it is a person who signed the document. The CDA standard supports multiple document signers, but only one person can be recorded as the legal authenticator of a CDA document. Legal authentication applies to the entire human readable portion of the CDA document.

Context

A clinical document tells a story about care being provided to a patient. Like any other story, the clinical document has a particular setting in space and time and a cast of characters that the reader should understand in order to make sense of what has been recorded. These components complete the background associated with the clinical story. This is the context of the clinical document, and it includes:

- The document identifier,
- relevant dates and times associated with the document,
- the type of document,
- the author of the document,
- the legal authenticator,
- the patient (or patients) whose care it describes,
- the clinical encounter and services which it describes,
- any preceding documents it may have replaced or amended,
- the intended recipient of the information at the time the document was written,
- the sources of information contained within the document, and
- the performers of the care described.

This information is stored in the CDA header and provides the default context for all information contained within the body of the document.

The context of the document is also an important feature that enables its retrieval. The clinical documents stored within information retrieval systems are indexed by at least one, and usually more than one of the context components. Health information exchanges are often configured to be able to retrieve clinical documents by this context information. Paper documents are often filed by date of the document and the patient to which they pertain.

Rule #2: If you cannot find a document, it may as well not exist. In which case, see Rule #1.

Wholeness

Like any other story, the story told by the clinical document is more than just the sum of the individual facts and suppositions recorded inside it. Each statement of the story is related to other statements contained in the document. The clinical document may indicate that a certain medication is given to the patient. The statement about the medication is important, but it may not be fully understood without looking at the particular diagnosis, or the set of known drug allergies and intolerances recorded. Thus, a clinical document is legally authenticated as a complete unit of information. The information contained within it is expected to be understood in the context of the whole.

The principle of wholeness does not require the whole content of the document to present to make use of individual statements inside it, but caution is indicated when doing so. Clinical document are often “sliced and diced” to extract and store the clinical statements found inside them. When these statements are stored in separate information

systems, they should contain a reference back to clinical document from which they came. This allows users of those clinical statements to access the statements in their original context should any questions arise about them.

Human Readability

Clinical documents are intended to communicate information between healthcare providers. Healthcare providers are humans so clinical documents must be human readable. The principle of human readability means that there must be a way to display the contents of the clinical document in a way that will allow a human to read it. This display can be through a separate application using proprietary formats such as a word processor, or it can be through the narrative format defined in the CDA standard.

This principle means that the CDA standard must support the display of rich multimedia content. While the standard focuses on "reading", that doesn't necessarily mean text. Healthcare providers read graphs and pictures just as often as they read text.

In fact, the multimedia content supported by the standard is much richer that what can be done on paper. It supports audio, video or waveform information as well as narrative text. The key requirement of human readability is that the information supports human consumption.

Several of the developers of the CDA standard started their careers in the realm of technical publishing. The text model they designed in the CDA narrative format supports a model of technical narrative that has been used for decades in electronic publishing. In addition to the traditional hierarchical sections, paragraph, lists and tables, the standard also supports links and footnotes. You can also include links to rich multimedia as separate content, or as embedded and legally authenticated content. The CDA model maps closely to the HTML and XHTML standards from the W3C. Furthermore, it uses the XHTML table model in the CDA XML to support the representation of tables.

One model found in technical publishing that is not found in the CDA narrative model is one of "flows". In publishing, a flow is a continuous stream of text that may be "flowed" into specified portions of the generated output. The CDA standard does not address pagination or rendering issues such as these. These are just another section of text in the CDA document. It is up to the rendering application to determine where the text is placed. Pagination created by the rendering application may include page headers or footers. The CDA standard does not state or directly support document headers or footers, as these are just special kinds of flow objects.

Questions

1. Can a CDA document be used to document care provided to a herd of miniature ponies? A clinical document? Why or why not?
2. What are the four C's of effective clinical documentation?
3. True or False: A clinical document only appears within a patient's medical record.
4. What are the six principal characteristics of a CDA document?
5. What organization is responsible for the development of the CDA standard?

Research Questions

1. How many years must a clinical document be maintained by the organization creating it in your jurisdiction?
2. Who is allowed to legally authenticate (sign) a clinical document in your jurisdiction?
3. What are the legal responsibilities of document signers in your jurisdiction?
4. What is the law in your jurisdiction with respect to electronic or digital signatures?
5. What technologies are required to be used in digital signatures in your jurisdiction?

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