

# Clinical Data Standards Explained

---

November 2004

## Introduction

To the average health care professional, the subject of clinical data standards can seem abstract, confusing, and cluttered with cryptic acronyms.

Nevertheless, clinical data standards play a key role in improving the efficiency and quality of health care delivery. Without data standards, organizations cannot readily share clinical information, public health initiatives become unnecessarily cumbersome, and medical care remains geographically isolated and highly variable.

This fact sheet provides a basic understanding of clinical data standards: what they are, what they mean, and how they can help improve clinical care. For more information, visit the Web site [www.calinxstandards.org](http://www.calinxstandards.org).

## What Are Clinical Data Standards?

Simply put, data standards are an agreed upon set of rules that allow information to be shared and processed in a uniform and consistent manner.

Most of us are familiar with data standards, whether we use computers or not. For example, data standards can be found in the rules of written language. Sentences should end with a period, lists should be separated by commas,

and names of individuals should be capitalized. Likewise, common standards allow appliances to be plugged into a standard socket and be fully operational in any household setting. Other analogies can be found in vehicle traffic regulations. In the United States, drivers must stay on the right-hand side of the road and stop at all red lights. These standards not only help us act and communicate with each other, but also prevent costly misunderstandings and accidents.

Clinical data standards apply this concept to clinical delivery care. Which information from a patient's medical history should be communicated to a physician, and how? If a patient has a life-threatening allergy, who ought to know, and when? Should a patient's gender be documented as "M" or "male"? Rules that answer such questions allow individuals and organizations to share medical information using a standard set of practices, creating more efficient communications and preventing errors.

## Understanding Clinical Data Standards

Much of the discussion about clinical data standards centers on information technology systems and the development of software that is written to ensure standard rules of communication. Though not a prerequisite for

the adoption of standards, such an approach provides an efficient environment for their development and proliferation, as well as reinforcing their use.

The benefit of encoding clinical data standards in software applications is that, once developed and adopted, they can be followed reliably with a low error rate—allowing automation of repetitive processes and consistency across applications. Thus, clinical information can have the same meaning and usability

in a wide range of settings. The challenge, however, is agreeing to and coding for every possible rule and exception to handle the enormous complexity and variability of clinical processes.

Some of the more commonly known clinical data standards currently in development or already in use include ICD-9, SNOMED, RIM, LOINC, UMLS, CCR, HL7, DICOM, IEEE, NCPDP, and CCOW (see Table 1). Though the number of acronyms appears

**Table 1: Guide to Clinical Data Standards**

Standard Name	Subject Area	Description
<b>Terminology Standards</b>		
<i>International Classification of Disease version 9 (ICD-9)</i>	Disease Names	A common set of terms and codes for clinical diagnoses. Commonly used in billing and clinical applications.
<i>Systematized Nomenclature of Medicine (SNOMED)</i>	Clinical Terms	A broad set of standardized clinical terms commonly used in a variety of software applications including EHRs.
Logical Observation Identifiers Names and Codes (LOINC)	Lab Terms	A standard set of universal names and codes for identifying lab results. Facilitates the exchange of lab information between different systems.
<b>Conceptual Standards</b>		
<i>Health Level 7 – Reference Information Model (HL7 RIM)</i>	Clinical Concepts	An important object-oriented model that maps a broad array of clinical concepts and domains. Allows for interoperability between different and competing standards.
<i>Unified Medical Language System (UMLS)</i>	Medical Terms and Concepts	A large vocabulary database that maps a variety of medical terms to common clinical concepts.
<b>Document Standards</b>		
<i>Continuity of Care Record (CCR)</i>	Clinical Summary Documents	A document standard that codifies the manner by which important clinical information (such as problem list and allergies) should be shared.
<i>Health Level 7 - Clinical Document Architecture (HL7 CDA)</i>	Clinical Documents	A standard exchange model for clinical documents such as discharge summaries and progress notes. Formerly known as the Patient Record Architecture.
<b>Messaging Standards</b>		
<i>Health Level 7: HL7 v2.x, v3.0</i>	Data Exchange Messaging	A messaging standard for the exchange of clinical, financial, and administrative data.
<i>Digital Imaging and Communications in Medicine (DICOM)</i>	Radiology Messaging	A common language structure for sharing radiology images.
<i>Institute of Electrical and Electronics Engineers (IEEE)</i>	Medical Device Messaging	A common messaging structure for sharing medical device communications.
<i>National Council for Prescription Drug Programs (NCPDP)</i>	Prescribing Messaging	A standard for exchange of prescription-related information. Facilitates online prescribing and other pharmacy-related processes.
<b>Application Standards</b>		
<i>Health Level 7 - Clinical Concept Object Workgroup (HL7 CCOW)</i>	Application Interoperability	An architecture that allows secure access to separate software applications.

overwhelming, their functions can be sorted into the following general categories:

*Terminology Standards* (ICD-9, SNOMED, LOINC): Much like a dictionary does for language, terminology standards define which terms and codes are the accepted vocabulary for clinical software and how they should be used. In ICD-9 coding, for example, “chest pain” is a recognized term and is linked to a standardized code. “Chest pressure,” “pain in the chest,” and other similar phrases are not. Similarly, LOINC provides a standard nomenclature for laboratory test names and documenting clinical observations.

*Conceptual Standards* (HL7 RIM, UMLS): At a more abstract level, a conceptual or “meta-element” standard defines how certain informational concepts get conveyed in a standardized fashion. This type of standard enables systems to interpret and use data in a more meaningful manner. Just as sentences are more than a collection of words, so are concepts more than a collection of terms.

*Document Standards* (CCR, CDA): A document standard generally includes several informational elements and lets someone (or a software application) know which type of information is included in a document and where it can be found. A common standard in paper medical records is the SOAP (Subjective, Objective, Assessment, Plan) format. CCR provides a standard format for inter-provider communication and includes patient identifying information, medical history, current medications, allergies, and a care plan recommendation.

*Messaging Standards* (HL7, DICOM, IEEE, NCPDP): Messaging standards define how information is packaged and communicated from one party to another. They set the language, structure, and data types needed for seamless integration. DICOM is the messaging standard for radiology imaging, while NCPDP is used for exchanging prescription information.

*Application Standards* (CCOW): An application standard such as CCOW is used to integrate the functions of different software applications so they can work together seamlessly. With CCOW, the same username and password combination can be recognized across different software applications for better user performance, and a common user interface can be employed to view data from a variety of sources.

When used in concert, clinical data standards have the potential to dramatically transform the quality and efficiency of health care delivery. Information becomes more readily accessible, reliable, and useable. Data elements such as lab results, medication doses, and clinical notes can be gathered from multiple locations and assembled into a clinical overview or summary, facilitating patient care, chronic disease management, and public health reporting.

From a technical perspective, medical software applications become more “plug-and-play.” Custom integration costs are significantly decreased and applications perform more seamlessly. With adoption of clinical data standards, application interoperability becomes a real possibility.

## The Road Ahead

Though the promise of clinical data standards is high, much work remains to be done. Unlike traffic laws,

clinical data standards are still in their infancy. Though several types of standards have been developed and others have been implemented, most medical software applications continue to function in isolation and integration of applications requires some degree of customization.

The remaining barriers to widespread adoption of clinical data standards can be understood by examining the process by which standards are generally developed.

1. Standards are created either organically by a cooperative set of organizations and individuals, or via mandate from a controlling body. In the former case, problems arise because of competing agendas, varying levels of commitment, and lack of leadership. In the latter, the controlling body might not have the necessary vision or expertise to meet the needs of the constituents. With clinical data standards, the problem is compounded by a highly fragmented marketplace with many small, loosely structured organizations with limited resources.
2. Data standards can only be created if they can be codified. Sentence structure and traffic signals are relatively simple. Medical information is not. Because the field of health care is so broad, deep, and complex,

it is difficult to codify standards without a moderate amount of controversy, dissent, and impatience. In order to be usable, therefore, standard specifications must be precisely tailored to suit the clinical needs of the users.

3. Once a data standard is developed it must then be adopted by health care and government organizations, as well as vendors. Without the appropriate incentives, this can prove difficult. And without the appropriate oversight, monitoring, and governance, adherence to adopted standards becomes a troublesome problem. In these scenarios, mandates can prove helpful.

Despite such challenges, hope for progress is increasing. Mandates, such as HIPAA, have facilitated the adoption of some message standards. Coalitions have formed to begin drawing up document standards such as the Continuity of Care Record. The California Clinical Data Project (CCDP) is now working to develop and implement lab and pharmacy standards across California. And other standards such as HL7 and LOINC continue to make strides in both acceptance and adoption.

For implementation status and additional details, visit [www.calinxstandards.org](http://www.calinxstandards.org).