Clinical Data Standards in Health Care: Five Case Studies

July 2005
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About the Foundation
The California HealthCare Foundation, based in Oakland, is an independent philanthropy committed to improving California’s healthcare delivery and financing systems. Formed in 1996, our goal is to ensure that all Californians have access to affordable, quality health care. For more information about CHCF, visit us online at www.chcf.org.

The iHealth Reports series focuses on the effective adoption of IT in health care by analyzing the marketplace, inspiring innovation, and providing practical information on emerging technology trends.
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I. Overview

“Interoperability is technology dependent. We have stretched the limits of manual process. Without technology we can’t move forward.”

— David Brailer, M.D., Ph.D., National Health Information Technology Coordinator, U.S. Department of Health and Human Services.

Great attention has been paid recently to the need for interoperability in health care information systems. Interoperability—the enabling of communication across software and hardware from multiple vendors—is necessary to provide comprehensive and accurate patient information in an electronic health record. At the federal level, the Health and Human Services Agency (HHS) advocates adoption of standards-based electronic health records for Americans; an executive order created the position of National Health Information Coordinator to help achieve this goal. In addition, the Institute of Medicine’s seminal work, *Crossing the Quality Chasm*, promotes the use of standardized information technology to reduce medical errors and improve clinical quality.

The need for interoperable systems is evident in every part of our health care organizations. For example, a physician seeing a patient in the emergency room needs to know the patient’s medical history, current medications, and recent lab test results in order to provide appropriate care. To ensure appropriate follow-up, the ED physician needs to be able to communicate and send test results back to the patient’s regular doctor. It is not practical for the ED physician to rely on the patient for all this information, gather data from multiple unconnected information systems, or wait for a medical chart that usually lacks most of the above information. The system should automatically and seamlessly share information across institutions and display it in useful ways.

Interoperability requires the creation, acceptance, and implementation of clinical data standards to assure that data in one part of the health system is available and meaningful across a variety of clinical settings. These standards are rules that govern the way patient information is electronically stored and exchanged. Ideally, a single set of standards for text, numerical, and image-based data is easily accessed and shared by health care providers, payers, regulators, and consumers.

Certain industries, such as international banking, have developed and implemented standards for electronic data exchange. In health care, standards come from a variety of organizational
sources, and progress toward interoperability faces a number of challenges. Patient records typically are accumulations of interactions between providers, patients, insurance companies, and government agencies. The data they contain are uncategorized and full of personalized text descriptions and images. Not surprisingly, clinical data standards are sometimes viewed as a complex “alphabet soup” of different vocabularies and obscure technical details.

It is important, however, for managers, clinicians, and policymakers to understand the basics of standards. Key decisions must be made about how and when standards should be implemented to assure quality of care. The purpose of this report is twofold: (1) to provide background information about clinical standards; and (2) to present case examples from a variety of health care sectors that demonstrate ways organizations are making progress toward interoperability.

**Categories of Standards**

Interoperability depends upon two important concepts: syntax and semantics. Syntax refers to the structure of a communication, the equivalent of rules for spelling and grammar. Data exchange, or messaging, standards such as Health Level Seven (HL7) are examples. Semantics convey the meaning of the communication, the equivalent of a dictionary and thesaurus. Terminologies such as SNOMED and LOINC and document standards such as HL7 Clinical Document Architecture (CDA) are examples of semantic standards. Without semantic interoperability, data can be exchanged but there is no assurance that it can be used or understood by the receiver.

The available standards today address both types of interoperability. They are organized into the six categories described below, and the specific examples are further detailed in Table 1. The table also provides a quick guide to understanding the many acronyms used in the standards environment.

**Data Exchange/Messaging Standards.** These allow transactions to flow consistently between systems or organizations because they contain instructions (or specifications) for format, data elements, and structure. Common standards include HL7 for administrative data such as patient demographics or encounters; DICOM for radiology images; and NCPDP for electronic prescriptions.

**Terminology Standards.** These vocabularies provide specific codes for clinical concepts such as diseases, problem lists, allergies, medications, and diagnoses that might have varying textual descriptions in a paper chart or a transcription. Examples of terminologies are LOINC for lab results; SNOMED for clinical terms; and ICD for medical diagnoses.

**Document Standards.** These indicate what 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. The CCR (Continuity of Care Record) provides a standard format for inter-provider communication, including: patient identifying information, medical history, current medications, allergies, and a care plan recommendation.

**Conceptual Standards.** These allow data to be transported across systems without losing meaning and context. For example, the HL7 RIM (Reference Information Model) provides a framework for describing clinical data and the context surrounding it: who, what, when, where, and how.

**Application Standards.** These determine the way business rules are implemented and software systems interact. Examples include single sign-on, which simultaneously logs a user into multiple applications within the same environment; and standards for providing a comprehensive way of viewing information across multiple, non-integrated databases.

**Architecture Standards.** These define the processes involved in data storage and distribution. The
Centers for Disease Control’s Public Health Information Networks/National Electronic Disease Surveillance System is an example. An emerging functional architecture is the national electronic health record proposed by the Institute of Medicine and HL7, commissioned by the HHS.

Who Sets the Standards?
Standards have been created by a variety of health care organizations, including service delivery entities, regulators, vendors, and consultants. Typically, standards development involves technical committees that define methods, and groups organized around communities of interest. Representing stakeholders in these development projects are clinicians, researchers, bioinformaticists, chief information officers, database administrators, information systems analysts, and project managers. In addition, special interest entities in public health, patient safety, and electronic health records work to ensure that the standards are relevant to practice in those areas.

Health data standard setting is typically a voluntary effort, and a standard’s success depends on the developing organization’s credibility and ability to gain adoption in the industry. Credibility requires having a large enough membership of important players in the particular industry sector. The early adopters generally come from this group and they validate that the standard is appropriate. They also serve as “champions” who communicate the standard to the wider audience of users. The standard is finally accredited or given the seal of approval by an external source. Two such accrediting organizations are the American National Standards Institute (ANSI) and the International Organization for Standards (ISO).

Table 1 summarizes key standards and the organizations responsible for developing and maintaining them. They are organized according to the categories of standards described above and include the standards that are already adopted or ready for adoption.2

<table>
<thead>
<tr>
<th>STANDARD</th>
<th>Acronym</th>
<th>Description</th>
<th>Developer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Exchange/ Messaging</td>
<td>HL7 V2.x (^1) and V3</td>
<td>Electronic message formats for clinical, financial, and administrative data. V2 is common in commercially available software. V3 was launched in January 2005.</td>
<td>Health Level Seven <a href="http://www.hl7.org">www.hl7.org</a></td>
</tr>
<tr>
<td>Clinical Data Interchange Standards Consortium</td>
<td>CDISC</td>
<td>Format for reporting data collected in clinical trials.</td>
<td>Clinical Data Interchange Standards Consortium <a href="http://www.cdisc.org">www.cdisc.org</a></td>
</tr>
<tr>
<td>Accredited Standards Committee X12</td>
<td>ASC X12</td>
<td>Electronic messages for claims, eligibility, and payments.</td>
<td>American National Standards Institute, Accredited Standards Committee <a href="http://www.x12.org/x12org/index.cfm">www.x12.org/x12org/index.cfm</a></td>
</tr>
</tbody>
</table>
### Table 1: Summary of Key Standards and Developer Organizations, cont.

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<tr>
<th>STANDARD</th>
<th>Acronym</th>
<th>Description</th>
<th>Developer</th>
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<tbody>
<tr>
<td>Data Exchange/Messaging, cont.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Institute of Electrical and Electronics Engineers Standard 1073</td>
<td>IEEE1073</td>
<td>Messages for medical device communications.</td>
<td>Institute of Electrical and Electronics Engineers Standards Association</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Terminology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>International Classification of Diseases-9</td>
<td>ICD-9</td>
<td>Diagnosis and disease codes commonly used in billing and claims. Version 9 is often used in the U.S. for billing and reimbursement.</td>
<td>World Health Organization</td>
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<tr>
<td>Logical Observation Identifiers Names and Codes</td>
<td>LOINC</td>
<td>Concept-based terminology for lab orders and results.</td>
<td>Regenstrief Institute for Health Care</td>
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<tr>
<td>Systematized Nomenclature of Medicine</td>
<td>SNOMED</td>
<td>Mapping of clinical concepts with standard descriptive terms.</td>
<td>College of American Pathologists</td>
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<td></td>
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</tr>
<tr>
<td>Unified Medical Language System®</td>
<td>LOINC</td>
<td>Database of 100 medical terminologies with concept mapping tools.</td>
<td>National Library of Medicine</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Document</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuity of Care Record</td>
<td>CCR</td>
<td>Document format that gives snapshot of a patient’s core data and recent encounter (allergies, meds, treatment, care plan) and makes it available to next caregiver.</td>
<td>ASTM International, E31 Committee on Health Informatics</td>
</tr>
<tr>
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<tr>
<td>Clinical Document Architecture</td>
<td>CDA</td>
<td>Standard exchange model for clinical documents such as discharge summaries and progress notes. Formerly known as Patient Record Architecture.</td>
<td>Health Level Seven</td>
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<td></td>
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<tr>
<td>Conceptual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference Information Model: Health Level Seven Version 3</td>
<td>HL7 V3 RIM</td>
<td>Shared, generic model that facilitates interoperability. It standardizes all data models to a norm rather than each model to every other model. V3 RIM is used with V3 messages.</td>
<td>Health Level Seven</td>
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<tr>
<td>Application</td>
<td></td>
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</tr>
<tr>
<td>Clinical Context Object Working Group</td>
<td>CCOW</td>
<td>Standard for providing comprehensive view and single sign-on capability across systems without integrating databases.</td>
<td>Health Level Seven</td>
</tr>
<tr>
<td></td>
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<tr>
<td>Architecture</td>
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<tr>
<td>Public Health Information Network</td>
<td>PHIN</td>
<td>Components of an electronic surveillance and management system for integrated bioterrorism and public health preparedness. Formerly National Electronic Disease Surveillance System (NEDSS).</td>
<td>Centers for Disease Control</td>
</tr>
</tbody>
</table>
II. How Standards Are Being Used: Five Case Studies

*Early adopters are partnering with others in non-traditional collaborations.*

Today, there is growing enthusiasm for standardized clinical data exchange, and many national, regional, and local efforts are underway to define and implement standards. Project areas include electronic health records, computerized physician order entry, public health safety and security, clinical research, and pay for performance.

The five case studies below highlight different strategies for how clinical data standards are being used. The organizations come from across the health care landscape: a federal research agency, a local public health agency, a private integrated delivery system, a payer-sponsored physician network, and a statewide collaborative. These early adopters are partnering with others in nontraditional collaborations to achieve their goals. They use an array of strategies from a single-vendor format to a custom-created open-source system, employing existing syntactic standards for data exchange as well as pioneering adoption of cutting-edge semantic standards.

**Taconic IPA/MedAllies Regional Health Information Exchange**

Taconic IPA is an independent practice association of 2,500 doctors in the greater Hudson Valley affiliated with MVP Healthcare. See [www.taconicipa.com](http://www.taconicipa.com).

### Why Change?

Taconic IPA physicians are organized primarily in small practices and see their patients in multiple community hospitals. They needed a health record that consolidated data from the various hospitals and labs and made the process for reviewing and approving hospital charts less onerous. With an average practice size of four doctors, it was not cost-effective for individual practices to acquire the technology or integrate with the hospital information system. The IPA could not require that all the independent practices use a particular practice management or electronic health record system.

Taconic wanted a community-wide system that could, in real time, integrate data from all the hospitals and labs. It needed to cover 100 percent of patient care so that physicians could go to
one source for all the hospitals at which they worked.

**Project Description**

In 2002, the IPA created a subsidiary, MedAllies, to implement the project on behalf of the physicians and provide training and support. They selected a system from Healthvision to provide Web-viewing access to inpatient and outpatient lab and radiology reports. The data from hospitals and labs were consolidated in the MedAllies data repository. The portal was integrated with the hospitals’ medical records system to allow electronic review and signature of transcriptions. It is currently integrated with four community hospitals and two national lab companies. Some 160 practices with 500 doctors and 1,200 staff users are registered to use the system.

The second phase (see Table 2), begun in late 2004 and set to launch in late 2005, is expanding the system to include:

- Electronic medical records from two vendors certified to meet MedAllies standards that will interoperate with the central clinical data repository;
- ePrescribing integrated with pharmacies and pharmacy benefit management systems (PBMs);
- Clinical data repository populated by the hospitals, commercial labs, and electronic medical records systems; and
- Single sign-on capability with the hospital system.

**Impact of Clinical Data Standards**

Taconic IPA provided a viewing capability for lab results and radiology reports to its network of physicians using existing data exchange standards and off-the-shelf portal technology. In less than two years, they have gained adoption by over 50 percent of the network in the two target counties — 20 percent of the IPA’s overall provider base. The organization leveraged standards to a greater extent in the second phase. By incorporating medications with patient demographics and lab results, they began to populate a community-wide electronic health record. Without the use of HL7 and NCPDP data exchange standards, the information could not be consolidated easily.

**Challenges and Lessons**

MedAllies, understanding the needs of independent practices, budgeted extensive resources beyond what vendors or hospitals typically provide. They planned for 80 hours of training and customer support per physician in the first year and 40 hours per year thereafter. This level of engagement and commitment built a close relationship with the physician offices, which came to view MedAllies as a trusted source.

Gaining agreement from competing electronic medical record vendors to be on the same portal was challenging, but the IPA was committed to offering a choice to physicians. Because of their trust relationship, the IPA physicians themselves asked that vendors be vetted by MedAllies and integrated with the portal before they would consider using them.

### Table 2. Taconic IPA Standards

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<thead>
<tr>
<th>CATEGORY</th>
<th>SOLUTION</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Exchange</td>
<td>HL7 messaging</td>
<td>Uses hospitals’ existing interface engines to produce HL7 V2.x patient demographics and lab results</td>
</tr>
<tr>
<td></td>
<td>NCPDP</td>
<td>To use for ePrescribing starting in the second quarter of 2005</td>
</tr>
<tr>
<td>Terminology</td>
<td>SNOMED</td>
<td>Requires standard terminology be used by EMR vendors in addition to standard data exchange to ensure interoperability with the portal</td>
</tr>
<tr>
<td>Application</td>
<td>Single sign-on</td>
<td>Plans to offer the capability for single sign-on to the portal from hospital information systems</td>
</tr>
</tbody>
</table>
A greater challenge was convincing competing hospitals to have their data on the same portal, although not intermingled. Fortunately, the physician leadership had good relationships with the first partner hospitals. These leaders championed the concept with the hospital administration. Once the first hospital agreed to partner, several other hospitals followed closely behind.

Financial incentives play an important role in gaining adoption among physicians. Taconic IPA received funding from MVP Healthcare to start MedAllies and build the portal. Physicians have free portal access and purchase their own electronic medical record system. The hospitals and labs pay a fee to interface with the portal.

**Future**

MedAllies will launch and market the full portal functionality with electronic health records options from two vendors and ePrescribing linked to retail pharmacies in the third quarter of 2005. At that time, MVP Healthcare, other health plans, and self-insured employers such as IBM, will fund an incentive program that includes a bonus of $0.40 per member per month to physicians who use the ePrescribing system, and an additional $0.20 per member per month for generic substitution of drugs. Over the next year, MedAllies will be working with Bridges to Excellence, an employer-sponsored pay-for-performance project, government and commercial health plans, and employers to automate reporting of the clinical quality matrices for incentives that begin in July 2006.

They will expand access to the portal and all data exchange services outside the IPA. Physicians who are not members of the IPA but practice in the same market areas will be able to buy the services for a monthly fee. The IPA expects to have a certification process for electronic health record vendors that will begin granting by the end of 2005.

The program will be evaluated by researchers at Boston’s Brigham & Women’s Hospital with a grant from the Agency for Health Research and Quality. The evaluation will include a comparison of 100 practices using EMR, ePrescribing, and paper. Results will be available by 2007.

**California Clinical Data Project: Setting Standards**

California Clinical Data Project: Setting Standards is a collaborative, statewide project for establishing uniform pharmacy and laboratory data standards and rules of exchange. It is coordinated by the California HealthCare Foundation (CHCF). This project used existing exchange standards and added details within those standards such as specific definition of the data to be exchanged and the timing of the interchange. See [www.calinxstandards.org](http://www.calinxstandards.org).

**Why Change?**

The executive committee for Setting Standards believes that usable and reliable patient data at the point of care—regardless of the insurer, facility, or provider—is critical to the management of patients, especially the chronically ill. A previous collaboration called CALINX, led by the Pacific Business Group on Health, had achieved agreement on a pharmacy data format, CALINX 1.0, by major health plans in the state. But without specific oversight, each plan drifted from the specifications, and medical groups that received the data had to manage multiple formats. In order to spur the adoption of uniform specifications and ease the ability of providers to aggregate data, CHCF stepped in to coordinate Setting Standards and fund the collaborative’s activities.

**Project Description**

The goal of this project was to standardize clinical data exchange among medical groups, labs, hospitals, and insurers to improve population disease management, outcomes analysis, and reporting. The data needed to be computable—not just viewable—for clinicians to integrate it into the patient care process. The project was initiated in 2004 and governed by an executive committee of provider
organizations, health plans, hospitals, commercial laboratories, community clinics, purchasers, both local and state government. Two workgroups of technical experts were created, one for lab and one for pharmacy.

The pharmacy workgroup updated the existing CALINX 1.1 standard and improved documentation to support consistent implementations. By fall 2004, the new CALINX Rx 2.0 specification was adopted. Six health plans and six medical groups were in the beta test group. By May 2005, seven major health plans were transmitting data using the new standard. The lab workgroup adopted CALINX Lab 1.0, based on the HL7 V2.4 messaging standard, creating a California-specific implementation (Table 3). The lab workgroup will begin testing in summer 2005.

Setting Standards developed a toolkit and made it available free of charge. The toolkit includes a sample database with pharmacy content, macros for loading files, examples of queries, and a users guide. It is available at www.chcf.org/topics/chronicdisease/clinicaldata/index.cfm?itemID=109329. In addition, a software tool is available free to users; it verifies the formatting of data files to help assure compliance with the format standard. Support for those implementing the standard was provided in the form of direct consultation by a project data manager.

**Impact of Clinical Data Standards**

By gaining agreement on a single, fully specified data exchange format and providing project management, technical assistance, and monitoring of implementations, Setting Standards is making progress toward giving providers timely access to clinical data.

**Challenges and Lessons**

The greater challenge is not in the development and agreement upon a standard, but its implementation and adoption. Jonah Frohlich, the project’s data consultant, says the work is: “meticulous and gritty. It is not glamorous and you need sustained attention by a committed workgroup.”

A multi-stakeholder oversight group — which included representatives of labs, health plans, hospitals, and medical groups — also helped to assure that the standard would be practical and meet a range of quality improvement needs.

The first phase of the project, pharmacy standards, is live at the time of this report; the second phase, for labs, is in beta testing. In interviewing groups, Setting Standards staff found that some groups who had previously received pharmacy data from insurers never loaded it into their systems. Some were not adept at extracting data from their internal systems and did not have data warehouses. Their analyses were limited to pre-loaded reports from their operating systems. Medical groups, in general, have limited technical and analytical staff — often financial or systems analysts — who may be less experienced with clinical data. They need training and support to load HL7 files into a database, classify clinical data into meaningful categories, and create appropriate queries for analysis and reporting.

Table 3. California Clinical Data Project Standards

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>SOLUTION</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Exchange</td>
<td>CALINX Rx 2.0</td>
<td>Defined a “post-adjudicated pharmacy claim” flat file format based on NCPDP batch specification and telecommunications standard 5.1. Includes patient, prescription dispensed, insurance, amounts due, claim number, prescriber, and primary physician; data are used for clinical analysis rather than payment.</td>
</tr>
<tr>
<td></td>
<td>CALINX Lab 1.0</td>
<td>Based on HL7 V2.4 lab messaging standard, defined a California-specific implementation of this standard lab result message.</td>
</tr>
<tr>
<td>Terminology</td>
<td>LOINC</td>
<td>Limited use of LOINC for identifying lab tests related to HEDIS quality indicators in year one; expands to most commonly ordered tests in year two.</td>
</tr>
</tbody>
</table>
The toolkit and access to a data consultant are necessary resources that help address the need for training and support.

The project adapted a local standard for pharmacy because it built on existing statewide efforts. It later recognized that using nationally accepted standards was a better strategy and the lab workgroup opted to use HL7 V2.4.

An important element in the adoption of these standards was the participation of the six beta-testing health plans and medical groups who are part of the Integrated Healthcare Association’s Pay for Performance (P4P) demonstration project. The P4P demonstration tied bonuses to submission of electronic data and performance on selected quality indicators. The most active interest among medical groups in Setting Standards came from approximately 45 groups that reported their own 2004 data to P4P or were expecting to report for 2005.

**Future**
Setting Standards hopes to support the adoption of uniform clinical data standards across California. CALINX Rx 2.0 is now available to 182 medical groups, who manage 6 million patients. Project staff are optimistic because they have attended to important keys to adoption: leadership commitment to standards, outreach to users, direct technical assistance, implementation guides, and linkage to incentives.

**PeaceHealth Integrated Hospital Information System/Electronic Medical Record**
PeaceHealth is a Catholic health ministry that operates an integrated delivery network (IDN) with six acute care facilities in Alaska, Washington, and Oregon. The organization also has 350 employed physicians. See www.peacehealth.org.

**Why Change?**
As PeaceHealth grew to an IDN that served three states, they found that tracking patients and their care became more complicated. Their patients were mobile but the IDN’s systems weren’t keeping pace. PeaceHealth was also mobilized in part by the Institute of Medicine’s call to improve patient safety and quality, by making clinical information “available no matter where, no matter when.” They made the improvement of information systems a strategic priority throughout the enterprise.

**Project Description**
The project goal was the creation of a computerized, community health record that was interoperable between facilities across the continuum of care. PeaceHealth opted for a single-vendor system that includes ADT, pharmacy, lab results, and financial and clinical documentation applications.

They rolled out an integrated health information system from IDX across all facilities over the course of seven years. Facilities range from a 350-bed acute care hospital to an 11-bed rural, critical access hospital. The system uses the same core clinical system and data model across applications (Table 4). A data warehouse was created for analysis and reporting purposes. Rather than relying on an MPI product, PeaceHealth enforced a single medical record number across the network.

**Impact of Clinical Data Standards**
The comprehensive patient record accommodates patients’ movement among all locations where care is provided: inpatient, outpatient, and clinic settings. This allows the organization to conduct outcomes analysis with comparable data. Instead of conducting manual chart reviews and relying on individual interpretation of narrative notes, the system provides semantically consistent data that can be analyzed. There are also unintended benefits. The improved charting has led to better charge capture, since charges are a function of documentation and not a separate activity. And, by bringing various regions together to plan and design the
system, staff have come to see each other as internal consultants who share best practices on policies and procedures, patient education programs, and preparation for accreditation visits. A planned single medication list per patient will cover inpatient and outpatient environments; it is expected to improve case management, prevent adverse drug interactions, and enhance patient satisfaction.

Challenges and Lessons
The work to define and implement standard definitions took sustained effort across multiple disciplines for several years.

One of the strategies PeaceHealth used was a multi-disciplinary, multi-region oversight committee. In addition to facilitating buy-in, this oversight committee was able to network with colleagues they didn’t interact with otherwise. The organization also created a project management office to support the standardization effort and system implementation. PeaceHealth’s information technology department is part of the Healthcare Improvement Division, and is headed by a physician executive and a nurse director of clinical applications. These leadership decisions continually reinforce the message that the purpose of standardization is quality and patient safety.

A planned six-month implementation of the first facility actually took 18 months. The delay was not due to technical challenges as much as gaining trust with the staff. Planners underestimated the system’s impact on business processes and workflow. Rather than introducing modules in sequence they tried to implement the system wholesale. With the subsequent facilities, they took an incremental approach and built in time for business process design and staff education.

Future
With the core system in place — offering access to a comprehensive view of the patient record — the demand for analysis and reporting is increasing. Once clinicians saw the power of a standardized information system, they became more confident about the possibilities for patient care. They focused first on getting data across the enterprise into the system, and now need to simplify the process of analyzing and reporting it. The choice of a single-vendor system made internal standardization easier. But, as users become more sophisticated, the proprietary database underlying this system may prove to be a barrier.

PeaceHealth’s vendor, IDX, plans to move to a commercial standard database to improve their ability to integrate external sources of data and use additional applications such as workflow and business intelligence. They hope to change the model of care from a department-specific focus to an interdisciplinary one. For example, they hope to develop an overall patient rehabilitation assessment and status record that will accommodate contributions from Occupational Therapy, Physical Therapy, Respiratory Therapy, and Nursing. This would replace today’s four separate assessments.

Washington D.C. Department of Health Automated Disease Surveillance System
Washington, D.C. Department of Health (DC DOH) is the public health agency responsible for the District of Columbia. See www.dchealth.dc.gov/index.asp.

<table>
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<th>Table 4. PeaceHealth Standards</th>
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<td><strong>CATEGORY</strong></td>
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Why Change?
After the postal anthrax crisis in 2002, DC DOH was under intense scrutiny and the agency felt responsible to serve as a model for the rest of the country. The DC DOH realized it had systematic problems, including information silos, long delays in obtaining clinical information, and incomplete planning for known and unknown hazards. All case reports were submitted manually, on paper, via mail or fax, which was time-consuming and error-prone for both the submitters and the DC DOH epidemiologists receiving the information. If hospital staff were not working during holidays, weekends, or evenings, information was inconsistently captured and reports could be missed. As a result, DC DOH could not be confident it had complete information and that its investigations were accurate and prompt.

Project Description
The DC DOH sought to demonstrate more effective bioterrorism and disease surveillance through an integrated public health infrastructure. This infrastructure would enable automated public health data collection, real-time monitoring and analysis, and early detection and intervention. The system would integrate hospitals, labs, and other sources such as poison control, emergency services, and animal disease control for a truly comprehensive public health system.

During 2003 and 2004, DC DOH developed the Washington, D.C. Disease Surveillance System (WADSS) built on Oracle technology with custom applications developed by AMCI and Sierra Systems. This system, implemented as a pilot with four hospitals and one lab, automated data collection from two hospitals, labs, and other public health services. The pilot electronically captured patient demographics, diagnosis, chief complaints from emergency rooms, results from the commercial lab, and cases from poison control, fire, emergency services, and animal disease control. In addition, a syndromic surveillance program from Johns Hopkins Applied Physics Laboratory, Electronic Surveillance System for the Early Notification of Community-Based Epidemics (ESSENCE), used timely regional data from over-the-counter pharmaceutical sales and school absenteeism records to detect patterns that could be an early indication of a bioterrorism event or disease outbreak. They also implemented a data quality algorithm that was part of the integrated data repository to check for duplicate patient records across all the incoming data sources and merge them.

Because DC DOH partners were at different stages of using standards and technology, and the system allowed for various data-exchange strategies, several of the hospitals and the lab were capable of producing HL7 V2.3 and V2.4 standard messages (Table 5). An integration engine was used to convert these messages to HL7 V3.0 for storage in a RIM-based repository. One hospital had a Web-based system that did not produce standard messages, but did allow downloading of batch files on a nightly basis.

Impact of Clinical Data Standards
DC DOH’s pilot system allowed a comprehensive and timely review of potential disease outbreaks, bioterrorism attacks, and actual public health cases. Responsiveness was no longer dependent on staff work schedules, since data were collected automatically. The data flowing into the system was standardized in HL7 messages using standard terminologies. The use of an integration hub avoided cost by creating a single interface rather than a different one for each source system. The integrated data repository with MPI capability ensured that records were not duplicated, and that clinical information from various sources was associated with the correct patient. In addition, the repository leveraged the RIM to normalize the data from disparate sources so that it could be analyzed. Without these standards, it would have been a daunting task to create agreement with all the stakeholders on data-exchange formats alone. Having the endorsement of the CDC and the HL7 standards organization on the PHIN architecture convinced DC DOH that their pioneering work would be expandable and reproducible.
Challenges and Lessons

DC DOH faced organizational challenges that had an impact on the adoption of standards. Hospitals that had been sending reports on paper were reluctant to begin using an electronic interface for fear of losing control of the data. The value to those partners was emphasized: The new system would allow hospitals to streamline data submission and ensure compliance with the reporting requirements while reducing burden on staff. The same patient data gathered in the emergency room was reused in reporting to DC DOH.

Technical assistance to the partners was important. Expertise in PHIN standards at the DC DOH and at hospital sites was attained through two strategies: (1) investment in staff training via industry conferences held by the CDC and other organizations; and (2) hiring consultants familiar with the PHIN standards and HL7 and CDC. Despite the presence of consultants, internal IT staff needed to be fully engaged so that the system could be supported following implementation. For this reason, the program managers, epidemiologists, and other users were active participants in designing the data structure, verifying data collection methods, describing use cases and scenarios, and testing the system.

Future

DC DOH plans to expand access to all nine hospitals in the district and integrate the public health labs in 2005. They hope to interface with the Health Alert Network for real-time incident alerts.

The department is interested in enabling online reporting of cases, investigation results, and regional summaries for the hospitals. As HL7 moves toward approval of the public health case report messages, and CDC accepts V3.0, the DC DOH will be prepared to operationalize the full cycle of standards-compliant reporting from provider to public health department to CDC.

National Cancer Institute, Center for Bioinformatics

The National Cancer Institute Center for Bioinformatics (NCICB) is the division of the National Cancer Institute responsible for providing informatics and integration support to the cancer research community. See www.ncicb.nci.nih.gov.

Why Change?

NCI was determined to modernize the management of its research portfolio and the data produced by clinical trials. A large number of protocols were being used. Basic statistics such as the number of patients enrolled in a trial were inaccessible because reports were filed on paper. In multi-site trials, each institution might decide to collect different data elements and create their own data collection form. Even sites within the same institution sometimes differed. Because there were no standards for coding data, analysis across sites was hampered.
Project Description

In order to knock down barriers to research silos, NCICB wanted a shared cancer informatics infrastructure for researchers and clinicians that included a common architecture. It would include a standards repository, enterprise vocabulary, open-source applications, and tools for managing interoperable systems. This would enable researchers to design their protocols, data collection, and coding methods, and consolidate information in a way that could be shared readily with others.

The NCICB used a gradual, collaborative approach that evolved into agreed-upon standards. Over the past decade, the NCI Cooperative Groups, representing hundreds of hospitals, other patient care settings, and Designated Cancer Centers, have weighed in on data standards. This collaboration has been driven by practice in clinical trials rather than abstract conceptualization. Certain standards became required for all NCI-funded clinical trials.

NCICB developed caCORE, an open-source platform for managing and deploying data and architectural standards. The platform consists of components that support standards-based biomedical informatics system development. It accommodates existing standards and terminologies from a number of sources and organizations, and also provides for new standards development when necessary (Table 6). The architecture is an implementation of the Model Driven Architecture paradigm espoused by the Object Management Group. The implementation of caCORE provides an excellent example of the development and adoption of terminology, metadata, and architecture standards.

Impact of Clinical Data Standards

With the infrastructure provided by caCORE, NCICB now supports a shared understanding of clinical data, provides standard ways to tag and store data, and provides a centralized repository that is populated and accessed easily by the cancer research community. Programmers can build applications or integrate data from various systems; researchers can directly use the Web tools for searching and downloading the centrally hosted databases. Data are comparable across studies and easily accessible for current and future research. The caCORE also supports both clinical and biomedical research informatics in areas such as model organism studies, microarray data management, protein information, and tissue banking.

Challenges and Lessons

Organizational and cultural challenges were more important than technical ones. The sites had limited bioinformatics staff for design of data models and user screens, and limited technical staff for development and implementation of systems to support

| Table 6. National Cancer Institute, Center for Bioinformatics Standards |
|---------------------------------|-----------------------------|-------------------------------------------------|
| CATEGORY                       | SOLUTION                    | DESCRIPTION                                     |
| Terminology                    | Enterprise Vocabulary Services (EVS) | NCI Thesaurus is a cancer-specific vocabulary and classification scheme that has browser search capability and is available as a download. NCI Metathesaurus is a collection of medical, basic biology, and research vocabularies from 56 sources; it is based on the National Library of Medicine’s Unified Medical Language System. Other systems can access the EVS via application programming interface (API) called caBIO. Both are formally and systematically reviewed and updated. |
| Architecture                   | caBIO | Object model and architecture for data integration. A data layer includes all caCORE data in a warehouse plus integration with EVS, caDSR, and external databases such as the human genome database. An object layer represents biological, lab, and clinical entities or relationships. These objects support data access. A presentation layer includes a Web server, application server, and SOAP engine. |
|                                | caDSR | Data standards repository that provides metadata management. |

Description adapted from “caCORE: A common infrastructure for cancer informatics.”

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research. Participation in the standards effort was voluntary, and progress was limited by participants' capacity. Agreements to share data were also challenging. These take the form of patient consent to access medical records and participate in clinical trials as well as agreements between hospitals and physicians to share data. The business processes between hospitals, physicians, and patients were highly manual and inefficient. The policy and procedural issues needed to be resolved before technology could automate their activities.

NCICB found that a gradual, consensus-driven process was critical to adoption of standards. They first needed to gain buy-in from the research community that standards were important, then play a facilitator role in the development process. It was crucial that NCICB provide technology and technical support to implement the standards for their resource-scarce researchers.

**Future**

NCICB is moving to a new phase of adoption with the creation of Cancer Bioinformatics Grid (CaBIG), a network of cancer centers committed to clinical standards. They agree on best practices, publish their data models and metadata for use by the community, and use standardized terminologies. NCICB is exploring a new model of contracting to make funding available to cancer centers for adoption of infrastructure to support standards-compliant systems and system integration.

The NCICB hopes to seamlessly channel the data collected in clinical care to research. This would reduce cost of data collection, improve the ability of clinicians to easily identify candidates and refer them to trials, and make comprehensive patient information available to researchers.
SUCCESSFUL PROJECT IMPLEMENTATIONS REQUIRE adoption of a range of data standards types and approaches and are primarily driven by the scope, content, and organizational partners involved in data exchange. The development of these projects requires a focused objective, trust between partners, and time. The operational experience of the projects described ranged between one to ten years. The length of time was not necessarily correlated to the results achieved. Rather, the speed with which adoption occurred may be related to the particular readiness of the community for change, complexity of the project, and the resources available to assist in implementation.

The two longest-running projects have achieved qualitative improvements in collaboration, data quality, and interoperability across multiple locations. NCICB has evolved over a decade from a database of clinical trials to a comprehensive set of standards, shared infrastructure, and tools for implementation that many of the designated cancer centers and clinical trials organizations are using. NCICB has had the additional challenge of being a standards development organization as well as a catalyst for adoption. PeaceHealth, on the other hand, used commercially available software and implemented it in all locations. The bulk of their seven-year implementation was used to gain agreement on a common clinical terminology, sequential implementation at each location, and user acceptance.

The more recent projects have taken advantage of existing clinical data standards developed by formally sanctioned standards development organizations (or national standards). Beyond the existing standards, however, even more detail, or specification, is required for successful implementation. Setting Standards has progressed quickly in less than a year. It launched with six health plans and medical groups in February 2005, while DC DOH completed its pilot with two hospitals and one lab in mid-2004. Both used a data exchange and terminology standard. DC DOH also used the CDC PHIN as its base architecture and pioneered the use of HL7 RIM and V3 messages. Taconic IPA has achieved rapid uptake within two years with 500 physicians and 1,200 staff using their system. Anecdotal evidence suggests that physicians are very satisfied with the MedAllies system. Taconic IPA is embarking on
a formal evaluation of its project; results will be available in two years.

The case studies showed the greatest level of adoption in data exchange, followed by terminologies. Once there is agreement on the syntactic data specifications, the next level of interoperability should address semantic standards. In other words, the data must be normalized across systems so that common terms and meanings are used and understood. A 2004 HIMSS survey\(^6\) showed that the ICD-9 code sets and HL7 V2 messages were the most common standards adopted. But even these are used by only half the industry. In the terminology category, SNOMED has been available for 25 years, but still has a percentage of adoption in the teens. There is minimal use of documentation, architecture, or application standards. In 2004, HHS licensed SNOMED and is making it available at no charge with the hope that it will be adopted more broadly.

### Barriers

There are a number of unaddressed barriers to implementation. The availability of funding for capital and infrastructure is a primary concern.

The case studies used different financing strategies. Taconic IPA/Med Allies received start-up funding from its sponsoring insurer, which covered development and implementation for physicians who are members of the IPA. It is unclear how additional development will be financed and made available to non-IPA physicians. PeaceHealth funded their system internally. Setting Standards was funded through a foundation grant for coordination and technical assistance. The NCICB and CDC PHIN programs both provide funding for infrastructure that complies with their architecture standards. NCICB makes grants and contracts available to cancer centers for implementation. The CDC, through bioterrorism preparedness grants, makes implementation funds available to all states, the District of Columbia, and three cities. The states determine how funds are used and distributed to counties and cities. These programs are vulnerable to federal budget cuts and changing funding priorities.

Pay for performance has been noted by some as a potential financing strategy for hospitals and medical groups. But these programs generally pay bonuses or levy penalties based on results rather than providing capital. For medical groups and small physician practices, lack of capital will be a challenge.

Funding is necessary but insufficient to ensure a successful technology implementation.\(^7\) Many other factors need to be considered. Cultural change is required for independent entities to share data that previously was held within an organization’s walls. For example, physician offices will have access to data from multiple, competing hospitals within the Taconic IPA. Hospitals may see technology as a competitive differentiator in terms of physician relations and patient perception; by participating in a shared system with other hospitals they relinquish this differentiator. At Taconic, this concern was overcome by physician and hospital leadership working together.

It is a major cultural change for organizations to be comfortable with electronic sharing of data and trusting their partners with access to their systems. The 2004 HIMSS survey showed that the lack of agreed-upon policies regarding access to patient information was the top barrier to the creation of a National Health Information Infrastructure (NHII). At DC DOH the providers were worried about losing control of their internal systems and data. Their concern was alleviated by focusing on the value the system would provide in efficiency and quality of reporting.

The perception that standardization means loss of local autonomy is another barrier. At PeaceHealth, clinicians were concerned that they would not have flexibility to meet their local needs. The collaborative decision-making process they undertook helped address these concerns. The implementation team
created cross-regional workgroups to define requirements, agree on terminology, share lessons learned, and brainstorm future uses of technology. Implementation at each facility built on lessons learned at previous sites, and additional time was allocated to ensure that the system worked within the local business process and culture. In addition, the leadership and steering group constantly reinforced the message that standardization was a means to improving patient safety and quality.

Syntactic interoperability — focused on issues such as field length and format — is not as difficult a challenge as semantic interoperability — the dictionary and thesaurus needed to share common meanings. The information required for purposes such as electronic health records, computerized physician order entry, or evidence-based medicine is more complex and broader than that for financial and billing needs. These clinical needs require a leap to semantic interoperability. Several of the case study organizations have made the leap. DC DOH implemented an HL7 RIM-based repository to normalize the data coming from two hospitals and a commercial lab. NCICB used the National Library of Medicine UML and consolidated multiple research and medical terminologies.

An obstacle to making the leap to semantic interoperability is the dearth of skilled informaticists and clinicians adept at data management to lead organizations in their efforts. Such leaders can be developed. The use of new terminology usually entails much more significant changes in clinical operations, well beyond the IT operational changes required for data exchange standard implementation. At PeaceHealth, the leadership came from nursing and physician quality leaders who invested in learning about data management. DC DOH hired consultants and vendors with the needed expertise to kick-start their implementation, while IT and clinical staff became educated about clinical data standards related to PHIN.

Leadership may be the most significant barrier. Because clinical data standards are sometimes seen as an obscure technical domain, executives tend to leave it to IT staff. The leaders in the case studies are not technical experts, but they grasped the fundamental notion that standards were the keys to interoperability, not an afterthought of technical implementation. John Blair, president of Taconic IPA, says, “We are using clinical data standards to enable interoperability and to fundamentally transform the model of working as a physician in the community.” Demi Rewick, R.N., director of clinical applications at PeaceHealth, offers the executive team’s consistently reinforced message: “Patient safety and quality depends on information available no matter where, no matter when.”

Industry Catalysts

Industry catalysts — whether government agencies, professional associations, or private entities — aggregate the efforts of others and push forward the adoption of standards. The government has been an important catalyst for adoption of ICD-9 and CPT, used for billing and claims. These were mandated by CMS, the largest payer in the country, and were part of the HIPAA code set regulations.

There are several recent indicators that the government will continue to be a catalyst. The 108th Congress passed the National Health Information Infrastructure Act of 2003, a voluntary effort to assess and recommend strategies for vetting, selecting, implementing, and maintaining standards-based information technology. It does not require public agencies or the private sector to comply with any of its recommendations, but its effect is already being felt. Dr. David Brailer, the national health IT coordinator, is a key opinion leader who is sparking a nationwide discussion of interoperability. Per NHII recommendations, a public-private certification body, the national Certification Commission for Health Information Technology, has been formed to validate industry standards and certify compliance of information systems. Taconic IPA
hopes to the use the proposed certification body to validate electronic health record vendors.

The federal government is requiring standardization across its health agencies through the Consolidated Health Informatics Initiative (CHI). The CHI is governed by 20 federal agencies including the Departments of Health and Human Services, Defense, and Veterans Affairs. It has established a portfolio of clinical vocabularies and messaging standards enabling federal agencies to build interoperable federal health data systems. The selected standards are not newly developed; they are currently available. The CHI is attempting to educate the wider industry of the availability of those standards that are market-ready.

The Centers for Disease Control and Prevention (CDC) has defined a set of standards for public health infrastructure called the Public Health Information Network (PHIN). While targeted at public health departments, this infrastructure is designed to integrate data from hospitals, physicians, emergency responders, epidemiologists, and the public. Gartner, a leading provider of research and analysis on the global IT industry, describes the CDC as the catalyst in public health because of its determination: “...to adopt the standard and force the standard on other players as a condition of doing business with it. This is essentially how traditional electronic data interchange (EDI) gained traction in the defense contracting and automotive parts industries before spreading out to other industries.”

Federal funding is offered to states and cities that implement the PHIN architecture. Because the data standards are equally useful for public health preparedness, clinical practice, and compliance with HIPAA, an investment in this infrastructure serves multiple purposes. Alignment with the CDC vision was a driving factor for DC DOH.

Private efforts have been just as important to the adoption of standards. The Institute of Medicine’s seminal works *Crossing the Quality Chasm* and *To Err Is Human* promoted the use of standardized IT to reduce medical errors and improve clinical quality. By making these linkages explicit, the IOM had a major impact on the industry’s recognition of the need for standards. In fact, PeaceHealth identified the IOM’s findings as a leading factor in spurring their adoption of standards.

Pay for performance incentive programs have been catalysts in California’s Setting Standards and the Taconic IPA experiences. In California, a concurrent project of the Integrated Healthcare Association (IHA), sought to demonstrate the effectiveness of health plan bonuses in improving quality. All six medical groups in the Setting Standards beta test group and almost all inquiries and requests for assistance from other medical groups came from the 45 groups who were participating in the IHA project and reporting their own data. The groups’ ability to respond to incentives for collecting and reporting quality data to the health plans will be enhanced by the availability of statewide standards and the technical assistance provided by Setting Standards.

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TO MOVE FROM A HANDBUF OF EARLY ADOPTERS TO mass adoption of clinical data standards, a great deal more movement is needed. It took the Internet three years to make its first ten-fold expansion. But it has taken 25 years for SNOMED to gain adoption by just 16 percent of the industry. What strategies can be employed to drive the adoption of standards in our own organizations? Lessons learned from the pioneering organizations such as those profiled in this report can help move all parts of the industry forward:

**Use national standards.** Several national efforts to define clinical data standards take advantage of the collective wisdom and experience of thousands of members and use structured processes to create, refine, adopt, and maintain standards. While it may be tempting for organizations to use a locally developed terminology or data exchange format for a project with a particular partner, this will require regular maintenance and upgrading as systems and partners change. In addition, this custom-build strategy restricts the ability to interoperate at an enterprise level or with a community of partners.

**Be informed leaders.** Establishing standards requires leaders from all sectors of the industry who understand the benefits of standards and can promote a common vision for their use. This is not an area where it is possible to rely solely on vendors or the largest providers. Such leadership is needed to stay abreast of developments and to leverage technology investments for multiple purposes. Dr. David Brailer, National Health IT Coordinator, sums up the need this way: “Executives create a milieu where standards are relevant and can be addressed. Informatics and IT have toiled in a vacuum but we need to elevate standards so that interoperability is achievable.”

**Build a collaborative culture.** By definition, data standards development and adoption require collaboration. A standard has no value until there is broad commitment among stakeholders to use it. The case studies show how workgroups developed trust relationships that enhanced sharing of best practices, strengthened collaborative efforts, and spurred greater confidence in IT. This benefit is also seen in collaborations built on community-wide
participation. Four of the five case studies are regional or national in scope and involve participation by at least four distinct organizations.

Explore alternative financing models. Adoption of clinical data standards requires not only an organizational commitment, but a financial one. Capital financing and stable funding are perennial challenges. The strategies described in this report are diverse: internal system funding, foundation grants, federal grants, sponsorship from hospitals and health plans, and combinations of these. Other financing models are being proposed by the industry to spur adoption of standards-based IT systems. These include a revolving loan fund, government funding, pay for performance, and community-wide collaborative funding. All these options should be explored.

Use incentives to drive adoption. In cases where organizations have moved quickly along the adoption curve, incentives have played an important role. This report includes two examples in which payment differentials and bonuses resulted in medical groups adopting standards. Technical assistance, coordination, and other administrative support can also be seen as incentives — particularly for organizations without the capacity or in-house skills to achieve adoption on their own.

Cultivate staff skills and knowledge. Despite a critical need for informaticists and clinical data standards experts, few programs provide training in this area. More staff, particularly clinicians, need to become in-house experts. The initial gap can be filled with consultants or sometimes by IT vendors, but knowledgeable in-house staff can be the most effective at leading the change needed to adopt standards. Recruiting staff with specific expertise is expeditious, but existing staff can also gain expertise by participating in standards development organizations, attending health IT conferences, and through on-the-job learning.

With early successes from case studies such as those shared in this report, commitment from leading organizations, and continued national attention to these issues, clinical data standards can become a reality.
1. Health Level Seven is one of several American National Standards Institute (ANSI)-accredited Standards Developing Organizations (SDOs) operating in the health care arena. Most SDOs produce standards (sometimes called specifications or protocols) for a particular health care domain such as pharmacy, medical devices, imaging, or insurance (claims processing) transactions. Health Level Seven’s domain is clinical and administrative data.


3. Version 2.”x” is a naming convention in which the first digit stands for the major release and the second digit is for updates to that release. Common versions of HL7 in use today are Version 2.3 and 2.4. Version 3.0 is a major change from Version 2.x.


