



**Certification Commission
for Health Information
Technology**

200 S. Wacker Drive, Suite 3100
Chicago, Illinois 60606
Tel 312.674.4930 Fax 312.896.1466
cchit.org

Interoperability: Supplying the Building Blocks for a Patient-centered EHR



Interoperability of computerized information is an intriguing, attractive and demanding concept in today's healthcare field and among those in policy circles who expect much of health information technology.

While all electronically represented information is much more accessible to healthcare professionals compared with details confined to paper charts, the value of digitized data multiplies when it is structured, standardized and readily exchangeable among different information systems – bringing a new level of integration to our currently fragmented healthcare process. Interoperability provides a way to pass information between separate electronic health record (EHR) systems and connect with other outside sources of essential information.

Simply stated, before any element of information (like a lab result, prescribed drug, allergy note, measles shot) can be exchanged by computer beyond the original source, there has to be a common way of “saying” it and a uniform and secure method of transporting it from one place to another. To transform that simple statement into successful practice, however, requires:

- A plan to incorporate still-maturing standards for representing, sending and receiving a wide range of information types, each with a multitude of possible results, values and other content.
- Agreement on uniform ways to put those standards into practice in certified EHRs simultaneously.
- A logical sequence of EHR requirements that over time supplies the building blocks of a solid foundation for sending, receiving and productively using information on a single individual from many different electronic points of origin – the essence of a patient-oriented EHR.
- A secure electronic highway for conducting health information exchange (HIE) on a large scale.



Since 2004, the Certification Commission for Healthcare Information Technology (CCHIT®)¹ has led efforts to build consensus and acceptance for an ambitious yet achievable pace of requiring features, functions and future innovation in EHR products. Those that meet 100% of these requirements receive a seal that certifies they have demonstrated all of them in a rigorous live test.

Since its first cycle of certification in 2006 for EHRs designed for use in physician offices and clinics, the Commission and its volunteer work groups of medical and technical experts in healthcare have established a minimum set of criteria for certification, raised the bar each year, and set both near-term and longer-range targets for EHR developers to start working on if they want to be recertified in years to come. The same process was expanded to include EHRs for inpatient and emergency department settings as well as entities formed to enable health information exchange (HIE).

It is through this rigor of setting expectations for products and devising new requirements that build on each other from year to year that the Commission has been able to induce an initial burst of progress in standardized data exchange in the areas of laboratory results management and functions related to prescribing medications electronically – two of the highest-volume information-related activities in the nation’s physician offices. The current focus of the Commission’s interoperability blueprint is on preparing EHRs to use recently identified national standards for representing a patient summary, comprising the types of information that physicians typically ask of others when assuming responsibility for the care of an individual.

This report summarizes the methodical march to levels of information interoperability that will enable the healthcare field to update and aggregate patient-specific medical profiles, report more comprehensively the actions taken to improve care coordination and quality, and feed the software engines that inform and support clinical decisions in healthcare settings. It’s also an attempt to inject a dose of reality into the discussion of interoperability – from practical expectations for the near term and future years to the challenges of developing software architecture and implementation guides that can execute new interoperability criteria uniformly and successfully. All of this aims to serve the best interests of health professionals and those who rely on them.



Interoperability Timeline

July* Certified EHRs require single lab standard with more review capabilities, e-prescribing extends to hospital EHRs and the patient summary becomes more structured with an advanced option for document sharing

February ARRA requires certified EHRs for funding

November Certified EHRs for hospitals and emergency departments available

July Certified EHRs receive lab results and e-prescribe using basic standards

September HHS funds certification development

Standards first recognized for DOD, HHS, VA

NCVHS notes health IT leadership gap

2010* CCHIT develops advanced requirements for clinical decision support, interoperability, quality and security

2009

2008 **July** Certified EHRs meet tighter lab standards, require advanced e-prescribing capabilities and receive a basic patient summary

July MIPPA requires advanced e-prescribing for funding

2007

2006 **August** HHS safe harbor rules require interoperability

July Certified EHRs for physician offices available

May CCHIT launches 1st EHR certification program

2005

2004

September CCHIT formed

April Office of the National Coordinator for Health IT created

January President calls out need for Health IT

2003

2002

AHA forms National Alliance for Health IT

2001

*Future



Receiving lab results in the same language

Before certification requirements made their impact beginning in 2007, providers using their EHRs could not receive a laboratory result in a standard format without the cost and expertise of outside consultants. Results came in a different way from every lab source. Now there is substantial movement toward a common interface to handle results from all labs, whether a large reference lab, local hospital-based labs or in-clinic facilities that may be established for routine tests such as blood chemistry or cell counts. This allows results from reporting systems to be filed directly into EHR systems.

To attain this level of progress, two challenges had to be addressed and resolved through certification:

- The “standard” for sending messages electronically was anything but. A format in the healthcare industry for exchanging clinical and administrative data, called Health Level Seven (HL7), is valuable and constantly evolving, but there are economic and practical considerations involved in updating it and until recently there was no formal coordination to lock onto the same version industrywide. Consequently, HL7 messaging was deployed in a range of versions, and even identical versions were implemented differently – confounding the aim of standardizing such messages.
- The intricate coding necessary to communicate the results and test values could vary among EHR systems just enough to cause problems receiving results accurately and fully. Also, there was no agreement on the specific sets of codes to include in all EHR systems from among the tens of thousands available in the universal code system for reporting lab observations, known as LOINC.

In the certification cycle that began in July 2007 and ended in June 2008 (version 07), CCHIT began requiring EHRs to receive general lab results in a limited span of HL7 versions, using a subset of commonly used LOINC codes. In the current 08 cycle, EHRs are required to receive and store general and microbiology lab results in a single standardized HL7 format. In the coming 09 cycle, systems not only will have to standardize on that single format (v2.5.1) but also differentiate between a preliminary and final result, process a corrected result, and include and highlight information on abnormal results.



With this level of uniformity, some technical configuration is still involved but not nearly as much as before, which is a net cost saving with positive implications for accurate communication of clinical details. As codes are accepted for lab data and their contents readable electronically, EHRs have become able to “parse” messages: they can break up the lab message into separate parts and put them in their assigned places on a display of clinical information.

Although compliance by lab companies is not mandatory, the fact that certified EHRs now use a standardized interface should lead the labs to embrace that format as well.

Strong momentum behind e-prescribing

Electronic prescribing requires cooperation at all points of the transaction from provider to pharmacist, but the impetus was not there until certification got the ball rolling. It had been difficult to get pharmacies to hook up to a network that acted as an intermediary for e-prescribing transactions, to get EHR vendors to put e-prescribing capabilities in their products, and for doctors to use the feature. In 2006 products, it was very rare for doctors to have applications capable of standards-based electronic transmission of prescriptions. A doctor would use an EHR to order the medication and update the medication list but print the script or fax it to the pharmacy.

For 07 certification, EHRs had to be able to create and send a basic order for a new medication or renewal of an existing one in the standard format known as NCPDP SCRIPT. For 08, EHRs additionally had to include “advanced” e-prescribing capabilities: presenting a medication history on a patient, looking up and displaying insurance eligibility for the prescribed medication, and consulting the insurance plan’s drug formulary for any limits on coverage. At the time, there were two competing e-prescribing networks: SureScripts, which built links to the nation’s retail pharmacies, and RxHub, which served mail-order pharmacy businesses and also assembled medication histories and lookups for eligibility and formulary. The two companies merged in 2008 and the new entity has taken the name SureScripts.

CCHIT certification requirements, in combination with the SureScripts network, cleared a path for rapid momentum as measured by both the number of e-prescribing transactions and the number of participating pharmacies and e-prescribers. Volume statistics kept by



SureScripts have documented² an increase in transactions from 13 million in 2006 to an estimated 100 million in 2008. Participation by e-prescribing doctors and other clinicians rose from 15,000 in 2006 to 35,000 in 2007 and an estimated 85,000 in 2008.

For 09, e-prescribing criteria now incorporated into EHRs for the physician office or clinic will also be required for certification of inpatient EHR systems.

Exchanging discrete bits of information about a patient

Doctors have always needed a concise but complete set of clinical and administrative facts in front of them on whatever patients they are treating, culled from all the other multitudinous details and focused on what will summarize the patient's history and condition sufficiently to inform a plan of action. A clinician or assistant can sort through pages for the information in a paper chart or look at a scanned or e-mailed document to find these key elements of a patient summary.

But for a computer to select and provide such information, it needs to have the elements structured and coded so it can pick them discretely from the electronic record. To exchange these discrete elements with other computer systems, the sending and receiving systems have to work with standardized representations of all the bits of data contained in the elements, while also using the same assumptions to guide implementation of the agreed-upon standards in their software frameworks, or architectures.

Only in the last few years has the healthcare industry come together to devise the electronic version of a patient summary, complete with instructions for splitting the summary into chunks, or subsets, of information codes that get very specific about the messages and content they convey from one computer to another. This feat of standardization, called the Continuity of Care Document or CCD, is now being incorporated in stages into the CCHIT certification process as part of its growing interoperability requirements.

The number of possible discrete elements in a CCD is lengthy; for starters, certification criteria encompass subsets for demographic information, medication history and allergies. The 08 set of criteria required an EHR to be able to receive and display a standard



document for a CCD with information from these subsets. Also in 08, an EHR had to be able to generate and format these CCD subsets. In the 09 cycle, requirements will extend to using structured vocabularies/terminologies (such as RxNORM and SNOMED) for generating the above CCD document subsets, an advanced implementation of the data-exchange capability. Receiving the subsets in coded terminology, a more challenging task than just generating them, is a requirement in 10.

The breadth and depth of patient summary information

The basic capacity to represent clinical information in a standard format to be sent and received will be achieved in CCHIT Certified EHRs through a sequence of requirements that takes into account both the breadth of elements contained in the CCD and the levels of information depth each element can contain.

Those elements currently in the criteria for certification – basic information on a patient, the medications being taken, and allergic reactions to drugs, foods and environmental triggers – would be recognizable on the clipboard form that people time and again are asked to fill out in a physician-office or hospital waiting room. In fact, the logic behind picking this starter set from among all the possible elements in the CCD is the notion of “clipboard replacement,” a useful and hopefully welcome objective for clinicians and patients alike. The ultimate outcome of making this information interoperable would be to populate it in EHRs electronically from existing sources and retire the clipboards.

For the 10 certification cycle, subsets in the areas of immunization records and patient problem lists are scheduled to be added to the interoperability requirements.

Besides gradually adding to the number of patient-summary elements required of certified EHRs, the phasing of criteria induces EHR interoperability by requiring development through three levels of depth in content and function, from simple document exchange to precisely communicated attributes of the information.

- Level 1 establishes and recognizes that a transaction is a CCD. The information then can be handled manually in the record.

- Level 2 recognizes subsets of the CCD generally, allowing them to be categorized by an EHR. The specific content of these sections are not encoded, but the EHR can be instructed to route them in discrete ways (putting patient demographics in a certain place, representing medication lists in a screen display according to established rules, etc.). No manual triage of the incoming information is needed to drop documents into patient charts or a digital dashboard.
- Level 3 represents information as structured data, precisely coded using standard terminology (like RxNORM, NDC) so each bit of detail can be read by the system (for example, every element of a medication order: drug name, dosage form, strength or concentration, dosage, and administration route, frequency, and duration) and used to trigger clinical decision support. This is semantic interoperability with no ambiguity from computer to computer. For example, a current medication list forwarded from another provider can be used to trigger alerts if a new, interacting drug is prescribed.

Adoption of structured, coded terminologies – Level 3 – is critically important for importing discrete data into an EHR. An e-mailed document can't begin to accomplish what structured coding can. "Machine-understandable" documents using industry-standard terminologies and vocabularies enable the information to be not only displayed in a variety of ways at the point of care but also understood by the receiving system.

The actual import of such information from another system is a separate interoperability challenge described below, but in the chain of events leading up to clinical data exchange, the use of standard codes for creating precision in data elements comes first. Requiring a means to transport data among different clinical information systems makes sense only after EHRs can generate standard elements to share and process.



Standard methods for transporting standard documents

In non-technical terms, the transport package in this interoperability equation is a standard “envelope” for computers to ship the standard data elements from source to destination. The industry-standard transaction package being employed to perform this function is called Cross Enterprise Document Sharing, or XDS.

In 09, the use of this transaction package will debut as a requirement of a new certification program for optional “advanced interoperability.” Introducing this first as an advanced capability enables leading-edge EHR vendors to bring transport to market and build a track record of successful implementation before the capability is required of all EHR products. Also in 09, the advanced interoperability certification will include a requirement to support one or both of the two standard approaches for coordinating patient identification between an EHR and other system, an essential middle step in completing the exchange of data. These approaches are called Patient Identifier Cross-referencing (PIX) and Patient Demographic Query (PDQ).

The ability to send Level 3 Continuity of Care Documents via the standard XDS transaction package gets healthcare IT to the stage at which information from other points of origin can be used as directed in the receiving EHR. A health information exchange (HIE) entity may still be needed to supply this transport, but with the addition of the XDS standard transaction package, all the component parts of end-to-end exchange will be in place for this exchange to occur.



Interoperability in a fragmented industry

Putting the standard elements in place for interoperability is a breakthrough in itself for an industry so historically fragmented. The research, development and implementation of software and services for health IT are the separate pursuits of hundreds of companies each seeking to distinguish their products for competitive advantage while controlling production costs. Their customers are independent clinical facilities and individuals with widely varying information needs depending on the nature of their healthcare services and size of their organization, among many other factors.

Given this state of healthcare affairs, the Commission—through the direction of its Interoperability Work Group—has concentrated on driving the IT vendor community forward by defining the steps toward interoperability that are most important to the healthcare process and are the farthest along in terms of standards and architectures to support implementation.

In the case of lab results, some electronic reporting was already established but required leadership in moving it toward a standardized, streamlined and semantically clear state. For e-prescribing, the federal government had already begun the standardization process with the passage of the Medicare Modernization Act of 2003, and a data exchange network was in operation; the challenge was to create the conditions for wide adoption by requiring in EHR products the capabilities to deploy e-prescribing successfully.

As these initiatives were playing out, the means for exchanging elements of a patient summary were coming together through the efforts of the federally supported Healthcare Information Technology Standards Panel, or HITSP. Once standards and coded values in the CCD became available to implement, the certification process was faced with many choices about where to start as well as the reality that the standard sets still were largely untested and would need intense attention to the architectures and medical vocabularies necessary for reliable implementation. Focusing on one subset at a time improves the chances of bringing the independent vendors of health IT down the same path together and creating consistency rather than cacophony to development.



Structuring a strategy for constant progress

The CCD's premise is that it contains a clinically relevant and manageable set of information on a patient – the essence of a patient's medical situation, short and sweet. Putting each element into discrete, structured and standard form, however, is a series of separate technological projects, with significant latitude for executing steps differently unless all efforts are guided by a common reference point such as that provided by certification criteria, pilot testing and detailed scenarios to execute in live demonstrations.

Technologically speaking, there are so many different sections of the CCD that if all vendors were left to decide on their own what to tackle first, different EHR systems would go to market with quite different and incompatible data-exchange capabilities – some with ability to put out standard medication lists while others focused on vital signs, allergy documentation or immunization history. By leading a logical progression of simultaneous steps to standardize elements of data for inter-system exchange, CCHIT does a service to the healthcare industry by harnessing the expertise and concentration to take on a task, nail it and move on.

Multiply this work load by the thousands of data fields in an EHR and it's clear that the structured-data interoperability of the full record is not the near-term goal. For the hard work and development time involved, the path to progress starts with operationalizing what's most important to medical practice – like clipboard replacement – getting good with the new standards and architectures, and building onto the existing level of interoperability in decreasing priority order, expanding the circle ever wider.

Interoperability then is fundamentally an evolutionary task that proceeds through layers of experimentation, testing and adoption. It must be based on realistic and achievable goals with high clinical value and relevance to clinicians, patients and policymakers alike.

First, get broader adoption of basic capabilities

For all the attention heaped on the objective of making the full EHR interoperable, most physician practices would be fine with initially a limited number of data elements delivered accurately, comprehensively and reliably. The CCD itself is a key mover of data; the typical medical group could be well-served by the information represented in patient problem lists, allergies, medication lists, recent lab results and family history.



Providing broader adoption of basic EHR capabilities first, before taking on the deeper adoption of the technology's full range, gets everyone connected and exchanging information while the infrastructure for more complex data exchange evolves. Even if the capabilities are basic, the ability to present the full picture on a limited set of information for recent encounters would be a significant step forward for healthcare treatment.

For example, broad aggregation of like information is important for quality improvement and reporting efforts. Outcomes information now may not include all the data that providers capture in all the places a patient is treated and tested, and consequently a provider doesn't realize what the results of treatment are, what to do additionally or differently, and what the full reportable picture is on quality measures. Reporting on meaningful use of IT or adherence to standard practices in managing a medical condition requires assemblage of data from enough providers and other sources of information to form a complete and valid picture. Incentives in the American Recovery and Reinvestment Act (ARRA) focus on attaining increased breadth of information.

With breadth and volume of new information come new challenges for EHR development that will have to be brought under control and made valuable to end users. The issue of designing computer functions and data displays to be quick and easy for clinicians to use is a rising concern, and the prospect of new waves of data on recent tests and encounters being continually presented to EHRs for action and routing into records raises the issue of usability to a more difficult level of challenge.

This concern highlights the higher complexity of receiving standard data transmissions compared with generating and sending them out. Sending involves making a document available to one place. Receiving requires intake from many places: different provider systems, patient communication, pharmacies, labs and so on. Besides managing the variety of sources, an EHR system and its users may have to reconcile partial or conflicting details on the same information depending on the source. There's much more for an EHR to do as it fields the range of incoming data and tries to make sense of all the partial views of the "truth" on a patient.

End users may not be prepared to deal with the wealth of information, even when it is enhanced by the standardization of terminology. For example, medication reconciliation is defined as a priority by the Joint Commission and other authorities but there's no standard for how it's done. As the XDS transport package becomes a standard, it will use registries



for managing CCD and other types of documents, including recent patient encounters that contribute medication information and ask it of other data sources. Through these registries, EHR systems will be picking up “snapshots” of updated transactions continually. How do EHRs deal with this volume? How frequently or under what conditions does the provider need to be informed? How is the information organized (for example, relevant vs. historical)? What is the working definition of “relevant,” and how does it change from one type of clinician to another?

The proliferation of new information creates the next challenge for health IT development. The healthcare industry needs to resolve the implementation and usage challenges arising from adoption of new standards and new functions to take advantage of the higher levels of information availability.

Creating an express lane for advanced capabilities

The importance of getting basic functions right for all EHRs doesn’t mean that leading-edge developers can’t go on ahead and distinguish their products as having advanced capabilities to exchange information and perform other advanced functions such as higher-level security and quality measurement. Certification sets a common benchmark for what EHR products are able to do for their users, but the competitive market can, and does, prompt IT vendors to offer more than the minimum.

Starting in the summer of 2009, CCHIT will develop optional certification programs in Advanced Interoperability, Advanced Security, Advanced Quality and Advanced Clinical Decision Support. These programs will begin testing applicant EHR vendors for accelerated capabilities in their commercially available products in mid-2010.

These optional advanced certification programs move the industry forward while not suddenly cutting off the bulk of the marketplace. The approach of certification up to now has been to identify certain criteria to be met in the current year but also place new and more rigorous criteria on a roadmap for vendors to see what they will be responsible for demonstrating during the next several years. In the case of advanced certification, the roadmap becomes an express lane for vendors that see benefit in getting to future destinations faster.



CCHIT and its work groups are in the early stages of planning the specifics of advanced interoperability and other accelerated programs. Some of the decisions may depend on how the federal government elects to implement provisions in the ARRA around the objectives of incentives for “meaningful use” of certified EHRs. The certification process meanwhile continues its course of criteria development pegged to the current roadmap while remaining flexible and responsive to new or revised requirements that may be necessary.

Putting progress in a historical perspective

Interoperability and deployment of standards for data exchange are technology challenges for which increasingly demanding expectations are being set within the healthcare industry and in the highest reaches of the federal government. The demands of the present make it easy to forget how far the pursuit of EHR interoperability has come in less than four years. Indeed, there was no visible leadership on information interoperability, or even health IT standards in general, as the healthcare industry entered the new millennium.

Consider this recent history:

- As far back as 2000, the National Committee on Vital and Health Statistics (NCVHS) was urging the federal government to take a leadership role in the formulation of policy and targets for health IT. In a 2001 report to the secretary of Health and Human Services, the committee listed impediments to health IT adoption and identified “the lack of a strong Federal presence to guide the development of the (national health information infrastructure) as the most significant gap impeding its realization.”³
- In January 2002, the American Hospital Association announced its intention to form an executive-level healthcare industry group to deal with what it saw as the lack of momentum behind the use of health IT, the root of which was the low level of information compatibility among healthcare information systems. The first task of this new group, the National Alliance for Health Information Technology, was to make sense of all the standards created by various technical groups and provide a starting point for reaching industry consensus.



- In March 2003, the federal government first recognized a common starter set of healthcare technology standards and committed to deploying them in the departments of Health and Human Services, Defense and Veterans Affairs. It was the first step in leading by example to select and adopt information standards. But the government could not require them of the private sector.
- In April 2004, the Bush administration created the Office of National Coordinator for Health Information Technology (ONC), a move that the NCVHS had recommended in 2001. A year into its operation, the ONC designed and contracted for a line-up of entities for specific purposes: resolve standards adoption and harmonization (HITSP), create and test for a set of capabilities in health IT products and services (CCHIT), and lead the development of standards and solutions necessary to exchange information among sources of healthcare information (the Nationwide Health Information Network).

From a standing start in late 2004, CCHIT has built a foundation of essential criteria for EHR functionality and security while incorporating the standards coming from HITSP and other standards development initiatives as they become mature enough and sufficiently accepted by the industry to require in certified products.

Interoperability and medical progress intertwined

Two important factors to keep in mind are that:

- Interoperability is a means to many different ends and not an end in itself.
- Delivering on the possibilities that interoperability opens up will be a whole new development challenge for software architects, developers and clinical informatics professionals. Just having the information doesn't guarantee that it will be a cakewalk to reconcile medication records, merge patient-specific data and medical knowledge into proactive condition management, or coordinate the efforts of HIEs, among the many higher-level endeavors envisioned to increase healthcare efficiency and effectiveness.



It's just as important to keep in mind, however, that these high-level uses of health information systems are not possible without the accessibility to information that standards-based data generation and transport will provide to the healthcare industry and out to the public via personal health records, public health registries and the like. To lift a familiar phrase from Sinatra, you can't have one without the other.

It will take time to get there, but each step of the way on the interoperability path will take healthcare delivery and care coordination to a better place than before. As the path becomes more traveled, new development will spring up alongside it, until the health information landscape becomes the vibrant environment we need it to be instead of the sparsely populated hodgepodge of unconnected locales it is now.

The current plan of action – purposeful incorporation of criteria into certified health information technology, and federal support for its wide adoption – is the ambitious yet achievable approach to moving the healthcare field down the path together, just briskly enough to make good time while not stumbling along the way. ■

Footnotes

¹ The Commission is a nonprofit, 501(c)3 organization with the sole public mission of accelerating the adoption of robust, interoperable health IT. Since 2005 it has been successfully executing a contract from the Department of Health and Human Services (HHS) to develop certification programs for electronic health records and health information exchanges. CCHIT was recognized by HHS as a certifying body in 2006, and remains the only organization of its type to have received federal approval.

² SureScripts LLC, National Progress Report on E-Prescribing, November 2007.

³ National Committee on Vital and Health Statistics, Information for Health: A Strategy for Building the National Health Information Infrastructure, November 15, 2001, available at <http://www.ncvhs.hhs.gov/nhiilayo.pdf>

Acknowledgements

This paper is the collective result of the expertise, insight and factual grasp of many CCHIT volunteers and staff members. Special recognition goes to: Amit Trivedi, strategic lead, CCHIT Interoperability Work Group; Dennis Wilson, CCHIT Certification Technology Director; David Tao, senior key expert and interoperability champion, Siemens Healthcare, and co-chair, CCHIT Interoperability Work Group; George Robinson, pharmacy informatics consultant, and member, CCHIT Interoperability Work Group.

Writer: John Morrissey, CCHIT Communication Manager