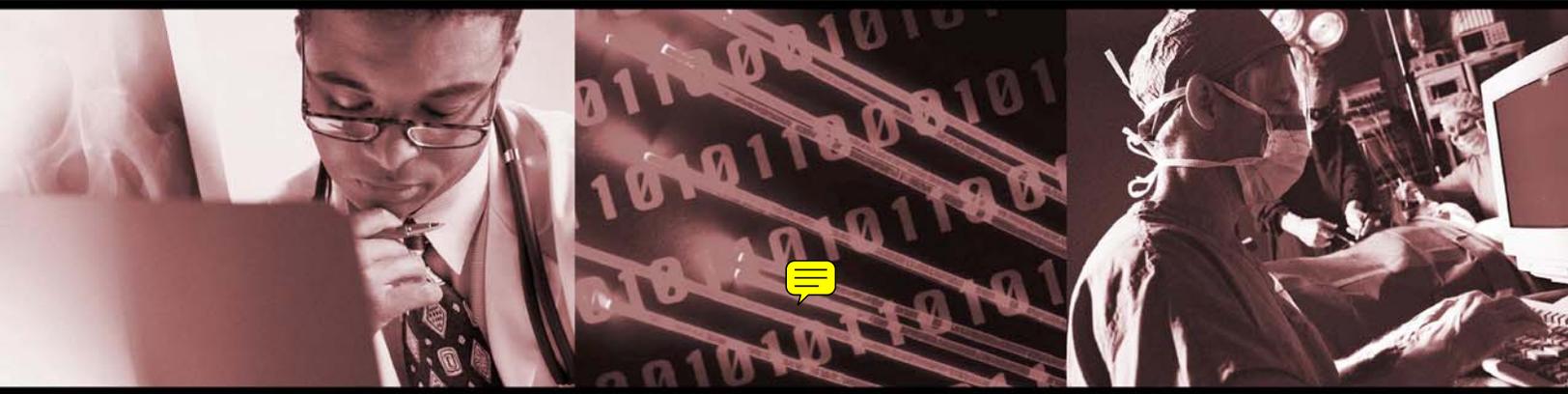


MARKLE FOUNDATION

CONNECTING FOR HEALTH

A Public-Private Collaborative



The Data Standards Working Group

Report and Recommendations

June 5, 2003

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I. INTRODUCTION AND OVERVIEW

Background

The purpose of this report is to outline the purpose, goals, and outcomes of the work of the Data Standards Working Group of *Connecting for Health...A Public-Private Collaborative*. Connecting for Health consists of over 100 stakeholders representing every part of the health care system – healthcare organizations and clinicians, patients, payers, accreditors, government agencies, researchers and health care information systems suppliers.

Our Mission

Connecting for Health is working to transform how information flows through all segments of the health care system in order to improve the health and health care of every American. Our twin goals are empowering patients to maintain and improve their health and enabling clinicians and health-care organizations to provide safer and more evidence-based care. Achieving these goals requires creating a dynamic, networked information infrastructure that, in turn, must reliably ensure the private and secure movement of vital health information at the time that it's needed to the place where it's needed.

There is a critical need to push health care into the Information Age. Our nation faces an aging population, a rising tide of consumerism, escalating health care costs, medical safety lapses, and an increased complexity of care decisions brought about by technological advances such as genetic engineering. Yet those who work in health care are not taking full advantage of the information and communications technologies that have revolutionized other industries. Indeed, one of the largest challenges facing our system is enabling timely and efficient access to information that can improve both the quality and cost-effectiveness of care.

Because of the highly fragmented nature of our health care system -- care is delivered by a variety of independent physicians and other providers working in a broad spectrum of inpatient and ambulatory settings - medical information is often collected and reported in a piecemeal fashion. This fragmentation has concrete consequences:

- Physicians and other clinicians sometimes provide patient care without knowing what has been done previously and by whom, resulting both in wasteful duplication and in clinical decisions that do not take into account critical data related to patient health. In fact, studies show that paper hospital records are unavailable when needed approximately one-third of the time.
- Hospitals and physicians are often unable to obtain usable information that will help either in applying research breakthroughs to the confusing particularities of individual patients or in avoiding preventable medical mistakes.

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- Public health agencies and providers are unable to exchange the information that is critical to identifying, tracking, and responding to health threats ranging from traditional epidemics to deliberate bioterror attacks.
- Health services researchers do not have ready access to the data required to develop improved processes of care that will lead, in turn, to improved health outcomes.
- Patients who wish to collaborate with their doctors in managing their own health are given little information with which to work. Meanwhile, private and governmental payers, as well as individual workers, taxpayers, and consumers, continue to bear the financial burden of clinical inefficiency.

While the advent of electronic information systems has brought us closer to connecting health care information from disparate sources, there is still a significant amount of work to do. The lack of clinical data standardization, even within a single institution, has resulted in incompatible systems that frequently cannot communicate with each other in an efficient manner. Without standards for interoperability, there will still be significant gaps in the availability of important information needed by both patients and clinicians.

The Case for an Interoperable Healthcare System

Interoperability is meant to ensure the rapid flow of secure, private and complete digitized information about all facets of patient care, ranging from common administrative tasks to rarefied clinical minutiae. Interoperability can open the way for 21st-century clinicians to take advantage of a torrent of new information and make current information more usable. There will be information at the "point of care" (where patients are treated); information for research into new treatments; and information that can be fed back in an interactive learning environment to improve the safety and effectiveness of the treatments we use today.

The benefits of building this new information infrastructure will extend to clinicians trying to provide the best care to individual patients as well as researchers looking for new treatments. Patients, meanwhile, will be able to access the information they need to assemble a personal health record and collaborate with their doctors.

More broadly, the ability to aggregate digitized information for rapid and thorough analysis – while meeting strict privacy rules -- can also help to protect and improve the health of entire populations, whether the threat comes from naturally occurring disease or from deliberate attack.

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The Mission of Connecting for Health

Participants in Connecting for Health were challenged at their initial meeting in September of 2002 to agree within nine months on a set of clinical data standards and to put into motion a series of actions designed to accelerate the adoption of those standards. By explicitly characterizing the process as a search for “workable answers,” the leaders of the Collaborative recognized that their primary role was neither to exhort nor to report. Instead, the most pressing task was to catalyze specific actions on a national scale that would rapidly clear the way for an interconnected, electronic health information infrastructure.

In pursuing this objective, the Collaborative focused on three key areas:

- Accelerating the rate of adoption of national clinical data standards in order to facilitate true interoperability. This was the task of the Data Standards Working Group.
- Identifying practical strategies and solutions for ensuring the secure and private transmission of medical information. This was the task of the Privacy and Security Working Group.
- Actively working to understand what consumers will need and expect from an interconnected health information system. This was the task of the Personal Health Working Group.

Overview Of The Report

This report is organized into five sections:

- Section I Introduction and Overview:**
Provides a high-level overview of Connecting for Health and the work of the Data Standards Working Group.
- Section II A Standards-Based Interoperable Healthcare Information System—The Value**
Provides a high-level summary of the value that accrues to each stakeholder group from the adoption of interoperable healthcare systems. It also provides a high-level summary of the evidence base related to information technology and standards and emphasizes the role of demonstration projects in enhancing this evidence base.
- Section III Standards for an Interoperable Healthcare System.**
Outlines the full set of standards that are needed to move towards an interoperable healthcare system. It also summarizes those standards that are “ready to move to adoption,” as well as additional actions required to move to an interoperable healthcare system.
- Section IV Framework for Migration to an Interoperable Healthcare System**
Provides a high-level framework for and discussion of the key considerations that must be taken into account in the migration toward an interoperable healthcare system. It also provides considerations related to the creation of a standards-based, electronic model of data interchange within a community-based setting.
- Section V Demonstrating Feasibility and Value: The Healthcare Collaborative Network...A National Demonstration Project**
Provides an overview of the Healthcare Collaborative Network , a national demonstration project launched in conjunction with Connecting for Health.
- Section VI: Accelerating Interoperability With Commitment and Action**
Highlights the actions that can be taken by the many stakeholders in the health care community, including practicing clinicians, hospitals and other healthcare organizations, employers and other third-party payers, federal agencies, health care information technology suppliers, academic and research institutions, national standards groups, manufacturers, and consumer groups, to facilitate the movement toward an interoperable healthcare system. Many Connecting for Health participants have taken individual and organizational actions to promote and achieve the adoption of clinical data standards. These are specifically elaborated in the report of the Connecting for Health Steering Group.

There are also two appendices to this report:

Appendix I Clinical Data Exchange Efforts in the United States: An Overview

Provides a detailed overview of the various community-based electronic data exchange projects that are well underway, summarizing their scope, the challenges they have faced, strategies they have used to overcome challenges, and early achievements.

Appendix II The Clinical Community.

Highlights the important role of the clinical community in driving towards standards adoption and the use of information systems. This section includes two papers authored by physicians participating in Connecting for Health. These papers elaborate the challenges and opportunities specific to practicing clinicians.

Overview Of The Work Of The Data Standards Working Group

Purpose and Goals of the Data Standards Working Group

As noted above, the purpose of the Data Standards Working Group is to focus on the first goal of Connecting for Health: that is, accelerating the rate of adoption of national clinical data standards in order to facilitate true interoperability on a national scale. The three primary goals of the Data Standards Working Group are to:

- Establish general agreement on a core set of data and communication standards, specifications and related components to enable the movement of data and knowledge within health care;
- Define the key barriers to the widespread adoption of those standards, specifications, and related components;
- Identify and implement strategies to accelerate the adoption of standards and an interoperable health care system.

Our Operating Model and Approach

In alignment with the general model of Connecting for Health, the Data Standards Working Group brings together participants from every stakeholder group in health care. The model for participation has been one of inclusion as we realize that broad support and participation is essential to creating enough momentum behind the adoption of clinical data standards. Over 80 organizations, representing practicing clinicians, hospitals, employers and other third-party payers, federal agencies, health care information technology suppliers, academic and research institutions, national standards groups, manufacturers, and other healthcare organizations, chose to participate in the Data Standards Working Group.

The Data Standards Working Group is chaired by W. Edward Hammond, PhD, President of the American Medical Informatics Association; Vice-Chair of the Technical Steering Committee of HL7; Convenor, WG2 Messaging and Cocommunications, ISO TC 215 Health Informatics; Professor-emeritus, Community and Family Medicine at Duke University; Professor-emeritus, Biomedical Engineering at Duke University; and Adjunct Professor, Fuqua School of Business at Duke University. The two vice-chairs are J. Marc Overhage, MD, PhD, Associate Professor of Medicine, Indiana University School of Medicine and Senior Investigator, Regenstrief Institute, and Ned McCulloch, JD, Senior Program Manager, IBM Corporation.

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The specific objectives of the Data Standards Working Group are organized into five categories which are designed to address the goals of the project:

1. Identification of Standards
 - Identify the necessary common standards and definitions to enable the movement of data and knowledge within health care.
 - Identify those standards that are ready to move into adoption.
 - Articulate the gaps in standards and the actions that need to be taken to address them.
2. Articulation of Value
 - Provide a high-level summary of the current evidence that supports the value of interoperable healthcare information systems as a means of addressing quality, safety and efficiency goals.
 - Conduct interviews and hold meetings with key healthcare stakeholders to gain a greater understanding of the value to each constituency and the system as a whole.
3. Demonstration of Feasibility and Value
 - Gather information from existing community-based models of electronic data interchange to gain a greater understanding of challenges faced, lessons learned, and the value that accrues to each stakeholder group involved in data interchange projects.
 - Launch a national demonstration project involving providers, payers, public health organizations, federal government agencies, to demonstrate both the technical feasibility and value of an electronic, standards-based model of data interchange.
4. Support for Migration
 - Develop a migration framework to highlight alternative approaches and considerations for moving to an interoperable healthcare system.
5. Accelerating Interoperability With Commitment and Action
 - Identify ways in which various stakeholder groups can facilitate movement towards the adoption of data standards and an interoperable healthcare system.
 - Highlight specific actions that have been or will be taken by specific organizations to accelerate the adoption of data standards.

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II. A STANDARDS-BASED INTEROPERABLE HEALTHCARE INFORMATION SYSTEM—THE VALUE

Overview

Over the last twelve months, there has been an increasing recognition by both the public and private sectors of the ability to improve the quality and safety of healthcare with interoperable healthcare information technology (IT) systems. The need for standards adoption to enable information systems to exchange clinical data in a private and secure manner both within and across institutions is also more widely recognized than ever before. This recognition has in part been fueled by the growing number of studies articulating the improvements in quality, safety and cost-effectiveness that can result from using IT to enhance and inform healthcare delivery. However, this value can only be realized fully if healthcare information systems are able to communicate rapidly and seamlessly through the use of data standards in a way that protects patient privacy and security.

This paper will: (1) provide an overview of the significant activity that is occurring both within the public and private sectors regarding interoperable information systems and data standards; (2) provide a high-level summary of the evidence supporting the use of information technology in healthcare; (3) summarize both the limited research and anecdotal evidence that currently exists related to the value of connectivity across systems; (4) describe the importance of pilot projects for both better understanding the value and of an interconnected electronic health system and for developing an effective migration strategy towards such a system; and (5) highlight the additional work needed in this area.

Momentum Building Within the Public and Private Sectors

Leaders from within both Congress and the Executive Branch of government are increasingly addressing the need for clinical data standards. In Congress, legislation has recently been introduced calling for the adoption of voluntary clinical data standards, with the public and private sectors working together to guide their development and adoption. Within the executive branch, support has come from the president, the Secretary of Health and Human Services (HHS) and the senior leadership of HHS agencies. That verbal support, in turn, has been backed by concrete actions such as the recent launch of the Consolidated Health Informatics (CHI) initiative, an inter-agency eGov Initiative involving several agencies within the Department of Health and Human Services, the Department of Defense, and the Veterans Administration. The objective of CHI is to gain consensus on and implement data standards for health information across all agencies of the Federal government.

In addition, HHS has created a new position, Senior Advisor, designed to serve as a focal point for all initiatives related to building a “National Health Information Infrastructure” (NHII).

The public sector’s efforts in this area are bolstered by equally significant activities elsewhere. The Institute of Medicine has released a series of reports highlighting the value of IT interoperability in healthcare and the important role of demonstration projects. The IOM is

scheduled to release another report this fall that is specifically focused on the value and importance of data standards in patient safety efforts. The Leapfrog Group, a coalition of major corporate employers, is planning to add an additional standard to its current three "leaps" which would oblige the use of standards-based information technology to support prescribing lab results, and other clinically-related activities. In addition, a number of IT industry groups have begun aggressively expanding their activities in support of a standards-based, interoperable healthcare system. These groups include the American Health Industry Management Association, the American Medical Informatics Association, the eHealth Initiative, the Health Industry Management Systems Society and the National Alliance for Health Information Technology.

The Value of Information Technology

There is clear and compelling evidence that appropriate use of information technology can help make the U.S. health-care system safer, of higher quality and more efficient. A number of the studies are listed below:

- In the 20th Century, bricks and mortar constituted the basic infrastructure of the health care delivery system. To deliver care in the 21st century, the system must have a health information and communications technology infrastructure that is accessible to all patients and providers...The development of a secure [IT] platform to support clinical, administrative and financial transactions, as well as the use of computer-based clinical records, should over time reduce some administrative costs and dramatically improve the effectiveness, safety and timeliness of the health care system.¹
- It is estimated that primary care physicians will save \$86,400 over five years, compared to traditional paper-based methods, according to a study at a Boston-area health system. Once implemented, benefits started to accrue in year two. These benefits included adverse error reduction, reduced spending on drugs, reductions in radiology expenses, decreased billing errors, and improved charge capture for billing.²
- Nationwide adoption of advanced computerized order entry systems in ambulatory care would eliminate more than two million adverse drug events and 190,000 hospitalizations per year, saving up to \$44 billion as a result of reduced medication, radiology, laboratory, and hospitalization expenditures.³ Such systems help with the legibility of prescriptions, dosing calculations, selection of drugs, eliminating potentially harmful interactions between drugs, and monitoring patients for adverse side effects.
- Serious medication errors plunged 55 percent, from 10.7 to 4.9 errors per 1,000 patient days, at an academic medical center examining the impact of computerized physician order entry (CPOE).⁴ In another study, the rate of all types of medication errors fell 83

¹ Institute of Medicine, *Fostering Rapid Advances in Health Care*, 2002.

² Wang SJ, Middleton B, Prosser LA, Bardon CG, Spurr CD, Carchidi PJ, Kittler AF, Goldszer RC, Fairchild DG, Sussman AJ, Kuperman GJ, Bates DW. A cost-benefit analysis of electronic medical records in primary care. *Am J Med* 2003 Apr 1;114(5):397-403

³ Johnson D, Pan E, Walker J, Bates, DW, Middleton, B. The Value of Computerized Provider Order Entry in Ambulatory Settings. Center for Information Technology Leadership, Partners Healthcare. 2003. pp 2-7.

⁴ Bates DW, Leape LL, Cullen DJ, Laird N, Petersen LA, Teich JM, et al. Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. *JAMA* 1998; 280:1311-1316

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percent. The Leapfrog Group estimates that CPOE systems, if adopted nationwide, have the potential to avoid 522,000 serious medication errors each year.⁵

- In one study of an intensive care unit, the incidence of allergic drug reactions and excessive drug dosages dropped by more than 75 percent when physicians used a CPOE system. The average time patients spent in the ICU dropped from 4.9 days to 2.7, slashing total hospitalization costs by 25 percent.⁶
- The Veterans Health Administration estimates a minimum two-to-one return on its investment in its VistA electronic system.⁷ The Centers for Medicare and Medicaid Services estimates that it could save more than \$26 billion annually by shifting to an electronic data interchange system.⁸

Despite the evidence in its favor, however, the diffusion of information in healthcare continues to be quite low:

- Only a third of hospitals nationwide have computerized physician order entry systems completely or partially available. Of those, only 4.9 percent require its usage, over half report usage by less than 10 percent of physicians, and over half report that fewer than 10 percent of orders are entered this way.⁹
- More than 90 percent of the estimated 30 billion health transactions each year are conducted by phone, fax or mail.¹⁰
- 40% of surveyed healthcare organizations planned to spend 1.5% or less of their total operating budgets this year on IT, and 36% set spending at 2% to 4%.¹¹ This can be compared with an average of 10 percent in other industries.¹²

Key barriers to diffusion of clinical information systems among hospitals, practicing clinicians, and other providers include lack of capital, organizational change issues, and concerns about the lack of interoperability.

- In a survey of provider CEOs, 25 percent cited lack of financial support as a barrier, while 17 percent cited the need to provide quantifiable benefits or return on investment as the greatest barrier. CEOs also listed the implementation of common data standards (5 percent) as the key barrier to implementation of information technology.¹³

⁵ Birkmeyer JD, Birkmeyer CM, Wennberg, DE, Young MP. Leapfrog safety standards: potential benefits of universal adoption. The Leapfrog Group. Washington, DC: 2000.

⁶ Evans RS, Pestotnik SL, Classen DC, et al: A computer-assisted management program for antibiotics and other anti-infective agents. *N Engl J Med* 1998; 338:232-238

⁷ Personal Communication by Molly Joel Coye with Veterans Health Administration.

⁸ Marhula DC and Shannon EG, "eHealth 2.0: Defining the "ePPI-center" of eHealth" US Bancorp Piper Jaffray, 2000.

⁹ Ash JS, Gorman PN, Hersh WR. Physician Order Entry in U.S. Hospitals. *Proceedings / AMIA Annual Symposium*. 1998:235-239.

¹⁰ Michael Menduno, "apothecary.now," *Hospitals and Health Networks*, July 1999, 35-36.

¹¹ An info-tech disconnect, *Modern Healthcare*, February 10, 2003.

¹² Millenson M, *Demanding medical excellence*, 1997, Chicago: University of Chicago Press.

¹³ Healthcare Information and Management Systems Society and Superior Consultant Company, 14th Annual HIMSS Leadership Survey. 2003.

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- A study by McKesson Corporation and Harris Interactive found that the majority of physicians (54 percent) see themselves collectively as an obstacle to adopting IT.¹⁴
- A recent survey of 5,000 family physicians conducted by the American Academy of Family Physicians found that 60.5 percent cited affordability as a barrier to adopting electronic medical records: 54.2 percent cited worries about slower workflow or lower productivity; while 38.7 percent said they were afraid they would choose a software vendor that would go out of business.¹⁵
- A 2002 survey conducted by the Medical Records Institute found that clinicians across a variety of settings identified the top barriers to the implementation of an electronic medical record as being: lack of adequate funding or resources (59 percent); lack of support by the medical staff (35 percent); affordability (32 percent); difficulty in creating a migration plan from paper to electronic health records (31 percent); and difficulty in finding an electronic medical record solution that is not fragmented over several vendors or IT platforms (29 percent).¹⁶

The Value of Standards and Interoperable IT Systems in Healthcare

Evidence suggests that the value of IT systems in healthcare accelerates considerably when individual applications can “talk to one another” through the use of standards and connectivity. Indeed, creating a well-articulated value proposition for interoperable, electronic health information systems can help address many of the specific issues cited in the previous section of this paper as barriers to diffusion.

Reliable and consistent open data standards are the basic foundation of an information infrastructure. Without those standards, interoperability – the ability of different information systems to securely, rapidly and privately communicate information when it’s needed to where it’s needed – is impossible.

The value of being able to exchange data electronically was strongly supported by discussions with the entire range of healthcare stakeholders.

- Practicing clinicians will improve their decision-making through access to patient data across multiple points within the delivery system. Clinicians are often asked to make important care decisions without access to the majority of a patient’s clinical record.
- Hospitals will benefit from reduced technical integration costs, reductions in their reporting burden, and improvements in the quality of care delivered to their patients.

¹⁴ Chaiken B, “Physician Adoption of Technology Linked to Providing Benefits.” *Journal of Quality Healthcare*. Vol 1. Issue No 2. April/June 2002.

¹⁵ AAFP Pushes for Affordable EMR System. *Family Practice Management Monitor*. February 2003. Vol. 10 No. 2.

¹⁶ The Medical Records Institute and SNOMED. *Fourth Annual MRI Survey of Electronic Health Record Trends and Usage*. 2002.

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- Payers will benefit from reductions in costs and improvement in their ability to evaluate and manage the effectiveness and quality of care. Interoperable and interconnected systems will help to reduce duplicative diagnostic tests. Costs for medical record abstraction efforts that support quality improvement and medical management activities and processing requests for payments that require additional clinical information will be significantly reduced.
- Quality improvement and patient safety-related organizations will benefit from the reduced cost and burden related to the accreditation and certification process for all parties, as well as improvements in their ability to effectively measure health outcomes. This will ultimately improve health and healthcare for all Americans.
- Public health agencies will benefit from improved, more timely and comprehensive access to information that enables them to detect, analyze, and respond to public health threats. The recent global response to SARS has underscored the vital significance of disease surveillance in protecting the public's health and has highlighted gaps and weaknesses in that surveillance and response.
- Pharmaceutical development and the general work of clinical research, both of which rely heavily on data, will benefit from timelier, comprehensive access to information. The current lack of standardized, electronic clinical data translates into long delays, restricted studies, and a large proportion of research dollars being focused on the manual collection of data. In addition, incorporating the rapidly growing body of scientific knowledge into the everyday practice of medicine is nearly impossible without the assistance of IT-enabled decision-support tools.
- Patients will derive the most value from interoperability and electronic data exchange. Benefits will include better quality care, improved outcomes, reduced errors, and the ability for patients to participate more fully in addressing their own health-care needs. Patients will also benefit from a reduction in duplicate diagnostic tests and unnecessary hospital admissions that result from having only a partial picture of the patient's past care.

Research suggests that IT systems in healthcare can improve the quality, safety and cost-effectiveness of care.

- Physicians spend an estimated 20 to 30 percent of their time searching for and organizing information.¹⁷
- A study in an internal medicine clinic found that pertinent patient data were unavailable in 81 percent of cases, with an average of 4 missing data items per case. The entire medical record was unavailable 5 percent of the time.¹⁸

¹⁶ Soule D, Handler S, Simplifying data entry in electronic health record systems, Conference proceeding towards and electronic health record Europe, 1999, Center for Advancement for Electronic Records. (Secondary source: Clinical Information: Achieving the Vision, 2002; Kaiser Permanente)

¹⁸ Tang PC, Faichamps D, Shortliffe EH. Traditional Medical Records As A Source Of Clinical Data In The Outpatient Setting. Proc Annu Symp Comput Appl Med Care. 1994; 575-9.

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- Unnecessary diagnostic tests are a financial burden on the healthcare industry and an imposition on patients. Using a computer system that alerted doctors to tests that appeared redundant, 69 percent of truly redundant tests were identified as such and cancelled.¹⁹
- A Regenstrief Institute study found that computers can assist physicians in estimating the risk of disease, thereby reducing the ordering of unnecessary diagnostic tests in an outpatient setting. During a six-month controlled trial, when there were more than 15,000 scheduled patient visits, patient charges for the eight study tests were 8.8 percent less for the intervention patients. This was true particularly for the two most frequently ordered tests, electrolyte levels and blood cell counts.²⁰
- A clinical laboratory alerting system used at LDS Hospital to increase the likelihood that patients in life-threatening situations receive appropriate care decreased length of stay from 14.6 to 8.8 days for some conditions.²¹
- The use of computer-based reminder systems that facilitate both physician and patient adherence to protocols also has made patient care more consistent and more effective. Clinicians who used such a reminder system had higher rates of documentation of compliance with influenza-vaccination guidelines than did those who used a paper record.²²
- In a study conducted at the Regenstrief Institute, a physician order entry system in an inpatient setting was found to lower patient charges and hospital costs mainly by reducing length of stay, test charges, and drug costs. The total charges per admission were \$887 (12.7%) lower per admission for teams that utilized the order entry system than those that did not.²³
- In the state of Illinois, electronic transmission of laboratory data from local healthcare organizations and clinicians to the state according to HL-7 standards has eliminated unnecessary steps in the reporting process and decreased reporting time.²⁴
- Electronic laboratory reporting of “notifiable” diseases in Hawaii yielded a 2.3-fold increase in the number of reports and reduced the time needed to receive the reports by four days. They were also more likely to provide more complete information.²⁵

¹⁹ Bates DW, Kuperman GJ, Rittenberg E, Teich JM, Fiskio J, Ma'luf N, Onderdonk A, Wybenga D, Winkelman J, Brennan TA, Komaroff AL, Tanasijevic M. A randomized trial of a computer-based intervention to reduce utilization of redundant laboratory tests. *Am J Med.* 1999 Feb;106(2):144-50.

²⁰ Tierney WM, McDonald CJ, Hui SL, Martin DK. Computer predictions of abnormal test results, *JAMA*, 1988, 259:1194.

²¹ Tate KE, Gardner RM, Weaver LK. A computerized laboratory alerting system, *M.D. Computing*, 1990, 7(5):296-301.

²² Tang, Paul C. et al., “Measuring the Effects of Reminders for Outpatient Influenza Immunizations at the Point of Clinical Opportunity,” *Journal of the American Medical Informatics Association*, 6 (1999)

²³ Tierney WM, Miller ME, Overhage JM, McDonald CJ. Physician Inpatient Order Writing On Microcomputer Workstations: Effects On Resource Utilization, *JAMA*, 1993, 269:379-83.

²⁴ The Lewin Group, Inc. and The National Association of Health Data Organizations. Public Health Data Standards Consortium Education Strategy. Appendix D: Rationale For Moving To Data Standards. Draft Report for Distribution at March Meeting Prepared for National Center for Health Statistics. March 2, 2001

- Pharmaceutical companies expect interface costs to drop by 35 percent with the adoption of data standards. Additionally, this will shorten the time needed to complete clinical trials by as much as a year.²⁶

The Role of Demonstration and Implementation Projects

Overview

As highlighted in the IOM Report, "Fostering Rapid Advances in Healthcare: Learning from System Demonstrations," demonstration and implementation projects play a critical role in helping organizations to migrate from our current paper-based, fragmented healthcare system to one that is interconnected, interoperable, and electronic.

The translation of research into practice can be slow. Demonstration and implementation projects both at the national level and within local communities can help accelerate the process of change by identifying barriers and by producing workable, practical solutions to address them.

Existing Demonstration and Implementation Projects

Several demonstration and implementation projects are already in progress, including the work related to the Indianapolis Network for Patient Care, the North Carolina Healthcare Information and Communications Alliance, the New England Health Information Network, the Patient Safety Institute's Washington State project, and the Santa Barbara Care Data Exchange. In addition, as part of Connecting for Health, over 20 organizations representing healthcare providers, centers of clinical excellence, public health agencies, payers, federal agencies, and leading information technology companies have come together to demonstrate the value of an interconnected, electronic health information infrastructure in supporting better health and healthcare through a national demonstration project—the Healthcare Collaborative Network. An overview of the national demonstration project is located in Section V of the report. A detailed summary of community-based demonstration projects is located in Appendix A of this report.

Where Do We Go from Here?

As noted throughout this report, there has been an increasing recognition of the value that interoperable healthcare IT systems can offer to a wide range of healthcare stakeholders to support quality and safety goals. Significant momentum has been building both within the public and private sectors to take the actions that are necessary to move interoperable information technology applications into the hands of those who deliver actual care. While the evidence base related to the value of information technology to address quality, safety,

²⁵ Effler, Paul. Presentation: "Electronic Laboratory Reporting: The State Experience." Electronic Reporting of Laboratory Information for Public Health. Summary of Centers for Disease Control and Prevention Meeting Proceedings. January 7–8, 1999.

²⁶ Klein, James – Gartner Health IT Research and Advisory Service. Interview for Bio-IT World. Nov. 12, 2002.

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and efficiency goals is significant, recent research and anecdotal evidence suggests that this value can only be fully realized if such information technology is made interoperable through the adoption of standards.

Still, more research is needed, and that research, in turn, should be augmented by the launch of “real-world” demonstration and implementation projects on a national and community basis. Such projects would build upon what we already know today, explore alternative solutions to key issues (including privacy and security, leadership, and technical architecture questions) and seek to expand the evidence base related to value of interoperable systems for the entire spectrum of health-care stakeholders.

III. STANDARDS FOR AN INTEROPERABLE HEALTH CARE SYSTEM

The vital importance of information and reporting systems for measuring and improving healthcare safety and quality have been brought to the forefront of health care discussions by reports from the Institute of Medicine and others. These calls to action cannot be answered without the creation and adoption of standards for the coding, sharing, and structuring of clinical information. Until clinical information can be reliably, efficiently and consistently shared and integrated, we will continue to struggle with large gaps in the information needed at the bedside, in the office, in the emergency room, at the local and state public health departments and to report and measure health care outcomes.

The current fragmented state of clinical information mirrors the fragmented nature of our health care system—where care is delivered by a variety of independent physicians and other providers working in a broad spectrum of inpatient and ambulatory settings. Clinical data is collected, used and reported in a piecemeal fashion. Information is often unavailable when needed most. Such a complex system with disparate data collection and usage cannot optimize quality and efficiency without a common framework for integration and communication of data.

Full set of standards needed for interoperability

The Data Standards Working Group at its first meeting established a framework for identifying and assessing the full set of standards required for interoperability. The DSWG identified classes of standards. Within each standard class, the DSWG identified specific standards to be assessed. The assessment of standards was based on three criteria:

- **Balloted/Formalized** – Has the standard undergone the review of a standards development organization?
- **Vendor Acceptance** – Have the major vendors incorporated the standard into their software products?
- **User Acceptance** – Are the purchasers of systems requiring vendors to adopt these standards in what they purchase and implementing the standards in their organizations?

The table below provides an overview of the standards types and the DSWG assessment of their current level of adoption.

STANDARDS ASSESSMENT MATRIX
DATA STANDARDS WORKING GROUP

STANDARD TYPE	BALLOTTED/ FORMALIZED	VENDOR ACCEPTANCE	USER ACCEPTANCE
<i>META-ELEMENTS...</i>			
RIM	Yes	Yes	Yes
Data Types	In process	Yes	Yes
Terminology	Yes/No	Yes/No	Yes/No
LOINC	Yes	Yes	Yes
RXNorm	N/A	Partial	Yes
Data Elements	No	No	No
<i>INDEXING...</i>			
Identifiers	Yes/No	Yes	Yes
Geographical Standards	Yes	No	No
<i>VALIDATION...</i>			
Implementation Guides/Integration Profiles	Yes	Yes	Yes
Conformance Testing	N/A	Varied	Yes
<i>DATA INTERCHANGE...</i>			
Data Interchange	Yes	Yes	Yes
Clinical Documents	Level 1: Yes	Level 1: Yes	Level 1: Yes
Clinical Templates	No	No	No
<i>APPLICATION...</i>			
Business Rules	No	No	Yes, requiring
Decision Support Rules	Yes	beginning	Partial
CCOW	Yes	Yes	Yes
Tool Sets	N/A	Yes	Yes
Clinical Guidelines	No	Some	Some
Disease Registries	No	Limited	Beginning
Terminology Services	Yes	Beginning	Partial
<i>ARCHITECTURE...</i>			
EHR	No	Proprietary	Some
<i>SECURITY...</i>			
Security	Limited	Limited	Limited

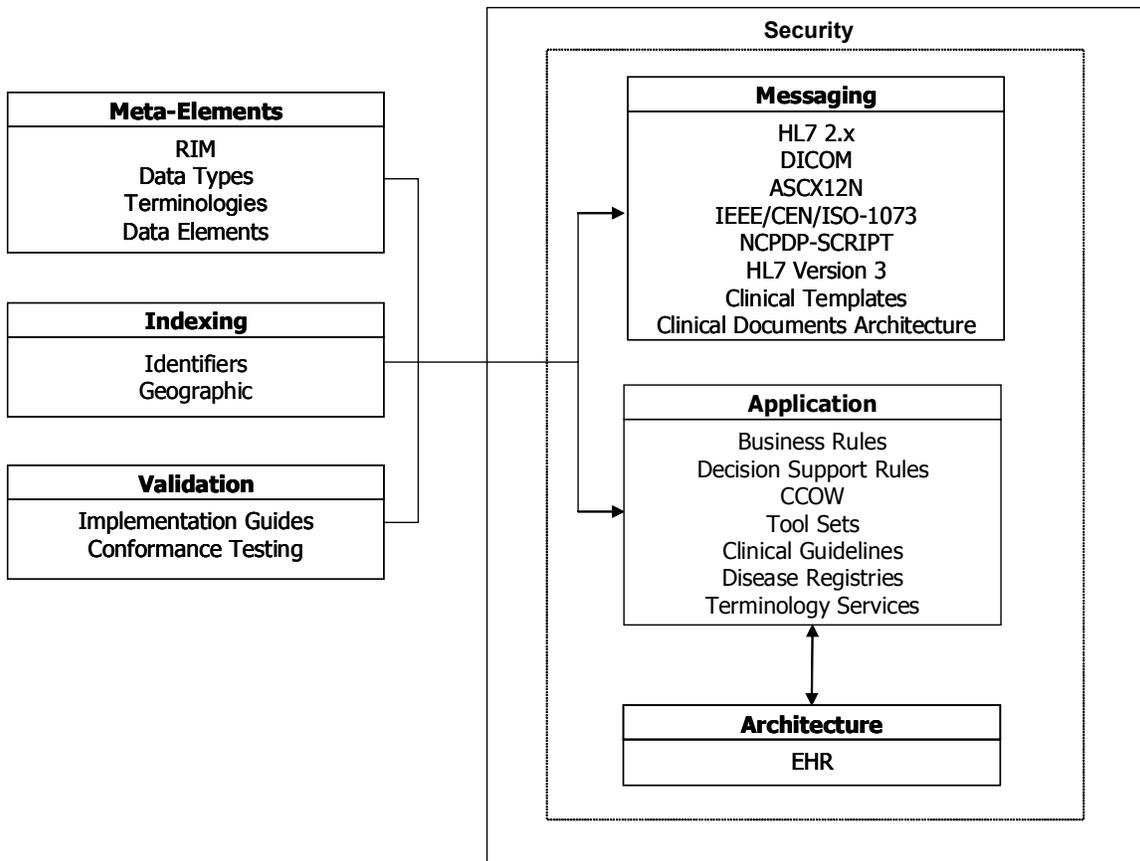
The Data Standards Consensus Committee believes that the set of standards they have identified encompasses the full range of data standards currently known to be needed for an interoperable healthcare system. The level of development within each standards area varies considerably. There are at least the beginning steps toward standardization in all areas. Our recommendations in each specific area indicate what further development is needed.

Overview of Recommendations

The assessments of the standards against the criteria presented above were used to categorize the adoption readiness of each standard. Three levels of assessment were defined and are used to organize the presentation in the sections that follow. The three levels are:

- Adoption ready – These standards are balloted and formalized, incorporated into leading software products, and implemented by a significant number of users
- Emerging – These standards are balloted or formalized. They are beginning to be incorporated into software products and are seeing early adoption among some users.
- Under development – These standards are generally not balloted or formalized. Development of a standard specification has begun, but significant work is needed to develop a standard that vendors and users can adopt and implement. Moving these standards forward will be critical to meeting the full set of requirements for an interconnected health care system.

The recommendations can also be categorized into an overall framework of standards. The graphic below provides an overview of the DSWG recommendations in the context of the area of standardization that they support.



At the center of the model are data interchange and application-related standards. The data interchange standards enable consistent communication between applications within an institution and across user organizations. The application-related standards support consistent and efficient implementation of specifications, enable integration of applications, and provide software components that can be implemented in different applications.

Data interchange and application standards integrate meta-elements and content that are standardized. Meta-elements are consistently defined representations of data that are used across all standards, e.g, the representation of measurements such as temperature. Content standards specify values and representation of data for specific messages or records within an application, e.g, identifiers.

Validation ensures the consistency of implementation of standards across software applications and user implementations.

Architecture and security standards support the integration and control of information generated by the applications. Architecture standards define the structure and distribution of data that is stored in repositories or directly accessed across user organizations. Security standards provide consistent protections to data and enable the sending and receiving system to communicate within a consistent security framework.

Adoption Ready Standards

The DSWG assessment identified a core set of standards that are balloted and formalized, incorporated into leading software products, and implemented by a significant number of users. These standards are considered adoption ready. The following standards are recommended as ready for adoption:

- HL7 Reference Information Model (RIM)
- HL7 Data Types
- HL7 V2.X
- DICOM
- ASCX12
- IEEE/CEN/ISO – 1073
- NCPDP SCRIPT
- CCOW
- CLINICAL DOCUMENT ARCHITECTURE, level 1
- LOINC

An overview of each standard and the rationale for the DSWG recommendation are presented below.

Reference Information Model (RIM)

Recommendation:

- A single standard reference information model should be adopted.
- The HL7 Reference Information Model (RIM) should be endorsed as the single model to support all health care data standards development.

Background and Rationale

In order to establish interoperability, there must be a single foundation upon which all work can build. The foundation is a reference information model. It is absolutely essential that there be only one such model, or chances for interoperability will be significantly diminished.

Ensuring consistency across standards definitions can be a highly resource intensive effort that increases the cost and slows the standards development process. A single standards organization might make the investment to ensure consistency within their standards, but the cost and complexity can be a significant barrier to harmonizing across standards groups. For the end user implementing standards from multiple sources there is an increased cost to reconcile and integrate the differing implicit and explicit models of data.

A broad set of standards are required for interoperability. Many of these standards will be developed by different organizations or even by different groups in the same standards developer organization. For these standards to standards to work together interoperably, there must be a common reference structure – the RIM. We recommend that the HL7 RIM be that model.

“The [Reference Information Model](#) (RIM) is ... (a) an object model created as part of the [HL7] [Version 3](#) methodology, the RIM is a large pictorial representation of the clinical data (domains) and identifies the life cycle of events that a message or groups of related messages will carry. It is a shared model between all the domains and as such is the model from which all domains create their messages”. www.hl7.org

The HL7 RIM is recommended for the following reasons:

- It represents the best model currently available;
- Work has progressed to the point that the model is stable;
- It has been balloted as a formal standards and is presently awaiting ANSI approval
- The HL7 RIM will be submitted to ISO (at TC 215's request) for approval as an ISO standard;
- Current and emerging standards are based on the RIM;
- There is a stable process for updates and maintenance;
- It is the basis for related work in CEN and ISO.

Data Types

Recommendation:

- Standardized data types should be adopted and used consistently in all applications of the corresponding data element.
- The HL7 Version 3 Data Types, e.g., numeric integers, strings, text, dates, names, addresses, coded elements, etc., should be accepted as the standard set of possible data types for how data may be represented.

Background and Rationale

Representation of data such as measurements and time, can vary within a set of “standards compliant” messages. This variation in representation requires users of messages from multiple sources to develop techniques and tools to make map these inconsistent representations. How data is represented in both simple and complex data objects is critical for sharing and understandability. The simple example of how dates are written in the U.S. and in Europe illustrates the confusion. Data written as 05/08/03 would represent May 8th, 2003 in the United States and August 8th, 2003 in Europe. Simple data types include date, time, numbers, integers, strings, text, coded elements, currency, and such. More complex data types include telephone numbers, names and addresses. Data types should be assigned for every data object or element used. Use of standardized data type definitions eliminates these incompatibilities and the need to invest in and maintain tools to map data with non-standard representations.

“Data types are defined for (1) character strings and display data, which accommodates both character based text and multimedia data; (2) codes and identifiers for concepts and instances both of the real world and of technical artifacts; (3) all kinds of quantities including integer and real numbers, physical measurements with units, various kinds of time. Data types are classified (generalized) in various ways with respect to certain properties of interest.” <http://aurora.rg.iupui.edu/~shadow/v3dt/report.html>

The HL7 Data Types are recommended for the following reasons:

- The HL7 Data Types incorporate the broadest range of data type definition;
- They are now being used as the basis for standards development by ISO and European standards organizations;
- The HL7 Data Types are currently accepted by both vendors and users and adoption is underway.

Data Interchange: HL7 V2.X, DICOM, ASCX12N, IEEE/CEN/ISO – 1073, NCPDP - SCRIPT

Recommendation:

- HL7 v2.x (active versions are 2.2, 2.3; current ANSI approved version is V2.4; V2.5 in final ballot)
- DICOM – imaging standard
- ASC X12N – transaction standards
 - X12 837 Claims and Encounter
 - X12 835 Remittance Advice
 - X12 837 Coordination of Benefits
 - X12 276/277 Claim Status
 - X12 834 Health Plan Enrollment
 - X12 270/271 Eligibility for Health Plan
 - X12 820 Health Premium Payments
 - X12 278 Referral and Authorization
- IEEE/CEN/ISO – 1073 series of medical device communication standards

Background and Rationale

Just as people from different countries are able to communicate with each other if they know a common language (even if their native tongues are completely different), computer applications can share information if they speak a common language. However, the health care industry is encumbered by technical terms and jargon all its own--separate from the dialects of the world. Thus, it isn't always possible for people or computers to communicate clinical information to each other just because they speak a common language. In order for people or computers to share clinical data with one another, they must both speak a common language (in terms of grammatical structure, etc.) *and* share the same technical vocabulary that allows them to discuss complex medical conditions and concepts.

<http://www.timesquared.net/HealthCare/HL7/WhatIsHL7.asp>

In order to exchange data interoperably from one organization to another, a data interchange standard is required. Such a standard must define when a message is sent, what the message contains, the syntax of the message, data fields, standardized data elements with defined data types, terminologies used, and acknowledgement rules. When the message is activated by a set of trigger events the message contents varies with the trigger event.

A number of standards are sufficiently developed and tested to merit consideration for widespread adoption. The rate of implementation of the standards is slow. One factor limiting full adoption is uncertainty about whether one standard or another will be accepted by vendors and parties receiving data. The endorsement of these mature standards will ensure system developers and implementers that their investment in a specific standard will have long run returns.

HL7 is a standard for the electronic interchange of clinical data and associated financial and administrative data within and between health care institutions.... Health Level Seven is one of several ANSI-accredited Standards Developing Organizations (SDOs) operating in the

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healthcare arena.... Health Level Seven's domain is clinical and administrative data. <http://www.hl7.org/> The Health Level Seven (HL7) protocol was developed to address (the) need for data sharing among medical applications. It is a computer communication "language" that allows clinical applications to communicate essential information about patients' demographic information, medical history, financial information, and any diagnoses and/or procedures that they may have received at a given facility.

The requirements for transmission of diagnostic images and their associated annotations cannot be fully met by the current HL7 CDA standard. "With the introduction of computed tomography (CT) followed by other digital diagnostic imaging modalities in the 1970's and the increasing use of computers in clinical applications, the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) recognized the emerging need for a standard method for transferring images and associated annotations between devices manufactured by various vendors. These devices produce a variety of digital image formats....

The DICOM Standard facilitates interoperability of medical imaging equipment by specifying:

- A set of protocols to be followed by devices claiming conformance to the Standard
- The syntax and semantics of the Commands and associated information which can be exchange using these protocols
- Information that must be supplied with an implementation for which conformance to the Standard."

DICOM version 3.0 incorporates "a number of major enhancements to previous versions of the Standard:

- It is applicable in a networked environment....
- It specifies how devices claiming conformance to the Standard react to commands and data being exchanged....
- It specifies levels of conformance....
- It introduces explicit Information Objects....
- It specifies an established technique for uniquely identifying any information Object."
<http://medical.nema.org/dicom/2001.html>

DICOM is the predominant standard for transmitting radiologic images. DICOM Version 3.0 is the current standard. Updates of the DICOM V3 standard occur at yearly intervals. Although DICOM is widely used in health care, it is an industry consortium and not an ANSI-approved standards organization. DICOM has, however, realized world-wide acceptance and it is the standard of use by all manufacturers of imaging and picture devices and PACs systems. The main DICOM data structure has 4 levels: the patient, the study, the series, and the image. ...DICOM defines attributes for delivering all of the details about the capture of each image, as well as delivering the image itself in electronic form. ¹

The Accredited Standards Committee (ASC) X12 develops standards for cross-industry electronic exchange of business information. The committee X12N has the responsibility for developing business standards for health care. HIPAA legislation mandates the use of X12N standards for claims and business-related transactions.

The IEEE committee 1073 is the world dominant developer of medical device standards. Much of this work is done in cooperation with the European Standards body CEN and the ISO Technical Committee 215 – Health Information. IEEE has approximately 35 medical device standards at some process of development.

The National Council of Prescription Drug Programs (NCPDP) message standard is used by virtually every community pharmacy in the United States. It is the transaction standard for prescription drug reimbursement. This standard was developed by the NCPDP, another ANSI-approved standards development organization. This standard was originally developed to facilitate uniform communication between pharmacies and pharmacy benefits systems. The NCPDP messages are also being used for other purposes, such as, prescription writing and refill requests. The NCPDP message structure has a syntax similar to that of HL7 and X12.¹ The use of this standard is also required by HIPAA for prescription drug reimbursement.

The recommendation for adoption of these standards is based on the following factors:

- The National Committee for Vital and Health Statistics (NCVHS) after extensive hearings and study have recommended these standards for early adoption;
- These standards have been vetted through a formal balloting process within a recognized Standards Development Organization (SDO);
- The vendor community has demonstrated acceptance of these standards by incorporating them into their applications;
- Adoption of these standards will represent a significant advance toward implementation of an Electronic Health Record.

CCOW

Recommendation:

- A standard for Clinical Context Management Specification should be adopted.
- The HL7 Clinical Context Management Specification (CCOW) should be accepted as the standard for context management, enabling a variety of standards-based application integration capabilities including those generally known as single sign on and single patient selection.

Background and Rationale

Caregivers who use computers to facilitate the care delivery process are generally confronted with the need to use different applications to perform different tasks. This is because no one application encompasses all of the functionality needed to support the diverse and complex needs of healthcare. Instead, applications are often specialized and optimized for tasks such as scheduling patients, ordering medications, reviewing lab test results, and examining physiological images. These applications may be sourced by different vendors and/or may have been developed using different technologies.

Although the combination of applications can provide a powerful electronic environment for affecting the healthcare delivery process, there are fundamental obstacles to the safe and

¹ Data Standards in Health Care. Clement J. McDonald et al. Annals of Emergency Medicine. Vol. 38 September 2001. pgs. 303-311.

secure use of such applications in the aggregate. These obstacles include the need for the caregiver to sign on to each application one at a time, often with a different name and password. This situation incites myriad of security issues, for example the sharing of names and passwords among users to avoid the need to sign on in the first place. Further, once signed on, the need for the caregiver to select the same patient within each application introduces a myriad of patient safety issues due to the risk of not necessarily having the same patient in all of the applications. Similar risks are represented from other types of discordance between the user's intent and the actual state of the collection of applications being used.

"Aimed at facilitating the integration of applications at the point of use, CCOW is an end-user-focused standard that complements HL7's traditional emphasis on data interchange and enterprise workflow. Using a technique known as context management, the clinical user's experience is one of interacting with a single system, when in fact he or she may be using multiple, independent applications from many different systems, each via its native user interface.

Specifically, the Context Management Standard defines a protocol for securely "linking" applications so that they "tune" to the same context. The context is represented as a set of subjects, each of which generally identifies a real-world entity such as a patient or a real-world concept such as an encounter. By synchronizing and coordinating applications so that they automatically follow the user's context, the CCOW Standard serves as the basis for ensuring secure and consistent access to patient information from heterogeneous sources. The benefits include applications that are easier to use, increased utilization of electronically available information, and an increase in patient safety. Further, CCOW support for secure context management provides a healthcare standards basis for addressing HIPAA requirements. For example, CCOW enables the deployment of highly secure single sign-on solutions

The CCOW architecture was designed to be easily implemented within all types of health care applications and using a variety of technologies. As a technology-neutral standard, CCOW enables the creation of compliant applications in a wide array of technologies and architectures, ranging from green-screen to client-server to web. Particular emphasis was given to ensuring that CCOW compliance could be easily retrofitted into existing applications. It is not necessary for an application developer to implement a context manager or mapping agents, the core components that coordinate CCOW-compliant applications in a system, as these components are external to the application can be obtained from other sources.²⁷

All of the major HIS vendors are now shipping or planning on shipping both Windows- and Web-based CCOW-compliant applications, while vendors in virtually every segment of the clinical healthcare market have adopted the standard as well. VHA Inc.—a nationwide network of 1,900 leading community-owned healthcare organizations and their affiliated institutions—now requires all of its new business partners to be CCOW-compliant. A growing number of healthcare organizations are also implementing context management solutions to

²⁷ Overview of HL7's CCOW Standard, Robert Seliger, Co-Chair, CCOW Technical Committee

link together diverse multi-vendor, multi-technology IT systems on an enterprise-wide basis....

LOINC

Recommendation:

- LOINC should be endorsed for adoption as the vocabulary for the names of laboratory tests.

Background and Rationale

Currently, most laboratories and other diagnostic services use HL7 to send their results electronically from their reporting systems to their care systems. However, most laboratories and other diagnostic care services identify tests in these messages by means of their internal and idiosyncratic code values. Thus, the care system cannot fully "understand" and properly file the results they receive unless they either adopt the producer's laboratory codes (which is impossible if they receive results from multiple sources), or invest in the work to map each result producer's code system to their internal code system.

<http://www.regenstrief.org/loinc/>

"The purpose of the LOINC database is to facilitate the exchange and pooling of results, such as blood hemoglobin, serum potassium, or vital signs, for clinical care, outcomes management, and research.... LOINC codes are universal identifiers for laboratory and other clinical observations that solve this problem.

The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts you would find reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. "

<http://www.regenstrief.org/loinc/>

LOINC is recommended for the following reasons:

- The majority of large commercial clinical laboratories currently implement LOINC.
- Federal funding supports development and maintenance of this vocabulary thereby ensuring that it will remain current and will be available at no cost to.
- LOINC is endorsed by the Federal Government's Consolidate Health Informatics (CHI) initiative

Emerging standards

Emerging standards are sufficiently specified and tested to be considered ready for incorporation into software applications. Users of these standards can be considered early adopters. Moving these standards into the mainstream will advance interoperability. The following standards are recommended for adoption:

- HL7 Version 3

- VA NDF RT, RxNorm, Daily Med
- Clinical Documents
- Implementation Guides/Integration Profiles
- Terminology Services

Data Interchange: HL7 Version 3

Recommendation:

- HL7v3 for clinical data interchange should be recommended as an emerging standard for data interchange. Early adoption by vendors should be encouraged.

Background and Rationale

The HL7 "V2.x series of messages were widely implemented and very successful. These messages evolved over several years using a "bottom-up" approach that has addressed individual needs through an evolving ad-hoc methodology. There is neither a consistent view of that data that HL7 moves nor that data's relationship to other data. HL7's [V2's] success is also largely attributable to its flexibility. It contains many optional data elements and data segments, making it adaptable to almost any site. While providing great flexibility, its optionality also makes it impossible to have reliable conformance tests of any vendor's implementation and also forces implementers to spend more time analyzing and planning their interfaces to ensure that both parties are using the same optional features."

HL7 Version 3 uses "a well-defined methodology based on a reference information (i.e., data) model.... Using rigorous analytic and message building techniques and incorporating more trigger events and message formats with very little optionality, HL7's primary goal for Version 3 is to offer a standard that is definite and testable, and provides the ability to certify vendors' conformance." www.HL7.org

HL7 Version 3...incorporates both an object-oriented high level model, a standardized process for message development (HL7 Message Development Framework) and deep and extensible medical information structures and enables strict conformance testing for optimal interoperability....HL7 Version 3 messages will use Extensible Markup Language (XML) as their syntax. XML is a universal format for representing structured documents and data on the Internet. Many free and commercially supported tools are available for manipulating XML-structured information.²

Early adoption focuses on migrating to a new standard by incorporating the standard into new application development and the definition of a migration path for existing applications. Vendors are the key drivers of early adoption. Some examples of early HL 7 Version 3 adoption are the UK's GP2GP project and Japan's diabetes project and the CDC's use of V3 for its public health surveillance messages.

HL7v3 is currently in its third round of committee balloting. It is expected to become an approved standard during 2003. V3 supports the following transaction sets:

- Administration Management

² Data Standards in Health Care. Clement J. McDonald et al. Annals of Emergency Medicine. Vol. 38 September 2001. pgs. 303-311.

- Health and Clinical management
- Infrastructure Management

RxNorm, DailyMed, VA NDF RT

Recommendation:

- The RXNORM/Daily Med/VA NDF RT drug terminology set should be recommended for early adoption.

Background and Rationale

There is significant inconsistency in drug nomenclature, including: naming, specification of routes, forms, administration route and device, and anatomy. A single drug may have many different and incompatible representations across information systems. Historically there has not been a single vocabulary that could enable efficient communication of drug information across applications. The representation of drugs in a vocabulary designed to support one application may not have all the information or be defined in a way that meets the needs of another application, e.g., drug dispensing vocabularies may not meet the requirements of the FDA. These differences are so great that attempts to automate cross matching across vocabularies have been unsuccessful.

NLM, FDA, and the VA have collaborated in the development of RxNorm and Daily Med. The VA's NDF RT is an important source of the drug terminology for this process. "(T)here was hope that developing a new method might lead to improved interoperability of drug terminology; the area of clinical drugs was seen as important in the growing issues of patient safety; and there was a growing consensus in the HL7 vocabulary technical committee of what a model for clinical drugs should be. The HL7 model was based on what a clinician might order, and what type of order might be sent to the pharmacy. The dose form would be the form in which a drug was administered to a patient, as opposed to the form in which the manufacturer had supplied it. It was clearly distinct from the choices the pharmacy might make in fulfilling that order. This project has become known as the RxNorm project.

RXNORM/Daily Med is recommended for the following reasons:

- The Veterans Health Administration, FDA, and NLM have developed DNF RT/RXNORM/Daily Med terminology collaboratively;
- The terminology used in RXNORM/Daily Med has been created in cooperation with most of the key stakeholders;
- VA and FDA involvement ensures that the terminology will be comprehensive;
- Drug knowledge bases are compatible with this standard;
- US Pharmacopeia is considering adopting this as their standard for drug terminology;
- HL7 elements for route and form are being incorporated;
- This terminology is being harmonized to the extent possible with the British National Formulary.
- HL7 and others have recommended that the health care industry adopt RXNORM for drug terminology

Clinical Documents

Recommendation:

- The HL7 Clinical Document Architecture (CDA), Release 1 and its continued evolution should be accepted as the format for clinical documents other than digital images.
- DICOM structured reports should be accepted as the standard for annotations associated with the transmission of digital images

Background and Rationale

Much important clinical information resides in unstructured clinical notes. Existing standards mandate structures and vocabularies that cannot be readily applied to the unstructured text in clinical notes. A standard adapted to this type of textual information would enable sharing of clinical notes across applications.

"The CDA provides an exchange model for clinical documents (such as discharge summaries and progress notes)—.... The CDA Standard" is an ANSI approved standard. "www.hl7.org

The CDA document is a defined and complete information object that can include text, images, sounds, and other multimedia content. The CDA provides a simple set of tags for the narrative documents with rich document metadata based on the HL7 RIM. The CDA specifications include the characteristics of persistence, stewardship, authentication, wholeness, and human readability.

The HL7 Clinical Document Architecture is in a transition period. CDA, Release One became an ANSI-approved HL7 Standard in November 2000, representing the first specification derived from the HL7 Reference Information Model (RIM). Since then, the RIM has matured, as has the methodology used to derive RIM-based specifications. In addition, early adopters are posing new use cases for incorporation.

DICOM structured reports are used to pass the parameters of the image creations as well as associated annotations. HL7 CDA does not provide for this structure. DICOM and HL7 are working together to harmonize naming and registration of these documents, and the DICOM Structured Reports may be contained in a CDA document. We recommend the appropriate use of both the HL7 CDA and the DICOM Structured Reports.

The HL7 CDA is recommended for the following reasons:

- The CDA, Release 1 is already in the broadest use;
- The FDA has proposed the HL7 CDA as the standard for drug labeling.

The DICOM Structured Reports standard is recommended for the following reasons:

- It is the most widely used standard for parameters and annotations to images
- Efforts are underway to ensure that the DICOM standard is compatible with other standards recommended by the DSWG.

Implementation Guides/Integration Profiles

Recommendation:

- The definition of a coordinated set of HealthCare Integration Profiles addressing the most common needs of interoperable relationship between healthcare information systems is a critical step in the practical deployment of standards.
- The Integrating the Healthcare Enterprise (IHE) Integration profiles process definition and organization should be used as the foundation for this process with a broader involvement from all stakeholders.
- An Integration Profile should address or take into account all of the issues relevant to its business integration need. These include:
 - Explicit reference to stable standards
 - Selection of options in the referenced standards
 - Extension to data content
 - Restrictions to data format (syntax) and coding
 - Communications approach
 - Relationship between standards within the profile (e.g. data model links).
 - Security Approach or links to security related Integration Profiles
 - Handling for errors
 - Minimal conformance requirements and explicit Options if any.
 - Impact on business and legal issues (e.g., operational responsibilities)
- Integration profiles should be publicly available from a repository at little or no cost.

Background and Rationale

In driving the use of standards, three level of specification appear necessary to create an interoperable relationship between a set of healthcare information systems that need to cooperate. They are:

- **Standard.** Any specific healthcare or general purpose IT standard, or part of standard that address a well-defined scope. Such standards are designed to provide enough flexibility to be used in a broad range of business situations within the standard's scope. Standards or any legitimate subset generally include the rules that an implementation shall follow to claim its support (called in a variety of ways: standards conformance statement, standard conformance profile, etc.).
- **Integration Profile** – Also called implementation guide (e.g. in the HIPAA context). This level of specification is focused on a specific business use or integration problem. An integration profile generally relies upon **a set** of standards or proper subsets of it. A Integration Profiles specifies **a choice of options** applicable to the specific business use intended as well defines the **dependencies** between the standards used. Integration profiles provide users and vendors with a specification for a near-plug and play solution to a specific integration problem. Statements of Conformance should be explicit.
- **Companion Guide** -- interprets the integration profile for a specific trading partner (either a users RFP or a vendor product specification). It may extend and/or restrict an Integration Profile for example to address some trading partner legacy issues.

There is no general consensus on the names for these documents, but the need for all three levels always seems to exist. This recommendation is focused on the second level in this recommendation that we propose to call Integration Profiles.

IHE has already defined 11 Integration Profiles and has had industry endorsement of these profiles. IHE has experience in the definition of Integration Profiles in a collaborative manner between provider associations and vendors, including the adoption by large numbers of vendors, the testing of implementations (tools and connections), encouraging deployment in provider organizations and actual operational use. This model has proven successful not only in the USA but also in several European and Asian countries.

Terminology Services

Recommendation:

- Standardized terminology service tools should be developed and adopted

Background and Rationale

Standardization of terminology services will enable health care applications to use an interface application to identify, access, and use disparate terminologies. Terminology service tools address the inconsistency and terminology data structures where they exist. The API specification focuses on the functions that the terminology must provide, e.g., determining if a code is valid.

Standard functions that would need to be supported by a terminology services API would enable user applications to:

- Interact with terminologies that reside in different locations
- Determine if the terminology is complete, up-to-date, and authoritative
- Assess whether a specific terminology source has the information needed
- Display or validate the textual meaning of a term based on codes or textual searches
- Apply restrictions to a term search
- Validate values for terminology codes
- Map codes from one code set to another²⁸

Standards under Development

The DSWG identified a group of standards that are required for an interoperable health care system but have not evolved far enough to be recommended for adoption. Many of these areas address the more challenging areas of health care automation, such as, a consistent standard framework for the development, storage and sharing of clinical guidelines. The development and adoption of standards in some of these areas will be critical to advancing the types of automation that can improve the quality of care. Other standards in this group are central to establishing and sustaining consistency in the adoption and implementation of

²⁸ HL7 Common Terminology Services Version 0.8: Draft in Development, November 26, 2002

standards. The recommendations in this section focus on what is needed for the current work in each area to advance to the level of formalization that they can be adopted by software vendors and implemented by system users. The areas identified by the DSWG as having standards under development are:

- Terminology
- Clinical guidelines
- Clinical templates
- Representation of business rules
- Representation of decision support rules
- Tool sets
- Identifiers
- Security
- Disease registries
- Data elements
- Electronic health record

Terminology: General

Recommendations:

- Health care terminology must address the following key requirements:
 - Be integrated into a single reference terminology set
 - Have a set of common characteristics across all terminology domains
 - Be supported by an overall health care information model
 - Provide value to all stakeholders
 - Address health status, health care, and populations
- The process for development, maintenance, and implementation of health care terminologies should have the following characteristics:
 - Have an open development process that represents the needs of all stakeholders
 - Be implemented consistently across all health care entities
 - Have clearly defined functions, roles, and responsibilities
 - Be uniformly distributed by an appropriate Federal agency, such as NLM through its UMLS
- The process for integrating terminologies should have the following characteristics:
 - Is independent of vested interests, representative of all stakeholders, and is empowered to take action
 - Harmonizes terminologies to eliminate overlaps, redundancies, and inconsistencies
 - Eliminates over time the need for mapping among terminologies
 - Specifies domain boundaries and identifies linkages across domains
 - The details for how this gets done and who will be responsible requires extensive discussion and agreement among all stakeholders

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- Demonstration projects should be undertaken to determine how to optimize the development and implementation of integrated health care terminology

Clinical Guidelines

Recommendation:

- Support the current efforts of the HL7 Clinical Decision Support Technical Committee and Clinical Guidelines Special Interest Group in developing standard approaches to (a) a common data model, (b) terminology management model, (c) a formalism for queries and expressions, (d) a formal method for describing process flow/work flow, and (e) a taxonomy of services or actions that can be invoked by steps within a clinical guideline.
- Priority should be given to the development of a common data model, terminology model, and formalism for queries and expressions.
- Demonstrations and proofs of concept for all elements of clinical guidelines should be undertaken. These demonstrations should incorporate clinical guideline components should be into existing operational environments and new ones that deliver guidelines at the point of care. The research should address how operational variations impact the variation in the implementation of the guideline.
- Vendors and users should share their experiences in the development, automation, and implementation of clinical guidelines.
- Specialty societies should be encouraged to contribute content to a common library of clinical guidelines that can be shared by clinicians, researchers, and system developers.

Background and Rationale

Clinical Guideline knowledge exists in diverse forms that do not lend themselves readily to computer-based implementation, despite major efforts by professional specialty organizations and other entities to create high quality, evidence-based guidelines. A number of models for computer-based representation have been developed by various research teams (e.g., Prodigy, Proforma, EON, Asbru, GUIDE, GLIF). Convergence on a single model is hampered by the differing purposes of the developers, which have resulted in differing functional requirements and features of the various models.

In 2001, HL7 established a Clinical Guideline Special Interest Group (CG SIG), under the Clinical Decision Support Technical Committee (CDS TC), in order to promote standardization. The work of the CDS TC and the CG SIG has recognized the lack of convergence of functional requirements, and has determined that the most effective activities would be to focus on components of clinical guidelines that are common to or needed by all models. These include: (a) a common data model, (b) terminology management model, (c) a formalism for queries and expressions, (d) a formal method for describing process flow/work flow, and (e) a taxonomy of services or actions that can be invoked by steps within a clinical guideline.

The outcome should be convergence on a standard representation for encoding the logic and process flow of clinical guidelines (CGs) that is unambiguous, and logically consistent. The goal is to foster the authoring of clinical guideline knowledge in a manner that can be disseminated and shared, and that can lend itself to implementation.

The convergence on a standard representation for clinical guidelines will need to await convergence on the components discussed above. The common data model, terminology model, and formalism for queries and expressions are common to most decision support, including alerts and reminders as well as multi-step guidelines, and are critical to platform-independent specification, hence they are given priority.

Clinical Templates

Recommendation:

- The HL7 development of the formal expression of templates should be supported.
- The formalization of the constraint specification process for clinical templates should be consistent with that used in decision rules and clinical guidelines.
- Resources and mechanisms should be put in place for the development and maintenance of clinical templates.
- Grant funding should be directed to projects that will test the implementation of clinical templates.
- The content of clinical templates should be standardized.
- Tools should be developed for the creation and maintenance of clinical templates.
- Open source libraries of clinical templates should be established and maintained

Background and Rationale

Many clinical systems applications use collections of items in various documents, forms, and menus. Because of their importance and ubiquity, sharing of them would provide efficiencies and support the adoption of consistent patient care practices.

Templates are groupings of related items that occur frequently, and that can thus be used as building blocks for groupings items such as, order sets, clinical form development, and other purposes. Formal definition of templates must refer to clinical terminology and be able to be mapped to clinical data elements or to knowledge base elements. Constraints on template elements must be defined in terms of rules, so as to provide context specific adaptation of templates, as well as context-specific selection of them for particular clinical circumstances.

HL7 has sought to define a process for specifying templates, through the HL7 Templates Special Interest Group.

The Template definition process in HL7 is the only organized effort to address this issue of which we are aware.

Business Rules

Recommendation:

- A standard format should be created for defining and representing business rules. The format should facilitate consistent automation of business rules across software applications.
- The standardized business rules should facilitate the exchange of rules across business partners.
- Rules for reimbursement should be defined in a machine readable format so that they can be implemented and updated in a standardized way across applications. This would also facilitate the auditing of rules for consistency.

Problem We Are Trying To Solve:

The task of interpreting the rules into a logical form that can be computerized is daunting at best and impossible at worst. Staying up to date is difficult and expensive. Different interpretations of a single rule make automation very difficult and may limit the realization of benefits that can result for consistency across settings and applications.

An example of the problems in the current implementation of business rules can be seen in the methods that are applied to communicate and implement CMS' reimbursement rules. CMS currently defines rules under which certain tests may be reimbursed for Medicare and Medicaid. At the present time, these rules are presented in narrative form and are sometimes ambiguous and inconsistent with other rules. The problem is further compounded when humans who implement these rules in computer systems interpret the same rule differently. Health care organizations may be dealing with more than one fiscal intermediary, and each may have a different interpretation of the same rule.

Most early systems and many that exist today have business rules programmed directly into the application code. As a result, changes in those business rules are difficult to make and costly to maintain. Furthermore, when the programmer who wrote the code moves to other jobs and projects, it is difficult for new staff to find the hard-coded business logic.

Tools and methods now exist for the specification and automation of business rules. The actual representation of business rules in health care is not yet standardized.

A standardized representation of business rules would enable system developers to consistently implement a rule across applications. This would ensure that a single rule is applied consistently regardless of the system in which it is implemented.

Decision Support Rules

Recommendation:

- The structure of decision support rules should be standardized.

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- A taxonomy of actions that represent the *then* portion of an *if... then* decision support rule should be defined. These should map to application services that are provided by most clinical information systems.
- Activities in the following areas should be supported because they are integral to the adoption and implementation of decision support rules:
 - Definition of a common formal query and expression language for specifying the conditional components of decision support rules
 - Development of a common integrated data and terminology model
- These activities should be coordinated with standards development for clinical guidelines, template specification, alerts/reminders, and other applications.
- The HL7 discussions and creation of standards in these areas should be supported.
- Content libraries of decision support rules should be created. Open source efforts, consortia, and other approaches should be encouraged.
- Demonstration projects to develop authoring and implementation tools for decision support rules should be funded.

Background and Rationale

Decision support applications represent medical knowledge in application specific forms. Medical knowledge and decision rules cannot be readily shared and replicated across applications. The cost of automating the same rule is duplicated in each application. It is also likely that the same algorithm would be applied inconsistently across applications leading to variations in care rather than consistency in care.

Decision support rules (DSRs) are single-step expressions that describe the logical conditions governing specific actions. Decision support rules are needed in a variety of settings. They may occur as alerts or reminders, in which case they are triggered by an event, and execute as background or asynchronous activities. Decision support rules may alternatively be part of multi-step guidelines, the implementation of which may vary depending on how the guidelines are incorporated into applications. Alternatively, they may represent logic that is applied synchronously, as part of the process flow of an application, for example, to evaluate inputs from interactive data entry. Or they may operate at a meta-level in an application, for example, governing the instantiation of templates specifying elements on lists, menus, or forms (e.g., interactive history forms, order set lists). Decision support rules have features in common with business rules.

The aim is to develop a formal representation for decision support rules that is system/platform independent, yet readily implemented in systems. This is intended to foster sharing of high-quality, evidence-based rules for decision support. Any solution should also recognize the fact that such rules will both require local adaptation and frequently need to be updated, so processes for accomplishing these tasks are required.

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Decision rules represent high-payoff opportunities to demonstrate the usefulness of Electronic Medical Records and clinical information systems. Rules can have direct impact on patient safety, health care quality, and efficiency. As such, a focus on this activity is considered to be high priority.

Tool Sets

Recommendation:

- Development of tools should remain decentralized.
- An agency or organization should be designated and funded to identify and publish the availability of tools sets.
- Standard specifications should be developed for each tool type.

Background and Rationale

Activities that are repetitive and that require many different people to perform can be considerably streamlined through the use of specific tools to enable the process. Examples of tools include:

- A tool to simplify the process of defining and documenting a use case. Increasingly, as the HL7 interface standard is finding new uses for the transferring and sharing of data, new use cases need to be defined as the starting point for the creation of messages to support the data interchange. HL7 has developed a crude VISIO-based tool, but additional work needs to be done.
- A tool set that permits the submission of terms (for a terminology set) for approval and inclusion in a controlled terminology. HL7 has a number of vocabulary facilitators who take terminology requirements from a number of Technical Committees representing a number of clinical domains and submit the terms for both harmonization and exclusion in the terminology set. Without an appropriate tool, this process becomes long and tedious and prone to errors.
- Tools that simplify the actual creation of messages, using the HL7 message development framework.
- Tools that support the authoring of clinical guidelines, decision support rules, and business rule using a tool kit.

These are only a few of the tools required to speed up to process of creating and populating the health data standards.

Identifiers

Recommendation:

- DHHS should move forward to adopt and promulgate standard identifiers for providers and plans.
- Perhaps the most challenging problem faced in clinical data exchange is matching patient data across organizations. Because a consistent health identifier isn't available

today approaches that rely on statistical matching (either deterministic or probabilistic) are the mainstay. We believe more work needs to be done in this area so that a reliable, consistent method is available to link information.

Background and Rationale

The identification of providers, places, facilities and health plans is an expensive and error prone task in the absence of standard identifiers. Names cannot act as identifiers because of the inconsistency in their use. – sometimes full names, sometimes with suffix, some times first name and others middle name, initials, combination initials and names, and nicknames. Computers and humans are often confused and either cannot match names or match incorrectly. HIPAA recognized the cost and risk of errors in having no identifiers and recommended HHS create or defined the appropriate set of identifiers. We recommend that identifiers for ALL health care providers and plans be created as quickly as possible along with funding for distribution, support and maintenance.

Security

Recommendation:

- Additional work is needed to address standardization of security in healthcare; The following areas should be addressed:
 - Public Key Infrastructure (PKI)
 - Digital signature
 - Encoding algorithms
 - Firewalls
 - Remote communications
 - E-mail security
 - Certificate of authority

Background and Rationale

The proposed HIPAA Security Standard states "Comprehensive adoption of security standards in health care, not piecemeal implementation, is advocated to provide security to data that is exchanged between health care entities." Specifically, communications within a system or between systems must satisfy requirements of a general system security framework (Identification and Authentication; Authorization and Access Control; Accountability; Integrity and Availability; Security of Communication; and Security Administration.) in order to be essentially secure. Further, such security standards should be technology neutral and scalable.

HIPAA identified four categories of security:

- Administrative procedures— documented, formal practices to manage the selection and execution of security measures to protect data and the conduct of personnel in relation to the protection of data.
- Physical safeguards -- the protection of physical computer systems and related buildings and equipment from fire and other natural and environmental hazards, as well as from intrusion. Physical safeguards also cover the use of locks, keys, and administrative measures used to control access to computer systems and facilities.

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- Technical security – the processes that are put in place to protect and to control and monitor information access.
- Technical security mechanisms—the processes that are put in place to prevent unauthorized access to data that is transmitted over a communications network.

Most of the standards required for security are being worked on by groups not specific to health care. The creation of security standards is further complicated by the existence of many alternatives. There has been activity on the part of health-related groups, including ASTM, ISO TC 215, and HL7, to move toward recommendations on security standards. However, few decisions have been made at the present time.

Connecting for Health will monitor these activities and, after discussion by all affected stakeholders, will make recommendations for specific standards when there is more than one option. These recommendations should include when and how these standards should be used.

Disease Registries

Recommendation:

- Existing disease registries should be integrated and harmonized within and across diseases.
- A repository of disease registries with the selection criteria, the data items, and the quality indicators should be developed.
- The registry specifications should be available at little or no charge.
- A responsible organization should be designated to maintain the repository of disease registries and promote their use.
- Public health reporting requirements should be included in the repository of disease registries.
- Additional disease registries should be developed to fill gaps identified by the Institute of Medicine

Background and Rationale

There is a growing interest in the use of disease registries for risk management, quality improvement and public health reporting. The specification and automation of current disease registries is not currently coordinated. This leads to duplication of effort and inconsistencies in the measurement of disease incidence, patterns of care, and outcomes.

Disease registries have evolved to support a variety of functions: public health reporting, quality measurement, and risk management. Many of these registries rely on manual reporting or stand alone applications that require duplicate data entry. There are no integrated and coordinated efforts to standardize the specification and implementation of

disease registries. The absence of a standard representation of registry requirements and a central resource to access these requirements limits the integration of disease registry requirements into clinical health care applications.

Current legislation requires healthcare practitioners to report certain conditions and diagnosis to public health. These include both infectious and chronic diseases. Much of this reporting is done by manual review of healthcare records to identify those patients that have conditions that are reportable, or by laboratories that are given specific guidelines for tests and test results that are reportable. When the condition is determined to be reportable the report is then prepared for delivery to public health. Delivery of the report is generally done by fax, mail, phone call or electronic transfer. The public health reporting systems are generally add-on systems that need to be customized for individual reporting jurisdictions. There is growing automation of public health reporting, but there is no single reference point for obtaining specifications of the reporting requirements in support of automation.

A central repository of disease registry specifications will lead to standardization across registries and facilitate the incorporation of these requirements into clinical information systems.

By including public health reporting requirements in the design of disease registries the ability to include the information necessary for public health can be built in on the front end and not added in on the back end. This would help to decrease the lag in reporting of conditions to public health in a time when healthcare organization and clinician resources to perform this type of reporting is at a premium.

Data Elements

Recommendation:

- A super set of data elements should be created. This set would encompass every data item to be used in any health care application including clinical care, research, public health, reimbursement, education, surveillance, evaluation or administration.
- The super set of data elements should comply with the international standard ISO/IEC 11179-1: Information Technology – Specification and Standardization of Data Elements.
- Funding should be made available to support the creation, maintenance and disseminations of the super set of data elements.
- The standardization of data elements should be coordinated with the development of standardized terminology sets, data types, messaging, clinical document architecture, clinical templates, and the HL7 RIM.

Background and Rationale

One of the most consistent problems in attempting to create a single composite database aggregating data from multiple clinics, offices or hospitals, is that organizations do not collect the same data and they do not call the data they do collect by the same names. Data often have different values sets or different codes. A common solution is to create a minimum

data set for a specific business requirement. There are defined data sets for nursing, emergency departments, public health applications including immunizations, and for managing certain business applications. An institution might participate in multiple business agreements, resulting in the use of multiple, different data sets. The apparent "same" data element might be named or described differently in the various data sets. Maintaining multiple data sets is expensive, in addition to the maintenance cost, time and effort must be invested to create and maintain each different minimum data set.

In the area of public health reporting and research, often public health is not at the table when requirements are being defined. As a result public health shows up asking for data elements after systems have been developed, and often with extremely short "ramp up" time frames. This often requires that "special" interfaces be written to meet public health requirements. These interfaces are generally expensive and require additional maintenance of cross walk tables for coding data elements. This can be further complicated by different public health jurisdictions specifying different data element definitions.

"Humans are aware of anything that exists in the natural world through its properties. Data represents the properties of these things. Specification of data elements, the basic units of data, involves documenting relevant characteristics of each data element to ensure its representation of the natural world item is consistent and accurate. Data that has been carefully specified and standardized greatly enhances its usefulness and share-ability across systems and environments. Sharing data involves the ability to locate desired data, retrieve the data, and to exchange the data with others. When data elements are well documented according to ISO/IEC 11179 and the documentation is managed in a Data Element Registry, finding and retrieving them from disparate databases as well as sending and receiving them via electronic communications are made easier." (Final Draft International Standard: ISO/IEC 11179-1 Specification and standardization of data elements - Part 1: Framework)

Standardization of data elements will provide the following benefits:

- Users will have a common understanding of data
- System developers will be able to reuse data element specifications across applications
- Data can be moved and shared across applications

Geographic Standards

Recommendation:

- All healthcare transactions should adopt standardized geographical codes as published by the various Federal agencies charged with the responsibility to formulate and promulgate standardized geographic codes and geocoding standards.
- Healthcare providers and payors creating, exchanging, and disseminating health information should use geographic standards and street addressing processes that conform to standards set forth by the National Spatial Data Infrastructure (NSDI), and the Federal Geographic Data Committee (FGDC), following the guidelines of the Federal Information Processing Standards (FIPS).

Background and Rationale

The presence of some type of geographical information is inherent in most healthcare transactions both in the public and private healthcare system. The geographical locations of health events, healthcare providers, clinical services, service delivery sites, and the geographical origins of patients and diseases are required to support the informational needs of payors, providers, and public health policy making bodies. Geographical codes, including postal codes (zip codes), country and county identifiers, state and administrative area codes, and valid street address are critical to the efficient and timely exchange of information across organizational entities as well as across geopolitical boundaries. To fully realize interoperability, geographic standards are required. For example, the tracking of SARS requires the exchange of geographic data that conforms to international and national geographic schema similar to that used to communicate and report clinical signs, symptoms, diagnosis, treatments, and outcomes.

In addition to the administrative uses of geographic information, the need for accurate geographic information for the conduct of medical research, clinical trials, and environmental assessments of health or disease is critical. The ability to track diseases, across international and national boundaries will require healthcare transactions to conform to geographical standards and codes published by various national and international governmental and non-governmental agencies such as:

- Federal Information Processing Standards (FIPS) <http://www.itl.nist.gov/fipspubs/>
- Federal Geographic Data Committee (FGDC) <http://www.fgdc.gov>
- United States Postal Service (USPS) <http://www.usps.gov>
- National Spatial Data Infrastructure NSDI <http://www.fgdc.gov/nsdi/nsdi.html>
- International Standards Organization (ISO) <http://www.iso.ch> (11179)

Electronic Health Record

Recommendation:

- The Electronic Health Record (EHR) is a critical component of the National Health Information Infrastructure. The creation of a national network of EHRs requires the following:
 - Determine what sites will participate in NHII, e.g., hospital of a specific size, clinics/group practices greater than 10 members (or all), nursing homes, pharmacies, Public Health, others
 - Define the functionality of the EHR. Identify the minimum set of functions that is necessary to participate in NHII. Create set of specifications for the industry to comply with the full and minimum function sets and ensure interoperability.
 - Identify standards required for interoperability.
 - Define generic contents of a summary record, including generic data items with data types and terminology.
 - Define a process for establishing infrastructure for NHII.
 - Determine the appropriate geographic distribution of the EHR, e.g., states with regional nodes.

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- Examine scalability issues to determine the size (number of persons) per geographic area and thereby determine the number and structure of geographic areas.
- Contract with local groups to manage the local EHR region.
- Establish an interconnected Master Patient Index that can be referenced across geographic areas
- Implement capabilities that will ensure redundancy, back up, and real time updates.
- Establish a national oversight group to set policy, evaluate performance, and identify needs, etc.
- Implement polices and practices to support research on populations
- Establish privacy and security standards and rules

Background and Rationale

The Electronic Health Record (EHR), or more appropriately the EHR System, is the centerpiece of healthcare IT. It is the source of data from which knowledge and evidence is mined and with that knowledge creates the information for health care. Data is the necessary component for everything we are trying to do in healthcare – delivering effective healthcare, making systems, evaluating treatment, extracting knowledge, conducting research, preventing errors, improving quality, reducing cost, etc. Data is the power behind an effective and affordable health system. However, the data must be aggregated and shared across traditional boundaries. Standards must be established for the EHR that will permit sending and receiving person data in a semantically understandable manner.

The EHR is many faceted. We still have difficulty in agreeing on what to call it, much less defining what it is. Some people are willing consider unstructured text types into a word processor as an EHR; others require a highly structured, organized database. There is not yet a consensus on whether there is a minimum set of functions that must be provided before you have an EHR. It is important that we move toward a definition of the EHR and these functionalities if we are to support the concepts of a national healthcare information infrastructure.

Several groups have now established initiatives to create standards for the EHR. One such effort undertakes to define the potential functions for the EHR, and identify the minimum functionalities required for particular settings and use.

We recommend this activity be supported. The specifications for EHR requirements should be compared to the standards matrix presented in this report to determine if additional standards will be required for interoperable EHRs.

Actions needed in the standards arena to continue to move to an interoperable health care system

The DSWG identified overarching actions that are needed in three areas:

- Funding for standards
- Involvement of medical specialty societies
- Conformance testing

Funding for Standards

Sufficient and sustained funding is needed to ensure the ongoing adoption, distribution and support for standards. Commitments of public, private, and philanthropic sources will be needed. A mix of funding among these entities will ensure that there is an appropriate balance between stakeholders with a direct interest in specific standards and parties with a broad interest in advancing interoperability in healthcare.

Medical Specialties

The DSWG conducted a meeting with representatives of a broad range of medical societies. This meeting highlighted the importance of ongoing engagement between the standards community and the medical societies. The meeting identified the following as key areas of collaboration between medical societies and the standards community:

- A standard set of system requirements should be developed and made available to health care organizations and clinicians for use in acquiring information systems. The specifications should encompass features, functions, and interoperability
- The medical specialty societies should be directly involved in the development process of the selection of standards and options to solve a specific business integration need (e.g., integration profiles) that directly impacts their clinical domain. The societies should exercise leadership in identifying key needs; mobilizing members; sponsoring testing of products; educating members on the value of interoperability standards; promoting the use of standards in their institutions acquisition and development of information systems.
- Medical specialty societies should contribute to the development of standards compliant (Medbiquitous/SCORM) educational resources, so that these can be seamlessly integrated in to EMRs and clinical decision support applications.
- An ongoing mechanism should be established to enable medical societies to contribute to a repository of clinical guidelines. This repository should be publicly available and structured to facilitate the incorporation of guidelines into healthcare information systems.
- A funding mechanism should be established to enable medical societies to participate in standards development groups.

Conformance Testing

A key barrier to interoperability is the absence of a broadly available, independent, and reliable process for verifying the conformance of an application with an specific set of standards for a specific business use. The DSWG identified key actions that are needed to establish a reliable conformance testing process:

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- A compliance assurance process should be developed and implemented to provide users with an authoritative demonstration that information system products are interoperable.
- Conformance testing should be guided by fully specified business uses, such as, implementation guides, and Integration profiles
- The compliance assurance approach refined by the IHE and effectively used by providers and vendors should be leveraged. It has addressed most aspects of this recommendation while offering balance between effectiveness and effort needed.
- Certification specifications being defined by NIST should be used as a measure of compliance of vendors with the standard.
- The compliance assurance process should strive to identify and remove as many incompatibilities as possible before products are installed and in clinical use.
- Purchasers of information systems should require that vendors provide documentation that their product has undergone formal compliance testing for the specific business use cases anticipated in the system implementation.
- An independent entity should be designated to test information system conformance with standards.
- A governance mechanism should be put into place to oversee the methods and processes for conformance testing.
- An ongoing funding mechanism should be put in place to support the conformance testing process.

The many issues and standards discussed above indicate the enormous progress that has been made in the understanding, specification, and adoption of standards. The discussion also reinforces the need for a significant and sustained commitment to adopting emerging standards and completing development of new standards. Standards are not static, they must continue to evolve to meet the continuous advances in the delivery of health care.

IV. FRAMEWORK FOR MIGRATION TO AN INTEROPERABLE HEALTHCARE SYSTEM

Introduction

This document lays out a migration framework designed to move health care from silos of information to an interconnected and interoperable information infrastructure.

Motivation for Adoption of Interoperability Standards

To achieve the full benefits of using electronic medical record systems and point-of-care decision support tools, data and clinical-guideline knowledge encoded in computers must share consistent definitions understood by all clinical systems, thereby enabling data to be seamlessly exchanged among systems.

Clinical data exchange benefits all stakeholders in the health system, as we discuss in earlier sections of this report, but it begins with the healthcare organizations and clinicians who directly deliver care – and who make direct investments in the systems and processes that support that care.

Overview of the Document

Healthcare executives must take a leadership role in determining a migration strategy, whether for a local organization or for the nation as a whole. This document enumerates various approaches and options to consider when deciding upon a core strategy.

Achieving Interoperability

In order to exchange clinical data and create interoperability, the same clinical data standards should be used in all communities. For our purposes, the word “community” refers not only to a geographical community, but also to the virtual community formed by the organization’s clinical and business partners and to the community of patients that receive services from these partners. These virtual communities exist at the local, state, national and international level.

While data exchange might start within a single hospital community, a health system community or a community consisting of a geographic region, the ultimate goal is to be able to exchange data across the national community. Exchanging data for a national community will be greatly simplified by a common set of clinical data standards.

We identified five possible paths that migration might follow. These included migration driven by:

- Business partners
- Data sources

- Data recipients
- Community consensus
- National mandate

Business Partners

Once there is clear direction about which standards to use, organizations that must exchange data with business partners will find that using these standards will be easier than creating unique approaches for each exchange. As these point-to-point, standards-based exchanges increase in volume, data exchange “brokers” will emerge to provide routing services and act as clearinghouses for these exchanges.

The advantage of this bottom-up approach by business partners is that the organizations that need to exchange data will receive the value and bear the expense of standardization. The risk in relying upon this approach is the time involved and that it will take a long time for this process to unfold or it may never happen. Educating numerous and diverse organizations about standards is difficult, and there is no guarantee that enough individual organizations will adopt standards to move the entire health-care system in that direction. Moreover, a market-based approach may make it more difficult to use these data that public health and research need, for which aggregation across sources is often necessary.

Data Sources

Top-down approaches rely on a dominant participant in healthcare that creates “carrots” or “sticks” to drive adoption of standards. A migration to standards driven by sources of data assumes that organizations that receive this data will be influenced to change. For example, if all reference laboratories adopted HL7 v2.4 for transmitting results, LOINC codes for test identification and a vocabulary for coding results, then data recipients such as physician offices and hospitals would be likely to develop the capacity to receive data transmitted in those formats.

The main advantage of this approach is that there are a modest number of large data sources to educate about implementation of the standards. Moreover, these organizations have the financial resources needed to create interfaces. The recipients of the information, meanwhile, have a financial incentive to use the interfaces since their use promises an end to manual data entry and paper management. In addition, this migration strategy allows for a gradual phase-in by beginning with one type of data – say, from labs – and then expanding to other data sources, such as pharmacy data. Finally, once doctors’ offices, hospitals and others gain the ability to accept standardized data from large data sources, smaller organizations will have an incentive to use the standards, too.

The primary disadvantage of this approach is that the data recipients may not fulfill their part of the bargain; that is, they may have neither the knowledge and skills nor a sufficient financial motivation to create the needed interfaces.

Data Recipients

The mirror image of the previous approach is a migration strategy based on data recipients. This assumes that a relatively small number of organizations that have very important

regulatory or reimbursement relationships with providers will require that data be transmitted in a standardized electronic format. If, for example, the Medicare program required data for quality measurement to be submitted in a standardized format, many institutions would soon develop the capacity to do so. This approach is attractive because a relatively small number of organizations could drive a large proportion of data sources to implement interfaces.

One disadvantage of this approach is that the costs are imposed on the data "sources" (in this case, providers). Again, the providers may not recognize that it is in their interest to develop it despite the fact that without it they will increasingly need to create and maintain a broad range of different clinical interfaces. One way to overcome this is with the creative use of economic incentives to support these efforts.

Community Consensus

The community consensus migration strategy relies on the members of a community recognizing the value of interoperable data exchange and then acting upon that recognition.

The biggest advantage to this approach is that it is a local decision. In addition, with this approach exchange of various data types can be phased in. The New England Health Information Network (NEHIN), for example, started with eligibility and payment transactions but is expanding to other types of information. Other communities include Oregon-based PeaceHealth and the Indianapolis Network for Patient Care.

The disadvantage of this approach is that community consensus-building can be difficult, and it requires everyone to migrate in parallel so that the value proposition can be fully achieved.

National Mandate

Of course, a law or set of regulations requiring migration to interoperability will clearly move all parties to comply. The advantage of such an approach would be a consistent target and shared timeline. The disadvantage is that attempts to accomplish similar changes of this magnitude with a national mandate have been expensive, unpopular and not terribly successful.

Many Paths to One Goal

In reality, the migration will likely occur along more than one path. Whatever path or combination of paths is chosen, the probability of success is increased if the steps are incremental and financially self-sustaining. Software and implementation costs for a population of 100,000 have been estimated at \$1 to \$40 million over five years depending on whether operational systems need to be replaced or not.^{29,30} As a result, any approach that depends on creating a large infrastructure which would result in a long period before any incremental financial return is realized will likely fail.

²⁹ Community Clinical Data Exchange: By the Numbers, PowerPoint presentation by James Kalamas, 13-Jan-2003

³⁰ The Gordian Project, White Paper by Jeffery W. Rose, 1-Mar-2003h

Planning Your Approach

There are several key issues to consider when planning migration.

The first step in building is to gain recognition by all stakeholders of the value that standards-based data exchange provides. This step requires constant communication and discussions among the organizations.

In some communities, administrative data such as patient eligibility information and electronic funds transfers are most highly valued. In others, clinical data, such as laboratory results and encounter information, provide the most value. In addition, organizations must take into account the degree of technical and political difficulty involved in operationalizing exchange of specific types of data. So, for instance, if the dominant payer in the community cannot provide electronic access to a certain type of information, it may be better to start with an alternative type of data.

What data are initially selected is less important than having an early success. Once connections between organizations are created, additional data can be added relatively easily. Once more data are exchanged, organizations become more motivated to participate and make more data available.

In that regard, clinical data exchange represents a network externality problem. Network externalities arise when each adopter of a product benefits from subsequent adoptions. One organization being ready to exchange data has no value at all; adding a second organization has some value and so on until nearly all organizations in a community are ready to exchange data. At that later stage the value is very high, and the costs are very low.

Arguably the most challenging issue that a community faces when developing clinical data exchange is privacy and security. There are fairly well developed solutions for technical problems; the more difficult issues are the policy and procedural ones. No matter what approach the community chooses, acceptance and support of that approach *by the patients* is critical.

One approach is to explicitly obtain each patient's consent individually. Another, slightly less conservative approach is to rely on the HIPAA patient-disclosure provisions related to sharing data for clinical care or billing purposes. The central tenet of whatever approach is chosen is that the patient should benefit from their information being shared and that risk of any risk of privacy loss should be aggressively minimized.

Knowing What to Expect

There are several technical challenges that need to be overcome in order to implement clinical data exchange. The most challenging include:

- Data architecture
- Messaging model
- Patient data linkage
- Transitioning from local to standard vocabularies

Data Architecture

How the data will be stored is a critical decision; there are only a few basic choices. A monolithic, centralized database is conceptually the simplest. As data is generated it is stored in the common database and can be retrieved when needed. The advantages include simplicity of approach, short retrieval times and insulation from changes or problems with the data guardian's systems. However, it may also be difficult for data guardians to completely protect data privacy and security in this type of database. Second, a large centralized infrastructure can be costly.

In peer-to-peer or virtual data integration, as exemplified by the Care Sciences/California HealthCare Foundation's Santa Barbara Project, the data are retained in the source system until needed. After that, the information is extracted and merged. Advantages include the fact that the data remain entirely within the data guardian's systems until needed, and centralized infrastructure is minimized. Potential disadvantages include slow response times, dependence on source system availability and retention strategies, and its tendency to make support and maintenance complex.

Hybrid approaches have been developed in some communities. In Indianapolis, the Indiana Network for Patient Care stores each organization's data in a completely independent database, but the data are standardized in format and content.

Advantages include independence from changes or problems in the data guardian systems, short retrieval times and the ability for the data guardians to retain complete control over their data. The hybrid systems differ from peer-to-peer systems primarily by standardizing the data "up front" – when the data are generated – and by the requirement for a place to store that standardized data. They differ from centralized databases by providing complete control of the data by data guardian. The disadvantage of this approach is that more centralized infrastructure is required than for peer-to-peer, but less so than for a centralized database.

The last approach is a patient "carried" record, such as a smart card or a web-based patient record. There are some strong potential advantages, particularly with regard to the patient having control over the privacy of their own information. There are several disadvantages to this approach, including updating the record and consistent access (if, for example, the patient forgets to carry the card).

Messaging Model

Closely related to the choice of where the data are stored is the question of how data will be exchanged. In the messaging approach, exemplified by HL7, data are packaged into messages that have a standard format that can be "understood" by the sending and receiving software. Typically, the sending software converts data from its internal data model to the standard message format, the message is sent over a network and the receiving software converts the data in the message into its internal data model and stores it. The advantage is that the software only has to "know" about the standard message format in order to send and receive data.

Alternatively, query approaches built around structured query language (SQL), either directly or through HL7, can be a very efficient way to access data. The query must be constructed based on detailed information about the internal data representation in the systems. The data are usually going to be moved over a data network such as the Internet and, given today's technologies for encryption and tunneling data, it is not absolutely necessary to construct dedicated networks to move healthcare data. There do, however, exist dedicated networks that carry important healthcare transaction data that must be considered as well.

Patient Data Linkage

Perhaps the most challenging problem faced in clinical data exchange is matching patient data across organizations. Since a uniform national health identifier is neither available today nor on the immediate horizon, approaches that rely on statistical matching to confirm patient identity will be the mainstay for some time to come. This matching can be done using a Master or Enterprise Patient Index that allows access to a multi-organizational index of patient data. However, this approach requires extensive integration and coordination between the participants.

An alternative is to match patients based on the registration data that each organization obtains and then adjust the algorithm to eliminate false matches. This approach will lead to some information being unavailable because patient records cannot be matched statistically, but it minimizes the privacy risk to the patient or the possibility of medical errors due to incorrect information being attributed to the patient. For some purposes such as public health research, the patient's privacy can be further protected by careful de-identification of the data.

Transition from Local to Standard Vocabularies

The other major challenge for clinical data exchange is standardizing the codes and vocabulary. The ideal approach would be for every organization in a community to convert their codes to the community standard. Unfortunately, this can be a difficult task because these codes are often used by other systems within an organization (such as billing systems), and some IT systems may not accommodate the format (alphanumeric versus numeric, or length restrictions) of the standard codes.

Most organizations will need to adopt a strategy in which their codes are mapped to the standard codes, and a translation step happens somewhere in the data flow. The mapping process can be tedious, and it requires specialized expertise from lab personnel for example.

One way to minimize the time and effort required is to map the codes that account for 80 percent of the organization's data volume and then create a mechanism to accommodate the unmapped data in the exchange process. Remaining codes can be mapped at a later time. The disadvantages of this approach are that "unmapped" data are much less useful for clinical, public health or research purposes.

Creating Your Own Roadmap

Every community will have different motivations, technical challenges and resource capabilities; no single roadmap can serve the needs of all communities. As one example, we will describe the evolution of clinical data exchange for a mid-size community of one to two million patients.

In our example, the community is a single city (we'll call it Exchange City) and its immediate suburban areas. There are about 3,000 physicians, 15 hospitals some of which are allied, 30 percent managed care penetration and no dominant payer.

The Exchange City community didn't start out to create community-wide data exchange but the hospitals decided to start sharing some obstetrical data in order to address the problem of low infant birth weight that the community was facing. By working together to share this very limited set of information, the hospitals with help from public health agencies and local government overcame some initial resistance to sharing data and progress stopped there for a few years.

Later, a few doctors convinced one of the hospitals to make its data available for emergency department care at the others. Using grant funds, the hospitals' networks were connected and access for emergency department physicians to the hospitals clinical data repository was set up. One year later, the doctors in the emergency department were asking why they couldn't get data from more than just the one hospital's repository and the larger hospitals all agreed to participate.

Again, using grant money, the hospitals mapped their local laboratory and other codes to standard codes (LOINC codes for laboratory and HL7 suggested codes for ADT messages) and wrote software to convert their local HL7 message versions to standard HL7. The data were exchanged using a messaging model and the codes were mapped by the local institutions to standard codes. Patients' information was matched using a statistical method. This step, conducted with patients' explicit consent and careful security procedures, provided access to much of the clinical data needed by for physicians in the emergency departments. Soon primary care physicians affiliated with the hospitals were asking the hospitals why they couldn't get access to this integrated data.

Authenticating the doctors became a significant challenge so they adopted an approach requiring the hospital to authenticate doctors they were affiliated with (e.g. were on their medical staff). This approach also meant that the hospitals would trust each other's authentication.

A few other sources of information were soon added to the data that the doctors could access, including immunization registry data from the public health department. In addition, a few large medical groups who found the system particularly helpful added their data to the system because it provided them with a more integrated view of their patients' care.

While this system gave some clinicians access to more integrated clinical data there were still challenges to optimizing its use. The physicians were required to "pull " each piece of information they needed. They had to go to the system and look up their patient's data.

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This is not how clinicians practice in an outpatient setting in today's paper-based health care system, and therefore represented a change to the current workflow at the point of care. They rely instead on reports of various kinds delivered to the patient's chart by various means including courier, facsimile and printing.

The hospitals saw an opportunity to simplify their processes, and provide better service to the physicians, by integrating report delivery for all the hospitals through an electronic system. They created a community-based corporation that licensed software that could consolidate reports from many sources. Using an office-based PC, physicians were now able to retrieve, sort and print results.

The hospitals were able to fund this service and still save a good deal of money because costs were so dramatically reduced compared to the manual costs they previously incurred. The start-up costs were low particularly since the HL7 data streams that they set up for data sharing could be reused for this purpose. They expect that over time, the doctors' offices will start using more automation in their offices as a result of this simple but valuable tool. The availability of experienced practice facilitators provided by the community-based corporation to support the application greatly enhanced its acceptance and support.

Public health officials soon recognized the value of this information to their mission and they were able, to create electronic laboratory reporting and outbreak surveillance systems that ran behind the hospital's firewalls. This was possible at modest cost because of the existing data flows and network connections. These systems analyzed the data flowing through the system to identify results from laboratories that represent reportable conditions and transmit them electronically to the local public health department. This allowed them to analyze information more rapidly than ever before, greatly improving their ability to identify and respond to disease outbreaks in specific areas of the community.

While Exchange City has created an enviable clinical data exchange environment, they understand that they are not finished yet and are now working to add information from more physician office visits, reference laboratories and outpatient pharmacies. In addition, they are exploring funding models that ensure that savings generated by the clinical data exchange are available to support the necessary infrastructure and are shared appropriately by the participants.

This community followed an evolutionary path, building relationships and capacity over time. They relied on messaging and data standards as a common foundational principle. This approach allowed them to reuse the data for multiple purposes including document delivery and public health (not to mention quality improvement and health services research).

Exchange City followed its own roadmap. Many will follow a somewhat similar roadmap and others will be dramatically different but, as you can see in this example, each will need to confront and manage the issues outlined in this migration framework.

Many experts believe the National Health Information Infrastructure ("NHII"). Will evolve from data exchange between Regional or Local Health Information Infrastructures (the clinical data exchange between communities that we have been discussing). The NHII will require similar considerations and steps, but on a national scale, transcending local and

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community-based clinical data exchange. The hope is that community processes will inform and guide the national evolution, which can only succeed if the community efforts succeed.

V. DEMONSTRATING FEASIBILITY AND VALUE: THE HEALTHCARE COLLABORATIVE NETWORK...A NATIONAL DEMONSTRATION PROJECT

Background and Overview

Participants in the Connecting for Health Data Standards Working Group recognized early on, that if we were going to “catalyze actions on a national basis to realize an interconnected, electronic health information infrastructure”, that we would not only need to deliver a report that would articulate the need for and the value of standards adoption and standards-based electronic data interchange, we would need to demonstrate its *technical feasibility* and the *value* that would accrue to a *wide variety of stakeholders* as a result of using electronic, standards-based data securely and responsibly to support a wide variety of healthcare needs.

With this recognition, a national demonstration project—the Healthcare Collaborative Network—was born.

The Healthcare Collaborative Network (HCN) is a growing consortium of over twenty organizations, including nationally-recognized healthcare providers, physician groups, centers of clinical excellence, public health agencies, payers, Federal agencies, and leading information technology companies with shared interests in demonstrating on a national basis, both the feasibility and value of an interconnected, electronic health information infrastructure to support better health and healthcare.

Catalyzing Factors

The Healthcare Collaborative Network grew out of the group’s shared goals to use the electronic exchange of health information to improve healthcare quality and safety, while reducing inefficiencies.

In the midst of this general concern exploded the public health crisis caused by the Anthrax attacks in New York, Maryland, Washington D.C., and Florida. The need for surveillance data was so pressing that many hospitals, vendors, and informaticists began exploring methods to provide critical data electronically to public health authorities, in a secure and private manner.

Connecting for Health then launched its project to catalyze changes on a national basis to lay the foundation for an interconnected, electronic health information infrastructure, bringing together stakeholders from across every sector of healthcare. The federal government began driving an effort to align its health information exchanges termed the Consolidated Health Initiative. CHI signaled an intent by the federal government to support open standards. Out of this environment, through Connecting for Health, a group of leading health systems,

health information system suppliers, informaticists, and agencies jointly began exploring an interoperability project.

Overview of the Purpose and Scope of the Project

Purpose

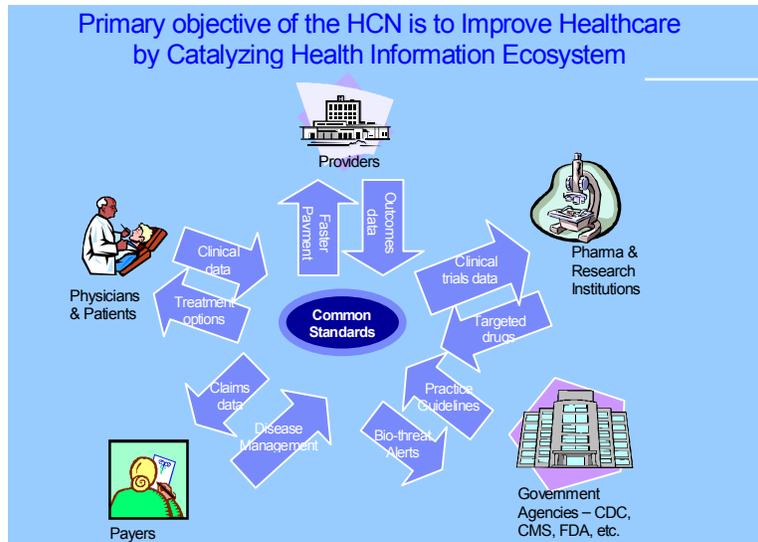
The purposes of the Healthcare Collaborative Network are as follows:

- Improve health and healthcare by answering critical public health, quality, and adverse event questions from a diverse set of participants
- Identify electronic sources of health data that are currently available and of significant value in addressing public health, quality, safety or health care delivery needs (e.g. health “questions”)
- Deliver data to address those needs (e.g. health “answers”)
- Implement privacy and security protections for patient health information
- Demonstrate the feasibility and value of a private and secure electronic, standards-based model of data transmission and exchange.
- Learn about implementation issues.
- Communicate that a wide variety of health care stakeholders, including hospitals, practicing clinicians, public health agencies, payers, federal agencies and patients will benefit from the use of an electronic standards-based infrastructure.
- Build momentum for policy actions and funding that will accelerate the adoption of clinical data standards, health system interoperability, and interconnected, electronic models of data interchange.

Scope of Work

In the first phase of the project, HCN will allow both providers and agencies to track adverse drug events, quality-of-care, and disease outbreaks quickly and accurately, as appropriate. Later phases of HCN are intended to address the needs of practicing clinicians, quality and disease management activities by payors, and research.

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The de-identified data transmitted as part of the demonstration includes those data elements that are necessary to measure the quality of care delivered for those with diabetes and cardiovascular disease; assist with public health surveillance and response; and drive improvements in patient safety through the rapid detection of adverse drug events. A subset of the specific data needs identified by the participants included the following: disease surveillance information including that related to Anthrax and Legionella; quality information including measures related to Ace Inhibitors prescribed for myocardial infarction patients and Hemoglobin A1C for diabetes patients; and adverse drug event data including the monitoring of liver function for Accutane recipients

Project Participants

On June 5, 2003, after approximately nine months of design and development, the participants are launching the HCN project as part of the final meeting of Connecting for Health. As part of the initial launch, three healthcare providers—New York Presbyterian Hospital (New York, NY), Vanderbilt University Medical Center (Nashville, TN), and Wishard Memorial Hospital (Indianapolis, IN) and three Federal agencies--the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, and the Food and Drug Administration—working with the support of the IBM Corporation, who is contributing project management, consulting, technology, and implementation services, for the project, will be exchanging data. The Foundation for eHealth Initiative is providing staffing support.

The participants are using open standards identified by Connecting for Health and an enabling architecture to demonstrate an electronic model of data interchange. Metatomix and ESRI are providing mapping and visualization capabilities and iNterfaceware is providing HL7 parsing software.

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A number of hospitals or health systems, including MedStar Health and University of Illinois Medical Center, a number of physician groups, and healthcare information and technology companies representing over 90% of the market, including Cerner Corporation, GE Medical Systems, McKesson Corporation, Siemens Corporation and NDC Health will begin exchanging data over the summer.

Other health systems such as Caregroup HealthCare System, Cleveland Clinic, and University of Pittsburgh Medical Center; public health agencies such as the Marion County Public Health Department; payers such as GHI; and an additional federal agency—the Department of Defense, are all now exploring and actively engaged in moving towards participation. It is anticipated that the number of participating organizations will continue to grow over the course of the project.

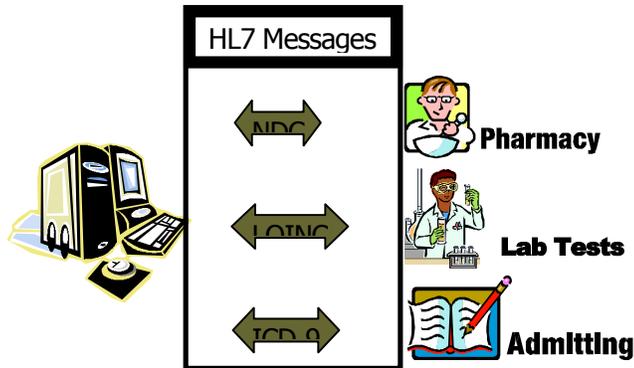
Developing the Healthcare Collaborative Network

In its first phase, HCN will demonstrate the value of standards-based electronic private and secure data reporting from existing hospital clinical systems to providers and agencies. Participating hospitals and health systems will identify relevant data as it flows through their existing clinical information systems and transmit it securely and responsibly using standards while complying with all privacy laws. Each recipient, including the originating hospital and each of the agencies, will receive data relevant and permitted for their clinical or health-related activity.

The first step in developing HCN was to identify the pressing “questions” or data needs for participants. As a starting point, the project asked key federal agencies to identify the most critical data that they needed for which they were authorized to receive. In general, the data was already being reported by healthcare providers, but on paper resulting in significant delays and a low compliance rate. Examples of the data include quality measures tracked by CMS, adverse drug events identified by the FDA, and diseases and other health indicators of public health interest to the CDC.

Second, we sought existing electronic sources for the information. Health systems such as New York Presbyterian Hospital, Vanderbilt University Medical Center, and Wishard Memorial Hospital, agreed to participate and supply the requested data from their existing clinical systems. We took the list of desired data and shared it with the health systems.

Certain Electronic Clinical Information Widely Present in Acute Care, Pharmacy, and Laboratories



The list was narrowed to data that was currently in electronic systems in open standard coding and terminology. This second step imposed dramatic limitations on the demonstration due to the lack of electronic health records in large portions of the health system (for example, physician offices) and the poor adoption of standards in particular areas such as those related to chief complaints and microbiology.

Third, IBM worked with the participating health systems and agencies to collect requirements for the development of an architecture for the demonstration project. Over the next several months the technology to deliver the data was designed and developed.

The result was a demonstration that allows relevant, private, secure, and dynamic health data to move in a diverse manner between participants. The data exchange will begin on June 5th, but during the remainder of 2003 additional participants and functionality will continue to be brought on board.

Successful demonstrations need not end – the best can be incorporated as building blocks in the construction of electronic data exchange. As patients, clinicians, communities, and nations move toward a robust use of electronic clinical data, demonstrations will provide a framework for growth. Over time the best demonstrations will survive and evolve into components of an ecosystem of diverse participants linked by the use of common standards.

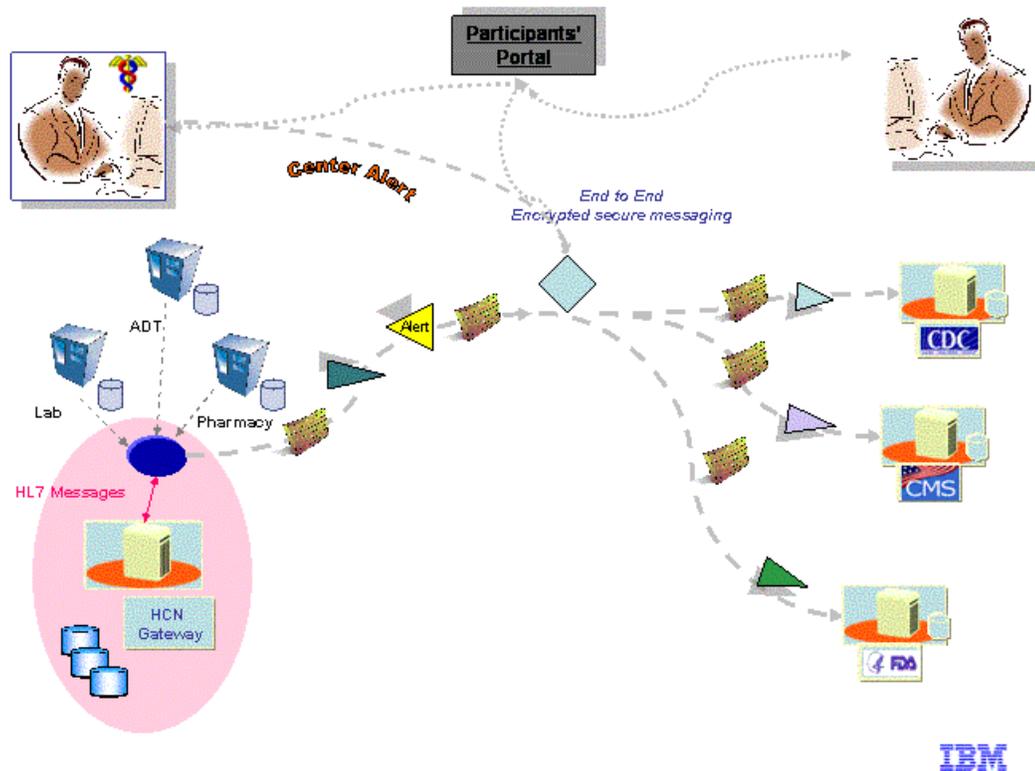
Critical Design Challenges

The HCN project had to address a number of challenges:

- Assuring strict privacy and security practices
- Providing relevant answers to critical health questions without creating new repositories or storing data outside the provider
- Uneven execution of standards and limited coding of desired health data.

V. DEMONSTRATING FEASIBILITY AND VALUE: THE HEALTHCARE COLLABORATIVE NETWORK...A NATIONAL DEMONSTRATION PROJECT

HCN developed responses to these core challenges. Determining which strategies and combinations of approaches to use will depend on the type of organization and local culture.



Privacy and Security

Due to the sensitivity of health information, HCN is removing names, addresses and most other identifiers from records before they leave the hospital in compliance with the limited data set restrictions of HIPAA. In their place a random identifier is attached by the hospital that allows the record to be tracked only within the hospital, without revealing the patient's identity. Links were possible using the random identifier so that data that arrived from different sources (lab, pharmacy, ADT) and at different times could be linked. When the linked data satisfies one of the topics, it moves forward as a record to the relevant subscriber. The random identifier can be used later by the hospital to follow up on patient care as necessary.

Hospital Control Over Data

Data within the HCN is not stored centrally, and continues to reside in the participating health systems or other data sources. HCN adopted a commonly used publish and subscribe model

of architecture. The publish and subscribe model allows authorized subscribers to dynamically alter the information requests to which they are entitled through a portal, can adapt to diverse needs and privileges, and minimizes scaling problems.

Messaging, Terminology and Coding

Open standards are the underpinning of the HCN. Information flows from the hospital data systems in standards such as HL7, into the gateway and are transmitted to the subscribers using open standards -- wherever possible.

However, there is considerable variation in the implementation of most health standards and significant gaps in their adoption. The most severe limitation to the HCN's ability to satisfy authorized requests were imposed by the lack of adoption of coding standards. For example, although standards exist for coding both complaints and microbiology reports, those standards are narrowly adopted. When the information is not coded, it has the same impact as locking a filing cabinet – the information is very difficult to access. Driving adoption of coding in complaints and microbiology is a critical step toward interoperability.

In addition, different providers use different versions of the common standards, and even within a standard may use different fields for similar data. Mapping the data from local codes was necessary in some cases, but mapping was far less of an impediment than the considerable amount of data that was simply uncoded (and therefore not usable in many cases) such as complaint data, administrative data, and microbiology reports. Pharmacy data coding required the highest level of mapping but was critical to the topics requested by the project participants.

Where Do We Go From Here?

During the months following the June 5, 2003 launch, the HCN in partnership with the Foundation for eHealth Initiative, will engage additional participants in the project and address a broader scope of data needs, including the needs of practicing clinicians and possibly other key constituencies. Barriers to the successful deployment of models of standards-based electronic data interchange will be identified and solutions developed to address them. These barriers and solutions will be widely disseminated to promote changes in policies and practices to support wider diffusion of related activities.

The value of the HCN—and other models of standards-based electronic data exchange like it—for all stakeholders, including practicing clinicians, hospitals and other healthcare organizations, researchers, payers, and public health agencies, will be documented and widely disseminated to support and promote the widespread adoption of data standards, and interconnected, electronic models of data interchange to drive improvements in the quality, safety, and cost-effectiveness of healthcare.

VI. ACCELERATING INTEROPERABILITY WITH COMMITMENT AND ACTION

Overview and Background

In support of the DSWG's goals, Working Group members focused on five key areas: identification of standards; articulation of value; demonstration of feasibility and value; support for migration; and commitment and action.

The purpose of this section of the report is to articulate how various stakeholders in healthcare can demonstrate commitment and take specific actions to accelerate the adoption of data standards and the usage of interoperable healthcare systems to support quality, safety, and cost-effectiveness improvements across the entire healthcare spectrum.

Specific Actions to Promote Adoption of Data Standards

There are a number of actions that various constituencies can take to accelerate the adoption of data standards and interoperable healthcare systems. The following chart summarizes just a sample of those key actions.

Stakeholder Group	Action to Accelerate Data Standards Adoption
CATEGORY 1:	Incorporate operable standards in formal organizational documents or processes that drive the transmission of data to support current requirements.
Public Sector Purchasers/Payers	Encourage existing electronic data transmission using operable standards by building these requirements into existing reporting requirements
Public Sector Purchasers/Payers	Encourage provider organizations to transmit data electronically using operable standards by providing incentives to those providers that do so.
Employers and Purchasers	When collecting data to assess quality of care delivered, ask that such data be transmitted in electronic forms, using operable standards
Employers	Incorporate use of operable standards into next "leap" related to utilization of information technology to support care in the ambulatory environment
Quality Improvement and Accrediting Organizations	Incorporate operable standards into quality measures
Quality Improvement and Accrediting Organizations	Promote use of standardized, electronic data in accreditation standards

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Stakeholder Group	Action to Accelerate Data Standards Adoption
Public Health – CDC	Embed operable standards into PHIN and NEDSS architecture and implementation guides
Public Health – public health agencies and associations	Build requests for electronically transmitted data using operable standards into standard data request documents
Those Responsible for Adverse Drug Event Reporting	Incorporate operable standards into adverse drug event reporting
Pharmaceutical Industry Food and Drug Administration	Incorporate operable standards into clinical trials work
Health Plans	Encourage providers with which health plans contract to transmit data electronically using operable standards for quality improvement or utilization management purposes.
Clinical Researchers	Encourage researchers to build the use of electronic data using operable standards into their data requests
CATEGORY 2	Incorporate language related to operable standards within RFPs when making purchasing and contracting decisions
Practicing Clinician Societies and Associations	Incorporate operable standards into educational materials and tools provided to members
Practicing Clinicians and Clinician Groups	Incorporate operable standards into RFPs and purchase only those systems that use operable standards
Health Systems and Hospitals Associations	Incorporate operable standards into educational materials and tools provided to members
Health Systems and Hospitals Associations	Provide sample “migration” strategies to assist hospitals in moving towards operable standards.
Health Systems and Hospitals	Incorporate operable standards into RFPs and purchase only those systems that use operable standards
Federal Agencies	Incorporate operable standards into contracts and RFPs
CATEGORY 3	Incorporate operable standards within software applications
Health Care IT Suppliers for Providers	Create systems that are “operable standards-compatible”
Health Care IT Suppliers for Providers	Incorporate operable standards into “starter kits” for applications
Health Care IT Suppliers for Health Plans and Payers	For those systems that rely heavily on X12, begin to incorporate HL7 (create systems that are “operable standards-compatible”)
Health Care IT Suppliers (Integrators and Consultants)	Require that all IT suppliers integrate operable standards into their systems

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Stakeholder Group	Action to Accelerate Data Standards Adoption
eRX Facilitators	Incorporate operable standards into connectivity plans and applications
CATEGORY 4:	Incorporate operable standards into local and regional data exchange projects.
Regional Clinical Data Exchange Initiatives	Incorporate operable standards into clinical data exchange activities
Demonstration Projects	Align operable standards and critical data needs within demonstration projects
Demonstration Project Participants	Incorporate use of operable standards into demonstration projects that are going on across the country
Public Health and Homeland Defense	Build operable standards and electronically transmitted data into demonstration projects
CATEGORY 5	Align operable standards with the work of other organizations focused on standards development and adoption.
Standards Organizations	Build bridges with standards related organizations
Accelerating Bodies	Align "operable standards" with the work and recommendations of "accelerating bodies"
CATEGORY 6	Build awareness of the need for other policy levers that can help to drive interoperable health care systems
Trade Groups	Educate policy makers on the importance of clinical data standards and interoperability
Policy-Makers	Drive policy changes that will support standards adoption and interoperable healthcare systems
CATEGORY 7:	Engage consumers and patients in the quest for an interoperable health care system.
Patient Groups	Incorporate operable standards into research-related and measurement-related activities
Patient and Consumer Groups	Perform outreach to constituencies to build patient and consumer awareness of the value of an electronic comprehensive picture of health care delivered.

More than 30 organizations and individuals involved in the Connecting for Health Steering Group have committed to taking key actions to support the migration to data standards and an interoperable healthcare system and have made public statements regarding those actions. They include hospital and health systems, public health organizations, practicing clinician groups, accrediting organizations, third party payers, health care information technology suppliers, manufacturers, and federal agencies.

These organizations have made a wide range of commitments, including those related to purchasing only those systems that use standards, educating members regarding the importance of data standards, embedding such standards in software application systems developed, including standards in accreditation and performance measurement related processes, and requiring standards as part of public health reporting requirements.

A full list of organizational commitments made by participants within Connecting for Health is included in the Steering Group report.

General Actions to support an Interconnected, Electronic Health Information Infrastructure

In addition to the adoption of data standards, a number of other key actions must be taken by both public and private sector stakeholders to realize our vision of an interconnected, electronic health information infrastructure to support quality, safety, and cost-effectiveness goals in healthcare. The following summarizes a list of the key actions that should be taken.

Continue to Support Strong Collaboration...Across Both the Public and Private Sectors

The Connecting for Health model, which engages leaders across every sector of healthcare, both within the public and private sectors, has been successful in creating dialogue and mobilizing collaboration and action amongst a very diverse set of stakeholders. The process has resulted in a greater shared understanding of different perspectives, and the development of better solutions that contemplate the various needs and concerns within healthcare. In order to continue to drive and support migration toward the widespread adoption of data standards and an interoperable healthcare system, this dialogue, amongst a diverse, and broad-based group must continue.

Promote Organizational Change Within and Across Institutions

Migrating to an interoperable healthcare system will not be easy. Connecting data in a manner that protects patient privacy and security across institutions to support more informed, higher quality, safer healthcare will require significant changes in organizational practices and policy and the investment of time and resources. Champions and leaders will be needed across all sectors of healthcare to drive the changes that are required and sustain the momentum as migration occurs. The value that will accrue to every stakeholder in the healthcare system will be significant, but leadership will be required to promote and sustain change both within and across institutions.

Participate in Demonstration and Implementation Projects

As noted in Section V of this report, demonstration and implementation projects are critically important to the migration of our current paper-based, fragmented health system to one that is interconnected, electronic, and interoperable, to support quality, safety, and efficiency goals. They assist with identification of barriers that have previously gone unnoticed and the development of practical solutions to address these barriers. They help to explore and find

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solutions to cross-cutting issues, such as those related to technical architecture, privacy and security, legal issues and community leadership. They also help to expand the evidence base supporting the value of an interoperable healthcare system for all stakeholders. Finally, the learning that occurs by demonstration project participants provides important feedback to all organizations and individuals seeking to link their systems through the use of standards.

A number of demonstration projects are already occurring both at the national level and the regional/local level. These should be expanded significantly with the support of both the public and private sectors.

Build Support for Funding of the Changes Needed to Support Migration to a Standards-Based Healthcare Information Technology Infrastructure

As noted in various sections of the report, practicing clinicians, hospitals, and other healthcare organizations cite the lack of investment and operating capital as a key barrier not only to migrating toward an electronic interoperable healthcare system enabled by data standards, but also to the basic purchase and use of information technology itself. Awareness of this need is growing both within Congress and the Administration. But this awareness must be strengthened and actions must be taken to ensure tangible and sustained policy change. It will take innovative investment strategies to support improvements in quality, safety, and cost-effectiveness that can only occur with an electronic, interoperable healthcare system.

Conclusion

All stakeholders within healthcare, including practicing clinicians, hospitals and other healthcare providers, payers, accreditors, government agencies, public health agencies, researchers, manufacturers, health care information systems suppliers, and most importantly, patients will benefit from the adoption of data standards and interoperable healthcare systems. Achieving this will require the leadership, commitment and action from every stakeholder group in healthcare.

The full value of an interoperable healthcare system will only be realized if all parties are engaged and committed to the changes that are necessary. This past year has resulted in a heightened level of awareness and a great deal of meaningful progress. This momentum must continue and these key actions must be taken, by every stakeholder across every sector of healthcare. Without it we cannot possibly address the significant challenges facing our healthcare system.

Appendix

APPENDIX A: CLINICAL DATA EXCHANGE EFFORTS IN THE UNITED STATES: AN OVERVIEW

Full Paper Available at: www.connectingforhealth.org

Executive Summary

As we prepared for the first meeting of Connecting for Health, we had great interest in uncovering early models of community-based projects. Models where an infrastructure for clinical data sharing had been created, while early in their evolution, were opportunities to study and understand in greater detail what would be necessary for us to consider as we contemplate a more interconnected health care system.

A bird's-eye view across community clinical data exchange efforts provides both an appreciation for the differing approaches as well as an opportunity to find some common themes. Given that clinical data exchange efforts at the local community level are still rare, we wanted to see if there were any common findings amongst them that might be helpful when considering future models. While we looked at each of these efforts individually, the purpose was to see if there were some common themes that might predict success. As part of this process we conducted interviews with the following community-based initiatives:

- California Information Exchange (CALINX)
- Community Health Information Technology Alliance (Foundation for Health Care Quality)
- HealthBridge
- Indianapolis Network for Patient Care (Regenstrief Institute for Healthcare)
- Massachusetts Health Data Consortium
- Minnesota Center for Healthcare Electronic Commerce and the Minnesota Health Data Institute
- North Carolina Healthcare Information and Communications Alliance
- Patient Safety Institute
- Santa Barbara County Care Data Exchange (CareScience and California Healthcare Foundation)

One of the first observations is that such exchanges are still few and far between, and in all cases; there were many barriers to success. The progress made by those who have been able to lead their communities forward is to be commended; and their efforts have much to teach us.

The overwhelming message we distilled from this overview is that it is not necessarily the technical roadblocks that have most limited opportunities for clinical data exchange – but instead:

- Overcoming the difficulty in bringing diverse stakeholders together towards a common goal, and

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- Carefully addressing the need to protect privacy and security; creating the governance models, agreements, policies and practices for building these kinds of exchanges, and
- Building a compelling and sustainable model for devoting ongoing funding, resources and commitment to these projects.

Leadership and vision of a community's hospital, physician, health plan, and public health agency, combined with the leadership of an effective convener, were common traits in all of the clinical exchange efforts reviewed in this report.

It was the breakdown of that organizational commitment and leadership that led to some of the initiatives' inability to move beyond the pilot stage. Additionally, there needed to be a strong and compelling reason for an organization to commit to data exchange, particularly standards-based exchange. If something is "working for [an organization] now", it is harder to convince them to move ahead to standardized ways of sharing information. This is where cooperative, innovative, strong leadership are necessary to pull communities together in order to enable networks like this to be created, which is so necessary for high quality healthcare.

Leadership mattered at all levels. These leaders were not only essential for understanding the importance of exchange, and of data standards for that exchange, but also in getting staff assigned to a project throughout, and committing the funds and resources throughout the lifecycle of the project. Visionaries also helped organizations move beyond competitive concerns to find ways in which they were able to control, yet share, data.

In most cases, the convener was a neutral, non-profit group that the participants could trust. The issue of trust and neutrality seemed to matter a lot in these examples. In some cases its members created the convener in order to bring the community together. That convener also played roles in developing formal governance structures and committees that tackled the day-to-day barriers that came up during the life of the project. In some cases that convener evolved to take on a technical maintenance role, in others it operated more as a project office for modeling of new methodologies and for adding providers, plans and public health agencies to its networks.

Some organizations did a fantastic level of work and demonstration, only to find that big efforts came along, like Y2K and HIPAA that became larger priorities than their effort, draining both staff and funding from the project. Without the staff and funding, they were limited in their ability to build support or move forward. Another organization noted that finding windows of opportunity was important – and that the current need was not just about private sector to private sector exchange, but very much about private to public sector exchange. September 11, 2001 changed the focus of the nation, and created urgency for finding more efficient and effective ways to enable the public health community to cope with the looming threat of bio-terrorism.

One area of significant variability was the data itself. The organizations differed in terms of the data they chose as their initial, or core, dataset – though some of the more common sets were immunization data, lab and radiology data. A number were also focused on clinical messaging and ways ensure its security.

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From a privacy and security standpoint, communities seemed to feel more comfortable with a networking approach as opposed to the clinical data repository architecture proposed in the CHIN efforts. Though some modeled and successfully tested PKI and other extensive security models, most opted for less intensive ways to get started in exchanging messages and packets of information – and continued to come up with innovative approaches to developing cooperative security standards for healthcare data among otherwise competitive vendors and providers.

In all cases, industry-accepted standards such as HL7 and LOINC were being used where participants were ready to do so, and customized interfaces were being built where they were not. Many of the groups also focused on bringing participants towards industry standards for data, and continued to identify open issues and new solutions as they moved forward. It was also noted that lab companies were interested in moving to standards if there was a need expressed by their customer base -- and that concept could be extended for technology suppliers and IT organizations in general.

APPENDIX B: THE CLINICAL COMMUNITY

JOINT MEDICAL SOCIETY MEETING: Washington, DC, March 5th, 2003

Connecting for Health...A Public-Private Collaborative, organized a meeting with the nation's leading medical societies and clinicians. We initiated this meeting in order to better understand the needs of the practicing clinicians as we work toward a more interoperable health information infrastructure with improved quality of care as its central goal.

Defining the Need

There are numerous recent government and private sector initiatives underway to encourage the nation's medical practices to adopt sophisticated health information technology. There is also growing demand from the public for clinicians and medical offices to 'go online' with routine services such as scheduling appointments, renewing prescriptions, reporting lab and other test results, and communications, such as e-mail.

Indeed the use of information technology has become vital to the practice of healthcare for a range of purposes, including tracking and collection of vital health information for patient care, automated clinical decision-support, medical error and safety reporting activities, benchmarking against established best practices, and for anti-terrorism and epidemiologic surveillance associated with national security.

How are physicians going to cope with this demand to employ more information technology and to become more interconnected with other parties in the health care system? Many have become frustrated trying to bring IT into their practice. They can quickly find themselves surrounded by incompatible software and hardware, confusion about which systems to use, a lack of confidence in support for the products and a sum of whose parts is not greater efficiency and productivity, but sometimes greater expense and hassle.

Dealing with an ever-expanding knowledge base is also a challenge for the practicing clinician. While the Internet affords doctors and medical staff access to a wealth of medical knowledge, information on best practices and peer-reviewed options for care, these information stores cannot be automated and made available through information systems without a great deal of effort.

Achieving true interoperability will depend on the full development and deployment of standards focused on medical knowledge, clinical guidelines, and decision support. These standards and the content necessary to support their use requires the direct input and involvement of office-based physicians working in the real world of medicine.

An interconnected health care system's central value is its potential to improve patient care. Standards developers and IT professionals can provide technical solutions, but their work will only have value if the clinicians delivering care have the tools and information they need in a

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form that they can use. The leadership of the clinical community will bring the standards to life and make them a vital factor in the improvement of the quality of care.

Accomplishments

A number of key results came out of the meeting and the discussion that followed. The following summarizes those outcomes:

- Raised general awareness of the role of information technology and standards in the delivery of care
- Gained a greater understanding of what each medical society and association is doing in the areas of information technology and standards
- Built an understanding of the standards that are needed to drive an interoperable system and the work underway in Connecting for Health
- Gained and provided input on the concept of an open source electronic health record and the role of government in accelerating the adoption of electronic health records
- Discussed concrete next steps to explore how we might work together
- Explored examples of standards-related efforts related to clinical guidelines and medical education.

Acknowledgements

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Special and important thanks are extended to Dr. David Kibbe and Dr. Peter Basch. Both of these physician leaders were motivated to write background papers on the topic of our meeting. These insightful and innovative pieces reflect the opportunities and challenges that lay ahead for practicing clinicians. They follow in the next section of this paper.

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Removing Gauge Breaks: The Role of Health Information Technology Standards in the Office-Based Medical Practice

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Overview

In the early 19th century, people and cargos traveling by train had to endure long delays and were forced to pay transfer fees at 'gauge breaks,' way stations where trains of different gauge track met one another. Gauge is simply the distance between rails on the train track, and states and regions ran their trains on gauges that varied from three to six feet. Jobbers and other 'middlemen' were the primary beneficiaries of this classic case of non-standardization through unloading and reloading fees generated by the inconvenience to the traveler, shipper, or box car manufacturer. Even the railroad consortiums would purposely maintain an odd size gauge within their region, solely to force customers to use their systems, keeping out competitors who utilized another size gauge. It was not until the rapid growth of regional networks of railroads that demand led to a nearly continent-wide standard gauge of four feet eight and one-half inches by the 1880's.

Health Information Technology in Today's Medical Practice

Today's physician office is an extremely busy place, one in which information technology increasingly plays an important role in managing the various and often complex tasks associated with information and data collection, storage, transmission, and reporting. In contrast, ten years ago most medical offices had either no computer or only a single desktop machine dedicated to processing bills and accounting information. Nowadays even very small medical offices and outpatient clinics own and operate multiple health information technology (HIT) devices and systems.

Among the hardware and software commonly found in today's medical practice are: systems used for practice management/billing/accounting (PMS); office productivity suites for letters and other clinical documents (e.g. MS Office); systems for maintaining electronic health records (EHR); personal digital assistants (PDA); and an array of paging, copying and faxing equipment. These devices are increasingly connected to local area networks (LAN) and to internal servers, and it is becoming typical for office-based practices to have at least one external connection to the Internet, to a local hospital, or to a corporate data center.

The current medical practice IT environment, however, is full of gauge breaks caused by hardware, software, and network incompatibility. This leads to an inability for systems to interact and communicate with one another within the medical office environment or to connect to and communicate with external systems. In general, office administrative or practice management systems (PMSs) do not transfer information directly to other systems,

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such as those of insurance companies and health plans, except by going through gauge breaks, known as clearinghouses. Electronic health records (EHR) software programs do not exchange messages from hospital or reference laboratories unless expensive interfaces have been programmed specifically for this purpose. Medical office computer systems also do not easily permit doctors to send out prescriptions electronically to pharmacies or to pharmacy benefits management companies, whose computer systems contain detailed information regarding health plan formularies.

Connections to the Internet afford doctors and medical staff a wealth of health and disease information on best practices and peer-reviewed options for care, but these information stores cannot be customized, personalized or validated for particular patients without a great deal of effort. Despite the automation of word processors, hand-held devices, the ubiquity of the Internet, and an increasingly robust broadband communications network throughout the country, the great majority of physician orders to hospitals, nursing homes, pharmacies, and other care settings still require paper, pen or pencil, and a reliance on couriers or FAX machines. The cost of these gauge breaks within the medical office and between it and the health care system at large are enormous, not only in terms of dollars wasted and time spent in redundant tasks, but also in terms of their negative impact on quality of care, patient safety, and the morale of health care workers who struggle within such a fragmented and disjointed system of information flow.

If anything, the situation has the potential to get much worse. The pressure is intensifying for the small medical office to purchase and to utilize more sophisticated information technology. Recent governmental and corporate initiatives are encouraging the nation's medical practices to adopt health information technology for a range of societal purposes, including the improvement of medical error and safety reporting activities, better benchmarking against established best practices, and for anti-terrorism and epidemiological surveillance associated with national security. Compliance with the national health information standards for privacy, security, and transactions and code sets mandated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) will cause many offices to discover that their current systems need to be updated or replaced. In addition, there is growing demand from the public for doctors and medical offices to 'go online' with routine services such as setting of appointments, reporting of lab and other test results, and for asynchronous communications, such as electronic mail.

How are physicians going to cope with this demand to employ more information technology and to become more interconnected with other parties in the health care system? Within the current state of health information technology, it will not be easy, as current systems and their components can cost a small fortune in hardware, software, and maintenance fees. Current systems also require frequent upgrades that can lead to unexpected additional expenses. All of this comes at a time when the health care economic environment is not physician-friendly. Reimbursements from Medicare, Medicaid, and other insurance plans are generally declining at the same time that the number of un-insured and under-insured, patients who may not be able to pay their doctors' bills at all, is growing. Both trends have a negative impact on medical office revenues, especially upon those practices in rural and urban areas additionally hard hit by financial recession.

The irony of this situation is that information technology is supposed to decrease the operating costs of a business by providing improvements in process quality and efficiency. How has it come to pass that physicians and medical practices could find themselves surrounded by non-interoperable computing devices and electronic equipment, the sum of whose parts is not greater efficiency and productivity, but greater expense and hassle? The answer to that question is at least as complex as the story behind the railroad industry's development of multiple gauges, and in one way just as simple: no one planned for a national railway system, and no one has planned for a national health information infrastructure.

Many of the reasons that account for the diversity and non-uniformity of health information technologies are historical, such as health plan requirements for unique versions of claims forms or for the use of proprietary coding systems. Systems were developed to solve a particular problem, at a particular time, in a particular way, without taking into consideration broader concerns of connectivity and data exchange. Many of these decisions were beyond the control of physicians, and physicians have assumed, perhaps naively, that commercial and academic electronic health record (EHR) efforts would lead to working solutions. Sadly, this has not been the case.

The current offerings among health care information systems and services for medical offices are artificially expensive, complex, and awkward to use due to a lack of interoperability standards – standards that exist in virtually all other industries. The problem is the frequency of gauge breaks, and the inability to date to eliminate them.

The Role of Standards in the Modern Economy

The answer to the gauge break dilemma lies, at least in part, in the adoption and widespread dissemination at the medical practice level of standards specific to health information technology. To put it in the simplest form possible, standards are rules, procedures, and specifications that provide a common framework for an industry, profession, or institution. The presence of standards has a lot to do with whether or not a product or service can be expected to work as described or anticipated, and may define acceptability criteria for many aspects of a wide variety of common products. Successful commerce of any kind requires consistency and standardization.

The absence of standards often leads to friction in the marketplace, additional costs in the chain of supply and demand due to redundant or wasted efforts, and, occasionally, monopolistic opportunism on the part of those who provide products or services, or those who offer a work around for the non-standardized industry.

There are a myriad of examples of productivity and efficiency gains achieved through the adoption of standards for information technology and communications in the post-World War II economy outside the health care industry. Most of these have benefited consumers through lower transactions costs, increased convenience, greater diversity of choice and price, or a combination of all three. These include:

- Credit card transactions

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- Automated Teller Machines (ATMs)
- Airline reservation management systems
- Cell phones
- Bar coding in supermarkets

Even within these standards efforts, we run into problems, such as the competing standards in cell phones, and the competition and exclusion between airlines on the various reservation management systems. Overall, however, standards provide a level of interoperability and choice to consumers and purchasers of services. What has been missing in health care are even the most basic data standards. This has led to the point that medical practices purchase information technology on a piecemeal basis to address various information management and communications needs as they arise, but with little choice or options.

What is required are a set of standards for data exchange and information systems interoperability that serve the broader goal of simplifying the information technology needed to run an office practice, and which can finally provide office efficiency similar to what other industries are able to obtain.

Standards and Standards Efforts Important to Office-based Medical Practices

There are a number of areas in which standards can improve the efficiency of medical office processes:

- Claims processing transactions and exchanges between medical offices, hospitals, and health plans.
- Order entry for diagnostic and therapeutic tests and ancillary procedures.
- Laboratory, radiology, and pathology results reporting.
- Automated prescriptions, including automated transmission, and standardized links to formulary and patient safety information.
- Standardized electronic health records.

Billing and Claims Processing

The standards with the most significant direct impact on office-based medical practices are the standards for claims submission and reimbursement.

The ideal would be for physician reimbursement to mimic credit card transactions where a national financial data network would provide the ability to submit a claim, value and approve or disapprove that claim in real-time, and provide direct deposit of payment into a medical practice's financial account. The problem with this ideal is that information systems for both commercial payors and state and federal payors are not set-up to do real-time claims adjudication, even if a national financial data network existed. The cost of replacing payors' legacy claims systems is so high that we will be lucky if we ever see real-time health care claims adjudication. In the meantime, standardization of claim formats and standardization of claim status and payment documentation will at least provide interoperability of health care claims and billing systems.

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When Congress passed the Health Insurance Portability and Accountability Act of 1996, commonly referred to as HIPAA, their primary intent was to allow portability of health insurance by employees when they changed employers. Within the legislation, they included an Administrative Simplification Section, which mandated that health care administrative transactions be automated, with the specific intent of decreasing the cost to all parties in adjudicating health care claims. A set of standardized transactions already existed, proposed by X12, the standards body that represents the insurance industry, but these standards had not been widely adopted. Under HIPAA, the Department of Health and Human Services (HHS) convened a number of public forums to address what standards should be adopted to address the Administrative Simplification Section of HIPAA. As a result of these forums, HHS has issued a regulation that all health care claims transactions be compliant with the X12 health care claims standards.

X12 standards define the format and fields for any kind of health care claim document, excluding attachments. Attachments such as operative reports and encounter notes, are not currently available in standardized electronic formats, and no standards were available to address them, therefore they were excluded in the initial HIPAA regulations, and are set to be addressed at a later date. The X12 standards cover claims, claim status, explanation of benefits, and all essential transactions for submission and payment of claims. They do not cover electronic funds transfer, as there are well-established standards for funds transfer in the financial industry, and there is no need to reinvent these solely for health care.

HIPAA requires that all electronic health care claims transactions comply with X12 health care claims standards by October 2003. The importance and benefit to health care practices are considerable, even if the transition to compliance is problematic. The core advantages of X12 claims compliance are as follows:

- Decreased error rate due to decreased manual claims handling.
- Improved speed of transmission of claims and claim status between practices and payors and payors and practices.
- Decreased office-based clerical time to deal with claims.
- Increased auto-adjudication rates by payors, resulting in faster payments to medical practices.
- Improved number of data fields and quality of content and description within the claim itself.

The problematic transition to these benefits rests primarily in the hands of practice management systems (PMS) vendors, who will need to upgrade most existing PMS installations to X12 compliant systems. There will be some cost, sometimes considerable to medical practices for this transition, but the benefits far outweigh the headache and expense. X12 compliant PMS systems coupled with direct funds transfer arrangement with a medical practice's payors will result in more rapid reimbursement, fewer errors, and improved practice-payor relations.

Order Entry and Results Reporting

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The ideal in the outpatient office would be for all orders to be electronic, entered on a computer or handheld device like a Palm-Pilot/Pocket-PC, with labels for all specimens and films automatically formatted and printed, and results returned electronically to an electronic version of the patient record (EHR). In addition, within those medical practices with their own laboratory equipment, direct connection of laboratory devices to the electronic network would be ideal. Once again, however, obtaining this ideal is difficult, due to a lack of standards.

In terms of electronic order entry, there are no standards, nor are there any proposed, other than for medications and prescriptions. There is a standard for the names of laboratory tests (LOINC), but not for the generation, formatting, and electronic handling of orders.

For results reporting, there are standards for medical device communications (IEEE), but many of our practices regrettably do not have the latest devices that feature electronic connectivity. Regional laboratories tend to use a standard format for results referred to as ASTM, while hospital laboratories tend to use a standard referred to as HL-7. These two standards are related, as HL-7 is based on ASTM, which is an earlier standard, but the two standards are not interoperable. An additional problem with HL-7 is that in its currently deployed versions (Version 2.x) so much variability is allowed at each site that HL-7 results messages from one health care entity are not compatible with HL-7 results messages from another health care entity. There is some hope that this will be improved with a new version of HL-7, Version 3, but the concern is that it will take an extremely long time for Version 3 to replace Version 2. Radiology results and images have yet another standard, DICOM.

Medical practices, therefore, are confronted with a myriad of problems:

- Medical practices with their own laboratory equipment will be dependent on the device vendor(s) to define whether or not they can obtain standardized electronic output.
- Medical practices that use outsourced local or regional labs that are not hospital affiliated will have some difficulty obtaining standardized electronic results due to the fact that not all labs support this and if they do it is usually with the ASTM standard.
- Medical practices that use hospital-based laboratories can sometimes get standardized electronic results, but the standards for hospital-based results, based on various versions of HL-7, are subject to different implementations and variations across different settings.
- Medical practices that own imaging equipment or use significant imaging resources from radiology groups or hospitals will have to depend on the radiology equipment vendors, or third party software vendors who are compliant with the DICOM standard, if they are to get automated delivery and viewing of image studies.

Medical practices are, therefore, dependent on vendors, most specifically EHR vendors, and the practice's laboratory device vendors and contracted labs to work out laboratory information exchange. The difficulty and expense is in direct proportion to the number of laboratories utilized, and the level of technical proficiency of each. Hospitals and hospital-based labs are reaching out increasingly to community medical practices, but in another sort of gauge break, hospital labs are often not part of approved outpatient lab networks for health care payors.

Electronic order entry and real-time results reporting would have a significant beneficial impact on office-based medical practices, but even with standards in place, this is an extremely complex issue. The ideal solution requires a broad scale agreement by all the regional labs, hospitals, and radiology groups within a practice area to all adopt consistent order management and complimentary versions of existing results reporting standards. This is extremely unlikely to occur. The alternative would be a community-based data exchange that aggregated information from all of a practice community's resources and then provided standardized access to the data to local medical practices. An approach such as this is being tested in Santa Barbara, California. Another solution would be a local, regional, or national community-based EHR that was standards-based, to which all health care entities would connect to aggregate the data, and to which medical practices could connect.

Electronic Prescribing

One area where some progress has been made in standardization is in electronic prescribing. There is an existing standard for electronic prescriptions (NCPDP SCRIPT), developed by the NCPDP, the organization that represents the prescription drug pharmacies. This standard addresses the format of the electronic prescription message, and is designed to link into the existing network of automation within pharmacies.

NCPDP SCRIPT, however, only addresses one of the core requirements for successful electronic prescribing in office-based medical practices. Electronic prescribing requires the following components:

- A standardized electronic drug database, standardized for drug names, doses, routes of administration, packaged amounts, preparations, and length of therapy.
- A standardized drug-drug, drug-lab, and drug-food interaction database.
- A drug allergy interface to the patient record or EHR, if an EHR exists.
- Real-time access to payor-specific formulary restrictions and rules.
- Electronic formatting of the prescription (covered by NCPDP SCRIPT).
- Feedback to the medical practice regarding whether or not a given prescription was dispensed and when.
- Electronic tracking and management of refills.
- Standardized and legally validated digital signatures.
- Confidential and secure messaging.

As we can see, NCPDP SCRIPT only addresses one of these requirements. Most of the others have very serious implications if not implemented in a standardized fashion and updated real-time on a consistent basis.

All of the current commercial drug databases, for example, are essentially based on a standard coding scheme known as NDC codes. A unique new NDC code is given to each manufacturer for each of the preparations and packaging of each drug, resulting in hundreds of NCD codes for a simple medication such as Tylenol. In addition, medications that can be given IM or IV are not described that way under NDC, they are described as 'powder for dilution' or 'solution.' There are commercial drug database vendors who build customized

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solutions for prescription writing, but there are no standards – no standards in an area of critical importance for patient and provide safety.

We have not even touched on the issue of prescription routing – whether the prescription should go to a retail pharmacy for the patient to fill, to a PBM for a mail order refill, or to a health plan, HMO, or hospital pharmacy. This is a complex political issue, with profound cost implications to our patients in regards to their potential out-of-pocket expense, and to health plans and employers in terms of overall drug costs. One of the biggest hassle factors for office-based medical practices is dealing with restricted drug formularies, for which no standards exist. Even drug pricing information is not only non-standardized, it is generally not available real-time at the time a prescription is written, and is wholly dependent on where the prescription will ultimately be filled.

The final two bullet points above, are worth discussing, as well. Any time that a document that require a legal signature from a physician is automated; a digital equivalent of that signature is required. This holds for most health care documentation and transactions, but is absolutely critical in drug order entry, dispensing, and prescribing. The generally accepted alternative to a written signature in the computer security world is a digital signature – a tamper-proof electronic token that could only be created by the person 'signing' the electronic document. Under the HIPAA regulations, digital signatures are encouraged, but again, no standards exist or are mandated, although good solutions exist in the non-health care computer industry.

The same holds true for the secure and confidential sending of electronic messages, be they health care claims, orders, results, images, prescriptions, or even email. HIPAA recommends a set of requirements, but there are no standards.

We are moving forward in electronic prescribing, but too many of the essential building blocks are missing or are not standardized for us to be able to have seamless and comprehensive electronic prescribing in our offices.

Electronic Health Records

Perhaps the most beneficial information technology for the office-based medical practice would be an electronic health record (EHR), closely modeled to existing workflow and decision-making, and allowing secure and confidential exchange of health care information. One of the key reasons EHRs are not widely deployed and utilized is an essential lack of appropriate standards. A working EHR requires more than a simple replication of the charting processes within the traditional paper record. EHRs are destined for failure if they are merely glorified automated word processors for generating clinical notes.

What is needed in the office-based medical practice is a virtual replacement of both the paper medical record and the administrative paperwork currently required to practice medicine. In essence, all administrative data and paperwork in a medical practice is primarily a derivative of the clinical workflow and decision process or the clinical notes and documentation. Unless an EHR simplifies clinical workflow and decision-making, and in the process automates and eliminates much of the paperwork burden of a practice, it will add work and inefficiency to the process. We are reaching the limit of non-clinical burden that

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we can bear in the practice of medicine, and we need tools to simplify, not to complicate our work.

Much of the above can be attained with proprietary non-standardized EHRs. A key benefit of an EHR, however, is also to facilitate the exchange of data between physicians and as a source of medical legal documentation and justification for health care claims and reimbursement. If standards that define the content of an EHR do not exist then comparability between individual patient records is difficult if not impossible. A working ambulatory care EHR also ideally includes order entry, electronic prescribing, and automated coding, claims generation, and billing. An EHR, therefore, requires not only all the standards we have already discussed, but standards for content, as well.

One of the simplest standards required for interoperable health records is a unique and comparable way to identify patients, usually described as a Master Patient Index (MPI). A unique patient record number has been discussed as a solution, specifically under HIPAA, but due to valid concerns regarding patient and physician confidentiality and privacy has been effectively dropped. MPI standards that would preserve patient and physician confidentiality have been discussed, but are not actively being pursued.

Another standard that is required, and also effects patient and physician confidentiality is an authentication standard. Authentication is the mechanism through which the identity and data access rights of an individual end-user are established and validated each time they access confidential data within a system. Without standards regarding authentication, there will be varying levels of trust between different systems at different sites and patients and physicians will be reluctant to allow access to their data, effectively defeating the basic concept of patient data portability and access. If we cannot trust the security of the system, then we cannot trust the accuracy, completeness, or quality of the data. In addition, physicians and patients will err on the safe side with minimal and often incomplete disclosure of key clinical data. Significant effort was expended while the HIPAA regulations were under discussion to establish detailed standards for security, confidentiality, privacy, and authentication, but they were effectively blocked by concerns over the complexity of retrofitting existing systems.

Even if secure, the data themselves also require standardization, and the principle efforts in this regard have been to establish standardized vocabularies and code sets for documentation, and although a number of valid models exist, competing interests have prevented agreement. The only areas where standardized code sets exist are in diagnoses (ICD codes) and procedures (CPT codes), and even within these, there are significant problems. ICD codes, for example were originally developed under the auspices of the World Health Organization (WHO) as codes for cause of death. They have been added to and modified extensively, but are still inadequate to accurately document disease states, trauma, and symptomatic conditions from a clinical perspective or to cover medical legal risk. They are adequate for billing purposes, but are not even ideal for that, as they do not even cover as simple a clinical concept as laterality, for example.

There are several standards that have been proposed for the electronic health record (EHR). The most prominent one currently is the HL-7 Clinical Document Architecture (CDA). The CDA is intended to cover all clinical documents other than images, which are covered, as

discussed previously, under the DICOM standard. The CDA is a document exchange format to standardize the exchange of data between disparate data representations in different EHR and clinical systems. HL-7 has also proposed a data model for health information and transactions (RIM). Both of these standards serve as models, but do not yet address the level of specificity really required to automate our current clinical documentation.

For an EHR to truly be useful for an office-based medical practice it would incorporate patient identification, documentation, order entry, results reporting, prescription and medication management, automated coding, and epidemiological and communicable disease reporting. Not only does this require the missing standards we have already discussed, but it requires a detailed level of clinical standardization, the knowledge of which must come from practicing physicians.

Conclusions

Significant progress is being made in setting standards in health care IT, but the existing standards are not widely enough adopted, nor are they comprehensive enough to provide all the things we really need in office-based medical practices. The only area of relatively complete standardization and pending wide adoption is in health care claims, where HIPAA is mandating essential compliance with the X12 claims and claims transaction standards. This is an area where vendors who supply practice management systems or EDI claims services to practices will shoulder the majority of the burden of compliance, with significant short and long term benefits to our practices. As noted, this is liable to cost us money for system upgrades or replacement, but these expenses will be quickly recouped in improved claim and payment flow.

Electronic order entry, electronic prescriptions, and on-line results reporting and image retrieval would be of great benefit to us, but all of the standards we need and the required cooperation between vendors and health care entities is not yet in place. We are moving in that direction, but will have to remain patient. The regret is that this is the area where we could have the greatest impact on lowering health care costs, and the greatest improvement in patient outcomes. The ultimate goal, community-based electronic health records, accessible in all of the health care settings we work, and portable across those settings, will depend on a wide array of standards, many of which would greatly benefit from direct input and involvement of office-based physicians working in the real world of medicine.

Standards are essential to remove the gauge breaks currently hampering the automation of our office-based medical practices, and active involvement of practicing physicians is the engine that will eventually drive that transition.

Data Excess and Document Overload: Barriers and Disincentives to an Interconnected / Interoperable Healthcare System

Peter Basch, MD

Executive Summary

The creation of a national health information infrastructure has the potential for enabling quantum improvements in quality, safety, and cost effectiveness. In healthcare, as in early railroad travel, lack of planning and standards led to added expense and inconvenience for consumers. Railroad “jobbers” functioned to breach these “gauge breaks,” much as “infomediaries” and clearinghouses do for healthcare. Instituting standards removed the need for jobbers, and led to more convenient and less costly railroad travel. Instituting standards can do similarly for healthcare, particularly when widespread use of these standards serves to enable throughput of a clearly delineated endpoint-defined workflow.

However, when the outcome of such standards adoption is either: a new type of medical service that is neither delineated nor episodic; or a cleaving of results or workflow from the ordering / responsible clinician, substantial disincentives may arise. Failure to address these issues of added duty, responsibility and liability, as well as those of insufficient reimbursement for what will be seen as a new type of medical service, is likely to engender physician resistance, and thus impede adoption of an interconnected / interoperable healthcare system. Additionally, examination of how reports and records are best integrated into an episode of care, calls into question current documentation standards and requirements.

Removing Gauge Breaks

“Removing Gauge Breaks: The Role of Health Information Technology Standards in the Office-Based Medical Practice,” by Drs. Kibbe and Peters, provides an excellent summary of the value of, and some of the problems associated with achieving health information interoperability. It starts with a valuable analogy drawn from the history of early train travel. This transportation system was not developed from a national plan, but rather was pieced together, one segment at a time. And each segment of track, and corresponding trains used on each segment, were all different, not primarily by design, but because there were no manufacturing standards.

Even on this nonstandard system, long-distance travel was possible. But breaching each gauge break added cost and delay. Passengers had to buy tickets segment by segment, and also had to pay handlers to help move them and their luggage from one system to another. While this need for railroad intermediaries added jobs and money to the local economy, there was a stronger business case for eliminating them. As our society became

more mobile, more travelers had a need for long-distance travel, and were willing to pay the price.

As standards were adopted, small railway systems merged or were bought by larger systems, and ultimately short and long-distance train travel was available from a smaller number of transportation companies, but with few or no gauge breaks. Underlying these connections and mergers was the understanding that the price of travel along these newly joined multiple segments was higher than the price of travel on a short segment. A ticket from New Haven to Chicago would cost more than a ticket from New Haven to New York City. Additionally, these connections did not result in unrecoverable costs or new liabilities for transportation carriers.

In railway transportation, the beneficiaries of standardization were the emerging large railway companies, the nation (making its workforce more mobile), and travelers. The costs of achieving standardization were borne by the beneficiaries. The only losers were the middlemen, whose job to breach gauge breaks was no longer necessary.

Health Information – a Need for Standards

Extending this metaphor to the mobilization of medical information holds true up to a point. From its earliest days to the present, most medical information has been contained on paper. Common terminology occurred only to the extent that it was standardized in medical education. Medical information systems developed without a national blueprint, each vendor followed its own design, based on perceived value and marketability.

Voices calling for better mobilization of medical data come from many differing perspectives, including:

- Consumers, who...
 - Have multiple physicians and other care givers
 - Change physicians
 - Want better / fuller / more timely access to their own health information
- Society, which...
 - Is more mobile, and
 - Is more concerned about quality and safety
- Payers, who must manage...
 - Eligibility determination
 - Claims status and payment
 - Pharmaceutical formularies
- Clinicians, who must navigate...
 - An expanding volume of medical knowledge with frequent updates
 - Obtaining relevant medical information from disparate sources
 - Communication with busy or unavailable colleagues
 - Increasing costs of moving medical and financial information through medical infomediaries
 - The expanding expense and hassle in care throughput

Clearly, removal of barriers that result in better, safer, and more cost effective care is a laudable goal. And where these actions result simply in enhanced throughput of delineated endpoint-defined workflows, there is no downside. For example, using standards and interoperability to enable a prescription from Dr. A's electronic prescribing tool directly into the pharmacy system of the patient's preferred drug store or PBM, will make prescribing safer and more efficient for all parties. However, our healthcare system attributes reimbursement and duty to a responsible provider for a defined episode of care. And this is where the analogy to breaching railroad track gauge breaks stops.

Episodes of Care – Definition / Reimbursement

Outpatient nonprocedural services have a defined beginning and endpoint, and a responsible provider. Services for new patients are reimbursed at a slightly higher level than for existing patients, because there is a full set of medical history questions that needs to be asked once, and this activity adds more time to the visit. Thereafter these questions are asked as briefer update questions (e.g. – "Your record shows that you are only allergic to penicillin, have you developed any other medication allergies?"). As updates can become extensive if a patient is not seen for some time, a clinician is typically allowed to consider that patient a "new patient" for billing purposes, if three or more years has elapsed between visits.

E/M billing codes base reimbursement primarily on the documentation of certain elements in each of three "buckets," history, physical, and management. While there is the possibility of basing a charge on time spent with the patient – time-based charges are rendered infrequently, except by mental health professionals.

Looking specifically at the history component of a visit, this segment is reimbursed with the understanding that a skilled clinician can rapidly obtain the relevant components of a history from a patient interview. For example, the history component of a 10-minute office visit is assumed to take 1-2 minutes (3-5 minutes for a new patient). The patient has a key role in this process, in that he/she is expected to be able to rapidly answer close-ended questions such as, "Have you ever had surgery?" or "What medications are you taking?"

Extending the Episode of Care

Occasionally a new patient will bring in old paper records from a prior clinician. While sometimes valuable, most doctors do not welcome such occurrences. Reading through old records to find critical information is very time-consuming, and only potentially partially reimbursable as part of a medical visit (one component of the management section of the current E/M codes allows one to include "record review" as a service, but adding this one subcomponent to the billing formula typically does not warrant an "upcode"). And, there is no way to bill for "record review" outside of a medical visit.

Unlike other professionals where time = money, physicians are expected to get the information they need in a short period of time. And if that historical information is obtained in 10 seconds ("are you feeling better, is the cough gone?"), the physician may come out ahead. If that information is obtained in 1-2 minutes – compensation is arguably adequate

for the effort. But if information gathering /reading / interpretation / analysis take 5 minutes, or 10 minutes, or 10 hours – the clinician has no recourse for added reimbursement. This major defect in our reimbursement system has not been in the forefront of the reimbursement debate, only because it happens infrequently. But would doctors be so sanguine if this overwhelming and uncompensated service occurred with each patient visit?

Doctors Need More Information

A “horror story” frequently raised by those in favor of interconnectedness is as follows – a person is brought to an emergency room in a distant city and is unable to give a history. However, thru an interconnected system, one could (with permission, and over a secure connection) pull the history from wherever it was generated (assuming that it existed in digital form), and then more appropriately care for the patient, and perhaps save a life. This example, while dramatic, has little bearing on what is more likely to result in less than optimal ER care – too few resources and too many patients. Additionally, it is much more likely that too much information exists about a patient within the walls of a hospital or health system, than too little. A more pressing and likely problem is that there is no system for filtering and thus presenting a brief and actionable summary of relevant data to the clinician.

Is More Information Better?

Indeed, what would happen if one had full access to all patient data at every patient visit (assuming of course that our systems fixed the problem of patient identification)? How would our emergency rooms and medical offices function if every patient, at every visit, presented with hundreds or thousands of pages of medical history and test results. The few minutes relegated to the history section of the visit would extend to hours, and emergency rooms, barely functional now in many locales, would be paralyzed with volume. And unless there is a sea change in the definition of medical liability, failure to read thru whatever information is readily available, could result in a massive increase in successful malpractice suits, further crippling our healthcare system.

The medical literature bemoans the fact that physicians make decisions without full information 70-80% of the time. One can easily see that this could result in a major problem if one of the pieces of information missing was, for example, an allergy to penicillin. However, as documentation requirements have forced clinicians to shift from producing bulleted shorthand to longwinded novellas (necessary for malpractice prevention and reimbursement); full information is more likely to yield multiple pages of medically irrelevant verbiage. Unless clinicians are reimbursed for time, they will only skim documents, and unless those documents are filtered for essential clinical lists (such as the problem list, medication list, and medication allergies) – significant errors may be more likely.

Several years ago I was presented with the opportunity to accept a data feed from our hospital information system directly into my office EMR. On the surface, it sounded like a good idea, as I (the primary care doctor) would then be able to integrate inpatient and outpatient data. Fortunately, prior to giving the final go-ahead, I was given the opportunity to examine a prototype of such a compilation. Where I was used to seeing my up-to-date and manageable active problem and medication list – the newly integrated “complete” lists

contained scores of diagnoses (many irrelevant and generated strictly for maximizing billing) as well as both current and discontinued medications. Attempting to provide quality care for a patient within the confines of a ten-minute office visit, previously doable, would have become impossible. Either care would suffer, or the time spent on medical history collection and correction would more than double – not something I (or any other provider would want) without a redefinition of the office service to include added reimbursement.

Data “Ownership” and Responsibility for Care

While one can argue about who “owns” the patient record, our current healthcare system is clear about duty, responsibility, and liability. Simply put, a duty exists for established patients of one’s practice, and for patients for whom one has been asked to consult. Once a duty exists, if a physician provides a service, he/she is responsible for choice of service (e.g. chest x-ray vs. chest CT), quality of service (e.g. leaving a sponge in the abdomen following an appendectomy), and follow-up of an ordered service (acquiring the result of the x-ray, making a judgment as to the need for further testing or treatment, and informing the patient).

What happens when our clinical systems allow, or even “push” results to all relevant clinicians (all clinicians for whom the patient has an active doctor-patient relationship)? Assuming that the problems of patient identification have been solved (no trivial task), and that concerns re patient privacy have been answered (again, no small order); how is medical duty, responsibility, and liability determined in such an environment? Is the cardiologist now responsible for the thinking, direction, and actions of the urologist? What would the workflow look like to a clinician who not only had access to all the data that he himself generated, but also to all data from all clinicians, over the course of a patient’s lifetime?

Again, a true story. Several months ago, a local imaging center, believing that HIPAA would forbid them from sending reports upon request to physicians other than the ordering physician, started proactively sending out (with patient permission) duplicate report copies to the primary care physician. My imaging report volume tripled, and an entirely new workflow emerged. Few medical problems have only one correct pathway for diagnosis and treatment, but fortunately, any differing opinions are visible only when a patient asks for a second opinion. Now, because of an unrequested interconnectedness, scores of my patients had unknowingly set in motion second opinions for imaging studies. For me this became an uncompensated duty, and one that caused far more confusion than good.

A specific example - I received a pelvic sonogram report on Jane Doe (ordered by her gynecologist) that described a benign-appearing cyst on the left ovary. Several possible actions became possible:

- Throw the report out – I didn’t order the test, I don’t want the result.
- Put the result in the chart, but don’t take any action – after all, I didn’t order the test.
- Put the result in the chart and simply notify the patient of the result.
- Put the result in the chart, call the gynecologist to make sure that she also got the result, and that she is handling further workup and treatment.

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- Put the result in the chart, call the gynecologist to make sure that she also got the result, but because she was gone for the day, notify the patient myself, and ask her to follow-up with the gynecologist.
- Put the result in the chart, forget the gynecologist, notify the patient of the result, and recommend a course of action myself.
- Put the result in the chart, forget the gynecologist, notify the patient of the result, and recommend a course of action myself. And then find out that the gynecologist already was aware of the result, and already recommended a different course of action to the patient.

Ok, this is not a true story, but a composite of several events – but I have at different times followed each of these seven pathways. What is clear is that once clinical results are sent or enabled to a clinician other than the ordering clinician, there is a blurring of duty, responsibility, and liability. Failure of each informed clinician to take action violates a duty to the patient and establishes a potential tort. However, multiple providers taking simultaneous action on the same results will lead to confusion on the part of the patient, and perhaps the patient failing to take any appropriate action (“as long as my doctors are disagreeing on what I should do, I’ll do nothing”), leading to a worsening of care.

The Value of Documentation

Clearly, getting the right information at the right time to the right person has value. And getting too much information to too many people all the time not only does not, but rather, it adds enough negatives as to disincite connectivity. Finding the right balance to this query raises a question as to the value of documentation, and points towards a new standard for documentation – less is better.

Documentation serves four purposes. First, it records a summary of the history, physical, assessment, and plan. Secondly, it provides a roadmap for future care. Third, by documenting patterns of thought and pertinent negatives, it provides for medicolegal protection for actions taken and not taken. And lastly, it serves as a basis for payment.

Documentation of an office visit was never meant to approximate a word-for-word transcript. In fact, a sign of advancement in medical education and sophistication was brevity. There is no extra value to a patient visit by papering a note. The more time spent on unnecessary documentation, the less time available for the patient.

As time consuming as a cluttered verbose note is to create, it is far more time consuming to read. Finding the few essential kernels from a multi-page note takes time and effort that could be better spent on direct patient care. Thus a record, or a view of previous records is generally more useful and usable if it is short and bulleted to begin with, or if it stripped of verbosity and provides a filtered view of the data.

Why do we then waste time and effort creating and then having to read unnecessary filler? To satisfy the non-clinical uses of documentation – verbiage for payment and verbiage to protect against feared litigation. And questioning the value of documentation-based reimbursement is not at all controversial. The Advisory Panel on Regulatory Reform for HHS

recommended (near unanimously) in June of 2002 to scrap the E/M payment system – citing added cost and complexity.

Clearly some level of documentation is necessary to provide a defense against a malpractice suit. Whether or not excessive documentation helps is a question for our colleagues in the legal profession to answer. And if the answer is not really, then we have a clear mandate – less is better on all fronts. Spend more time with the patient, less time papering a record. Be able to easily and more timely read prior medical records (and present a far easier task for filtering programs to present even a clearer view of old data). Base reimbursement on quality measures that are independent of verbosity. And hopefully be able to better defend against malpractice based on adherence to community standards and best practices, rather than creating an illusion of defense with sheer volume of words.

But if more documentation is required for payment purposes or due to fear of future litigation, then we must at a minimum filter such data before it is presented to other clinicians. Whereas several thousand pages of documents would add an enormous amount of work and liability, a filtered problem and medication list would not. Such intelligent specialty –specific filtering would also save time for the provider and patient, as well as to improve quality and safety. For example, while I, as a primary care provider, would find enormous value in a pre-populated and organized list of prior surgeries, I would find digital availability of complete operative reports more of an annoyance. Yet a surgeon would likely find such details crucial to future surgery.

Conclusions

Kibbe and Peters point out the irony of medical information technology, which is supposed to enhance efficiency and make care less expensive, actually creating greater expense and hassle, particularly if the multitude of disparate systems used by a clinician is not interoperable. While this situation is fixable by agreements on standards and improvements to technology, it would be tragic if such a fix, with the potential of improving quality, access, and reducing errors, was not adoptable due to failure to anticipate new problems with workflow and liability.

As we develop standard nomenclature and pathways for clinical activities, we must additionally address the consequences of these changes, including:

- Once more information is pushed, or becomes easily and readily available to all providers all the time (an interoperable / interconnected healthcare system), the added effort required to read, analyze, integrate, and interpret this data must be compensated.
- In this new world of interconnected health data, a national dialog should be started among clinicians, consumers, legislators, regulators and lawyers, to define new standards of duty, responsibility, and liability.
- Further, we must speak up about the consequences of medical documentation verbosity. It adds time but no value to the medical visit, and does not improve quality. It makes the record less useful and usable to the next provider. It makes the vision of a future where all data is digitized and readily available at a moment's notice something providers would rather avoid than embrace.

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- However, if reimbursement is reformed to incent information management, information availability does not imply duty, and documentation standards are readjusted away from verbosity and towards current and future quality care – the vision of interconnected healthcare is one that will be positive for all parties.