

PATIENT SAFETY: ACHIEVING A NEW STANDARD FOR CARE

Statement of

John R. Clarke, M.D.
Professor of Surgery
Drexel University

and

Adjunct Professor of Computer and Information Science
University of Pennsylvania

and

Member, Committee on Data Standards for Patient Safety
Board on Health Care Services
Institute of Medicine
The National Academies

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Introduction

Good morning, Chairman Buyer and members of the Committee. My name is John Clarke. I am a professor of surgery at Drexel University in Philadelphia, an adjunct professor of computer and information science at the University of Pennsylvania, and the physician project manager for the Pennsylvania patient safety reporting system. I have also served two years in the U.S. Army, primarily as an emergency physician at Martin Army Hospital in Ft. Benning, GA, and two years as Chief of the Medical College of Pennsylvania's Surgical Service at the Philadelphia VA Medical Center.

Over the past two years, I have served as a member of the Committee on Data Standards for Patient Safety of the Institute of Medicine. The Institute of Medicine is part of the National Academies, chartered by Congress in 1863 to advise the government on matters of science and technology.

The study that I am going to talk about today sought to foster health data standards to improve patient safety. The study was sponsored by the Department of Health and Human Services. A major part of the study's recommendations concerned the use of electronic health record systems.

A National Health Information Infrastructure Is Needed

All Americans, whether in service to our country or in civilian life, should be able to expect to receive health care that is safe. To achieve this, a new health care delivery system is needed – a system that provides accurate information that both prevents errors and learns from them when they occur. The development of such a system requires, first,

a commitment by all stakeholders to a culture of safety and, second, improved information systems.

Specifically, a national health information infrastructure is needed:

- To provide immediate access to complete patient information and decision-support tools for clinicians and their patients, and
- To capture patient safety information and other quality of care outcome measures as by-products of care and use this information to design even safer delivery systems.

Electronic health record systems and health data standards are both crucial building blocks of the national health information infrastructure.

Definition of an Electronic Health Record System

What does our committee mean by an electronic health record system? An Electronic health record system includes a longitudinal collection of electronic health information for and about individuals. It also provides immediate electronic access to individual- and population-level information by authorized users, and provides clinical knowledge and decision-support that enhance the quality, safety, and efficiency of patient care. It provides the essential information infrastructure for an efficient health care delivery system.

Benefits of Electronic Health Record Systems

The standard use of electronic health records has enormous potential to improve the safety, quality, and efficiency of health care in the United States, as called for in previous Institute of Medicine reports.

More immediate access to computer-based clinical information, such as laboratory and radiology results, can reduce redundancy and improve quality. Computer-assisted diagnosis and care management programs can improve clinical decision making and adherence to clinical guidelines designed to optimize outcomes.

Computer-based reminder systems for patients and clinicians can improve compliance with protocols for disease prevention. Likewise, the availability of complete patient health information at the point of care delivery, together with clinical decision support systems such as those supporting physician order entry, can prevent many errors and adverse events (injuries caused by medical management rather than by the underlying disease or condition of the patient) from occurring.

With a robust IT infrastructure, patient health information can be shared among all authorized participants in a patient's health care community.

Challenges

There are some excellent examples of successful electronic health records in health care settings in both the private and public sectors. A handful of communities and systems have established secure platforms for the exchange of data among providers, suppliers,

patients, and other authorized users. Among the most notable of these are the systems developed by the Veterans Health Administration (VHA) and the Department of Defense (DOD).

Other examples are the New England Healthcare Electronic Data Interchange Network, the Indiana Network for Patient Care, Intermountain Health Care, the Santa Barbara County Care Data Exchange, the Patient Safety Institute's National Benefit Trust Network, and the Markle Foundation's Healthcare Collaborative Network.

But these examples are the exception, not the rule. In most of the nation's hospitals, orders for medications, laboratory tests, x-ray studies, and other services are still written on paper, and many hospitals lack even the capability to deliver laboratory, radiology, pathology, and other results in an automated fashion. The situation is no different in most small practice settings, where there has been little migration to electronic records.

In addition to purely technological challenges, there are sizable policy, organizational, and financial challenges that must be addressed to facilitate the adoption of electronic health record systems. Some attempts to introduce computerized provider order entry systems and other components of an electronic health record system have been unsuccessful. Currently available personal health records, which allow patients to enter their own information, have demonstrated limited functionality to date.

Encouraging Deployment

Government health care programs, along with various private-sector stakeholders, are considering options to encourage the implementation of electronic health record systems

by providers. To achieve widespread implementation, some external funding, incentive programs, or other federal initiatives will be necessary. For example, the Centers for Medicare and Medicaid Services might provide some form of financial reward to providers participating in the Medicare program that have deployed electronic health record systems.

On the private-sector side, various insurers, purchasers, and employer groups are instituting quality incentive programs for specific electronic health record system functionalities, such as computerized provider order entry for prescription drugs and electronic reporting of performance measures.

In addition, a number of employers, health plans, and physicians have recently formed a coalition called Bridges to Excellence, which will provide financial bonuses to providers to encourage improved patient care management systems, including electronic health record systems. Another option is to provide grant funding or access to “low-cost” capital to enable providers, especially those with a safety net function, to invest in acquiring electronic health record systems. Certain regulatory strategies might also be pursued, such as requiring providers to have an electronic health record system as a condition of participation in Medicare.

Consideration should also be given to the best means of creating public-private partnerships in a geographic area to leverage existing resources and to ensure that no providers (for example, safety net providers) or citizens are excluded. One possibility might be for state government, VHA and private-sector health care organizations and

vendors to work in partnership to establish information and communications technology infrastructure. Additional support may be provided to the VHA so that it can offer safety net providers (e.g., public hospitals and community health centers) the opportunity to participate in the VHA's information and communications technology system and receive technical assistance for that purpose.

To implement any of the above strategies, one must first clearly define a functional model of the key capabilities for an electronic health record system. The committee's report detailed essential components of such a functional model.

Health Care Data Standards Are Also Needed

Electronic health records are important components of the national health information infrastructure. But to ensure that health information is understandable to all users and can be exchanged efficiently between health care settings, health care data standards are also needed.

The National Committee on Vital and Health Statistics, a public-private advisory committee established to provide advice to Department of Health and Human Services and Congress on national health information policy, has for many years recommended that the federal government assume a more active role in establishing national data standards. In 1996, Congress passed the Health Insurance Portability and Accountability Act, which mandated standardization of administrative and financial transactions.

In 2001, the Consolidated Health Informatics (CHI) initiative, an inter-agency effort, was established as part of the Office of Management and Budget's eGOV initiative to

streamline and consolidate government programs among like sectors. The mission of the CHI initiative is to articulate and execute a coherent strategy for the adoption of federal interoperability standards for health care information. Department of Health and Human Services was designated the managing partner for the CHI initiative, with both the Department of Defense and the Veterans Administration being major partners in the initiative. The CHI initiative played a pivotal role in the recent decision by the federal government that programs of the Department of Health and Human Services, the Veterans Administration, and the Department of Defense would incorporate certain data standards and terminologies.

The CHI initiative, although off to a very promising start, lacks a clear mandate to establish standards. In addition, once initial standards and gaps have been identified, the future of the initiative is unclear. The initiative would also benefit from closer collaboration with the National Committee on Vital and Health Statistics (NCVHS) to ensure the active participation of private-sector stakeholders.

The Committee's Recommendations regarding Health Care Data Standards

The Data Standards for Patient Safety Committee recommended that Congress should provide clear direction, enabling authority, and financial support for the establishment of *national* (not just federal) standards for data that support patient safety. Various government agencies will need to assume major new responsibilities, and additional support will be required. Specifically:

(1) The Department of Health and Human Services should be given the lead role in establishing and maintaining a public-private partnership for the promulgation of standards for data that support patient safety.

(2) The Consolidated Health Informatics initiative, in collaboration with the National Committee on Vital and Health Statistics, should identify data standards appropriate for national adoption and identify gaps in existing standards that need to be addressed. The membership of National Committee on Vital and Health Statistics should continue to be broad and diverse, with adequate representation of all stakeholders, including consumers, state governments, professional groups, and standards-setting bodies.

(3) The Agency for Healthcare Research and Quality in collaboration with the National Library of Medicine and others should provide administrative and technical support for the CHI and NCVHS efforts. In particular, these agencies should ensure the development of implementation guides, certification procedures, and conformance testing for all data standards. They should also provide financial support and oversight for developmental activities to fill gaps in data standards. And, finally, these agencies should coordinate activities and maintain a clearinghouse of information in support of national data standards and their implementation to improve patient safety.

(4) The National Library of Medicine should be designated as the responsible entity for distributing all national clinical terminologies that relate to patient safety, and for ensuring the quality of terminology mappings.

Using Government Leverage To Establish National Standards

Given both the sizable purchasing power (over 40 percent of health care expenditures) and the regulatory authority of the federal government, the incorporation of data standards into government programs is a logical approach to establishing national standards. After providing a reasonable time period for health care organizations to comply with national standards identified by CHI initiative, the major government health care programs, including those operated or sponsored by Department of Health and Human Services, the Veterans Administration, and the Department of Defense, should immediately incorporate these data standards into their contractual and regulatory requirements (e.g., Medicare conditions for participation).

The Data Standards for Patient Safety Committee detailed an action plan for the deployment of standards for classifying and coding health data, for electronically interchanging data, and representing clinical knowledge. With federal leadership in the establishment of standards for data that support patient safety, information technology systems built over the coming decades should achieve the success to support the delivery of safe and effective care that we have so long been waiting for. Our committee report offers a blueprint to address the standards necessary to make electronic health records universal not only within the federal sector, but across the country as well.

In conclusion, I would like to thank the subcommittee for the opportunity to testify. I would be happy to take questions at the appropriate time.