Federal Health Information Policy: A Case Of Arrested Development

Federal support is vital for the computerized patient record to evolve from a digital version of today’s paper chart into a navigational system for the care team.

by Jeff Goldsmith, David Blumenthal, and Wes Rishel

PROLOGUE: As large sectors of U.S. business and industry invest in computerized workflow and document management solutions to increase productivity, the health care sphere lags woefully behind. As of 2001 less than 10 percent of U.S. hospitals had adopted computerized patient records, and less than 5 percent had adopted computerized physician order entry. The bulk of the $20 billion or so investment in health care information technology (IT) went to financial infrastructure (billing). Bringing physician practice into the computerized realm is “more daunting still,” according to this paper’s authors. While 74 percent use the Internet to seek new medical knowledge, only 17 percent of physicians in office-based practice have computerized patient records.

The authors issue a provocative call to action to bring the U.S. health care sector up to the level of computerization now seen in other countries. To move ahead, they argue, standardization of clinical data systems is the key. And in the absence of a “Microsoft” for computerized patient records, federal government action is needed. The authors also call for federal subsidies to encourage rapid adoption of these technologies by health care providers. A Perspective by Molly Joel Coye and William Bernstein follows.

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ABSTRACT: Computerized patient records (CPRs) have reached a state of technical maturity that makes them an essential component of modern patient care. However, because uniform technical standards do not exist, CPRs constructed by different vendors do not convey clinical information easily from provider to provider. Moreover, unequal access to capital may mean a two-tier clinical information environment in the future. HIPAA, while important, did not anticipate the CPR revolution. New federal activism is required to assure not only interoperability of clinical data systems, but also that providers who lack capital and technical resources can make the needed digital conversion.

American health care services are the world’s largest and most complex knowledge enterprise. At roughly $1.5 trillion in 2002, U.S. health spending exceeds the size of the entire economies of Britain and most other Western nations. While information technology is advancing rapidly in other sectors of the U.S. economy, the U.S. health care system remains mired in a morass of paper records and bills, fax transmittals and unreturned telephone messages.

Despite more than $20 billion in information technology (IT) expenditures in 2001 by U.S. providers (less than one-third of which, $6.5 billion, was spent for hospital clinical systems), less than 10 percent have adopted computerized patient records (CPRs), and less than 5 percent have adopted computerized physician order entry (CPOE).1 Much of the large amount spent on IT goes toward upgrading and maintaining financial systems (such as billing), which are unnecessary in countries with a single payer.

The United States lags well behind other countries, notably Great Britain, Australia, and New Zealand, in the adoption of computerized clinical systems, especially in the outpatient area.2 All of these countries have a greater ability to standardize clinical data systems, because they have national health services or a single payer, and they have used their financial and administrative muscle to facilitate widespread use of some information technologies.3

If the antiquated U.S. administrative and clinical infrastructure merely wasted dollars and frustrated patients and caregivers, it might not present a compelling case for public action. However, a growing body of evidence suggests that fragmented and inaccessible clinical information also threatens the lives and health of many Americans. The Institute of Medicine (IOM) has cited poor information management as a major contributor to the unacceptably high level of medical errors in the United States.4 Illegible prescriptions, unconfirmed verbal orders, missed telephone calls, and lost medical records all place patients at risk.

However, combined with expert systems and clinical decision support, CPRs have reached a state of technical maturity that makes them an essential component of a modern patient care system. Further, ferocious market competition among CPR vendors and technical advances such as application service provision (remote computing delivered through a broadband Internet connection) promise to reduce the cost of acquiring and installing these costly technologies.
However, because of the lack of uniform technical standards and both financial and regulatory barriers to physician adoption of these tools, CPRs offered by different vendors will neither “interoperate” nor interface easily with legacy computer systems in hospitals or physicians’ offices. Moreover, unequal access to capital will mean a continued reliance on paper- and telephone-based clinical and financial systems in rural and public health systems and in physicians’ offices for decades to come.

Finally, as discovered after the fall 2001 anthrax episode, our current fragmented, largely paper-based clinical record system hampers an efficient and timely response to the all-too-real threat of bioterrorism. The inability to aggregate clinical information at the point of care (emergency rooms, primary care clinics, and physicians’ offices) will not only delay the “diagnosis” of a terrorist threat, but will also impede an expeditious, coordinated response to contain any episode. For all of these reasons, there is a need for a more aggressive federal role in health information policy.

**Technological Promise**

More than a decade ago the IOM reviewed the technical progress in automating clinical care processes and recommended that the CPR be adopted as the standard medical record. To accomplish this, the IOM called for the establishment of a computer-based patient record institute (CPRI) to promote and facilitate the development and implementation of the CPR. Further, it called for expanded support for the CPR from the public and private sectors and specifically recommended that Congress authorize and appropriate funds to implement CPR research and development (R&D). The IOM also recommended that the CPRI promulgate uniform national standards for data and security to facilitate the CPR's implementation. Few of these recommendations were adopted.

In the ensuing decade CPRs have evolved from difficult-to-use “science projects” in a handful of academic computing centers to commercially available, sophisticated (if costly) tools to guide and enhance day-to-day clinical care. Gartner, a respected information technology research organization, has concluded that the CPR has reached the stage of reliability and technical maturity to be adopted by all health care organizations. The IOM has also recognized that technological changes have occurred that favor the CPR’s adoption. A growing body of research has established that computerized support for clinical decision making can markedly reduce not only medication errors but also other forms of medical error. The CPR provides not only improved legibility and documentation but also, when combined with CPOE, an automated capacity to audit and review care decisions to assure that physicians have weighed their impact on the patient’s clinical risk.

CPR systems are being wedded to rules and logic engines, care pathways, and online knowledge repositories such as the National Library of Medicine’s Medline service, to frame the physician’s clinical decision-making alternatives based on the
patient’s condition at the moment. Software that weaves medical knowledge into the physician’s ordering process is generically known as a clinical decision support system (CDSS). While many physicians remain suspicious of “cookbook medicine,” new CPR systems will function as easy-to-use medical reference guides at the point of care, leaving to physicians’ discretion the ultimate decision about what is right for patients.

As clinical decision support becomes more robust, the CPR seems likely to evolve from a digital version of today’s paper chart into a navigational system for the care team. Moreover, when aggregated at the level of large patient populations, CPRs will enable sophisticated retrospective analysis of clinical effectiveness across patient groups with common medical risks and enable physicians to learn from the clinical care activity of their colleagues, a task that today is expensively wedded to manual chart review. CPRs also will simplify the conduct of clinical research activities, including testing of new drugs and therapies.

The Pace Of Adoption

Clinical informatics is expensive. The cost of implementation ultimately depends on the size of the hospital and its readiness to make the conversion. To go all the way to CPOE, which builds upon the CPR, requires a large monetary investment for technology as well as human resources. For larger hospitals to make the conversion to CPOE, it can cost as much as $30 million. According to Leapfrog Group estimates, a 200-bed hospital can expect to spend $1–$7 million. There is a large time investment as well. Between choosing a system and integrating it with the existing IT systems, hospitals need at least three years to implement a new CPOE package. It is not unreasonable to estimate that the complete conversion of U.S. hospitals from manual to digital clinical information systems could cost more than $100 billion over the next decade.

Funding for clinical information technology is a major looming capital expense for hospitals and physician groups. As such, it competes with the replacement of physical plant, radiological equipment, and other more routine capital expenditures in hospital and physician budgets. Hospitals have markedly unequal access to capital. According to the American Hospital Association (AHA), only 25–30 percent of hospitals have secured financing in the public market. Thirty-two percent of hospitals have negative total margins and are thus marginal credit risks. This means that a sizable number of hospitals lack the cash flow or credit to upgrade from manual to digital clinical systems. If this is left to the vagaries of the marketplace, one can easily envision a two-tier health information environment, where two decades from now, more fortunate practitioners and systems will have access to these digital tools, and their less fortunate peers will continue to use today’s inadequate paper- and telephone-based systems. Access to capital is not randomly distributed. Disadvantaged institutions are likely to be serving disadvantaged populations and geographic areas with less ability to pay for services.
Physician Practice Remains Paper-Based

The problems among the nation’s physicians are more daunting still. While a sizable fraction of U.S. physicians (36 percent) are employed by public or private health systems or are members of physician groups, or both, approximately 41 percent are still in solo or partnership practice. More than 90 percent already use electronic networks to manage their own investments and communicate with colleagues and family members through e-mail. An increasing number (74 percent) use the Internet to acquire new medical knowledge, and approximately 30 percent have automated their business office functions such as billing. Many have access to hospital orders and test results through Internet connections.

However, only 17 percent of physicians in office-based practice have computerized their patient records. This means that physicians are logistically constrained from sharing records with consulting colleagues unless they are copied and hand-carried, mailed, or faxed to them. Furthermore, physicians who use paper records face major barriers to coordinating access to their patient information with the record systems of the hospitals they use. The result is that crucial information (such as patients’ current medications) is not available to the inpatient and outpatient care teams at the hospital, pharmacies, and labs and must be gathered from patients or physicians’ offices at the time care is rendered.

Because many hospitals and health systems do have access to capital and can convene a community’s physicians, these institutions have the potential to assist physicians in making this needed conversion. It is not technically complex to provide a hospital-sponsored patient record in a format that physicians can access from either the office or the hospital.

Sadly, many physicians are suspicious of hospitals’ motivations and respect for their privacy and autonomy. However, with appropriate partitioning and security systems, physicians could use patient information “ported” from hospital CPR systems to support their office practices.

However, extending the hospital’s CPR technology to physicians may violate federal fraud-and-abuse guidelines and could compromise the hospitals’ tax-exempt status. The federal anti-kickback statute legitimately restricts hospitals from conveying gifts or other items of value to physicians in exchange for admitting patients to their facilities. Unless different hospitals’ information systems can transfer patient data reliably to one another, locking physicians into a particular CPR has the potential for restricting physicians’ admitting of patients to the institution that maintains their records.

If the record systems of competing hospitals were required though federally mandated standards to interoperate, hospitals’ ability to channel admissions through their patient record systems could be reduced or eliminated. Federal tax law needs to be clarified to assure that creating a unified CPR shared by hospitals and physician practices under appropriate circumstances is not construed as incurrence of benefits to individuals. Whatever personal benefits to physicians
might be created by a unified record architecture are far outweighed by benefits to the community in improved communication among physicians and between physicians and hospitals. In the absence of such changes in federal law, the ability of private markets to advance the U.S. health care information infrastructure will be profoundly compromised.

The Evolution Of Medical Data Standards

A key factor limiting the rate of adoption of a new technology is the pace of adoption of standards. Inevitably, at the dawn of a new technology, competing alternatives abound as new products are introduced. The struggle between Beta and VHS in videocassette recording and between Palm and Windows CE in handheld computing are examples. Often the market dictates the winner, and a commercial “consensus” forms on the right standard.

The arrival of such standardization is desperately needed in the CPR world. Today’s commercially available CPR software does not convey clinical records effectively from one vendor’s format to another. It is necessary to write costly custom interfaces to move clinical information between different clinical software platforms. Even with such an investment, differences in the CPR systems’ underlying architecture and the way that the systems are configured and used in individual institutions limit the quantity and quality of data that can be conveyed. Moreover, the prospect that private market competition will produce the necessary standardization of CPRs is slim. No vendor of CPRs has more than a 15 percent share of the CPR market. As such, there is no equivalent of Microsoft in clinical information technology to compel standardization. Previous efforts at standardization suggest the limitations facing private markets in this regard.

Previous Efforts At Standardization

Clinical information has seen a great deal of voluntary industry- and user-driven standardization. Among the success stories are the adoption of the DICOM standard for digital images by radiologists and imaging system manufacturers and HL7 Version 2 clinical messaging standards. In both cases, professionals and technology manufacturers collaborated in developing common formats and protocols for sharing clinical information. HL7 Version 2 has achieved almost complete penetration in the hospital market and among high-end outpatient practices that can afford a computer-based patient record. Nonetheless, it is applied in different ways by different institutions. This is not a flaw in the standard. Rather, it is an explicit recognition by its developers of the diversity of approaches to maintaining clinical data among health care enterprises and CPR vendors. Within an enterprise, it has been cheaper to adapt the standard to the enterprise than to change the systems and business practices of the enterprise to match a rigid standard.

The heterogeneity of interpretations of HL7 increases when it is applied to more complex forms of clinical data. It works well for administrative data, orders,
and structured lab results or reports that are conveyed as dictated reports. The standard offers little guidance, however, for more complex issues such as relating care plans to orders and results, and describing the results of physical exams and other multifarious procedures with discrete data and precise codes. The few enterprises that take on these issues develop idiosyncratic interpretations of HL7 to meet their needs. This can be tolerated within enterprises, but it destroys the ability to convey clinical information across institutions.

To overcome these problems and hasten further standardization, HL7 has undertaken a new series of standards: its Version 3, which is designed to be more precise when dealing with complex clinical data and more accurately specific in the use of terminologies. The approach is based on a Reference Information Model, which delineates the universe of clinical actors, transactions, and clinical events. Because the Reference Information Model provides a common conceptual framework for defining many different forms of information transfer, individual work groups can develop standard extensible markup language (XML) messages for applications as diverse and complex as care plans, microbiology results, and perinatal episodes with assurance that their work will not conflict with the work of other groups.

Even with the conceptual clarity and rigor of Version 3, however, there is no assurance that information will be conveyed faithfully across vendor systems and among enterprises. There are two reasons. First, medical information is extremely complex. To reach the level of structure where a CDSS can operate on data received from other systems, hundreds of thousands of kinds of utterances need to be standardized—everything from blood pressure readings to a diabetic consultation. HL7 is attacking the most important and universally applicable cases, but it has a long way to go. Standard nomenclature is a big barrier to interoperability, something that broad adoption of SNOMED (Systemized Nomenclature of Medicine), originally developed by the American College of Pathologists, could hasten. An even more important second reason is that the systems that collect the data have differing internal information models. If data are not collected at comparable levels of granularity and in a comparable structure, they will not flow to other CPR systems, even if the same coding schemes and nomenclature are used.

Unless there are uniform federal standards for CPR record structure, coding, and nomenclature, clinical information will be trapped inside vendor-constructed boxes and cannot follow the patient from institution to institution or from practitioner to consultant and back. The result will be duplication of tests, extensive duplicate record keeping (and the clerical cost to support it), and incomplete or inconsistent clinical information to support patient care.

That is not to say that all CPRs should look alike. The science of medical informatics is not so well understood that society would benefit by stifling innovation. The concern is, rather, to mandate a least common denominator for the structure, level of detail, and exchange format of information. Such a mandate should start
within the current capabilities of most CPRs and become more aggressive in later years. Initially, the mandate should cover the exchange of textual reports, structured lab results, orders, and specific other kinds of data that are commonly collected in a structured way today. As the mandates become more aggressive, CPRs, the way that they are to be used, and information standards will evolve with the growing mandate.

Given sufficient notice, CPR vendors will make the changes to comply if their customers need these changes to meet the mandates. Likewise, their customers will change their patterns of use of the CPRs to collect the necessary structured data, when they can do so within the cost and time constraints that are their overwhelming business concerns.

Such mandates can be tuned to give early attention to areas that are now high on the scale of national policy importance. For example, attention to patient safety and bioterrorism today might call for an emphasis on standards for the collection and conveyance of very specific kinds of data, and also might help to provide funding for health care institutions to implement the changes necessary to do so.

**Recent Federal Efforts At Standardization**

It is noteworthy that the federal government seems to be moving more rapidly than the private sector in pushing toward interoperability of clinical information. In March 2003 Health and Human Services (HHS) Secretary Tommy Thompson announced the Consolidated Health Informatics Initiative, an effort to standardize clinical record coding schemes across federal departments, including the Department of Veterans Affairs (VA) and the Department of Defense. The CHI initiative “blessed” a number of clinical record formats, including HL7 and DICOM, with a goal toward encouraging private-sector efforts. HHS is also negotiating to make SNOMED’s nomenclature system available more broadly and to adopt it as a federal terminology standard.

Further, HHS is exploring how to make VistA, the VA CPR, and a CPR developed by the American Academy of Family Physicians (AAFP) available on an open-source basis to physicians and hospitals that cannot afford commercial CPR installations. These efforts are important first steps, but they do not solve the problem of interoperability because they do not contain incentives for commercial vendors to standardize, nor do they address the thornier questions of record structure, granularity of data, and other variables that will interfere with interoperability even if coding schemes and clinical language were standardized. In our view, even with strong federal leadership, purely voluntary efforts will not achieve the portability of clinical records needed.

**Rethinking Federal Health Information Policy**

In 1996 Congress enacted the Health Insurance Portability and Accountability Act (HIPAA). This far-reaching law clarified federal policy toward the privacy and
security of personal health information. Less visibly but perhaps more importantly, it took the first steps toward standardizing coding and transaction sets for all electronic medical claims, federal or private. It established coding conventions for medical information conveyed through electronic means.

However far-reaching HIPAA may have been, it was enacted right at the cusp of an outpouring of new information technology innovation. HIPAA did not anticipate the medical Internet. It did not envision flexible and affordable broadband connectivity between payers and providers, since it was enacted in an era of electronic data interchange through expensive, dedicated telephone lines such as T-1. It did not anticipate the “intelligent” CPR, with its potential for simultaneous use in multiple sites for actual patient care.

As HIPAA regulations moved at glacial pace toward implementation, providers realized with dawning horror that it represented a staggering unfunded federal mandate. Based on a survey of health plans and hospitals/integrated delivery networks conducted by Gartner, average estimates of total HIPAA compliance costs were more than $14 billion for health plans and more than $5 billion for providers. This mandate coincided with a period of fiscal stringency for hospitals and health plans created by the Balanced Budget Act (BBA) of 1997, which flattened Medicare spending for an unprecedented four years. HIPAA was also a largely unfunded mandate to HCFA (now the Centers for Medicare and Medicaid Services, or CMS), since Congress did not allocate sufficient funds to develop implementation regulations for HIPAA and to guide their implementation.

Guiding principles. Thus, while HIPAA can serve as a foundation, Congress should revisit health information policy and broaden federal oversight over the implementation of CPR technology. We believe that several essential principles should guide the development of federal clinical information policy.

Interoperability. First, to the maximum extent possible, CPR development should assure that clinical records can flow safely and efficiently from institution to institution, and practitioner to practitioner. HIPAA’s privacy protections become even more vital here as genetic information becomes woven into those records to assure safe and accurate medication decisions.

Innovation and competition. Second, vendors should be encouraged to innovate within and around the standard record structures and language formats. These standards should be linked to economic incentives for providers to adopt and use CPR technology, so that only qualified record formats (proprietary or open source) would be eligible for incentive payments. Without the lever of financial incentives, providers will not pressure vendors to adopt systems that are interoperable. Policymakers should not preempt vendors’ efforts to improve ease of use or to develop linkages to guidelines or data sources, nor should new policies regulate clinical content or clinical decision support tools. CPR technology is evolving rapidly, and vendors have a major contribution to make in applying new technologies to supporting clinical care.
Access to the benefits of IT. Third, it is unreasonable to expect widespread adoption of CPRs without recognizing the costs these new mandates for standardization will impose on providers. Of course, many providers are funding clinical systems development as part of their capital budgets. Federal funding should be structured to supplement, not supplant, this private funding. Federal dollars should not subsidize institutions with the capability to construct state-of-the-art IT systems themselves. Rather, they should provide leverage to assure that institutions with impaired access to capital, particularly in public-sector and rural settings, can afford clinical information systems.

- Need for federal support. The federal government should provide matching funds for clinical systems development based on providers’ fiscal capacity and effort. It should also provide technical assistance to enable providers to convert their records to electronic format, and help in redesigning clinical workflow to maximize the potential for improving clinical care.

Specifically, Congress should consider the following interventions, which, we believe, are both desirable and consistent with the above principles: (1) Establish as a formal objective of federal health policy the adoption by health care providers of CPRs that meet a standard common denominator for collecting and exchanging clinical information. (2) Establish interoperation and endorse HL7, DICOM, and terminology standards for record structure, messaging format, and a controlled medical vocabulary to assure that multiple terms for the same medical condition are reconciled. Only CPR systems that meet these standards and should evolve over a period of years would be eligible for federal subsidy.

(3) Establish a policy forum for identifying the areas that must be emphasized in new mandates, and provide such mandates with enough advance notice that standards groups, vendors of CPRs, and users have time to adapt to them in the normal course of their business cycle. In our view, the present National Committee on Vital and Health Statistics (NCVHS) lacks the statutory mandate and visibility to achieve this goal. (4) Provide financial support to the work of the standards group in responding to the evolving mandates. Whether for terminology or information formats, the ongoing work takes more time and computer costs than can be funded on a voluntary basis.

(5) Remove barriers to hospitals’ propagation of their CPR systems to physicians’ office practices by amending fraud-and-abuse statutes to provide a legislative safe harbor for carefully defined cooperative IT activities between hospitals and physicians. Use of qualified systems that achieve a sufficient degree of interoperability of clinical records is the vital ingredient needed to assure that providers do not use their record systems to “channel” patients. Further, federal tax law should be clarified to assure that such extension is not viewed as inurement of benefits, protecting hospitals’ and systems’ not-for-profit tax status. Hospitals and physicians using approved CPR systems should also be subject to a cap on punitive damages under tort liability.
(6) Provide financial assistance for selected hospitals and physicians who lack the resources to purchase and implement approved CPR systems. This could take the form of grants or an annex to their Medicare diagnosis-related group (DRG) or physician fee payments. A reasonable starting point for defining such hospitals and clinics would be to include small rural and inner-city public institutions as well as facilities that qualify as disproportionate-share institutions under Medicaid statutes. Federally qualified community health centers and physicians practicing in medically underserved areas would form additional potential targets for such assistance. Later, other institutions might become eligible for federal assistance (perhaps in the form of federal loans) if they are able and willing to make the case that they lack the means to finance IT systems. (7) Extend the current HIPAA mandate to provide uniform assurance of prompt payment nationwide for standard electronic claims and to standardize claims justifications required by health plans (a major administrative burden for physician and hospital record keeping systems).

As the postwar Hill-Burton program recognized an unmet need for hospital capacity in the late 1940s, Congress must recognize that a modern health information architecture is an indispensable precondition of safe and effective clinical practice. A safe and effective health care system cannot be achieved without federal policy interventions that create the essential preconditions for markets to function where they can and to assure that access to the benefits of health care IT is available for the nation’s most vulnerable citizens.

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NOTES


8. Dick et al., eds., The Computer-Based Patient Record.
17. AMA, Technology Usage in Physician Practice Management: Benchmark Study (Chicago: AMA, October 2002).
18. Ibid.
22. Ibid.
28. Ibid.