CONNECTING FOR HEALTH℠

MARKLE FOUNDATION   *A Public-Private Collaborative*

ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE

A Preliminary Roadmap from the Nation's Public and Private-Sector Healthcare Leaders

Executive Summary

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PRELIMINARY ROADMAP RECOMMENDATIONS

Executive Summary

Emerging technologies offer an unprecedented ability to provide accurate and actionable medical information in a secure and private form when and where it is needed, whether by patients themselves or by the clinicians who care for them.

When Connecting for Health…*A Public-Private Collaborative* was launched by the Markle Foundation in June of 2002, its mission—identifying and removing barriers to the growth of electronic connectivity in healthcare—and its methodology—a broad-based coalition—were anomalies. Today, they have become the accepted wisdom. There is now widespread recognition that the economic and clinical inadequacy of a paper-based health information system is a serious problem. The need for "interoperability" in healthcare information technology (IT) has gone from an item on the private wish list of IT insiders to a public priority of the President of the United States. The Department of Health and Human Services has appointed a National Health Information Technology Coordinator to work with government and industry, and members of Congress have even connected across party lines to address the need for information technology to help transform the healthcare system.

While general acceptance of one's aspirations is certainly an accomplishment, a swelling of the ranks of those championing change cannot substitute for a concrete and deliberate implementation plan. This *Preliminary Roadmap* lays out a series of recommendations for practical strategies and specific actions to be taken over the next one to three years that will bring us measurably closer to solutions. This roadmap – like most – helps the traveler to choose directions and to take turns. Although we do not know which of the emerging innovations in U.S. healthcare will be most successful, we do know that most of them cannot be realized without the rapid, accurate, and secure exchange of personal health information among authorized users. And we believe that the greatest improvements in healthcare – leading to the most profound opportunities for better health – will occur when each American can access, control, and make use of their own health information in partnership with their care team.

Our recommendations are designed to be practical. We are proposing manageable actions to be taken over the realistic time frame of the next one to three years. It is not possible or even desirable to dramatically transform the healthcare system through a sudden "big bang," whether brought about by public or private efforts. We believe that the existing system needs to be improved and built upon, and that the effect of carefully planned incremental steps can be equally transformational and more likely to succeed over the long run. Our realistic recommendations are not intended to discourage bolder actions now or in the future, but they allow a large proportion of stakeholders to make measurable progress now. In fact, because of their strategic nature, they set the stage for bolder actions to follow.

The task of realizing electronic connectivity in healthcare will require a variety of stakeholders to take a range of different actions, some of which must be closely coordinated, while others may occur separately but in parallel. Our recommendations fall into three broad categories: Creating a Technical Framework for Connectivity, Addressing Financial Barriers, and Engaging the American Public. The three are, of course, closely intertwined; individual stakeholders may be required to take action in one, two, or all three areas.

The practicality of our recommendations may be most immediately apparent in the technical and financial areas. On the technical side, we recommend accelerating electronic connectivity by building on existing infrastructure to create a "network of networks," which is based on standards, decentralized, and federated to support broad use by clinicians and patients while safeguarding patient privacy. On the financial side, we recommend the realignment and, in some cases, creation of both financial and other incentives that are designed to promote the use of standards-based electronic health records and electronic connectivity. As part of this work, we investigated the question of what minimum level of financial incentives would be necessary to cause "tilt" or catalyze systemic change. We focused especially on small and medium sized ambulatory practices at this juncture, and found that the amount of investment is more manageable than many people had imagined.

Despite the powerful and even lofty ring of our recommendations to engage the American public, which involve educating and empowering patients, these may in fact be the most pragmatic recommendations of all. The current healthcare system is in dire need of improvement and modernization. Society cannot afford to infuse it with more money, and providers are already stretched to their capacity. The aging of the baby-boomers promises to stress the system even more. While the increased and smarter use of information technology is essential in addressing these problems, its impact will be greatly magnified by a higher level of patient involvement. How can we afford not to harness the underutilized power of patients to help advocate for and contribute to a system that can better serve them? No one has a greater level of investment in healthcare than the individuals who live or die based on its quality.

RECOMMENDATIONS IN BRIEF

1. **Creating a Technical Framework for Connectivity**: The creation of a non-proprietary "network of networks" to support the rapid acceleration of electronic connectivity that will enable the flow of information to support patient care. The network should be based on a "Common Framework" of agreements among participants. The network should use a decentralized, federated architecture that is based on standards, safeguards patient privacy and is built incrementally, without the use of a National Health ID or a centralized database of records.

2. **Addressing Financial Barriers**: The development of financial and other incentives and related processes, such as standards certification, to promote improvements in healthcare quality through the adoption of clinical applications and information exchange based on standards.

3. **Engaging the American Public**: Reaching out to the public with a consistent set of messages to be used by government, healthcare, and consumer leaders to promote the benefits of electronic connectivity and to encourage patients and consumers to access their own health information.

Creating a Technical Framework for Connectivity
In order to provide a majority of their benefits, clinical applications must interconnect with other clinical systems. The potential to avoid medical errors and drug interactions, to deliver real-time prompts and reminders at the point of care and directly to the patient or caregiver, and to improve the ability to conduct clinical research depend on a highly connected network

of regional healthcare communities that exchange data among effectively used clinical systems such as EHRs.

Unless close attention is paid to infrastructure requirements at the local, regional and national level, it is unlikely that piecemeal technology adoption will result in the connected infrastructure necessary to realize the quality of care and economic efficiency gains promised by IT. The network requires a high degree of connectivity that depends upon trust arising from safeguards for privacy and security and a strategy that minimizes risks of patient data misuse. With that said, the approach must be voluntary and built on the premise of patient control and authorization.

In order to accelerate electronic connectivity, a non-proprietary "network of networks" that is based on standards and a decentralized and federated architecture should be developed, building upon local and regional networks. To support the creation of the network where national standards are implemented locally and regionally, a "Common Framework" is needed immediately.

The "Common Framework" is comprised of standards, policies and methodologies that can be replicated quickly related to secure connectivity, reliable authentication, and a minimum suite of standards that work together to support information exchange. We recommend that the common framework be tested and evaluated through a reference implementation.

Because our incremental approach is designed to leverage existing infrastructure, it dictates that secure connectivity be built on the Internet and its communication protocols. Part of the function of the "Common Framework" is to select security standards for confidentiality, authentication, integrity and non-repudiation (CAIN). The "Common Framework" also addresses reliable authorization, a common set of standards and a minimum set of capabilities required to participate in the network.

To enable rapid implementation of the network of networks, emerging financial and other incentives should incorporate aspects that promote the usage of the standards-based interoperable health information infrastructure as well as clinical applications, such as electronic health records, electronic prescribing tools, and other clinical applications that utilize standards. Care should be taken to promote only those applications that do not represent "dead-ends." Certification of both applications and interfaces that emerge as part of the common framework will be needed to align incentives with standards-based IT. The certification process should place minimum burden on the system and encourage new entrants and continued innovation. Certification models may or may not require the creation of new entities. A range of models should be explored.

Among the important implications of our proposed system for a network of networks is that personal health information would continue to reside where it does now, primarily with hospitals and healthcare providers. According to the patient's preferences, relevant health data could be assembled from numerous sources at the point of care, enabling decision making to be informed by past treatment successes and failures and medication history. Both the patient and the clinician could have direct access to this vital information.

A new infrastructure element would be an index of pointers to the location of patient information, but which contain no personal health information themselves; no patient records would be

stored centrally. Decisions about sharing information would be made at the "edges" of the network by patients and providers together on a case by case basis.

The secure and confidential treatment of patient information is a fundamental design criterion of the health information infrastructure we endorse. We recommend the inclusion of architectural, technical, and policy safeguards within the "Common Framework" to safeguard the privacy and security of patient data while at the same time permitting the rapid and accurate exchange of information among authorized users. Proposed steps for safeguarding privacy and security are embedded in the fabric of all of the *Preliminary Roadmap* recommendation areas.

An important principle of our technical work is the need to leverage the potential of information technology through incremental efforts. We cannot simply shut down the healthcare system and rebuild it from scratch. Such an approach would be dangerously disruptive and prohibitively expensive. All of the technical recommendations of Connecting for Health assume an incremental migration toward the end goal of a truly interoperable healthcare system.

Finally, as noted above, we propose the development of one or more public-private pilot projects or "reference implementations" within the next 12 months in order to test and refine our technical recommendations, further define the "Common Framework," and promote rapid adoption of IT in a responsible manner.

Addressing Financial Barriers
Among the most often cited barriers to the adoption of information technology in healthcare are misaligned financial incentives. Physicians and hospitals are not adopting clinical information technology at a rapid rate due to the poor financial case, difficult modifications of clinical workflow and decision-making processes, perceived legal barriers to sharing information among disparate organizations, and limited capacity of healthcare organizations to organize regionally: factors that make a risky implementation even riskier.

The promise of EHRs and other clinical information technology remains, however, as studies demonstrate that they can advance the quality and efficiency of care, resulting in reduced medical errors, reduced utilization, improved ability to manage chronic disease, and improved longevity and health status, among other potential benefits. This gap between the potential of clinical information technology and the willingness to adopt these technologies raises the question of whether the market appropriately supports technology purchasers in society's efforts to realize value.

Because of the way the payment system is structured, for many providers, especially in the small practice primary care setting, the acquisition or use of IT results in a net financial loss. Ambulatory care practices are on the front line for the treatment of patients in the United States today, specifically those that care for the chronically ill, and have the lowest adoption rates of healthcare IT among the provider sector at an estimated 14% in 2002. We therefore chose to focus the majority of our analysis on the small to medium-sized physician practices in the ambulatory care setting.

We recommend that incentives for IT—including applications, electronic connectivity and information exchange—include the requirement of use of standards and interoperability, since the majority of the benefits of IT accrue only when systems can talk to each other. Failure to encourage interoperability could lead to the growth of technologically sophisticated islands or silos of information, which would decrease the potential value of the investment in IT dramatically.

Our recommendations include the results of our insights regarding the level of incentives that would require "tilt" or cause significant change in the number of small and ambulatory private practices that begin to adopt electronic health records as a result.

Engaging the American Public
Our own research found that most members of the public do not fully understand the problem we are trying to solve. Many are unaware, except for a general perception that costs are high, of the inadequacy of our healthcare system, which kills more people through medical error in hospitals alone each year than die in motor vehicle accidents or from breast cancer or AIDS.[20] In addition, the majority of Americans assume that their doctors use information technology far more than is actually the case. Given these gaps in knowledge, it is not surprising that most people have not thought about how better use of technology within the system might improve healthcare quality.

Our research further shows that most patients or consumers have not fully conceived how they could benefit from *their own* access to and control of personal health information. Patients are used to being somewhat peripheral players in the traditional pattern of care. Many assume that their care is primarily the responsibility of the professionals. However, our research indicates that the vast majority of patients, when presented with a description of services that would enable them to participate more fully and conveniently in self-care, such as the ability to view test results or e-mail doctors directly, shows a significant level of interest.

We believe that public awareness of the avoidable problems with healthcare delivery and the potential of technology to help overcome them is essential.

RECOMMENDATIONS

Engaging the American Public
1. Develop and employ a core set of messages, both general and tailored to specific audiences (e.g., chronically ill, caregivers), that will encourage members of the American public to become partners in improving healthcare through the use of IT.

2. Identify techniques, standards, and policies to be employed by all developers of personal health records in order to ensure that information can be exchanged between PHRs and other data sources for the patient's benefit.

3. Support demonstration projects that use these common practices to determine the value for patients of having access to health information.

Infrastructure
1. Develop the health information infrastructure in a way that safeguards privacy, leverages both bottom up and top down strategies, is incremental in nature, and is based on a decentralized and federated model— an interoperable, standards-based "network of networks" built on the Internet. The network should not contain a central repository for patient medical records. Instead, it should be a pathway that facilitates their identification and exchange, with appropriate authorization, in a private and secure way.

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[20] Additional facts and stats about the US healthcare system can be found in the introductory section of this document. For more detail about this specific data, see *To Err is Human, Building a Safer Health System* By Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, Editors. *Committee on Quality of Healthcare in America, Institute of Medicine, National Academy Press*, Washington, D.C. (2000) Available at: http://books.nap.edu/books/0309068371/html/index.html.

2. A "Common Framework" is needed immediately in order to pursue a decentralized strategy that builds out from a local and regionally driven approach to creating the infrastructure. Only by conforming to a Common Framework can we ensure that data exchange pilots, personal health records, and regional systems will be able to interoperate across and with other regional systems. The Common Framework is premised on secure transport over the Internet and provides minimal but basic components for the infrastructure including secure connectivity, reliable authentication, and a minimum suite of standards for information exchange. It is comprised of network software, common policies, documents and methodologies that can be shared in the public domain.

3. Public-private collaboration should fund and complete a Reference Implementation within 12 months.

4. Communities should assess their readiness for local and regional data sharing by conducting a rigorous review of the technical, clinical, organizational, community commitment and leadership aspects of their initiatives, all critical success factors in building and managing a local health information infrastructure.

5. Communities will require a source of activation to catalyze or enforce development of a health information infrastructure.

Accurate Linking of Health Records
1. Linking of patient information for high quality care can and should be done *without a National Health ID*.

Rate of Adoption of Clinical Applications
1. If funding and reimbursement incentives are provided to encourage the adoption of IT, they should support a wide range of applications from comprehensive EHRs and incremental applications to simple data exchanges, provided these applications do not represent "dead ends" in that they enable an evolution toward greater electronic connectivity.

2. Consider certification for EHR applications to assure that incentives result in the use of systems that meet a minimum set of functional capabilities using the HL-7 EHR functional standard and incorporate a minimum level of interoperability.

3. Represent all stakeholders in the governance of the certifying process and place minimal compliance burdens on care delivery organizations and encourage new entrants and continued innovation.

Data Standards
1. Focus on implementing the "ready set" of data standards that are mature and proven. Many of these standards have already been identified by the Consolidated Health Informatics initiative and Connecting for Health.

2. To ensure interoperability there is an immediate need for certifying interface conformance. The certification methodology should be developed in conjunction with the Reference Implementation.

3. Establish a certifying process and appropriate, affordable and scalable interface conformance methods based on combinations of standards for specific information exchange needs that support differing levels of sophistication.

4. Fund some regional and local health information exchange initiatives in addition to the Reference Implementation to provide a test-bed for these interface standards.

5. Publicize and share the approaches to secure Internet transport in the Reference Implementation, and facilitate a smooth transition to evolving standards that will make this problem more tractable for large networks.

Funding and Incentives

1. Realign financial incentives to promote quality care improvement via IT adoption, connectivity, and information exchange among all healthcare providers.

2. Financial incentives of the approximate range of $3 to $6 per patient visit or $0.50 to $1.00 per member per month, (based on 4,000 patient visits per year or a 2,000 patient panel over at least a three-year period) appear to be a sufficient starting point to encourage and sustain wide-spread adoption of basic EHR technologies by small, ambulatory primary care practices. This estimate represents approximately $7 billion – $14 billion per year for three years or 1.2% to 2.4% of total amount spent on ambulatory care in 2003 on an annual basis. Industry is experimenting with incentive models and will gradually migrate to incentives to encourage adoption as well as additional incentives that will be necessary on an on-going basis to encourage more extensive use of EHR technologies, e.g., coordinated care or advanced chronic disease management.

3. The qualitative analysis supports a business case that is better for some "incremental applications" than others. These incremental applications can be implemented as steps toward the full implementation of an EHR. Applications with a smaller investment or a very high net beneficial business case could be considered as candidates for initial implementation as long as they are not dead-end applications.

4. Small and medium-sized practices have greater potential than others to benefit from information exchange, but will require greater attention and support in order to achieve sustainability.

Legal Safe Harbors

1. Since we started developing this Roadmap, proposed regulatory modifications may have addressed the safe harbors issue through the regulatory exception under Stark II, Phase II (42CFR Parts 411 and 424; Section 411.357 (u)), for the provision of information technology items and services by a designated health services entity to a physician to participate in a community-wide health information system, proposed in CMS' interim final rule entitled "Medicare Program: Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II)." The comment period for this rule ended June 24, 2004. The proposed language in the interim final rule provides an expansion of permissible third party financing of community-wide information initiatives.

2. Public and private sector guidance is needed to clarify how providers can participate in data sharing pursuant to the Medicare Modernization Act of 2003, specifically through clinical pilots and electronic prescribing programs. Guidance will help to identify opportunities for provider-based connectivity that promote the expansion of widespread data sharing initiatives.

CONNECTING FOR HEALTH℠

Connecting for Health is an unprecedented collaborative of over 100 public and private stakeholders designed to address the barriers to electronic connectivity in healthcare. It is operated by the Markle Foundation and receives additional support from The Robert Wood Johnson Foundation. Connecting for Health is committed to accelerating actions on a national basis to tackle the technical, financial and policy challenges of bringing healthcare into the information age. Connecting for Health has demonstrated that blending together the knowledge and experience of the public and private sectors can provide a formula for progress, not paralysis. Early in its inception, Connecting for Health convened a remarkable group of government, industry and healthcare leaders that led the national debate on electronic clinical data standards. The group drove consensus on the adoption of an initial set of standards, developed case studies on privacy and security and helped define the electronic personal health record.

For more information, see www.connectingforhealth.org.