

CONNECTING FOR HEALTHSM
MARKLE FOUNDATION *A Public-Private Collaborative*

ACHIEVING ELECTRONIC CONNECTIVITY IN HEALTHCARE

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

July 2004

MARKLE FOUNDATION

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INTRODUCTION

*Two roads diverged in a yellow wood,
And sorry I could not travel both
And be one traveler, long I stood
And looked down one as far as I could
To where it bent in the undergrowth.*
(From “The Road Not Taken” – Robert Frost, 1916)

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. 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 form a Senate Bi-partisan Working Group on health information technology (HIT) and a “21st Century Healthcare Caucus” within the House of Representatives focused on IT.

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. Efforts to institute electronic medical records and clinical health information networks date back at least to the 1960s, but they have been unable to overcome formidable structural and financial barriers. The Connecting for Health Collaborative is determined to break open the logjam blocking the flow of vital healthcare information which is required to improve healthcare quality, safety, and efficiency.

The formal purpose of Connecting for Health is “to catalyze *specific actions* on a national basis that will *rapidly* clear the way for an interconnected, electronic health information infrastructure [emphasis added].” One of our core strategies is “*identifying practical strategies and solutions*...that will ensure the secure and private transmission of medical information and support the continuity of health information across plans and providers [emphasis added].” Our purpose in releasing this *Preliminary Roadmap* is to publicize our draft recommendations so that we can quickly, in collaboration with the broader healthcare community, refine and realize them.

Our impatience is rooted not only in a recognition that the current system is economically inefficient and, more often than we would like, clinically dangerous, but also in a desire to empower the individual. While the growth of IT has already altered the public’s relationship to health—searching for health information is now the third most popular reason that people go online—most consumers/patients are not yet able to work with their doctors and contribute to their overall care the way they might if they could see their own medication lists, laboratory test results, immunization records, and other elements of their personal medical record. For many patients, health and healthcare remain something of a black box, a realm in which they are neither able nor welcome to participate.

We believe that empowering patients through IT will benefit the healthcare system directly by enabling patients to better maintain and improve their own health through informed choices.

More informed patients are likely, in the long term, to push for higher quality, evidence-based care that is delivered as economically as possible.

The unusually sensitive nature of health information requires us to be particularly mindful of protecting privacy. We recognize that widespread trust in the privacy of health information exchange is critical. Without it, patients will be reluctant to participate in an electronically connected health system and may not tolerate increased information sharing among providers, payers, researchers or others. While mistakes in financial transactions may be repaired by shifting around dollars, privacy breaches involving health information can be both extremely hurtful and nearly impossible to undo. The development of electronic connectivity in healthcare must be carried out with an uncompromising emphasis on data privacy and security.

No description of the problem we are trying to solve is more compelling than the stories of the real difficulties faced by patients struggling to cope with the barriers to best care placed in their path by today's uncoordinated, paper-based system. The individuals who have agreed to share their stories in this report remind us how patients and their families struggle to overcome preventable information gaps in healthcare each and every day.

The U.S. healthcare system is vast, complex, and disorganized. Improvements depend upon multiple factors, including citizens equipped to manage their personal health; a delivery system that controls costs and optimizes quality and access; a public health system capable of monitoring, promoting, and protecting population health; and a research infrastructure robust enough to assure continued system success.¹ Many of the health sector's shortcomings can be linked to inadequate data, information or knowledge.

As this Collaborative pointed out early on, clinicians routinely provide patient care without knowing what has been done previously. For example, patients with medical emergencies too often are seen by doctors with no access to their drug allergies, current treatments or medications, prior diagnoses or other vital information. What results is often redundant, costly and even harmful treatments.

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.

Although we yet have miles to go, there has been significant progress since this Collaborative first began. There is now widespread recognition that the economic and clinical inadequacy of a paper-based health information system is a serious problem. HHS Secretary Tommy Thompson has made IT adoption in healthcare a priority, repeatedly contrasting the unsophisticated state of IT in the average doctor's office or hospital to the sophisticated IT capabilities in the average grocery store. President Bush, in his 2004 State of the Union message, noted: "By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care."² Prominent legislators such as Sen. Hillary Rodham Clinton (NY), Sen. Christopher Dodd (CT), Rep. Nancy Johnson (CT), Sen. Ted Kennedy (MA), and Rep. Patrick Kennedy (RI) have also become highly visible advocates for policies designed to accelerate clinical IT adoption.

¹ See *Addressing the Crisis in US health care: moving beyond denial*. By Detmer, D.E. In: *Quality and Safety in Health Care*, (2003) 12(1): 1-2.

² See *Health Care Excerpts from the 2004 State of the Union*, January 21, 2004. Available at <http://www.whitehouse.gov/news/releases/2004/01/20040120-11.html>.

The new Medicare drug law requires HHS to adopt e-prescribing standards by September of 2005 and promulgate them by 2008, but HHS Secretary Thompson has pledged to hold to a faster timetable. Other pending legislation in both the House and Senate would also broaden and accelerate the federal commitment to clinical IT implementation. Separately, the federal Consolidated Health Informatics initiative had identified 24 target domains for messaging and formatting standards as of June 2004.³

Still, changes that are ultimately transformational often occur in incremental stages. Manageable individual steps, while not magically resolving the roster of problems that plague the healthcare system, will nonetheless yield tangible benefits now and in the future as long as we are careful to pick out a path that leads us surely to ubiquitous electronic connectivity. For instance, patients can be a powerful force for change if we help them shed their self-perception as passive recipients of care and empower them to work with their doctors through electronic personal health records. Similarly, the healthcare industry will respond if we can even partially overcome key barriers blocking electronic connectivity, such as a lack of uniform data standards and misaligned financial incentives. In turn, this type of systemic change will enable researchers to collect and analyze disease treatment information and help public health officials to better track disease outbreaks and patterns.

In an article entitled, “Will Disruptive Innovations Cure Healthcare?” Harvard Business School professors Clayton M. Christensen, Richard Bohmer, and John Kenagy examined the impact of IT and the need for industry innovation.⁴ Yet, as much as the healthcare system is in need of outside pressure to break open its insularity, it is equally in need of internal resolve to make the most of this opportunity for true transformation. We believe that what is needed to make this transformation real is neither a regulatory edict nor a massive infusion of private-sector financing but, instead, the power of everyday choices made by providers, payers, plans, policymakers and patients.

Connecting for Health is a collaborative effort launched and supported financially by the Markle Foundation, and, in its second phase, also by the Robert Wood Johnson Foundation. It involves a wide array of stakeholders from both the public and private sectors. More than 100 Collaborative members represent providers, patients, payers, accreditors, government agencies, researchers, and information systems manufacturers. There are more than 60 members of the Steering Group, which is led by Daniel Garrett, Vice President and Managing Director of Computer Sciences Corporation’s Global Health Solutions Practice; Herbert Pardes, MD, President and CEO, New York-Presbyterian Hospital; John Lumpkin, MD, MPH, Senior Vice President for Healthcare, Robert Wood Johnson Foundation; and Carol Diamond, MD, MPH, Managing Director of the Markle Foundation’s Health Program. Janet Marchibroda, Executive Director of the Foundation for the eHealth Initiative, serves as the Collaborative’s Executive Director.

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. Although Steering Group members agreed on long-term goals, there was, unsurprisingly, a lack of unanimity about how best to reach them. In response, the Collaborative reached out to nationally recognized experts and thought leaders in order to identify the possi-

³ http://www.whitehouse.gov/omb/egov/gtob/health_informatics.htm.

⁴ See *Will Disruptive Innovations Cure Health Care?* By Clayton M. Christensen <<http://www.bookcost.com/author/clayton-m-christensen>>, Richard Bohmer <<http://www.bookcost.com/author/richard-bohmer>>, John Kenagy <<http://www.bookcost.com/author/john-kenagy>>, Harvard Business School Press <<http://www.bookcost.com/publisher/harvard-business-school-press>>, 27 March, 2004.

ble advantages and disadvantages of different actions related to different problem areas. The seven “forks in the road” identified in the next section of this document represent the spectrum of choices we considered and our recommendations for action.

Each of the “forks in the road” is complex and multi-faceted; there are not simply “two prongs.” Moreover, no one area is independent; each choice affects others. Ultimately, though, decisions must be made. The recommendations of the Steering Group are designed to move the Collaborative down a shared path. However, since Connecting for Health is committed to collaboration, the Steering Group is also seeking out the expertise of the broader healthcare community in relation to this *Preliminary Roadmap*. We are asking for your review and input so that the final Roadmap will constitute an action-oriented agenda with achievable goals. We do this knowing that some of the choices presented here may be altered significantly as a result of that input.

Members of the Steering Group of Connecting for Health are determined to continue to provide the leadership necessary to effect change of this scope while demonstrating that the public and private sectors can not only work speedily and cooperatively, but also become—together—a driving force for progress.

Benjamin Franklin once wrote, “Well done, is better than well said.” We invite all stakeholders in healthcare to examine this *Preliminary Roadmap* for what it says today and then to join with us in a concerted effort to make its recommendations “well done” accomplishments tomorrow.

Connecting for Health...A Public-Private Collaborative provides a unique forum for both airing differences and arranging alliances in order to achieve common goals. By acting both collaboratively and decisively, participants in Connecting for Health have demonstrated that blending the knowledge and experience of the public and private sectors provides a formula for progress, not paralysis. The expansion of the number of the Collaborative's participants since its launch in September, 2002, and the continued active involvement of senior industry and government leaders, testify to the success of that strategy.

The first phase of the Collaborative's work, from September, 2002 to June, 2003, was operated by the Markle Foundation, which provided a \$2 million investment to support it. That first phase:

- Built consensus on an initial set of healthcare data standards, since a lack of interoperable standards has made it technically impossible for many systems to "talk to" each other.
- Developed case studies on systems that could serve as potential models for privacy and security practices.
- Advanced understanding of the consumer/patient's role in an interconnected healthcare system by defining the personal health record and its use.

In January, 2004, we announced the start of the second phase of Connecting for Health with a similar financial commitment from Markle and the additional support of the Robert Wood Johnson Foundation. The second phase is expected to last twelve to eighteen months. It will include one or more demonstration projects guided by the final version of the Roadmap, which is set for release in September, 2004.

Reports of individual Collaborative Working Groups will also be released during the coming months. Those groups are focusing on the business issues, organizational issues and technical barriers that impede patient-centered information sharing. The Working Groups and their leaders are:

- *Working Group on Accurately Linking Health Information* chaired by Clay Shirky, Adjunct Professor, NYU Interactive Telecommunications Program.
- *Working Group on Financial, Organizational and Legal Sustainability* chaired by John P. Glaser, PhD, Vice President and Chief Information Officer, Partners Healthcare System. (David Brailer, MD, PhD, National Health Information Technology Coordinator, chaired this Working Group before assuming his current position).
- *Working Group on Policies for Electronic Information Sharing Between Doctors and Patients* chaired by David Lansky, PhD, President of the Foundation for Accountability (FACCT).
- *Technical Expert Panel*, a group of experts, comprised largely of members of the other Working Groups and the Steering Group, who are called upon as needed.

The Challenge—Facts and Stats

Between 44,000 and 98,000 people die in hospitals each year as the result of medical errors. Even using the lower estimate, this would make medical errors the eighth leading cause of death in the U.S.—higher than motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516). About 7,000 people per year are estimated to die from medication errors alone—about 16 percent more deaths than the number attributable to work-related injuries.⁵

Children in hospitals often experience adverse patient safety events such as medical injuries or errors. From a total of 5.7 million hospital discharge records for children under age 19 from 27 states, 51,615 patient safety events involving children were identified in hospitals during 2000.⁶

Elderly U.S. patients are prescribed improper medications in about one out of every 12 physician visits.⁷

More than one in five Americans reported that they or a family member had experienced a medical or prescription drug error. Of the 16 percent reporting a medication error, over one-fifth said the error turned out to be a very serious problem.⁸

More than 57,000 Americans die needlessly each year because they do not receive appropriate healthcare (not to be confused with those attributable to medical errors or lack of access to healthcare). The majority, almost 50,000, dies because known conditions, such as high blood pressure or elevated cholesterol, are not adequately monitored and controlled. Each year missed healthcare opportunities cost the nation more than \$1 billion dollars in avoidable hospital bills, and nearly 41 million work days, resulting in the loss of \$11.5 billion for American businesses.⁹

Overall adults in this country receive 55 percent of recommended care.¹⁰

Inadequate availability of patient information, such as the results of laboratory tests, is directly associated with 18 percent of adverse drug events.¹¹

The United States continues to top the industrialized countries (OECD) ranking for overall healthcare spending at \$5,267 per capita in 2002 - more than twice the OECD average of \$2,144.¹² Despite the high level of spending, various comparative studies have shown that:

⁵ 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>.

⁶ *Pediatric Patient Safety in Hospitals: A National Picture in 2000*, By Marlene R. Miller, M.D (et al), In: *Pediatrics* (June 2004).

⁷ *Inappropriate Medication Prescribing for Elderly Ambulatory Care Patients* By Margie Rauch Goulding, PhD. In: *Archives of Internal Medicine* (February 2004) Abstract of the study: <http://archinte.ama-assn.org/cgi/content/abstract/164/3/305>.

⁸ *Room for Improvement: Patients Report on the Quality of Their Healthcare*, by Karen Davis, Stephen C. Schoenbaum, Karen Scott Collins, Katie Tenney, Dora L. Hughes, and Anne-Marie J. Audet, *The Commonwealth Fund* (2002). Available at http://207.189.207.4/programs/quality/davis_improvement_bn_534.asp.

⁹ *The State of Healthcare Quality: 2003, Industry Trends and Analysis*, National Committee for Quality Assurance (2003).

¹⁰ McGlynn EA, Asch SM, Adams J, Keeseey J, Hicks J, DeCristofaro A, Kerr EA. The Quality of Healthcare Delivered to Adults in the United States, *New England Journal of Medicine*, Vol. 348, No. 26, June 26, 2003, pp. 2635-2645.

¹¹ Leape LL, Bates DW, Cullen DJ, Cooper J, Demonaco HJ, Gallivan T, et al. Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA*. 1995; 274: 35-43.

¹² See *Health Spending in Most OECD Countries Rises, with the U.S. far Outstripping all Others*. By: Organization for Economic Co-operation and Development (March 6, 2004). Available at http://www.oecd.org/document/12/0,2340,en_2649_37407_31938380_119656_1_1_37407,00.html.

- The United States does not rank high on most quality of care measures compared to other countries.
- Notably, a five-country study showed that it ranked poorly on care coordination, medical errors, overall rating of doctors, and getting questions by providers answered.
- The study showed that within the U.S., 57 percent of patients had to tell the same story to multiple health professionals; 26 percent received conflicting information from different health professionals; 22 percent had duplicative tests ordered by different health professionals, and 25 percent of test results didn't reach the office in time for the patient's appointment.¹³

A recent study by Center for the Evaluative Clinical Sciences (CECS) at Dartmouth argues that close to a third of the \$1.6 trillion the U.S. now spends on healthcare goes to care that is duplicative, fails to improve patient health, or may even make it worse.¹⁴

Nationwide adoption of advanced computer systems for physician drug ordering in the outpatient setting could significantly reduce errors. More than two million adverse drug events and 190,000 hospitalizations per year could be prevented using IT, saving up to \$44 billion annually in medication, radiology, laboratory, and hospitalization expenditures.¹⁵

Standardized healthcare information exchange among healthcare IT systems within the U.S. would deliver national savings of \$86.8 billion annually after full implementation and would result in significant direct financial benefits for providers and other stakeholders.¹⁶

The use of electronic systems for ordering medicines reduced the incidence of serious medication errors by 86 percent; including dose errors, frequency errors, route errors, substitution errors, and allergies.¹⁷

Electronic medical records would save the average primary care provider an estimated \$86,400 over five years, compared to traditional paper-based methods.¹⁸ Patients with hyperlipidemia involved in a program designed to create a seamless flow of information among patients, pharmacists and physicians using point-of-care testing technology had a medication compliance rate of 90 percent as compared to a 50 percent benchmark.¹⁹

¹³ See *Common Concerns Amid Diverse Systems: Healthcare Experiences In Five Countries*. By Robert Blendon et al., In: *Health Affairs* (May/June 2003).

¹⁴ See *Center for the Evaluative Clinical Sciences at Dartmouth*. By: Trustees of Dartmouth College (2002). Available at: <http://www.dartmouth.edu/~cecs/index.html>.

¹⁵ *The Value of Computerized Provider Order Entry in Ambulatory Settings*. By: The Center for Information Technology Leadership (2003).

¹⁶ See *New Findings Show The Investment in Standardized Healthcare Information Exchange Would Deliver \$87 Billion in Annual Healthcare Savings*. By: The Center for Information Technology Leadership (February 23, 2004). Available at: http://www.citl.org/news/HIEI_Findings.pdf.

¹⁷ See *The Impact of Computerized Physician Order Entry on Medication Error Prevention*. By: David W. Bates, Jonathan M. Teich, Joshua Lee, Diane Seger et al. In: *Journal of the American Medical Informatics Association* (6), 313 (1999).

¹⁸ See *A Cost-Benefit Analysis of Electronic Medical Records in Primary Care*. By: Wang, S. J., Middleton, B., and others. In: *American Journal of Medicine* (114: 397-403) (April 1, 2003).

¹⁹ Project ImPACT, 2000.

PRELIMINARY ROADMAP RECOMMENDATIONS

The Vision

This roadmap – like most – helps the traveler to choose directions and to take turns, but says little about the details of the destination city. Connecting for Health does not offer a prescription for changed clinical workflow, or redesign of chronic care, or evidence-based practice, or telemedicine, or performance reporting, or medication adherence systems. 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.

The steps forward described in this document will permit such innovations in care and patient engagement to occur. We believe that they will allow clinicians, entrepreneurs, and families to develop new and better ways to deliver services, to monitor health, and to manage care. They will also enhance the quality of research and public health. A system that provides an abundance of complete, reliable information to the point of care – and to the home – can reduce waste, error, and frustration while improving diagnostic accuracy, the quality of communications, and even the ability of family members to care for each other.

Even the most ambitiously plotted highway must take note of the demands of local terrain. Our model of change recognizes both the span and complexity of U.S. healthcare. It would be preposterous to design a single health record system that addresses every health problem and healthcare service available, and we appreciate that each person, at each moment in life, has a unique configuration of information assets and information needs. We therefore propose several inter-related incremental steps, not a comprehensive, uniform national initiative.

First, we accept, with appreciation, the good work already done in developing specific electronic health record (EHR) and personal health record (PHR) applications. Medication management tools are offered by pharmacies and pharmacy benefit managers; chronic disease tools are optimized for congestive heart failure or diabetes sufferers; secure e-mail and results reporting systems are being integrated with both hospital and ambulatory EHRs. Connecting for Health does not say that one approach is right and another wrong, but that the national infrastructure must support and accommodate connectivity among all of these – and that they must all conform to a small set of common principles, including use of an agreed upon set of standards.

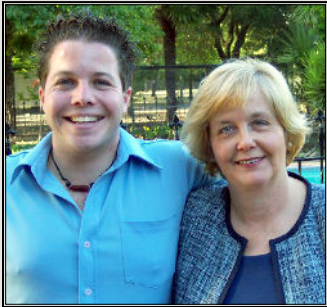
Second, this model allows individuals and their authorized health professionals to construct the health record appropriate to their needs exactly when and how it is needed. Information about an individual's health is usually stored in many different places by a variety of healthcare providers. According to the system we propose, information would be accessible only to authorized users and aggregated at the individual patient level only for the time that it is needed, without being stored in a database. A set of standards and secure networks would allow information – such as lab results, x-rays and medical history as well as clinical guidelines, drug labeling and current research findings – to move to where needed, immediately and securely. Regardless of

where a beneficiary is receiving care, health information exchange networks would allow for information about medication history and potentially serious drug interactions to be available in real-time, along with out of pocket costs and therapeutic alternatives, before the physician transmits a prescription to a pharmacy.

Implementation of the recommendations outlined here will not lead directly to a transformed health system, but it will surely enable the tens of thousands of committed health professionals and millions of patients to bring to reality their own ideas for improved healthcare and better health.

THE MOTHER'S BOND

CYNTHIA SOLOMON OF SONOMA, CALIFORNIA



My son Alex suffers from hydrocephalus, an uncommon condition that forces an abnormal accumulation of fluid inside his brain. His condition is treated with insertions of shunts into his skull to let the excess fluid drain. If the shunts should fail, Alex could lapse into a coma and even die. Quick and appropriate intervention for my son and other hydrocephalus patients is critical.

Since Alex was diagnosed more than 20 years ago with his condition he has had endless encounters with the health care system. Between ages 6 and 16, Alex had some 20 surgeries, most to replace or repair his shunts. When he was 7 Alex wasn't playing baseball, he was receiving hospice care.

But Alex is a survivor. There are many people, doctors and caregivers to thank for this, particularly one man who was willing to look at a problem in a different way. Because of this man, a bio-engineer, I didn't lose Alex when he was a child in hospice care. That, in turn, spurred me to challenge the status quo.

A Mother's Story in the Era of Paper Medical Records

Any parent who raises a chronically ill child knows the constant worry a family endures. Our family was always on call as Alex challenged death throughout his childhood. Small changes in Alex, such as mood swings or failing memory, were signals of possible shunt failure.

Worry was also my companion whenever we interacted with the medical system. I prayed the binders that made up copies of Alex's medical record made it to the numerous doctors involved in his care.

Quick access to Alex's voluminous medical history is crucial for his caregivers, whether or not they are familiar with my son's case. His medical record and brain scans detail the nuances in caring for Alex's hydrocephalus and other ailments, which have included seizures, dangerous allergies and pituitary gland problems. Whether or not a treating doctor readily has Alex's full medical record available can literally mean life or death.

I realized this five years ago when Alex was out of state in a small mountain town and had an accident. Having memory problems and feeling out of it, Alex suspected that one of his shunts was failing. He went to the local hospital.

The small hospital treating him didn't have any of his information, including his neurosurgeon contact, allergies and medical history.

Feeling ill and confused, Alex called me from the hospital. But emergency room personnel told me since my son was over 18, I couldn't interfere with his case. No one, including me, could get a hold of his neurosurgeon. I had all his brain scans and medical information, but I was here in Sonoma, California, and he was hundreds of miles away. I could only hope that Alex or the emergency room clerk would convey to the treating doctor that laying my son flat on his back or even giving him antibiotics posed a threat to my son.

It was a terrifying experience and potentially dangerous for Alex. When Alex was a child I was his walking medical record. I always had copies of it, and would grab a copy of every piece of paper a provider ever wrote about Alex's case. But I won't be around forever to do that for Alex. I realized as a mom that Alex's information needed to be easily available to anyone who might need to treat him, especially in an emergency.

The problem is that the health care system is dependent upon easily lost paper records and physician notes and orders that often are too sloppy to interpret. The paper medical record is still the standard. Medicine itself is advancing at mind-boggling rates—and is the big reason why Alex is among the first generation of hydrocephalus patients to reach adulthood—but the nation's health care infrastructure is mired in the past. It's closer to the industrial revolution than to the information age.

To help my son, I did what I could do. I took out a second mortgage, hired some programmers and developed an electronic medical record that a patient or a patient's doctor could access any time and any place. The program, called FollowMe, now helps more than 400 other families, many of whom have children who have hydrocephalus. It's also being used to keep personalized health records for migrant farm workers throughout the western U.S.

While Alex's small town emergency room visit motivated me to take a chance to create an accessible electronic medical record, my inspiration came years earlier.

When Alex was in hospice care instead of second grade, his nurse told her brother, a Hewlett Packard bioengineer, about her patient. In those days, a single shunt was the practice to drain excess fluid from a hydrocephalus patient's brain. But to Jim Rounds, also a parent, common practice wasn't necessarily the best practice. He dusted off old anatomy textbooks, put his engineering skill to work and came up with a better system, devising two independent shunts, to help Alex.

The difference in Alex ever since has been dramatic. Because of the two-shunt approach, which is standard practice today, hydrocephalus patients can lead normal and productive lives that include school, work, extracurricular activities and family vacations. For Alex, who is now 28 and a college graduate, it also meant surfing camp, soccer and now a career in hotel restaurant management.

Just as Jim Rounds helped save my son's life by improving "the standard," I too hope FollowMe can ease the pain of those who suffer from chronic conditions and soften the worry of these patients' families.

It amazes me that even with overwhelming evidence that electronic information systems reduce mistakes and save lives, the majority of doctors today are not using them.

Hopefully, that will change. With personal electronic health records, gone are the days of mothers having to become walking human medical records, keeping binders and boxes of detail close at all times in order to dodge looming slip-ups and medical mistakes that too often cut lives short or cause needless anxiety.

Now, the bond Alex and I share is not mired in constant worry but enhanced by the potential for a better life for him and other kids.

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.

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.

TRUST BUT VERIFY

JERILYN HEINOLD OF WINCHESTER, MASSACHUSETTS



A doctor I see for my thyroid tumor recently made a mistake. While the recommendation of the specialist, an endocrinologist, in this case didn't cause me to lose a limb or seriously jeopardize my health, the experience did give me first-hand insight of how easy medical mistakes happen when doctors don't have access to information when making decisions.

In 2001, I was diagnosed with a thyroid nodule, which, thankfully, turned out to be benign. Recently, since I hadn't seen an endocrinologist for three years, my primary care physician referred me to a leading expert in the field to see if the tumor had grown. The specialist gave me a clinical exam and pronounced the tumor had not grown, perhaps even shrunk. To substantiate that finding, she referred me for an ultrasound. The ultrasound report conflicted with the clinical findings and stated that the tumor had grown.

What happened next eroded my trust in our health care system and convinced me that patients need to play a bigger role in their own health care. Those patients who blindly put full faith in our current health care system, I'm now convinced, are those most likely to incur a medical mistake. If we are involved, it can sometimes mean the difference between getting the right care or getting the wrong care, or perhaps life and death.

Thanks to an effort by Beth Israel Deaconess Medical Center and other Boston-area institutions to allow patients to access their medical information on-line, I am able to electronically track my health care services, maintain my medical records and test results, and e-mail my primary care doctor. The initiative, called PatientSite, is a great resource for patients for many reasons, but I'm most grateful for how it allowed me to avoid a medical error.

Before my specialist called me about my ultrasound results, I was able to check the results myself from home via PatientSite. The first thing I noticed was that the results contradicted what the specialist found from her clinical examination. According to the new report my tumor was bigger. Puzzled and concerned, I pulled up my original 2001 report and compared those results to the new report. Then, I realized the new radiologist report was wrong.

The size of the original tumor they were referencing was wrong. As I could access my 2001 report to verify the size of the original tumor – something the radiologists did not do – I saw that my tumor had not in fact changed in size. Was the radiologists' reference based on someone else's tumor?

When the endocrinologist called me she told me right away my tumor had grown and I needed a biopsy. I knew she too had failed to pull up my original report, even though the new results conflicted with the results of her clinical exam. When I reminded her of that, she seemed more alarmed that I was questioning her and the two radiologists who signed off on the results than the fact that the ultrasound was different from the findings of her own clinical exam. When I told her that I could access my own medical records and discovered the mistake, she seemed surprised. Then she said she had a problem with me viewing my results before she did.

No, that's not a problem, I thought. The problem is that medical mistakes happen too frequently. If we want to be involved in our own medical care, working in partnership with our doctors, we need tools to do that. I've read that nearly 100,000 patients die needlessly each year in hospitals. How many patients die because of medical mistakes outside the hospital? I don't know, but I do know how easily it can happen.

I'm fortunate though. Simply by having access to my medical information and previous test results, I have more control over decisions regarding my treatment.

Most patients don't have the tools they need to become their own health advocates. Thanks to PatientSite, I do. Unfortunately, the days of Marcus Welby, M.D., are long gone. While well intentioned, doctors are now often overworked and overwhelmed. I can trust but also verify the information doctors give me. I now have the ability to reduce the chances of a medical error happening to me.

PRELIMINARY ROADMAP RECOMMENDATIONS

Context and Rationale

Connecting for Health began its Phase II journey by identifying areas in which near term actions could accelerate the development of electronic connectivity in healthcare. Carol Diamond, Kelly Cronin, and Bill Yasnoff conducted a series of in depth interviews of the Steering Group members and other healthcare leaders representing a variety of stakeholder interests, content expertise, and geographic regions. The interviews explored what actions should be taken by whom during the next one to three years to move us most effectively toward our goal.

While there was certainly controversy about some of the topics described in this section under the heading “Forks in the Road,” one theme that united all stakeholders was the importance of the public’s role. The interviews revealed a broad appreciation for the growing centrality of the individual as patient, consumer, and employee in the development of the connected healthcare system. Given that central role, interviewees recognized that both legitimate and sometimes not-so-justified concerns about privacy and security of the electronic infrastructure must be clearly addressed from the outset in order to earn public confidence.

The recommendations in this *Preliminary Roadmap* encompass these areas of agreement, as well as areas in which consensus for near-term actions did not exist, identified as “Forks in the Road.” The Steering Group was tasked with responding to them by balancing conflicting tensions to develop a plan of action that is acceptable to the majority. It is the members of the Steering Group and their cohort who will ultimately put the ideas they help to shape into policy and practice. Connecting for Health’s work is not an academic exercise, but a very practical and results-oriented one. Our recommendations, therefore, are not a comprehensive set of solutions, but an ambitious and realistic one.

This section is organized by topic. “Involving the American Public as Partners” is the first topic, followed by the six “Forks in the Road” topic areas, including “Infrastructure,” “Accurate Linking of Health Records,” and so on. There is a boxed recommendation or set of recommendations corresponding to each topic, as well as a “Rationale” section that describes the thinking behind the recommendations. In a few cases we also lay out the “Guiding Principles” we used to shape recommendations about a particular topic.

1. Engaging the American Public

All efforts to increase connectivity in healthcare are meant to serve only one constituency – made up of every person seeking to maintain or improve their health. Each of us – whether healthy consumer, needy patient, or caregiver – plays a vital role in healthcare. Each of us needs to receive useful information to help manage our own health and to be assured that professionals who provide services to us can get the information they need in a timely, accurate, and usable way.

The Steering Group identified three essential ways of involving individuals in the expanded information environment we contemplate:

- Through increased public understanding of the value of connectivity in healthcare;
- Through specific and comprehensive design principles and policies to assure the security and privacy of health information; and,
- Through expanding availability of and access to Personal Health Records.



A. INCREASING PUBLIC UNDERSTANDING OF HEALTH INFORMATION TECHNOLOGY

Recognizing that systemic communication with the public about electronic connectivity in healthcare is lacking, the Steering Group identified this early on as a core theme for the *Preliminary Roadmap*. Indeed our own research corroborates a need to inform patients about the benefits of increased electronic connectivity in healthcare—most Americans now believe that their records are already exchanged among healthcare providers, and few understand the link between connectivity and improved quality and a reduction in medical errors. There are questions, however, about the best ways to reach patients and to help them to become advocates for the transformation of the healthcare system.

RECOMMENDATION (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.

Rationale (Engaging the American Public)

The American public expresses high levels of interest in many of the potential functions of successful electronic health records (EHRs) and personal health records (PHRs). Unfortunately, more than half of consumers believe that their own doctor and the health system as a whole is far more “wired” than it actually is. Indeed they believe that the expected benefits are already in place. As a result, research suggests that the public first needs to be made aware of the possible advantages of a more connected health system and then needs to be told that it is not a reality today but could be tomorrow, with their support. We believe that a public that sees personal advantage in increased connectivity will support initiatives such as the financial, community and policy initiatives that are outlined below.

Connecting for Health tested a variety of “messages” with different consumer segments. Several key findings can guide the development of a common communications strategy:²¹

- Between 50 percent and 75 percent of all Americans have *not thought about* the implications of a more wired and connected healthcare system; they do not demand the same level of customer service and information sharing with their doctors as they do with their bank, library, or airline because they do not directly perceive the problem and do not have a model for how both care and communications could be quite different.
- Over 60 percent of Americans want to receive the specific services that a more connected health system could provide. In our 2003 survey of on-line Americans, respondents reported the following rates of interest in using each service, now or in the future:

Email my doctor	75 percent
Track immunizations	69 percent
Note mistakes in my record	69 percent
Transfer information to new doctors	65 percent
Get and track my test results	63 percent

- Most Americans are very concerned about the privacy of their personal health record, and wish to exercise control over how that information is shared. Many prefer physical storage of their record (on a CD, a memory device, or even on paper) over an internet-based storage to reduce the chance of unauthorized access. But they also believe that modern information technology can be implemented with appropriate protections. Strong technical security solutions and strong, candid communications with the public are essential.
- The “value proposition” for most Americans is personal and specific. For example, when presented with these statements:

“It’s my health information. I should have access to it anywhere, anytime,” 61 percent “strongly agreed” and 23 percent agreed “somewhat agreed.”

“I want to be involved in medical decisions that affect me. Having my own medical record would help me make better decisions,” 49 percent “strongly agreed” and 23 percent “somewhat agreed.”

“I’d like to have all my health information in place – and get to it with the click of a mouse,” 38 percent “strongly agreed” and 24 percent “somewhat agreed.”

DEFINITIONS

Personal Health Record (PHR): an electronic application through which individuals can access, manage and share their health information in a secure and confidential environment. It allows people to access and coordinate their health information and make appropriate parts of it available to those who need it.

Electronic Health Record (EHR): an electronic version of the patient medical record kept by doctors and hospitals. The data in the EHR are controlled by and intended for use by medical providers.

The EHR is also known as the Electronic Medical Record, Electronic Patient Record, Electronic Health Record, Computerized Patient Record and Computer-based Patient Record.

²¹ Through focus groups, cognitive interviews and two national surveys, Connecting for Health staff examined public attitudes toward access to online medical records. The data collection included 10 focus groups (six in 2003, four in 2004) with samples of the general population, caregivers and people with chronic illness. A 2003 series of focus groups studied attitudes of early PHR adopters. The 2003 survey was conducted online with 1,246 respondents, and examined interest in various features of personal health records, comfort with use of online tools for the storage of personal health information, concerns about privacy and security, and level of trust in various information sources and hosts. In 2004, our research progressed to testing messaging and communications strategies. We used a series of focus groups to develop messages of PHR benefits. A 2004 national telephone survey included 1,750 respondents (of whom 1,201 reported chronic illness) and emphasized how well people understood those various communications messages about use of electronic personal health records and related services. A small follow-up online survey also tested mock advertisements to see which images and ideas were most persuasive. For a more complete review of extant literature on consumer attitudes towards PHR, see Connecting for Health Phase 1 report at: http://www.connectingforhealth.org/resources/final_phwg_report1.pdf.

- These messages are particularly salient with several groups of healthcare consumers:
 - People with chronic conditions, taking multiple medications, and people with more than five doctor visits per year;
 - Younger (under age 45) patients and families, who are more comfortable with the internet and computer use;
 - Those caring for an ill parent or spouse, and parents with young children.

These and related research findings can be used to shape a “communications toolkit” that can be adapted by various vendors, health systems, consumer groups, and government programs so that the public begins to develop a common understanding of our vision, the expected benefits of progress, and the vocabulary of modern healthcare. These messages can empower patients and families to be more effective managers of their own health, better partners in care, and informed advocates of moving the health system towards greater connectivity.

B. DESIGNING FOR PRIVACY AND SECURITY

The Steering Group recognizes that designing and implementing a system for coordinating the exchange of health information carries with it a fundamental public obligation. Americans rightly believe that their personal health information is theirs, that its use and distribution should be under their control, and that any carelessness in its management could lead to irreparable harm. A majority of respondents to a 1999 California Healthcare Foundation survey agreed that the ability to link their medical records across providers would provide significant benefits, but a majority also felt that the risks of lost privacy and possible discrimination outweighed the potential benefits of linked records.²² The public must not only be made aware of the benefits of accessible information, it must also be convinced that the systems that manage that information are trustworthy. Failure to address this need could lead to a rapid unraveling of much good work.

In the past, however, there seemed to be no easy way to achieve the benefits of linking records without jeopardizing privacy and associated values. There are situations in which a patient would not want medical records to be easily retrievable. These include domestic violence situations, drug and alcohol abuse treatment, and cases involving celebrities or public figures. Until recently, it seemed hard to scale a system that linked records reliably for the majority of patient care requirements while also allowing for heightened confidentiality in selected cases.

Under the system we propose, decisions about linking and sharing are made at the “edges” of the network. This approach allows patients to determine locally with their providers what information to link and disclose. By leaving these decisions at the edges, the architecture supports a range of approaches.

The Steering Group has endorsed an infrastructure approach which makes the secure and confidential treatment of patient information a fundamental design criterion. The only new infrastructure element is an index of pointers to where patient information is housed, but which contain no personal health information; no patient records are centralized under this approach.

The Steering Group also recommends a series of policies that go beyond the minimal requirement of keeping personal information secure. People have a right to know if their information –

²² See *Medical Privacy and Confidentiality Survey*. By Princeton Survey Research Associates for the California HealthCare Foundation (January 1999).

even the index to their information – has been accessed, and by whom, and whether any clinical records have been shared between organizations. They have the right to exercise control over uses and disclosures, have access to data about themselves, and be able to ensure that data is accurate, timely and complete. Architectural, technical, and policy solutions must all be employed to guarantee that the privacy and security of patient data is protected, while also permitting the rapid and accurate exchange of information between authorized users. Therefore the more detailed recommendations for safeguarding privacy and security are embedded in the fabric of all of the *Preliminary Roadmap* areas and woven into the solutions they propose.

C. DEVELOPMENT OF PERSONAL HEALTH RECORDS

In a fragmented and pluralistic system of healthcare services, no single entity is capable of – or responsible for – collating all of the important health information about any one individual. Personal health information is scattered across insurance plans, private practice physician offices, hospitals, laboratories, retail pharmacies and PBMs, school clinics, and a myriad of alternative providers. Today, the person who wants to actively manage her own chronic illness or provide help to an ailing parent has enormous difficulty accessing and managing the key information. While some integrated delivery systems are moving rapidly to provide patients with views of their data as it resides in the electronic health record, few are providing patients with tools to integrate and manage all of their information across all providers and across time.

RECOMMENDATIONS (ENGAGING THE AMERICAN PUBLIC: DEVELOPING PERSONAL HEALTH RECORDS)

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.

Rationale (Engaging the American Public: Developing Personal Health Records)

Significant efforts are already underway to develop personal health records. Many of the best early projects provide specific and concrete benefit to well-defined patient populations – people receiving care from the Veterans' Health Administration, parents of children with hydrocephalus, people managing multiple medications, members of Group Health Cooperative of Puget Sound. Yet few of these systems, even those built on common software platforms, are able to exchange information with each other or directly with the patient and family, and few have been designed with a priority on direct benefits to patients. The Steering Group supports the continued efforts to meet patients' needs through the development of PHR products, and has no desire or ability to recommend any particular approach. Instead, we encourage the PHR and EHR communities to anticipate the increasing need for interoperability and the importance of sharing data directly with individuals by adopting a set of common standards and policies now.

In 2004 and 2005, several demonstration projects should be undertaken to implement the technical and policy recommendations presented here, to develop practical means of imple-

mentation, to evaluate public interest, and to determine the value provided to users. Candidate projects include:

- Projects to coordinate care for people with chronic illness;
- A personal medication record to consolidate all medications and apply medication management tools to support effective and safe patient use;
- Projects to track and manage a patient's healthcare expenditures.

THE FORKS IN THE ROAD

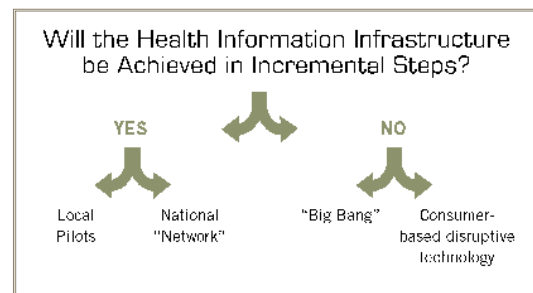
While all agreed on the importance of finding methods to better communicate with the public and the centrality of guaranteeing privacy and security for patient records, other questions yielded sometimes conflicting responses.

We called these topics “Forks in the Road.” The forks metaphor was chosen deliberately; each fork is an important marker along the road to electronic connectivity, but each is also a point at which the appropriate near-term direction is not obvious. On the other hand, the fork metaphor should not be taken too literally. The choices are not necessarily distinct or mutually exclusive; they often fall along a broad spectrum of options.

We have presented the following recommendations in the context of the “Forks in the Road” they were developed to address.

2. Infrastructure

This Fork concerns both the speed with which the infrastructure to support electronic connectivity can be built and the approach to be taken in building it. We asked interviewees whether they thought it would develop incrementally. Those who said Yes (on the left side of the diagram) were divided about whether we should promote regional activities (the “Local Pilots” approach), or whether we needed to invest in nationally driven efforts to build the infrastructure (the “National ‘Network’” approach).



Those favoring a nationally driven approach are concerned that a multiplicity of pilot projects and a resulting fragmentation of capital investment might lead to sub-optimization of the infrastructure as a whole. Others believed that the “Big Bang” model; i.e., a massive investment and provisioning effort by the federal government, similar to the strategic approach in other developed countries, was necessary. Others thought change would ultimately only come about through the pressures of a “consumer-based disruptive technology.” The theory was that consumers, empowered by a set of health information management technologies would team up with the intermediaries who created and managed these tools to demand change.

Ultimately, the Steering Group was persuaded by the incremental argument. Our commitment to identifying actions that might be realistically implemented in the next one to three years forced us to be practical. The existing strategies for funding local pilots in various regions and industries can produce immediate value to patients, clinicians, public health and research institutions, and should be encouraged. However, we believe that it is very unlikely that the development of the health infrastructure we envision will occur organically. To accommodate worries about further fragmentation, we propose a middle ground in hopes of leveraging individual initiatives and gaining synergies among them through incentives, coordination, and policy mechanisms. Guiding these projects towards standards will ensure that infrastructure segments can inter-operate to produce a greater good for individuals and society as a whole.

These recommendations are premised on the need to make interoperability and connectivity a public policy objective, therefore requiring an organized and purposeful agenda. We believe the following recommendations leverage the initial steps being taken to develop a healthcare information infrastructure and that they will be the most likely to achieve the results we desire.

RECOMMENDATIONS (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.

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.

GUIDING PRINCIPLES (INFRASTRUCTURE)

Please see Appendix D, “Proposed Network Illustration,” for an artist’s rendition of our proposed network.

1. **Safeguard Privacy:** In order to be accepted by patients and providers, the network must safeguard the privacy of health information. Trust is a crucial component of the doctor-patient relationship, including those elements of the relationship that involve the disclosure and sharing of sensitive information. If sensitive information is disclosed inappropriately then trust in both the provider to whom the information was entrusted and the network will be lost. Participation in the network must be voluntary and must be built on the premise of patient control and authorization.
2. **“Bottom Up” and “Top Down”:** The debate surrounding the formation of a health information infrastructure does not necessitate a stark choice between local and national initiatives. The strategy for implementing the *Roadmap* includes both top-down and bottom-up elements. Most healthcare is local, and the bulk of information transfer occurs in a patient’s own community. Many multi-institution systems, that are effectively local health information infrastructures, already exist. However, a common framework must be in place to ensure interoperability between those systems as they grow. The common framework will also permit each individual’s personal health record to interact with the network of electronic health records in any and all communities.

As with the growth of the fax network or the Internet, the bulk of the IT implementation will be undertaken locally, in response to local needs and resources. By basing the network on standards, the system will work with a variety of hardware and software thus saving participating institutions from being forced to adopt a ‘one size fits all’ solution. Given the “Common Framework,” the market will create solutions that are appropriate for small physician practices, multi-hospital institutions, families and other participants. These standards also assure support for stakeholders such as public health that by their nature extend beyond any one locale.

Ultimately, it is desirable to leave to the local systems those things best handled locally, while specifying at a national level those things required as universal in order to allow for interoperability among regional systems. In particular, the minimum security standards required to assure secure Internet transmission or patient matching methods must be

national, so that all participating institutions can connect to one another securely and without unworkable variation.

3. **Avoid “Rip and Replace”:** The requirements of economic sustainability and practicality demand an evolutionary approach and a clear migration path for all participants in the health information architecture. Given the non-stop demands of providing healthcare services, change must evolve incrementally.

Any proposed migration path must take into account the current structure of the healthcare system, and must work with that infrastructure where possible. Some of this infrastructure will need to be replaced, of course, and the replacement and migration will generate new costs, if only during the transition period. Where possible, however, the system should include what has been deployed today.

4. **Decentralization:** Data stay where they are. The U.S. healthcare system is fragmented. Many types of institutions exist as part of the current healthcare network, from giant hospital systems to individual practices, with all manner of specialists, clinics, and agencies in between. We do not believe there will be any wholesale change by 2010. Therefore, any proposed improvement to the healthcare system must assume that the participants will be decentralized and must accommodate voluntary, partial, and incremental participation.

The decentralized approach leaves clinical data in the control of those providers with a direct relationship with the patient. This approach greatly reduces the risk of misuse by ensuring that there is no single “bucket” holding identifiable clinical data, and leaves judgments about who should and should not see patient data in the hands of the patient and the physicians and institutions that are directly responsible for the patient’s care.

The decentralized approach also reflects the legal and market realities of healthcare. If institutions were required to share all of their data to participate (as is the case with some existing centralized approaches), many would choose not to do so.

Of course, the network facilitates the transfer of selected information from one end point of the system to another, as is required for providing care and supporting informed patient participation in care. The decentralized approach obviates the need for storing identifiable data in a central database. Even though the infrastructure is decentralized it still supports and facilitates aggregation for public health, quality management and other functions. The infrastructure facilitates transferring information to properly authorized end-point systems that aggregate data for such purposes.

5. **Federation:** To maintain the local autonomy of decentralization, a common set of policies, procedures, and standards to facilitate reliable, efficient sharing of health data among authorized users is required. These standards or practices spell out when patient information can be shared, which patient data can be shared and how the information can be used. That is, the participating members of the health network must belong to and comply with agreements of a federation. Federation, in this view, is a response to the organizational difficulties presented by the fact of decentralization. Formal federation with clear agreements allows participants to exchange information that the provider and patient have decided to exchange.

Specifically, agreements must be established between the participants in a federation that address how the participants share health data to treat patients, who has access to a

patient's record for treatment purposes, what information is accessible through the federation, what other uses of the data such as public health or research are permissible, how the federation will be governed, service level agreements, and a number of other issues.

Because many providers will not be able or perhaps willing to provide the levels of service required to participate in a federation, they may have to contract with business associates (in the HIPAA sense) to store their data in a repository that will sustain these service levels. Small physician practices might, for example, choose to store their data in a database provided by their system vendor (GE Logician users can already opt to store their data in an anonymized database) or they might choose instead to store data with other physicians in a medical society sponsored database. Some source systems' external data sources, such as commercial labs, currently store their data on-line for a limited period of time. They would have to either create or contract for long term storage.

RATIONALE (INFRASTRUCTURE)

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 between effectively used clinical systems such as EHRs.

Unless there is purposeful attention 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 arises from trust, 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.

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.

It is certainly possible to create sufficiently secure connectivity over the Internet today, but current approaches to such secure connectivity require a person-intensive process to establish and maintain electronic trust between the communicating parties. As networks get larger, the burden of creating and maintaining electronic trust will become overwhelming. A single, consistent secure connectivity approach will simplify these connections by eliminating the need for negotiating a different approach for each partner.

While we believe that a reference implementation is critical, we don't believe that it can or should slow progress, particularly on the bottom up portions of the work. The first steps in the reference implementation will involve selecting candidate suites or profiles of standards. The

implementation of these standards in the reference implementation will necessarily involve choices that eliminate some of the variability in the standards. However, these choices should not prevent organizations that are ready from moving ahead with implementations — small changes may be required but major changes should not.

We believe these recommendations are important next steps to creating a health information infrastructure that is safe in terms of privacy, reliable, and does not overburden the systems it interconnects.

In addition, to ensure that the technical infrastructure adoption can be sustained to enable information sharing on a local, regional and national basis, effectively addressing organizational and governance issues is critical. Academic research and initial evaluation of health care information sharing demonstration projects reveal that establishing clear vision, organizational principles and governance structures within and across organizations are critical steps to ensure a sustainable implementation.

Developing an information sharing infrastructure and relationships will be challenging in even the most mature markets, thus organizations should place a high priority on readiness assessment to determine whether there is a reasonable prospect of regional success in achieving comprehensive interoperability. Further, the approach to information sharing will be different depending upon the competitiveness of the market, the geographical characteristics and the extent of health care IT adoption, among other factors. There remains a lot to be learned about the most successful ways to achieve sustainability and the most appropriate roles and responsibilities among health care entities and government organizations.

RECOMMENDATIONS (INFRASTRUCTURE: ORGANIZATIONAL)

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.

RATIONALE (INFRASTRUCTURE: ORGANIZATIONAL)

Regions contemplating establishment of a health information exchange should conduct an organizational and technical diagnostic of community readiness for data sharing including strength of the business case for adoption and collaboration; ability to achieve community-wide participation; stakeholder willingness to commit to addressing the financial, technical, clinical, management, organizational, public, and consumer needs and concerns related to establishing a local or regional health information infrastructure; the number, complexity and nature of market and regulatory barriers to establishment of the local or regional health information; and willingness and ability to develop a strategic plan identifying the critical mass and incremental starting points necessary for proof of concept.

Communities developing health information exchanges must address critical success factors including the following:

- **Leadership:** Leadership among physicians and other clinical leaders is mandatory to achieve successful health information adoption and information exchange. Strong and continuous leadership by clinicians who, as individuals or representatives of provider organizations, accept the responsibility for change management and motivation of clinicians critical to success.
- **Activation:** An objective, well-respected, authoritative source will be needed to convene the community and begin the discussions and activities needed to address legal issues, establish governance mechanisms, determine the business case, and develop approaches that address the range of stakeholder needs.
- **Vision:** Establishing a strong vision is critical to maintaining focus and momentum and helps prevent potential derailment from individual organization or proprietary priorities.
- **Governance and management:** An inclusive structure with commitment by key leaders will be necessary to develop and manage the appropriate governance mechanism. Governance must establish clear responsibilities and processes for executing organizational and community plans.
- **Technical interoperability:** Organizations must understand and incorporate the technical standards requirements for interoperability in order to achieve on-going sustainability.
- **Practice transformation activities:** Clear definition of the functional requirements and resulting workflow changes is essential to enable sustainable adoption. Important components include organizational restructuring, resource allocations, clear work plans and training.
- **Training:** Adequate overall and targeted training and resources are essential to enable sustainable adoption. Successful adoption must have the appropriate support infrastructure necessary to manage the timeframe required to initiate and complete the entire transformation and adoption of the health information exchange infrastructure.

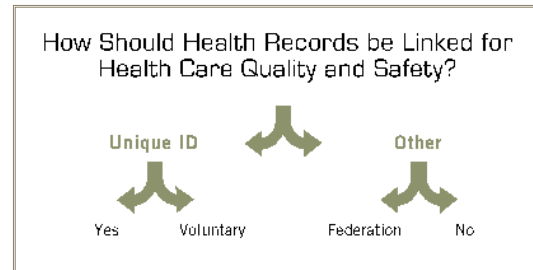
A source will be needed to convene the community and begin the discussions and activities needed to address legal issues, establish governance mechanisms and determine business case. The “convener” should be a neutral facilitator, a role that could be played by a number of different community members, highly dependent upon the market dynamics, including a major provider, major payer, business coalition, professional association, major employer, existing collaborative, state government, non-government organization, or an unrelated third-party.

Large providers have a natural clinical technology adoption advantage due to their infrastructure and business arrangements with physicians which could be a strategic advantage in helping the majority of the market toward health information exchange. Given the adoption challenges of small and medium-sized practices, it may make sense to focus adoption and incentive efforts on larger providers in the near-term to drive critical mass in the market.

Depending upon the degree to which communities identify a natural convener, additional steps to encourage greater convening of communities include providing grants to facilitate community planning for health information exchange, requiring state governments to develop an assessment of health information exchange activity or readiness in their state and plans to encourage that development or working with accrediting agencies to include health information exchange plan development as a component of the accrediting process.

3. Accurate Linking of Health Records

Most patients receive care from a number of healthcare providers in different locations. Privacy advocates have always agreed that patients will get better care at lower cost if providers can more easily retrieve medical records in the hands of other providers. The benefits of linking medical records electronically include more prompt and accurate diagnoses, more appropriate treatment decisions, and the avoidance of adverse consequences such as those that may result from drug interactions or allergies.²³ Efficiencies can be achieved if prior test results can be quickly retrieved without having to wait for new tests to be run and analyzed. Major cost savings flow from not having to replicate tests and other costs savings are realized (and privacy risks are reduced) by not having to copy and transport paper records.



In the past, however, there seemed to be no easy way to achieve the benefits of linking records without jeopardizing privacy and associated values. Previous proposals for a national health identifier have been a major source of contention in the privacy debates and a stumbling block to linking health records. One major concern was that any identifier created for healthcare purposes would become as ubiquitous as the Social Security Number, becoming the single national identifier for every purpose. If the health identifier became a key that could unlock many databases of sensitive information, it would make all personal data more vulnerable to abuse and misuse.

Yet, for progress to occur we cannot be asked to choose between our privacy and our health. The Connecting for Health Steering Group asked that any proposed solution offer major improvements in healthcare but also protect the privacy of patient information and offer patients control over their records.

RECOMMENDATION (LINKING)

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

GUIDING PRINCIPLES (LINKING)

1. Any proposed solution must support the accurate, timely, private and secure handling and transmission of patient records.
2. Any proposed solution must increase the quality of care, the economic sustainability of the healthcare system, and the privacy of patient data.

²³ According to the Institute of Medicine, more than 500,000 people are injured annually in the United States due to avoidable adverse drug events. 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 Health Care in America, Institute of Medicine, National Academy Press, Washington, D.C. (2000) Available at: <http://books.nap.edu/books/0309068371/html/index.html>.

3. Any proposed solution must create value for many different kinds of participants, including individual healthcare professionals and patients.

RATIONALE (LINKING)

In examining the advantages and disadvantages of various ways to link health information, we concluded that a national health ID is unworkable in the near-term and would not provide the hoped-for benefits even if it could be implemented. It is important to note that the recommendations on decentralized systems for inter-enterprise information sharing are important companion concepts. The system we propose radically eliminates the two largest perceived privacy threats associated with the linking of health records: centralization and national IDs.

Implementation of any national health ID has several critical weaknesses:

1. The political culture of the US is not amenable to national identifiers. The risk of privacy spills is also a significant disadvantage if one identifier is the key to all of a person's health data.
2. A national health ID could not be implemented in a short period for two reasons. First, creating and implementing a process to issue a national health identifier would be expensive and require years. Second, current health IT systems don't support the easy addition of external, searchable identifiers. A new national identifier would require upgrade expenses for every institution in the U.S. healthcare system, and therefore create a significant lag in adoption.
3. Even if simple implementation were practical, the health ID would simply be another identifier, and would be subject to the same inaccuracies and distortions that have plagued any single identifier approach we currently have. (One major health IT network we surveyed estimates that there are transpositions and other errors in Social Security numbers up to 12 percent of the time.) In contrast, linking using multiple identifiers has been the subject of intense research and development over the years, and methods exist to achieve accurate linking up to 99.8 percent of the time.

To mitigate certain major privacy risks, the best protection is not to aggregate data. From a privacy perspective, the fundamental contribution of the Connecting for Health Working Group on Accurately Linking Health Information is to show that the benefits of information sharing can be achieved without any centralization of records and without unique national identifiers. Instead, the system contemplates a network of networks, linked only by directories of identifying information pointing to the sources of records. The directory system knows where records are, not what is in them.

Under the system we propose, decisions about linking and sharing are made at the edges of the network. The system supports (1) linking of records via a directory of pointers and sharing among healthcare providers participating in the system, but it also allows (2) linking without sharing, or sharing pursuant only to higher authorization, as well as (3) the ability to choose not to link information in certain treatment situations, such as drug or alcohol rehabilitation. The approach is based on the proposition that we should leave it to patients to determine locally with their providers what to link and what to disclose. By leaving these decisions at the edges, the architecture supports a range of approaches. It also allows higher levels of approval to be set locally for sharing some records.

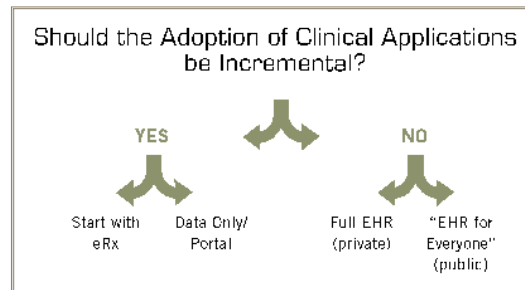
Preserving these privacy options is important to ensuring acceptance of the system and its benefits. Trust is a crucial component of the doctor-patient relationship, including those elements of the relationship that involve the disclosure and sharing of sensitive information. Privacy is an important factor contributing to that trust. Privacy advocates have long agreed that patients should be informed by providers of the benefits of linking records. However, even well-informed patients are reluctant to share information because of privacy concerns.²⁴ Patients will be more likely to accept a scheme of automatic widespread sharing for healthcare purposes if they can choose, with assurance, to ensure that certain records will not be linked or disclosed. In this regard, the proxy for patient trust is often the primary care physician's trust: patients are likely to trust a system that their personal doctor trusts.

The full report of the Connecting for Health Working Group on Accurately Linking Health Information will detail this proposal and be made available later this summer.

²⁴ A 1999 survey by the California HealthCare Foundation showed that even when people understood the advantages that could result from linking their health records, a majority believed that the risks of lost privacy and discrimination outweighed the benefits.

4. Rate of Adoption of Clinical Applications

While the first fork focused on the infrastructure needed, this fork focuses on the applications that connect to it. It does however ask the same question. Should policy focus on the use of a full EHR by physicians at this stage or is that too disruptive? Those who believe there is an incremental path toward automating clinical IT are on the left side of the forks diagram pictured here. People here tend to believe that EHRs are still an early technology, that they are costly and that the high costs of managing the clinical and administrative changes EHRs demand are not justified. The EHR creates changes in workflow, communication and decision-making. Therefore, in this group the value of incremental steps are identified and a variety of more incremental applications are proposed as first steps for policy change.



If the incremental path to the electronic health record is one you believe will not succeed, then you are more inclined to find yourself on the right side of the diagram. Here the risks of incremental and piecemeal technology adoption are perceived to be greater and the disruption and inefficiencies to the clinician’s workflow from these approaches make them untenable. In this group there is a strong feeling that we need to move focused public policy all the way to the benefits of a full electronic health record. How to get there can include private sector focus or can include the public availability of a “common EHR.” The latter group often talks about rapidly making available a federally developed or open-source EHR.

RECOMMENDATIONS (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.

GUIDING PRINCIPLES (APPLICATIONS)

1. Enable the Full Spectrum of Applications: The full EHR system, limited scope provider applications and specialized applications such as those that support reference laboratories will participate in the infrastructure.

2. There is a special need to facilitate the proliferation of EHR systems in order to engage more care providers in information-based collaboration.
3. Accept the Full Spectrum of Readiness: Accommodate diverse levels of readiness among providers.
4. Value-based Prioritization: Should choose candidate incremental applications by focusing on high-value use cases and exchange transactions.
5. No Dead-Ends: Incremental approaches are necessary and valuable, as long as they are not dead-ends. The criteria include:
 - a. Incremental steps must make adoption of the ultimate interoperable, standards-based EHR more likely, not create silos that do not integrate well.
 - b. Should provide a clear migration path to a seamless end-user experience without loss of time and money investments previously made.
 - c. Should utilize, and contribute to the building of, the “Common Framework,” and not create an incompatible or competitive networking technology.

RATIONALE (APPLICATIONS)

In order to provide a majority of their benefits, clinical applications must interconnect with other clinical systems. Electronic prescribing systems without data about the patient’s weight or renal function provide much less benefit than when these data are available. Similarly, a health information exchange infrastructure without any applications to originate and receive data is entirely useless. We must avoid implementing EHRs or EHR components that preclude health information exchange.

The healthcare applications to be implemented, and the common health information infrastructure needed for interconnectivity, are highly interdependent. This may present a dilemma about where to begin. Some would suggest focusing on incentives for EHR adoption as stand alone systems within provider enterprises, and trust that interconnectivity between them will emerge later. Others advocate constructing health data exchange networks first, assuming these will be a driver for the adoption of network-aware applications. Both of these extremes are to be avoided.

Focusing solely on accelerating adoption of local EHRs will continue the legacy that we have today—with proprietary, albeit more sophisticated, programs that cannot interoperate without a great deal of cost. Conversely, an isolated emphasis on infrastructure could leave us with an expensive network that lies unused, like the miles of “dark” fiber optic cable in the ground. Instead, our recommendation is that both applications and infrastructure should be developed and adopted simultaneously, in incremental steps that always bring us closer to the ultimate goal, and that deliver positive value for the adopters at every stage. Just as with the network, the incremental steps must follow a plan whereby each step is a move closer to the ideal.

Given the challenge of transitioning our incredibly complex \$1.6 trillion healthcare industry from paper records to digital data, no one is seriously advocating an extreme “big bang” approach. But there are risks in an incremental approach as well, because isolated steps taken without an integrated strategy toward the long-term goal can lead to dead ends. There were many strong views about this area, with valuable observations on both sides. Some felt that implementing the full EHR was too disruptive and that most products are still at early evolu-

tionary states, and cited current low penetration rates as proof. Others argued that a smorgasbord of isolated incremental applications would disrupt workflow, be difficult to learn and that without full EHR functionality, the safety and quality improvements from clinical decision support would never materialize.

Some participants pointed out that, readiness for IT varies widely among providers. Forcing “baby steps” on those who are fully ready for the jump to a full EHR is as counterproductive as expecting too big a leap from others. Therefore we designed our actions to accommodate this diversity of needs and readiness as well.

The Connecting for Health participants found several specific examples of incremental applications and data exchange that hold promise, including:

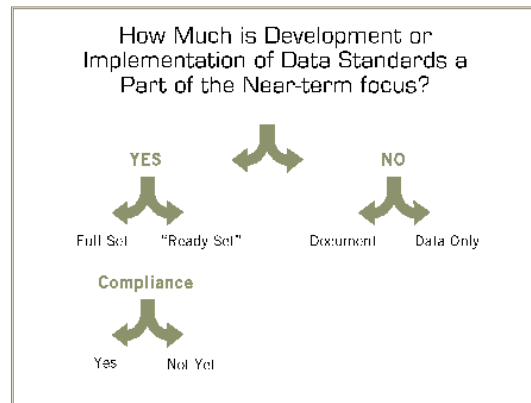
- Electronic Prescribing
- Electronic lab result reporting
- Electronic imaging reports
- Electronic disease registries
- Electronic medication management systems
- Continuity of Care Record data exchanges (if harmonized with HL7 standards)
- Electronic quality data submission
- Electronic symptom/disease surveillance for public health use cases
- Secure patient/physician email
- Administrative data exchange, e.g. eligibility, claims, remittance
- Clinical guideline prompts

However, these applications must be designed and implemented in such a way that the path toward the full EHR is clear and the likelihood of reaching that ultimate goal is increased, not decreased. For example, an electronic prescribing application should allow the user to add other functionality such as clinical documentation and decision support that move them toward the full EHR rather than requiring them to switch to a different product. Without this requirement, the sunk costs in money, time and staff disruption and the difficulty of carrying data forward will continue to hurt the marketplace.

In the near term, these incremental applications represent nimble opportunities to change provider behavior, and to build out the necessary infrastructure. Many of these incremental opportunities achieve their quick return by providing service directly to patients and in so doing increase public interest and trust in health IT. Over the long term, these incremental applications must become seamlessly integrated functions within the EHR, and their networks must mesh smoothly with the complete health information infrastructure. Imminent funding for some of these incremental applications represents a significant opportunity if these requirements are served, and a significant threat if not.

5. Data Standards

While everyone agrees that data standards are central to achieving our ultimate vision of a connected healthcare system, it is less clear whether a sustained focus on the development of new data standards in the near-term is equally essential. Those who believe it is essential are on the left side of Figure 3.0, and they raise a series of questions: What should the next steps be? Should we place an immediate focus on investing in and completing a full set of data standards as a precursor to development of the infrastructures they support? People in this group may point to the shortcomings of existing



standards. Or, should we place near-term focus on getting a partial set of standards implemented? People in this group believe that the “ready set” of data standards—those that have already been identified by Connecting for Health and Consolidated Health Informatics initiative—are enough to get started and that near term focus on implementation is essential. Everyone who falls into the left side of this figure agrees that without a strong emphasis on compliance and conformance with the standards, variability in implementation will continue to prevail and enabling interoperability will continue to be a highly labor-intensive process. Some worry that this might hamper the growth of technology adoption at an early stage.

Those who are on the right side of the fork believe that while standards are necessary to achieve the long-term vision, near-term focus should be placed on getting any information to move electronically that can enhance clinical care. This group manifests a growing impatience with the identification and implementation of standards and believes that increasing the exchange of information as soon as possible is the highest priority. Electronic documents that contain unstructured information or any portal that provides a “view” of information like a look-up for lab results is believed to be better than the current situation.

RECOMMENDATIONS (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.

GUIDING PRINCIPLES (DATA STANDARDS)

1. **Avoid “all or nothing” requirements.** Employ standards to work with high-function and lower-functioning systems and to facilitate the best possible interoperability among systems of differing levels of sophistication.
2. **Use nationally adopted standards in regional implementations.** The cost of conforming to standards will be spread over many more users if the manufacturers of information systems know that the code they develop will be used nationally. We assume minimal thresholds for participation in the system on the assumption that, by offering some value in return for some embrace of standards, we will be able to maximize early membership in such networks. Once in, the members will have both the incentive and opportunity to become increasingly standards-compliant, and therefore to have increasingly high levels of interaction with one another.
3. **Certification of interfaces is an important way to reduce the costs of building health information networks.** The few health information networks that now exist have been developed through a labor-intensive process of developing and testing interfaces. We can avoid replicating this expense for each new network through third-party, automated testing that uses automated methods to certify the conformance of an information system. Such certification must simultaneously apply to the full profile of standards that work together to achieve interoperation. There is considerable work to do on the methodology and governance necessary to make interface certification function optimally and thereby achieve the economies of scale that derive from uniformity of interfaces at a national level.

Certification methodology must be developed as part of the “Reference Implementation.” This is mandatory in order to ensure integrity of the standards, implementation guides, “Reference Implementation” and certification process. 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.

RATIONALE (DATA STANDARDS)

The importance of the use of data standards in realizing our vision remains paramount. All the standards that are needed to get started exist today. The question is how to best apply them to specific use cases and how they should evolve over time. Near-term focus should be on getting the “ready set” of standards identified by Connecting for Health and by Consolidated Health Informatics implemented. Implementing these standards requires profiles, certification (see below) and implementation in applications. We recognize there are many standards that are necessary for complete interoperability and none that are by themselves sufficient. These standards come from different organizations such as the Internet Engineering Task Force, World Wide Web Consortium, X12, HL7, NCPDP and the College of American Pathologists and serve different functions. Some are specific to healthcare while others are applicable across all industries. They must be combined in a coordinated fashion. These combinations or profiles of standards define a suite of standards that we need to fulfill the needs of a specific use case. Once developers implement the suite of standards within an application they must be certified to ensure that they will interoperate seamlessly.

For example, The Medicare Modernization Act (MMA) requires a suite or profile of standards to be chosen and specified sufficiently to address the use case. The MMA directs HHS to recommend standards required to support electronic prescribing. This profile will almost certainly contain the Internet and IP at the lower levels, NCPDP messages for data transfer at a higher level and RxNORM for content. Like most messaging standards, NCPDP provides a degree of flexibility and HHS will have to create implementation guides that eliminate most of this flexibility in order to create seamless interoperability. The lower level standards will have to be the same for all new initiatives in order to avoid dead ends.

When adopting clinical information standards there is an important trade-off between specifying a requirement that the data be minutely structured and coded, on the one hand, or allowing it to be represented as simple text, suitable for interpretation by a person. The former approach is required for computer decision support, abstracting for public health surveillance, or aggregation for research and quality determination. The latter approach is important in the short term because it minimize the burden on users.

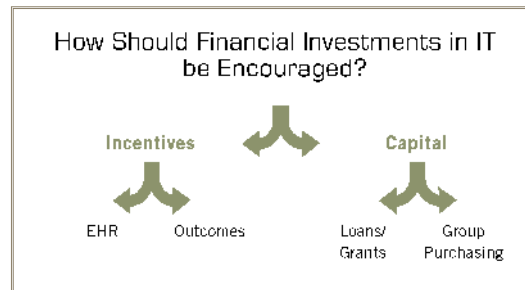
Certification of interfaces must therefore be based on use cases that involve interoperation of systems with different levels of sophistication with respect to handling structured data. They should consider the benefits of the HL7 Clinical Document Architecture for sending information in a mixed format (both structured and unstructured) useful both to unsophisticated systems and sophisticated ones.

If we create the methodological groundwork for interface certification, there is considerable opportunity to achieve this certification over the Internet without labor-intensive on-site testing. Organizations that fund regional health information projects should foment a collaboration between the National Institute of Standards and Technology, the standards development organizations, major IT vendors and healthcare information trade organizations to establish the methodology, and then use it on the early projects.

Standards-development will be a continuing process. As policymakers, providers, and vendors anticipate increased use of health IT by patients and families, and increasing patient self-care using information tools, data standards suitable to transmittal of patient-sourced information will be necessary. Some current standards work – such as the HL7 EHR functional model – contain most of the functionality needed by the PHR. Standards organizations should give greater attention to including codes and vocabularies for such information as symptom, behavior, functional, and adherence reporting as well as the need for patients to easily and uniformly interpret the presentation of EHR data that is now becoming available to them.

6. Funding and Incentives

Electronic systems are costly, and traditionally healthcare has spent proportionately less on them than most other industries. This Fork recognizes the debate over the need to encourage healthcare stakeholders to invest in IT. Some believe investments in IT should be encouraged through incentives, whether direct or indirect. Some in this group believe there is sufficient money in the U.S. healthcare system to fund the use of modern IT. Others believe that a level



of new capital spending is required for incentives to have results. Both groups believe incentives are necessary to counteract current economic realities that discourage such investment. Although providers bear the cost and the risk of investments in IT, they often do not realize the full benefits because of perverse financial incentives in the current system that rewards piecemeal and volume-based care. People disagree on whether the rewards should be direct—e.g., rewarding use of an EHR—or indirect—e.g., pay-for-performance program whose goals are achievable only through the use of interoperable clinical IT systems.

Another viewpoint holds that while incentives may be important, the critical limiting factor in IT investments is lack of easy access to capital. Some have suggested that this be addressed through use of revolving loan funds or federal grant programs. Others favor group purchasing arrangements to lower capital requirements.

It is important to note that the beliefs in the importance of incentives and in the importance of capital availability are not mutually exclusive. People who believe that there is an underlying latent demand for IT may focus primarily on the right side of this diagram, while those who believe the business case for electronic records and interoperability for providers is extremely weak may feel that access to capital is necessary but not sufficient without creating greater benefits for the user.

These recommendations come from our Working Group on Financial, Legal and Organizational Sustainability should be interpreted with the following notes:

- For analysis purposes, we defined a “typical” ambulatory physician practice (see below). Although the general lessons are thought to be applicable to a variety of small to medium-sized primary care practices (including dentists, optometrists, etc.), these should not be interpreted as an exact net benefit for all ambulatory practices. Many factors influence IT costs and benefits including practice size, specialty and geography. In addition, the variation in practice operational efficiency, hospital affiliation, degree of IT support mechanisms in place and the variety of current incentive mechanisms in the market cause us to exercise caution when extrapolating the analysis to other ambulatory settings.
- There is a dearth of data to work with concerning the financial impact of IT on the ambulatory practice. We conducted literature reviews, interviewed industry experts, developed an analysis methodology and utilized the expertise of the Working Group, consisting of healthcare informatics researchers, health system executives and legal professionals, to develop the framework. Hence, these are initial estimates that need to be improved upon for practical application.

- The financial incentive estimates are starting points only, thought to be the sufficient incentives to provide adoption momentum in the market. We recognize that there are a number of other factors that contribute to the successful and sustainable adoption of health care IT toward the goal of information sharing as well as realizing the value of interoperability, as the industry has demonstrated great difficulty in sustaining clinical IT applications. These estimates do not cover a physician practices' ability to participate in full regional and national interoperability due to the lack of complete data on these costs. However, the success factors and additional opportunities stated throughout the other organizational recommendations that will be presented in the Working Group's Final Paper should be considered essential companions of our financial recommendations.
- Our analysis had two major orientations. First, we examined the financial and support mechanisms necessary to significantly increase EHR adoption by the small to medium sized practice. Extensive regional and national interoperability will not be possible unless there is extensive EHR adoption in this critical segment of the industry. Second, we analyzed the barriers that need to be addressed to further regional and national interoperability. Extensive EHR adoption by all providers does not inherently result in clinical data exchange between providers.

RECOMMENDATIONS (FUNDING)

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 widespread 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.

GUIDING PRINCIPLES (FUNDING)

1. **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 health care 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, 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.

2. **Identify starting points, opportunities and sustainability factors:** Our objective was to perform an analysis of the legal and organizational issues and barriers to health information exchange as well as a high-level qualitative financial analysis of healthcare IT application adoption with a focus on health information exchange for both the ambulatory care physician practice. The goal of the analysis was to clarify and improve the understanding of barriers and opportunities to achieving sustainable adoption of health information technology and information exchange for the purchaser/implementer of a specific type of clinical information system application. Furthermore, we hoped to identify starting points and near-term opportunities for physician practices and inpatient providers to adopt healthcare information technology with the goal of health information exchange.
3. **Analyze market segment with the largest clinical technology adoption gap:** Ambulatory care practices are on the front line for the treatment of patients in the United States today, specifically the chronically ill, and have the lowest adoption rates of health care IT among the provider sector at an estimated 6 – 13% in 2001 (JHIM, 2004). Hence, we chose to focus the majority of our analysis on the small to medium-sized physician practices in the ambulatory care setting. We did not include other societal or stakeholder benefits related to health information sharing. We also have not, at this time, studied the incentives for CPOE in hospitals, for labs or for any other potential stakeholder.
4. **In our qualitative financial analysis, we examined the financial and support mechanisms necessary to significantly increase EHR adoption by the small to medium sized practice.** Extensive regional and national interoperability will not be possible unless there is extensive EHR adoption in this critical segment of the industry. Extensive EHR adoption by all providers does not inherently result in clinical data exchange between providers.
5. **We analyzed small and medium-sized physician practices in order to derive an incentive to equip this specific subset of the industry with clinical application technologies.** We developed an incentive that we believe would cause “tilt” in the adoption of clinical applications among clinicians and not for the application with complete interoperability or as part of participating in a community-based interoperable infrastructure. We do not intend to derive an incentive to attract clinicians to adopt complete interoperability since there is a significant dearth of data on which to base the cost of participating in a fully interoperable infrastructure. We analyzed some cases from the physician practice perspective. In two cases, we analyzed the inpatient provider perspective. The inpatient analyses are in progress and have not been factored into our recommendations.
6. **Our analysis is modeled for a “typical”, outpatient physician practice of five physicians** in a primary care practice and a cardiology specialty practice. Although there is great variation in size, specialty and geography across ambulatory care practices, we believe that the conclusions from analysis of the “typical” can be broadly extended across the majority of

small and medium-sized ambulatory care practices due to the similar set of implementation and infrastructure issues. We specifically analyzed use cases 1, 2, 3 and 4 (see Appendix A) which related to EHR, e-prescribing and on-line chronic care management tool adoption in the ambulatory care setting. We analyzed a comprehensive list of costs of adoption as well as benefits realized by the physician practice over a three-year period to account for capital costs and improved efficiencies.

RATIONALE (FUNDING)

The realignment of financial incentives for the ambulatory environment is paramount in accelerating the adoption of IT. Our analysis of physician practices providing ambulatory care confirms what several recent studies have found; the business case for IT adoption among physician practices is not sufficient and incentives are misaligned. Currently, providers bear the expense of clinical application technology adoption, but a significant portion of value attained from improved quality of care and more appropriate utilization of services accrue to organizations and groups other than physician or provider purchaser. This “value imbalance” leaves the physician exposed to a likelihood of a poor financial business case for EHR adoption. A positive business case must be in place to make clinical IT adoption work among physician purchasers.

Adoption of most types of technology in the absence of financial incentives for interoperability interventions, results in a net cost to the physician practice purchaser in at least the first three years. Among incentive vehicles, financial incentives have the greatest impact and can be designed as either direct (i.e. direct payment for EHR or e-prescribing use) or indirect (e.g., pay-for-performance for outcomes measures, care coordination or chronic care management). Incentives should include IT adoption with support of interoperability among data sources outside the physician practice. A recent study from the Center for Information Technology Leadership showed that the return on investment for IT use is significantly improved when interoperability of information is considered, as much of the operational and clinical gain can be more fully realized with patient-centric data transparency. Incentives that promote IT adoption without emphasis on interoperability have the potential to fund IT approaches that fail to enable the full clinical quality and economic efficiency gains that IT has to offer, resulting in a weaker business case.

The estimates of needed incentives should be interpreted as a starting point to encourage adoption, sufficient to cover the initial and three-year maintenance costs of an EHR application with very modest interoperability among providers (i.e. lab interfaces). These estimates should cover the technical basics for a small physician practice including hardware, software and installation, but may not be sufficient to cover the full costs of implementation assistance, on-going personnel necessary to support the application, cost of additional modules or modifications to further productive use, initial practice productivity impacts related to adoption (productivity decrease can be significant and can last for several months), high degrees of community-wide connectivity, impacts of practice paradigm shifts or the significant risk of adoption failure. However, incentives of these ranges are likely to lead to a significant increase in IT adoption by ambulatory care providers that, with the appropriate implementation and support assistance, will enable them to realize value and continue to invest to garner either greater practice efficiencies or take advantage of additional incentives (i.e. pay-for-performance).

The estimates are based on full time primary care provider with a patient panel of 2,000 or 4,000 patient visits per year. Assuming that the fully functioning EHR capital and on-going costs amortized over at least a three-year period cost a physician approximately \$12 - 15,000 per year, an incentive of \$3 - \$6 per patient visit or \$0.50 - \$1.00 PMPM would result in \$12,000 - \$24,000 per year per physician. The estimate range accounts for variability in implementation costs and practice size with the higher end of the range reflecting significant implementation and support costs which are quite necessary, an offset for revenue loss related to practice productivity loss, and/or failure to have incentives in place from all payers.

The Bridges to Excellence (BTE) program conducted an extensive literature search on incentives for IT adoption and practice re-engineering, the summary of which can be found on its web site (www.bridgestoexcellence.org). In 2003, BTE founders published an article in the *Journal of Clinical Outcomes Management* that summarized the research. Findings from focus groups were later validated by the work done by Bailit et al. (Bailit M, Dyer MB. *Provider Incentive Models for Improving Quality of Care*. National Health Care Purchasing Institute, March 2002) on incentive programs. A consensus view is that rewards and incentives have to be meaningful enough to more than compensate for the added cost associated to data collection and measurement of processes, perceived to be fair and equitable, attainable, periodically reviewed, incremental, with small step increments, as opposed to a "cliff". Bailit's work and independent focus groups from BTE both concluded that "meaningful" was achieved when the bonus was equivalent to 5% to 10% of a physician's income, which translates into \$10K to \$20K.

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. The estimates assume an aggregation of at-risk payments (i.e. direct reimbursement, pay-for-performance, etc.) with broad adoption by multiple financiers in concert to cover the vast majority of the patient panel or patient visits for a physician practice. Incentives by a limited number of practice's payers creates a first mover disadvantage for those payers and generates insufficient incentives to encourage technology adoption progress.

In addition to financial and non-financial policy actions that the federal government could take to improve the business case for provider-sector purchasers and realign market incentives, both health plans and self-insured employers must play a significant market intervention role to accelerate provider adoption by participating in complementary incentive strategies. The entire health care industry faces an increased public health focus on medical errors, rising health care costs in Medicare and the private sector, and industry-wide productivity losses caused by the inefficiency of the health care system. Both policy and industry leaders recognize the importance of greater transparency to permit purchasers and consumers to select and reward high-quality care along with the implementation of tools that permit both providers and patients to make informed, cost-conscious decisions about their use of care resources across the continuum.

Health plans interviewed as part of this process have expressed concern about the size of the incentive range and its effectiveness. Increases in financial incentives by payers and employers are likely to be incremental. Many payers and providers are experimenting with incentive approaches but the utility of these approaches is still being learned which will cause payers and employers to migrate gradually toward some form of adoption and/or use incentive. Many payers are struggling with their own margin pressures and are hesitant to devote significant dollars to incentives until the evidence of care improvement is clearer. Payers and employers also recognize that the small physician practice needs EHR selection and implementation support; the

absence of such support elevates the risk of the investment failing. An increasing number of industry forums are forming to enable employers and health plans to share ideas and learn from their experiences. The Working Group understands the issues raised by health plans and believes that incentives must be sufficient and in substantial enough increments to enable appropriate investments and effective implementation in order for the technology to benefit all stakeholders.

Widespread adoption of incentives by payers will require national standards for EHR technical capabilities and features as well as metrics for EHR use. These standards and metrics can help ensure that payers have reasonable assurance that they are “buying” an acceptable EHR that is being used in an acceptable fashion.

EHR adoption experience has shown that many physicians are highly resistant to full-scale practice changes required by EHR and very few have recognized the value for health information exchange. Hence, there is a strong hypothesis that the path to EHR adoption may occur via incremental technology adoption. Our qualitative financial analyses show that certain applications could be starting points to attract clinicians to IT adoption and information sharing. Applications with a smaller investment or a very high net beneficial business case could be considered as candidates for initial implementation. Incremental applications cannot, however, block other, highly important applications. They should both support practice workflow and provide the IT infrastructure improvements necessary to accommodate more comprehensive solution integration along the road to full interoperability.

Our analyses shows that e-prescribing and on-line tools for chronic disease management may be good starting points for building an information sharing pathway toward wide-scale EHR adoption. Although we did not specifically analyze the business case for other incremental application possibilities, the Working Group noted that applications such as disease registries and cross-organization information access may also provide strong starting points toward EHR adoption. However, these recommendations require some analyses before implementation in a specific physician practice. E-prescribing may have diminished physician acceptance if there are no fiscal incentives to switch medications to generics. Some of our task force members believe that non-visit based care should not be done out of the full context of EHR. The essential role of the patient in helping the system achieve the full potential benefits in these two areas – medication management and chronic care management – highlights the importance of selecting incremental clinical applications that deliver high value quickly.

Small practices have greater interoperability needs since small practices are more dependent on patient data from external sources. Hence, for these practices, interoperability is especially important. However, small to medium-sized ambulatory care practices will have greater challenges achieving sustainable implementation of interoperable health care IT due to the lack of a driving force for change and the management ability to effect change, as is present in many large groups or hospital-based physicians, and a dearth of resources available to dedicate to technical support, change management and implementation. In addition to business case development, consideration should be given to establishing implementation support structures for the small practice. Experimentation should be done to identify the most successful support models and these models may need financial support until the market for small practices matures. There should be financial support for local and regional information sharing collaboratives. These collaboratives should provide technical assistance, including resources describing viable collaboration models, practical implementation considerations and processes for multi-institutional and practice-level adoption and interoperability.

While the small practice is in the greatest need of IT adoption and interoperability, a case can be made that adoption strategies should initially focus on the larger providers in the region. These larger providers may require lower incentives and generally have established internal IT support mechanisms. If several larger providers accelerate their adoption of interoperable IT, this may result in encouraging the smaller providers to follow suit.

Regardless of the adoption strategy and incentive structure designed to encourage healthcare IT adoption with high degrees of interoperability among ambulatory care practices, investments will be needed to ensure sustainability of adoption at the local level. A wide range of activities, education and information will be necessary including rigorous financial analysis to support the incentive structure, implementation methodologies for small practices, change management approaches and implications, draft policies and procedures for information sharing (see recommendations for creating an information sharing infrastructure earlier in this section), case studies, product certifications and comparisons with user surveys and feedback, collaborative forums to continually refine practice implications and directories or brokering services for technical assistance to individuals and practices. Investments like these will create experience and work products that can be broadly shared across communities and support physicians in achieving improved healthcare through clinical IT application adoption as well as interoperability among other key health care providers.

7. Legal Safe-Harbors

Numerous laws may have unintentionally hampered the development of electronic connectivity in healthcare. The federal “Stark Law,” for example, effectively bans physicians from gaining financially from referring patients to organizations with which the physicians themselves are affiliated. (Referrals might be for a wide variety of healthcare services including diagnostic testing and treatment.) Some believe that the impact of the Stark Law on IT, however, is that physicians are discouraged from sharing electronic networks with health organizations because doing so can create a banned financial relationship. As a result, physicians and other healthcare stakeholders are discouraged from investing in development of such networks. Some experts believe that there should be exemptions to the Stark law and similar legislation as their requirements pertain to IT; others fear that such exemptions would result in abuses.



Some believe that the impact of the Stark Law on IT, however, is that physicians are discouraged from sharing electronic networks with health organizations because doing so can create a banned financial relationship. As a result, physicians and other healthcare stakeholders are discouraged from investing in development of such networks. Some experts believe that there should be exemptions to the Stark law and similar legislation as their requirements pertain to IT; others fear that such exemptions would result in abuses.

RECOMMENDATIONS (LEGAL)

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.

RATIONALE (LEGAL)

Current federal and state laws regulating the flow of health information are a complex and confusing patchwork. Harmonization and modernization of federal and state laws should be informed by technological and market realities that require greater standardization to ensure uniformity of actions and results to protect private property protect the security and privacy of health information, and to spur the development of interoperability across markets and jurisdictions.

As local and regional health information infrastructures are built, the need for robust security and privacy regimens must be supported, and provide the protections required by participating systems/members. This will require collaboration and development of local, regional and national health information exchange rules and operating procedures that respect local ownership and

control and enable interoperability across systems. Because some existing state laws conflict, we will need to consider educating state legislators about this issue so that they can address those that hamper information exchange across state lines.

Recent regulatory amendments to Stark physician anti-referral laws and anti-kickback laws provide a starting point for further modernization of legal barriers to exchange of health information for improving patient care. Additional interpretation of the recent amendments will be required to implement the rule to allow communities to take advantage of the changes.

The changing nature of medical practice is likely to require review and reform of existing medical malpractice and professional liability laws, as access to and use of clinical information for treatment itself leads to changes in care management and treatment protocols. Further review and drafting of model statutes based on changing practice patterns can provide a guide to states and medical societies in the long term.

Existing law and regulations provide sufficient protection and means by which individuals and organizations can immediately initiate adoption of electronic health records, and collaboration to exchange health information among multiple organizations.

FLYING BLIND

DR. JT FINNELL OF INDIANAPOLIS, INDIANA



A costly medical error common in ERs all across the country was averted recently at the emergency room I work in, thanks to a rare experiment in health information technology. As a result, a good deal of time, money and possibly a patient's life was saved.

The patient came into Indianapolis' Wishard Memorial Hospital complaining of crushing chest pain, but was unable to give ER doctors his medical history. Based on his symptoms, my colleagues feared he was having heart trouble, possibly a heart attack. In these situations, ER physicians typically give patients

blood thinners, as the medicine allows blood to restore the injured area of the heart. That didn't happen in this case. And it's a good thing.

Fortunately, the attending physicians were able to electronically access the man's medical records instantaneously, informing them that the man with chest pain sought treatment from a nearby hospital just three weeks prior for a head injury. Giving the patient a blood thinner might have increased bleeding to his brain, forcing an unnecessary head surgery and an injury that could have killed him.

With the right information, doctors were able to prescribe the proper treatment for their patient. The chest pain turned out to be angina, not a heart attack.

Had that patient gone to an ER without this technology, he would have been at risk to receive the blood thinner. Such medical mistakes are common because most other hospitals and doctors have to rely on a costly and inefficient paper-based system of medical records when caring for patients.

The inability for providers to get crucial medical information on patients seeking care leads to treatment that is redundant at best and can be ineffective, dangerous and even deadly. It's a big reason why more than 500,000 hospital patients are injured each year due to medication mistakes alone, and why thousands more die needlessly in U.S. hospitals each year.

My colleagues and I at Wishard are able to avert needless mistakes everyday because of an initiative allowing Indianapolis-area emergency medicine providers to immediately bring up a patient's medical record under a community-wide electronic medical record so that doctors can provide the right treatment at the right time to patients in need of emergency care. Almost every emergency room in America is unable to do this.

Instead, most emergency room departments are flying blind. It's like being an air traffic controller working at one of the nation's busiest airports during a blizzard and the radar goes out. You don't have much time or much information to make crucial decisions.

Everyday, emergency room physicians around the nation are making life-or-death decisions while flying blind. Whether they are saving the lives of victims of auto accidents, violence or other medical emergencies, the nation's frontline doctors too often don't know critical information needed to best care for their patients.

Contrary to most people's perception, emergency rooms don't have access to your medical record. Most ER doctors have never seen their patients before. Because the nation's health care system depends on paper records, an ER doctor can't access a record that is locked in a patient's personal physician's office, perhaps miles away.

I recently treated a patient who came to the ER only saying he didn't feel right. The patient couldn't volunteer any more information. Because of the community medical record, I discovered that the patient was treated at an across town ER for kidney failure only three weeks before. He didn't go to his follow-up appointments and wasn't taking his medicine. Knowing this, I admitted the patient to the hospital where the patient received treatment.

Knowing a patient's medical history or at least key parts of it helps 100% of the time. That knowledge helps me to zero in on a patient's problem, ensures needed care is provided more quickly, reduces unnecessary tests and treatment, and ultimately gives me a better change to save lives and avoid mistakes.

But most doctors rely on telephone, faxes and other 20th Century technology to track down their patients' test results, medication history and health care treatment records. And that can only be done during traditional business hours. Emergency situations aren't contained to 9-to-5 schedules.

If there's ever time that a patient wants a doctor to have his or her medical history in front of them, it's during an emergency. But unless you or a loved one constantly carries around your medical history, my colleagues and I are put into that position of the air traffic controller without working radar—at least as long as the system stays rooted in paper-based records.

I see how 21st Century information technology at work in other industries reduces mistakes, increases productivity and cuts costs. That's not the case in health care, or in the ER, where the inability to see a sick or injured person's medical record at the time when care is needed drive up health care costs with needless tests, force longer waits for treatment, and cut lives short.

The information revolution has made Americans' lives much easier and affords us more free time. Whether it's buying a home or a car, ordering gifts online or doing dozens of other daily transactions, electronic management of information has improved our lifestyle. However, when it comes to health care, McDonald's has more information management technology in their drive-thru lines than do most emergency rooms.

It's high time that we change this and luckily, the results of Wishard's high-tech experiment shows that we can.

NEXT STEPS AND CONCLUSION

This *Preliminary Roadmap for Electronic Connectivity in Healthcare* lays out a series of recommendations for practical strategies and specific actions to be taken over the next one to three years. It was developed collaboratively by the Steering Group, a broader set of stakeholders brought together through a leadership retreat, and three Working Groups as well as a Technical Expert Panel.

During the course of the next three months we will be seeking the input and expertise of the broader healthcare community on this document and others, to be released by the Working Groups, that address its specific content areas in greater detail. The feedback we receive will inform the *Final Roadmap*, to be released in the early fall of 2004.

MOVING TO ACTION

In Phase I of Connecting for Health, participants not only committed their time and energy to the development of deliverables, but also made commitments on behalf of their organizations and the constituencies they represent to take certain actions to promote electronic connectivity in healthcare to better serve patients.

As you review the recommendations of this report, we hope you will think about actions that your organization can take to help move our shared agenda forward.

Numerous existing initiatives by both the private and public sectors can be informed by our work. We hope that they benefit from our findings and join us in refining our recommendations. To name only a few:

- On July 21st, 2004 the Office of the National Coordinator for Health Information Technology will be discussing the Strategic Plan enumerated in the April 26th Executive Order.
- The *Medicare Prescription Drug, Improvement and Modernization Act of 2003* (MMA) provides critical provisions that will promote the adoption of data standards, including the standards requirements included in the electronic prescription program.
- In addition the MMA is creating a “Medicare Care Management Performance Demonstration” as well as a chronic care demonstration program, both of which are opportunities to test and evaluate IT and health information infrastructure adoption.
- The National Committee on Vital and Health Statistics is holding hearings designed to facilitate the identification of the standards necessary to fulfill the MMA.
- The Centers for Medicare and Medicaid Services is launching the Doctors’ Office Quality Information Technology (DOQ-IT) to promote the adoption of electronic health record (EHR) systems and information technology (IT) in small-to-medium sized physician offices with a vision of enhancing access to patient information, decision support, and reference data, as well as improving patient-clinician communications.

- Several employer and health plan-driven payment pilots are being designed to reward quality outcomes and use of IT. One example is Bridges to Excellence created by a group of employers, physicians, health plans and patients to create programs that will realign everyone's incentives around higher quality care.
- The Agency for Health Care Research and Quality (AHRQ) is providing funding through a number of programs to support IT application adoption, data sharing and interoperability-related activities aimed at improving the quality, safety, efficiency and effectiveness of healthcare for patients and populations.

CONCLUDING THOUGHTS

Robert Frost famously finished his poem, "The Road Not Taken," by writing that he chose the road "less traveled by,/ And that has made all the difference." We believe that the Connecting for Health Collaborative is, in its own way, also on a journey. We invite all stakeholders in healthcare to examine the choices presented in this *Preliminary Roadmap* and then join with us, on behalf of those whose lives and health are at stake, in finding those paths that will make the greatest positive difference.

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Connecting for Health Participants

There is no way to express adequate thanks for the extensive time, energy and expertise that have been given to this process. Connecting for Health, its Steering Group and its Working Groups, are built on the ideas, hard work and expertise of some of the most highly regarded experts in healthcare and information technology in the U.S. who volunteer their time, often personal time, to contribute to this work. It is impossible to fully acknowledge the thousands of hours spent, the richness of the meetings and conference calls or the spirit of camaraderie that we have been fortunate to experience in this process, other than to say that without it there would be no *Preliminary Roadmap*.

With that said, special thanks need to be extended to several volunteers who went far above and beyond the call of duty. Wes Rishel, Marc Overhage, Mark Leavitt and Paul Tang were the “engine” of the Technical Expert Panel. Wes Rishel’s tireless devotion to Connecting for Health and the work products was, and continues to be, a personal investment on his part from which we have all benefited greatly. In addition, Jim Dempsey took it upon himself to draft a set of documents on privacy that have supported and guided our work in numerous content areas.

We are also grateful for the talents and tireless dedication of our Working Group Chairs, David Lansky, Clay Shirky, David Brailer and John Glaser and the Working Group staff: Josh Lemieux, Julie Vaughn Murchinson, Robin Omata and Ben Reis. We thank the other Markle and consultant staff who gave their energy and creativity to this endeavor: Tom Benthin, Laura Blum, Kathy DeCarlo, Christopher Gearon, Todd Glass, Stefaan Verhulst and the people of Swandivedigital. We also thank Cynthia Soloman, Jerilyn Heinold, and Dr. JT Finnel for sharing their personal stories. Finally, we owe a special thanks to Michael L. Millenson and Lygeia Ricciardi for their combined creativity and talent in the drafting of this report.

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Models and Tools We Used

Although virtually all public and private sector stakeholders in the healthcare arena share our long-term goal of increasing electronic connectivity, the issue of how best to achieve that goal in the short- to medium-term remains controversial. Different stakeholders have legitimately different perspectives, and a lack of communication among diverse stakeholder groups is the norm. Even in cases in which there is agreement what should be done, coordination is often lacking.

To address these challenges Connecting for Health developed a problem-solving process that is, in the healthcare sector, uniquely open, inclusive, and constructive. The brief description of our method that follows is intended to help others understand how we, a group of individuals with strongly held and often oppositional views, came together as the Connecting for Health Steering Group in support of the set of recommendations for action spelled out in this *Preliminary Roadmap*.

Our process has evolved with our work, but the underlying principles that guide it have remained constant. We have worked to balance breadth and depth: breadth in the number and variety of participants' perspectives, and depth in the quality of the substantive contributions we bring to problems that have vexed the healthcare sector for decades. Our Steering Group membership includes more than 60 powerful healthcare stakeholders, representing government, for profit, and non-profit organizations. The Leadership Retreat attendees added important new voices to the discussion. The fact that we have come together under the auspices of two foundations—the Markle Foundation, which launched Connecting for Health in 2002, and the Robert Wood Johnson Foundation, which has since joined in supporting us—enables all of our members to freely exchange ideas on neutral ground.

Following the success of Phase I, which ended in June of 2003, members of the Steering Group reconvened in January of 2004 to renew our commitment to advancing electronic connectivity in healthcare. We agreed to complete three tasks:

1. Develop a *Roadmap* containing recommendations for action that will push our agenda forward in the near term. This document is a preliminary version of the final Roadmap, to be released in fall, 2004.
2. Establish Working Groups to address specific barriers hampering the development of electronic connectivity in healthcare.
3. Design a demonstration project or projects to test our recommendations in a real-world setting.

These three tasks are closely intertwined. Development of the *Preliminary Roadmap* has drawn heavily on the contributions of the Working Groups, although ultimate responsibility for its recommendations lies with the Steering Group. At the same time, the Working Groups, which will continue their work into the summer of 2004, have been exploring particular topics in depth. In addition to supporting the development of the Roadmap, they are each preparing a separate

report containing more comprehensive treatments of their respective subjects. These reports will be issued in the months ahead. Plans for our demonstration project(s) will be announced in the fall along with publication of the final Roadmap.

THE WORKING GROUPS

In this second phase of Connecting for Health, the task of the Working Groups has been to start addressing the barriers to increased connectivity in healthcare that had been identified in the project's first phase. The groups' chairs and participants include many of the nation's most highly regarded experts in their respective subject areas; their names are listed in the section immediately prior to this. Following is a précis of each Working Group's purview:

Working Group on Accurately Linking Health Information

Finding a way to accurately link the records of a patient receiving care from multiple doctors and hospitals in a fragmented health system while maintaining or enhancing quality and safety is a longstanding challenge. This group is developing an array of possible technological options for linking health information in the existing healthcare environment. Options are being evaluated in relation to privacy, policy, and market considerations.

Working Group on Financial, Organizational and Legal Sustainability

Financial, organizational, and legal models are needed to justify significant private sector investment in IT and the development of pro-IT laws and policies. This group is addressing these sustainability-related concerns by developing a framework for analysis and a set of tools to assist private and public sector leaders. The group's particular focus is on enabling the integration of IT and health at the community level.

Working Group on Policies for Electronic Information Sharing Between Doctors and Patients

This group is primarily concerned with the relationship between doctor- or hospital-oriented electronic health records (EHRs) and patient-oriented electronic health records (PHRs). It is pursuing several activities in parallel, including creating a functional definition of the PHR, recommending policies for the integration of PHRs and EHRs, and developing messaging strategies to identify themes and ideas that will be most effective in explaining the importance of healthcare connectivity to patients/consumers.

Technical Expert Panel

This group was formed after the other Working Groups in response to the Steering Group's emphasis on technical issues as Roadmap priorities. It is comprised primarily of members of the Steering Group and Working Groups. Its charge is to provide additional support and input to the Steering Group in the areas of system architecture, infrastructure, standards and applications.

CONCEPTUAL TOOLS

The "Forks in the Road"—the areas that provide opportunities for near term change according to which we have organized our recommendations—were a starting point for meaningful and focused conversations as we built toward our recommendations. The Recommendations section of this document provides a more detailed description of the way in which the recommenda-

tions evolved. Since each Fork is complicated on its own—and together they are even more complex—the Working Group chairs developed tools to help steer the Steering Group away from unproductive detours into abstractions and keep us focused on practical recommendations.

The first tool involved real-life scenarios; that is, the use of real-life examples to describe situations or problems that need to be solved. The second tool involved the use of hypothetical future environments; that is, a structured way of imagining various possible future environments in order to better understand how environmental factors could influence our choices about which actions to recommend.

There are six real-life scenarios. They involve a variety of characters (i.e., patients, physicians, hospitals, etc.) in a variety of situations (i.e., routine care, emergency care, etc.) that help us to generate and analyze questions about technology and policy and their impact on real people and organizations. Each of the Working Groups chose one or more to facilitate and guide its thinking. The scenarios were also used by the Steering Group to ground its discussions in reality. The full text of the real life scenarios can be found at Appendix A of this document.

We wanted to take our thinking about the scenarios a step further by recognizing that characteristics of the healthcare environment influence the way in which actors in each of the scenarios make decisions. The simplified hypothetical future environments (Appendix B) we envisioned through the use of a 2x2 matrix emphasize the degree of technical interoperability of information systems and the level of financial incentives that support private investment in health IT. An alternative and more colorful articulation of these ideas is expressed in Appendix C, “The Legend of the Alternative Futures.”

APPENDIX A

Real Life Scenarios

SCENARIO #1: A PATIENT SWITCHES PHYSICIANS

Samantha, her husband and her one-year-old son live in San Francisco. After Samantha's employer changed health plans, she discovered that her new plan did not cover her current obstetrician/gynecologist (ob/gyn). Soon afterwards Samantha learned that she was pregnant again. She chose a new ob/gyn and found herself completing the same health history and medical forms that she knew were in her file at her former doctor's office. Unfortunately, she could not remember the name of the medication she was prescribed after her son's birth and she forgot to indicate her drug allergies. She spent her first appointment with her new provider recounting the problems she had experienced during her last pregnancy and birth; there was no time left for addressing how she wanted to approach this pregnancy or for learning anything about her new ob/gyn.

How electronic connectivity can help

An electronic health record at the office of Samantha's previous ob/gyn would have included all of the information she recounted during her visit, including medication and allergy lists and personal and family health histories. Her new doctor would use an EHR based at the doctor's practice to integrate Samantha's old record into a new one. Her new doctor could have reviewed the EHR prior to Samantha's appointment or they could have reviewed it together during the exam.

A personal health record in which Samantha kept information from all of the doctors, insurance providers, clinics and hospitals used during her last pregnancy and birth would allow her to share comprehensive information with her new doctor by granting that doctor permission to access the information. Or Samantha could simply bring it with her to the appointment. Since Samantha's PHR might contain information not included in her former doctor's EHR, she would be able to offer a more complete picture of her health history.

SCENARIO #2: A PATIENT WITH A CHRONIC DISEASE REQUIRES ONGOING MONITORING

Paul, who lives in New Orleans, has recently been diagnosed with Type 2 (adult onset) diabetes. His doctor has given him a glucometer to measure his blood sugar so as to help him keep track of his insulin needs. In addition, Paul is visiting a Certified Diabetes Educator (CDE) in order to learn how to improve his diet and activity level to better control his blood sugar.

Paul has had the typical experience of finding it difficult to manage his blood glucose levels since his new diagnosis. His doctor needs to monitor Paul's condition closely, especially in these early stages, to avoid any serious incidents of hyper- or hypoglycemia and to maintain the appropriate level of medication. In addition, Paul has had to make significant changes to his diet in order to better manage his condition. Before being diagnosed with Type 2 diabetes, Paul had little knowledge regarding healthy eating habits and the benefits of exercise. Paul needs to see how his diet and exercise habits influence his blood sugar levels.

Paul's CDE and doctor also need to monitor their patient's medication, insulin doses, diet and exercise regime on a weekly, if not daily, basis. The goal is to coordinate their treatment plans in a way that maximizes Paul's ability to adhere to the plans and thereby manage his diabetes. Both the doctor and CDE would like to add Paul's records to his EHR that is kept at their individual offices.

How electronic connectivity can help

An electronic health management system can help Paul monitor his diabetes at home. He would be able to download his glucometer readings onto his computer and add his diet and exercise habits throughout the day. Paul could then graph the relationships between his diet, blood sugar levels and insulin needs to see how each affects the other. He could also see if his blood sugar levels got dangerously high or low based on predetermined levels set by his healthcare team.

The results from Paul's electronic management system could be sent to his doctor and his CDE to enable them to better monitor the success of his treatment plan. Or, the doctor and CDE might be enabled to log into Paul's system and see the records for themselves. Both could send Paul emails or comment on Paul's progress directly on the system, pointing out to him how his diet and exercise habits influence his blood sugar levels and need for insulin.

SCENARIO #3: A DOCTOR STRUGGLES TO KEEP ON TOP OF PATIENT PRESCRIPTIONS

Dr. Jones is an internist in Boston. Many of the patients he sees have at least one chronic health condition, such as diabetes, asthma or GERD, for which they take medication. He spends a good amount of time during most appointments discussing his patients' medications with them. Appointments often end with him writing a new prescription either to replace a medication or to help with a new problem. Some of his patients take more than one medication, and he is often concerned that they may not be taking the medication properly or even filling their prescriptions on a regular basis. He also knows that many medications interfere with one another, including over the counter medications as well as drugs possibly prescribed by other doctors. Unfortunately Dr. Jones only knows about the medications he prescribes and what his patients tell him they are taking. Often patients don't view aspirin, Tylenol or vitamins as medications, so they neglect to report they are taking them. Or patients simply may forget which medications Dr. Jones knows about and which ones he does not.

Once the patient takes Dr. Jones' prescription to the pharmacy, he often faces even more demands on his time. He frequently receives phone calls from pharmacists who can't read what he wrote about the drug or its dosage, interaction issues, problems with the insurance coverage for a particular drug or a patient's unwillingness or inability to pay more money for a medication on one of the higher tiers of a health plan's payment scheme.

How electronic connectivity can help

An EHR would allow Dr. Jones quick and easy access to all the medications he had prescribed for any patient. By reviewing these before or during appointments, Dr. Jones could discuss with the patient any medication-related concerns. When prescribing a new medication using the EHR, Dr. Jones would be alerted to any potential adverse interactions with other medications he had prescribed previously. He could also use the EHR to quickly look up common over the counter medications to see if they might interact with the medications he prescribed. An EHR would allow patients to send secure messages to Dr. Jones if they were having problems with

their medications, or their health in general. He could make modifications to their drug regimens without necessarily asking patients to come in for an appointment.

By using PHRs Dr. Jones's patients could track the medications they were prescribed by other providers, as well as their over the counter drugs. Dr. Jones could request access to these medication lists and match them against his own to look for adverse reactions or possible allergies. His patients could also allow their pharmacists to access their PHRs to check for adverse interactions and indicate that a prescription had been filled.

SCENARIO #4: A PHYSICIAN ATTEMPTS TO FOLLOW A PATIENT'S TREATMENT BY OTHER PHYSICIANS

Dr. Bednarek has been Jane's primary care physician in for over 20 years in the same neighborhood of Chicago, so it both concerned and saddened her when she and Jane discovered as a result of a routine screening mammogram that Jane had breast cancer. Although the cancer was at an early stage, Jane nonetheless decided to see an oncologist for more tests and advice on treatment. Although Jane and her oncologist decided that chemotherapy would be the best treatment choice, Dr. Bednarek would like to stay informed as to how the chemotherapy is being administered, what side effects Jane is experiencing from treatment, and how the treatment is affecting the cancer. The oncologist, meanwhile, also wants to know how Jane is doing as she gets through her regular treatments and especially wants to be sure that Jane is still getting regular screenings to ensure that the cancer does not recur.

How electronic connectivity can help

An electronic health record would help the oncologist monitor Jane's treatment of her cancer and would also be available, with Jane's permission, for Dr. Bednarek. That way, Dr. Bednarek could stay up to date on Jane's progress without having to schedule extra appointments with either her patient or the oncologist. Once the cancer has gone into remission, the oncologist can monitor Jane's health on a less frequent basis. She can make sure that Jane is getting the proper cancer screenings and check in on the status of her overall health.

Jane could benefit from access to the EHR so that she can better recall the cancer treatments she received and how they worked. An EHR could also send a reminder to Jane to help her remember to get her proper cancer screenings.

SCENARIO #5: AN ER DOCTOR WORKS WITHOUT KNOWLEDGE OF HER PATIENTS

Dr. Kaplan is an emergency medicine physician at Miami General Hospital. Every day patients visit the ER where she works for a variety of problems ranging from major trauma to basic primary care needs. For patients who are in crisis, important personal medical information is often unavailable. Even patients who are conscious and able to communicate often do not know the names of the medications they are taking, their allergies and immunizations or the last time they saw a healthcare provider. In both cases, the lack of information can make it difficult to decide on the most effective treatment.

How electronic connectivity can help

If Miami General Hospital used an EHR, Dr. Kaplan would be able to look for ER patients with-

in the system to see if and when they had visited the hospital before and the nature of the problem. If she was able to access the name of the primary care physician, she might be able to implement a “break the glass” function and access electronically stored information that would be pertinent to emergency treatment, such as a list of drug allergies, current medications and recent surgeries. Dr. Kaplan might also find the patient’s emergency contact information and insurance information.

SCENARIO #6A: A DOCTOR IS OVERWHELMED BY RECORD REQUESTS

Dr. Della has a small but thriving pediatric practice in a San Antonio neighborhood that contains several local elementary schools. Every year around September, Dr. Della is bombarded with requests for immunization records from parents so that their children are able to attend school. Once school starts, both the parents and the school administration will be pressuring Dr. Della to send in those records as soon as possible.

A few months after school starts, one of the larger elementary schools has an outbreak of head lice. The school nurse begins screening the children for signs of the condition. She would like a way to inform the children’s doctors when she finds a case of head lice in a child so that the incident can be added into the medical record. She would also like to be able to easily inform parents about their children’s cases of head lice and tell them how to treat it.

How electronic connectivity can help

An EHR can help Dr. Della keep track of all the immunizations he has given to his patients. The EHR could also automatically generate authentic immunization records that easily can be transferred to the school for their record keeping needs. Dr. Della could also send the immunization record to his patients’ parents for storage in a PHR so that parents know what immunizations their children have received and when. Reminders when the immunizations need to be re-administered could also be sent.

An EHR can also be used so that schools can send Dr. Della records of head lice cases in his patients who attend their school. Dr. Della could then add the information to his patient’s records. Either the school or Dr. Della could send the head lice case records, along with treatment options, to parents so that they can be informed and add the incident to their child’s PHR.

SCENARIO #6B: AN INSTITUTION IS OVERWHELMED BY RECORDS REQUESTS

Riverview Hospital in eastern Washington State is the only major hospital in a 50-mile radius with a reputable, high-volume cardiology department and fully equipped ER. Whenever someone who lives within the vicinity of Riverview experiences any sort of heart trouble, they do everything in their power to get to Riverview for treatment. Similarly, Riverview’s ER is the destination of choice for those who other injuries or illnesses who can safely make their way there.

Although Riverview is proud of its reputation, the hospital staff is constantly burdened by calls from physicians who want to get copies of hospital records related to treatment their patients received while at their ER or cardiology department. As a result, Riverview has to pay salary and benefits for 35 full-time equivalents, just to provide those records to doctors throughout the area.

How electronic connectivity can help

An EHR can help Riverview Hospital keep track of all the tests and treatments administered in its ER or performed by its cardiology department. The information about these tests and treatments could be sent electronically to doctors' offices, where it could be uploaded into patient records. That, of course, would reduce or eliminate the need for paying workers to spend their day retrieving old medical charts.

Riverview Hospital could also send the records to the patients themselves for storage in individual PHRs so that patients would have a record of test results, drug prescriptions, and treatments. A patient who suffers another heart problem could then give the test results to another doctor to compare the old test results with the new ones.

Each of the above scenarios presents a series of questions for consideration. For example:

- Who are the primary parties involved in each scenario?
- What rights and responsibilities does each have in an information-sharing transaction?
- What standards are needed to enable information storage and sharing among the relevant parties, including patients and their families, healthcare providers, pharmacies, insurance providers, and non-healthcare organizations, such as schools?
- What legal and security measures must be in place?
- What are the financial costs associated with information sharing, and who pays them?
- What are the financial benefits associated with information sharing, and who receives them?
- How should patients authorize access by others to their records?
- Should ER doctors or others have a way to access records if a patient is non-responsive?
- Should patients have the ability to withhold some of the information in their records from others?
- How can patients know who has accessed their record and when?
- How can the accuracy and authentication of patient records be established?
- Who should have authorization to alter a patient's record? How can their identities be authenticated, especially if they are outside of the traditional healthcare system (i.e., family members)?

APPENDIX B

Hypothetical Future Environments

“It’s tough to make predictions, especially about the future.”
– Yogi Berra

We cannot know for certain what the healthcare environment will look like in a few years. Still, it is essential for us to make an educated guess in order to choose policies we believe are most likely to accelerate private-sector and governmental support of rapid clinical IT adoption.

Our “hypothetical future environments” are caricatures of reality that force us to examine the relationship between the healthcare system and its environment, and to think in a focused way about the potential impact of various actions. We chose to isolate and examine two dimensions of environmental change—the level and kinds of incentives available to accelerate the adoption of IT and improved health outcomes in the healthcare system, and the level of interoperability of information and systems. These areas are important because fundamental change in healthcare will require progress in both of them, and because many of our proposed recommendations would affect them.

The hypothetical future environments are expressed as a 2x2 table. The X-axis represents incentives for IT adoption and performance-based care. The left half of the X-axis represents, much as we have today, limited or no correlation between incentives and the use of IT to improve patient care. Today’s payment model rewards care based on volume, not health outcomes or the extent to which providers use information about patients or procedures to tailor their care to individuals’ needs. The right half of the X-axis represents a high level of financial and other incentives to stimulate IT adoption to improve processes and outcomes via information management. Examples of such incentives include group purchasing, revolving loan funds, increased reimbursement for EHR or other clinical IT application use, and altering pay-for-performance programs to encourage outcomes-driven care via information management.

The Y-axis represents interoperability. The bottom of the Y-axis reflects a state of low standards adoption and limited interoperability of information and systems. In this state there is variable interpretation of standards, there is little infrastructure available, and connecting disparate information systems is difficult and expensive. The top half of the Y-axis represents a state of widespread interoperability of information and systems. In this state there is widespread and uniform adoption of standards and a robust infrastructure for the interchange of health information. In this state interoperability is “out of the box” with low cost and few hassles.

The combination of these two axes creates four possible future states.

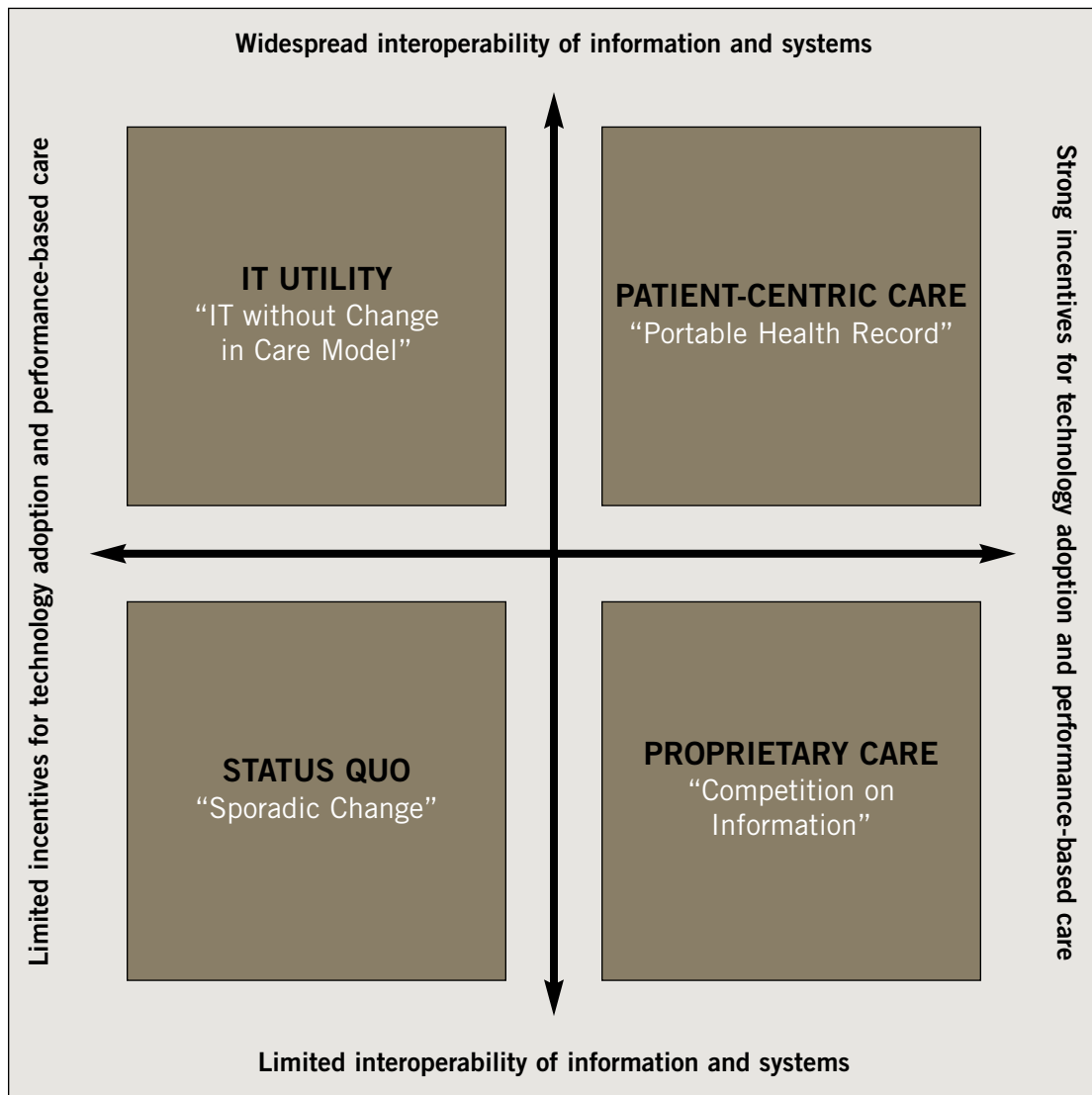
The Status Quo (low interoperability, low incentives): This state presumes no significant changes to current healthcare IT environment. Some data standards, IT adoption and interoperability exist but adoption is voluntary and unrewarded and interoperability is highly experimental and very unusual. Providers are paid for episodes of clinical service without incentives

for quality, outcomes, or patient-centeredness. The result is that the rate of IT adoption and interoperability remains highly inconsistent. Adoption is concentrated primarily among large integrated systems, and sharing of electronic clinical data is almost non-existent outside of them. There is inadequate capability to measure quality of care or outcomes and limited ability for consumers to access their personal healthcare information or to provide information to providers in a convenient way.

The IT Utility (high interoperability, low incentives): This state would be achieved if governments mandated adoption of uniform systems and standards but current payment systems remained unchanged. Payment provides neither explicit nor implicit support for IT acquisition and standardization. This state would result in the improved potential for care coordination via IT, but without economic incentives to encourage practice changes and information management to improve health outcomes. In other words, this state may be a success from an IT perspective, but care delivery remains unchanged.

Proprietary Care (low interoperability, high incentives): In this state, payment promotes IT adoption only without interoperability of information and systems. Incentives also encourage pay-for-performance and outcomes-based care but with no change in standards, data exchange and interoperability. Hence, patient information becomes a highly proprietary asset to health care providers, encouraging provider competition on the basis of patient information and preventing patients/consumers from integrating their personal health information as they move about the health care system. Providers will face a high cost of exchanging information to provide outcomes-based care. In this state, IT vendors compete without data standards; healthcare data is institution-based and compartmentalized.

Patient-Centric Care (high interoperability, high incentives): In this state incentives reward the use of IT and a high degree of interoperability. Here, data standards and interoperability are basic features of applications and other information tools. The public expects routine access to personal health information and there is point-of-care access to patient data for authorized users. Here, IT vendors compete on implementation, features, cost, and service excellence. This state is predicated on public and professional confidence in the privacy and security of the network.



While it would be wonderful to transition smoothly from the status quo at the bottom left quadrant to the ideal world at the top right, we recognize that even actions meant to help us get there, if not carefully considered, could create problems of their own. The label "sporadic change" in the status quo quadrant refers to the idea that the development of increased electronic connectivity in healthcare without carefully considered and coordinated actions on the part of the private and public sectors is likely to happen not only slowly, but also in isolated and hard-to-predict spurts.

In addition to serving as a warning about what is likely to happen if we changed one axis and held the other constant, the other two quadrants are useful for analytical purposes. The top left quadrant is labeled "IT Utility" to capture the idea that, like some government-subsidized utility services, inappropriate policies by the healthcare sector could lead to the development of an expensive but underutilized technological infrastructure. If government were to mandate adop-

tion of uniform data standards and systems, but existing payment mechanisms remained unchanged, there would be little demand to use the resulting interoperable infrastructure. As is the case now, the volume of patients treated and other factors would determine the payment of doctors and hospitals rather than the use of evidence-based guidelines. An alignment of these latter qualities with financial incentives is critical to persuading providers to make optimum use of any technologies available to them.

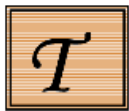
If, on the other hand, incentives were provided for technology use alone without a parallel focus on interoperability and health outcomes, as in the bottom right quadrant, we could end up with an equally unappealing situation. There might be pervasive use of information systems that added little value to comprehensive patient care since they would not enable interoperability of information and systems. Absent data standards, individuals and organizations could not exchange information and would therefore realize only a small subset of the benefits that would accrue from a highly connected and appropriately financed environment. Patient data would not be able to migrate from one provider to another to bridge the gaps of geography or time, and patients would not be motivated, through IT, to take on greater responsibility for their care. Providers would remain the central actors in the healthcare sector, except now they would compete—based on sophisticated but siloed information systems.

A more fanciful articulation of this matrix and the description that accompanies it, The Legend of the Alternative Futures, is in the next appendix, Appendix C.

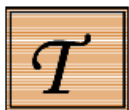
The Legend of the Alternative Futures



nce upon a time, a group of pioneers found themselves living in Status Quo Valley, a barren and desolate land where data is fragmented and enterprise-based, and where there are disincentives to use information to improve quality of efficiency. In this land, consumers, clinicians, and employers are unhappy, people die and money is wasted. You want to go to the fabled Land of Patient-Centric Care, where quality hangs on luscious trees, patient safety bubbles from sparkling brooks and efficiency grows wild across the land. Here, patients control their information, manage much of their care alongside providers and have accountability for their decisions.



o get to this mythic land, you have to cross a large and mysterious mountain. No one has been known to cross this mountain, and only the right team could attempt it. Two paths cross the mountain, and both are treacherous. To the right is the Trek of Financial Incentives, which encourages IT adoption and improved performance in delivery systems and other enterprises. Near the summit of the mountain, the Trek passes alongside Invigorated Enterprise Meadows, a sunny and warm place where health systems and clinicians are rejuvenated in their efforts to automate and improve care delivery. The path is perilous here because on its other side are cliffs with slippery rocks and landslides that fall down to Proprietary Care Jungle, a dangerous area roamed by carnivorous beasts with enormous appetites and where enterprise health systems use their information power to control markets, set prices and trap patients. No one has been known to return from the Jungle.

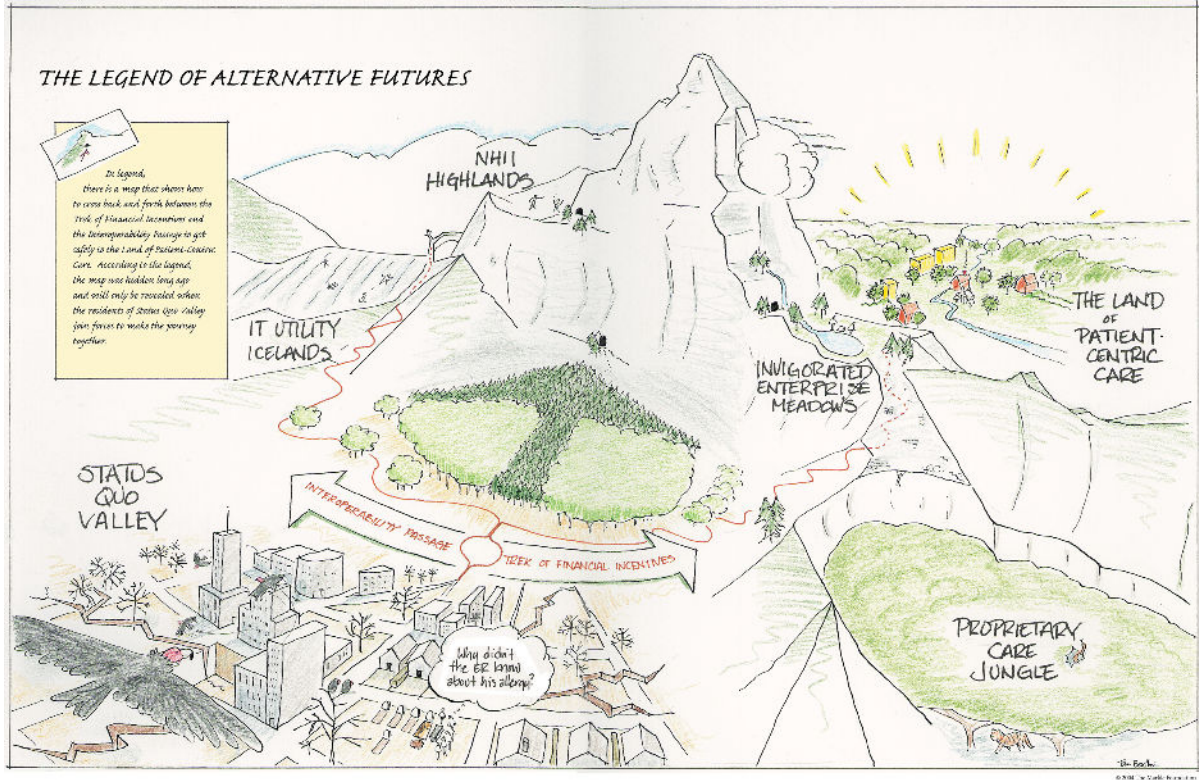


he path to the left is the Interoperability Passage, which standardizes information, terminology, rules and provides infrastructure and applications that are shared across enterprises. It crosses the summit near NHII Highlands, a plateau of majestic rock formations and billowing clouds where shared information tools are available to healthcare workers that allow them to perform clinical tasks anywhere, anytime and anyplace. The Passage becomes narrow in some places and crosses over a gorge that plunges down to IT Utility Icelands, a cold and desolate place where information tools are all the same and unchanging over time. Frozen carcasses of IT developers are strewn across the tundra, having long since succumbed to the low yield IT utilities that turned this into a capital-deprived land without innovation, customization or customer service. Clinicians wander the area, scavenging for resources to help their IT applications meet their needs and keep current with changes in medicine.



n legend, there is a map that shows how to cross back and forth between the Trek of Financial Incentives and the Interoperability Passage to get safely to the Land of Patient-Centric Care. According to the legend, the map was hidden long ago and will only be revealed when the residents of Status Quo Valley join forces to make the journey together.

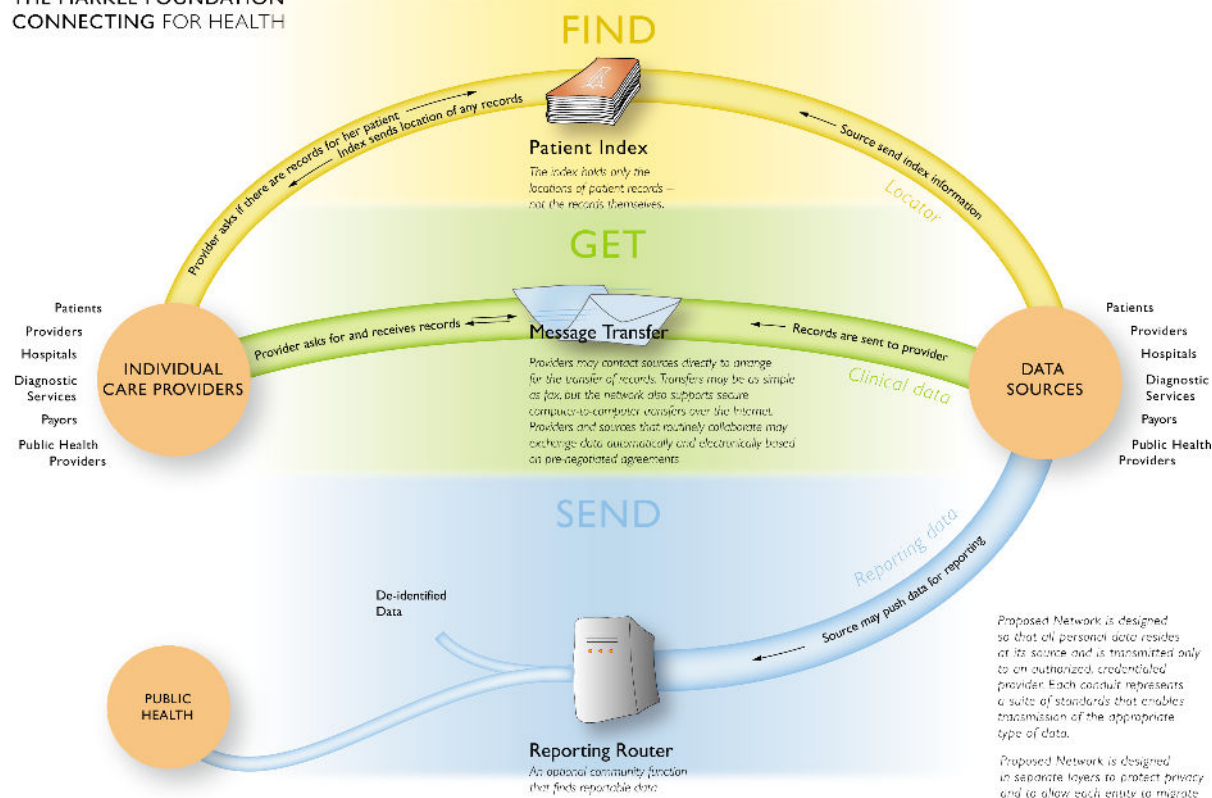




APPENDIX D

PROPOSED NETWORK

THE MARKLE FOUNDATION
CONNECTING FOR HEALTH



V.1.9 © 2004 The Markle Foundation Graphic by Tom Bendlin

CONNECTING FOR HEALTHSM
MARKLE FOUNDATION *A Public-Private Collaborative*

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.