# REPORT TO THE PRESIDENT REALIZING THE FULL POTENTIAL OF HEALTH INFORMATION TECHNOLOGY TO IMPROVE HEALTHCARE FOR AMERICANS: THE PATH FORWARD

Executive Office of the President

President's Council of Advisors
on Science and Technology

December 2010

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President Barack Obama
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Dear Mr. President,

We are pleased to send you this report, *Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward*, prepared by your President's Council of Advisors on Science and Technology (PCAST). This report examines how health information technology could improve the quality of healthcare and reduce its cost, and whether existing Federal efforts in health information technology are optimized for these goals.

To provide a solid scientific and economic basis for our recommendations, the Council assembled a Working Group of nongovernmental experts and also met with government officials, industry representatives, information technology experts, and healthcare professionals. PCAST has concluded that information technology can help catalyze a number of important benefits including improved access to patient data, which can help clinicians as they diagnose and treat patients and patients themselves as they strive to take more control over their health; streamlined monitoring of public health patterns and trends; an enhanced ability to conduct clinical trials of new diagnostic methods and treatments; and the creation of new high-technology markets and jobs. Health information technology can also help support a range of healthcare-related economic reforms needed to address our Nation's long-term fiscal challenges.

PCAST has also concluded that to achieve these objectives it is crucial that the Federal Government facilitate the nationwide adoption of a universal exchange language for healthcare information and a digital infrastructure for locating patient records while strictly ensuring patient privacy. More specifically, PCAST recommends that the Office of the National Coordinator for Health Information Technology and the Centers for Medicare and Medicaid Services develop guidelines to spur adoption of such a language and to facilitate a transition from traditional electronic health records to the use of healthcare data tagged with privacy and security specifications.

PCAST hopes that its report will help lay a foundation for the decisions that you and others in the Federal Government must make. We are grateful for the opportunity to serve you and the country in this way and would be pleased to brief you or your staff if you have questions about our recommendations.

Sincerely,

John P. Holdren
Co-Chair

Eric Lander
Co-Chair

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# Executive Summary

Information technology (IT) has the potential to transform healthcare as it has transformed many parts of our economy and society in recent decades. Properly implemented, health IT can:

- Integrate technology into the flow of clinical practice as an asset, while minimizing unproductive data entry work.
- Give clinicians real-time access to complete patient data, and provide them with information support to make the best decisions.
- Help patients become more involved in their own care.
- Enable a range of population-level public health monitoring and real-time research.
- Improve clinical trials, leading to more rapid advances in personalized medicine.
- Streamline processes, increase their transparency, and reduce administrative overhead, as it has in other industries.
- Lead to the creation of new high-technology markets and jobs.
- Help support a range of economic reforms in the healthcare system that will be needed to address our Nation's long-term fiscal challenges.

Despite this great promise, the impact of IT on healthcare over the past decade has so far been modest. Currently, almost 80 percent of physicians—the majority in small, independent practices—lack even rudimentary digital records. Where electronic records do exist, they are typically limited in functionality and poor in interoperability. As a result, the ability to integrate electronic health information about a patient and exchange it among clinical providers remains the exception rather than the rule. Compared to other industrialized nations, the United States lags far behind in the use of electronic health records.

As we will describe, the Administration and the Congress have recently made major investments to ensure that Americans soon enjoy the benefits of electronic health records. The Administration has been moving rapidly to promote the adoption by physicians and hospitals of electronic health systems, including through recent, important rule-making for 2011. The President's Council of Advisors on Science and Technology has undertaken this report to examine the critical issues for the next phase, which has just begun, and to make specific recommendations to the Administration to ensure that the full promise of health IT is realized.

In other sectors in which IT has had a transforming effect, rapid progress has been catalyzed by wise technology choices that open up markets to competition and innovation. Such technology choices include the standardization of simple universal methods for the exchange of information across multiple platforms and organizations. In other sectors, universal exchange standards have resulted in new products that knit together fragmented systems into a unified infrastructure. The resulting "network effect"[1] then increases the value of the infrastructure for all, and spurs rapid adoption. By contrast, health

1. Network effect is defined as the user externality by which the more people who use a network, the greater its value to each of them. The classic example is the rapid adoption of universal telephone service in the early 20th Century.

IT has not made this transition. The market for new products and services based on health IT remains relatively small and undeveloped compared with corresponding markets in most other sectors of the economy, and there is little or no network effect to spur adoption.

Several identifiable barriers in the healthcare system currently discourage innovation and vigorous competition in the market to create effective health IT systems. First, most current health IT systems are proprietary applications that are not easily adopted into the workflow of a clinician's day, and whose proprietary data formats are not directly exchangeable from one system to another. It is difficult for data to be disaggregated, indexed, searched, and assembled to provide accurate information to treat a patient, because the context for individual entries in a record is often implicit at best. Second, most healthcare organizations that utilize electronic health records (EHRs) view them as purely internal resources, and have little incentive for investment in secondary or external uses, such as making them accessible in appropriate form to patients, to a patient's healthcare providers at other organizations, and in de-identified or aggregated form to public health agencies and researchers. Third, legitimate patient concerns about privacy and security make patients uneasy about participating in health IT systems or granting consent for their information to be used in research. Fourth, health IT has historically been oriented toward administrative functions, not better care. This is in part because, under the current fee-for-service payment model, the economic benefits of investing in health IT can rarely be realized by the provider or organization that makes the investment.

Some healthcare organizations have overcome at least some of these barriers and successfully adopted electronic systems that measurably improve care within their own organization. Kaiser Permanente and the Veterans Health Administration are notable examples. Other leading hospitals and clinics also employ electronic record systems that allow them to consolidate patient health data generated within their organizations. However, even these successes, upon closer examination, highlight the limitations of current approaches. They are usually "one offs," designed for the particular organization, not for a wide range of other types of practices. They are generally closed, and not designed for the exchange of data with a heterogeneous and geographically diverse set of other organizations that may serve the patient now or in the future. They typically require capital investments that are beyond the reach of most small clinical practices. And, they are too limited in scope, and few in number, to drive a vigorous market in technological innovation.

Recent Federal legislation has charted a new path forward. The Health Information Technology for Economic and Clinical Health (HITECH) Act, a part of the American Recovery and Reinvestment Act (ARRA) of 2009, authorized expenditures of at least $20 billion to promote the adoption and use of EHR technologies that would ideally be connected through a national health information network. Hospitals and physicians who make "meaningful use" of interoperable EHRs can qualify for extra payments through Medicare and Medicaid.

Responsibility for developing policies that implement the overall HITECH Act lies primarily with the Office of the National Coordinator for Health Information Technology (ONC). In this role, ONC works closely with the Center for Medicare and Medicaid Services (CMS), which is responsible for promulgating policies that relate to Medicare and Medicaid payment for meaningful use of EHRs under HITECH. ONC and CMS recently released final rules to implement the first phase of the HITECH Act, which begins in 2011. The

ONC rule specifies the standards, implementation specifications and other criteria for EHR systems and technologies to be certified under HITECH and thus eligible for the Acts incentive programs while the CMS rule specifies how hospitals, physicians, and other eligible professionals must demonstrate their meaningful use of these technologies in order to receive Medicare and Medicaid payment incentives. Both sets of rules strongly indicate that standards and criteria for achieving meaningful use of EHRs will grow more rigorous in subsequent phases (2013 and 2015) as the technology continues to evolve and providers gain experience and sophistication in its use.

Given the national priority of health care reform, President Obama asked PCAST how health IT could improve the quality of healthcare and reduce its cost, and whether existing Federal efforts in health IT are optimized for these goals. In response, PCAST formed a working group consisting of PCAST members and prominent experts in both healthcare and information technology. Based on input from the working group, additional expert reviewers, and its own discussions, PCAST has reached six major conclusions.

1. **HHS's vigorous efforts have laid a foundation for progress in the adoption of electonic health records, including through projects launched by ONC, and through the issuance of the 2011 "meaningful use" rules under HITECH**. ONC has shown itself to be a technologically sophisticated agency, with outstanding outreach into the clinical community and good liaison with incumbent EHR system vendors. The Nationwide Health Information Network (NHIN) project has convened stakeholders and created an appropriate forum for the discussion of options. Strategic Health IT Advanced Research Projects (SHARP) in areas including network architectures and data use will produce important practical advances, as will work resulting from the establishment of a Federal "collaboratory" in clinical decision support. Importantly, the 2011 "meaningful use" rules recently released by ONC and CMS provide necessary first steps, and we endorse these rules.

2. **In analyzing the path forward, we conclude that achievement of the President's goals requires significantly accelerated progress toward the robust exchange of health information.** The initial approach to meaningful use has focused on driving physicians to adopt EHR systems that perform important quality-improving functions within the practice and, to a lesser extent, on developing capabilities for broader sharing. Though the rule expresses an intent to require more robust exchange of health information among providers at later stages of meaningful use, its initial requirements that EHR systems communicate with each other are very modest. This creates a danger that EHR adoption during early stages of meaningful use may exacerbate the problem of incompatible legacy systems. What is needed is a simultaneous focus on the capability for universal data exchange, able to unleash the power of the competitive market, to produce increasingly better and less expensive systems, and to create the "network effect" that spurs further adoption. While useful as an initial step, the adopted standards for data vocabulary and messaging will not be sufficient to advance the state of the art either of clinical practice or of a robust health IT infrastructure. Going forward, the critical issue is to facilitate progress by healthcare organizations by ensuring the creation and dissemination of a universal exchange language for healthcare information and an infrastructure for locating patient records, while rigorously protecting privacy and security. This would allow patient outcomes to become a larger part of meaningful use much more quickly, and make it less onerous for clinicians to generate and report a wide range of different kinds of information about the outcomes of their practice.

3. **National decisions can and should be made soon to establish a "universal exchange language" that enables health IT data to be shared across institutions; and also to create the infrastructure that allows physicians and patients to assemble a patient's data across institutional boundaries, subject to strong, persistent, privacy safeguards and consistent with applicable patient privacy preferences. Federal leadership is needed to create this infrastructure.** While the ability to exchange and integrate health data offers great advantages to patients, the economic benefits of these capabilities do not accrue directly to specific providers, or to providers' incumbent EHR system vendor (if any). As a result, market forces are unlikely to generate appropriate incentives for the necessary coordination to occur spontaneously. The nature of this coordination as a public good requires Federal leadership in ensuring the creation of the capabilities. The development of EHRs themselves should of course be left to the private sector.

4. **Creating the required capabilities is technically feasible, as demonstrated by technology frameworks with demonstrated success in other sectors of the economy.** The best way to manage and store data for advanced data-analytical techniques is to break data down into the smallest individual pieces that make sense to exchange or aggregate. These individual pieces are called "tagged data elements," because each unit of data is accompanied by a mandatory "metadata tag" that describes the attributes, provenance, and required security protections of the data. Universal exchange languages for metadata-tagged data, called "extensible markup languages" are widely and successfully used. Indeed, ONC's clinical document architecture standard (CDA) is such a markup language, and is an important step in the right direction. The indexing and retrieval of metadata-tagged data, across large numbers of geographically diverse locations, is an established, highly developed, technology—the basis of web search engines, for example. With ONC leadership, these technologies could rapidly be adapted and standardized for universal use in health IT. Innate, strong, privacy protection on all data, both at rest and in transit, with persistent patient-controlled privacy preferences, is likewise achievable, and must be designed in from the start.

5. **ONC should move rapidly to ensure the development of these capabilities; and ONC and CMS should focus meaningful use guidelines for 2013 and 2015 on the more comprehensive ability to exchange healthcare information.** ONC should act boldly to articulate a clear, common framework that will ensure that its various efforts converge into an effective healthcare IT ecosystem that serves patients and providers. The steps that must be taken can be accomplished within the required time frame. It can be accomplished via an *evolutionary* transition from traditional EHRs to a tagged data element model, along with a *more rapid* transition for the more limited purpose of data exchange by means of a universal exchange language. We note that these steps are not intended as an alternative to ONC's important work in promoting the adoption of electronic health records. Rather they are complementary to that work and will accelerate adoption.

6. **Finally, as CMS leadership already understands, CMS will require major modernization and restructuring of its IT platforms and staff expertise to be able to engage in sophisticated exchange of health information and to drive major progress in health IT.** This process has begun, but needs to be a more urgent priority for the Administration and Congress and should be funded as appropriate for an essential component of the Nation's healthcare quality and afford-

ability agenda. A recently initiated National Research Council study of CMS's IT capabilities should result in recommendations that will avoid replacing one inflexible architecture with another (a common trap in Federal IT acquisitions), but a successful outcome is at best several years away.

The approach that we describe requires that there be a common infrastructure for locating and assembling individual elements of a patient's records, via secure "data element access services" (DEAS). Importantly, this approach does not require any national database of healthcare records; the records themselves can remain in their original locations. Distinct DEAS could be operated by care delivery networks, by states or voluntary grouping of states, with possibly a national DEAS for use by Medicare providers. All DEAS will be interoperable and intercommunicating, so that a single authorized query can locate a patient's records, across multiple DEAS.

**Advantages of focusing on a universal exchange language**. Briefly, the approach described in this report, focused on the technical ability to exchange data in uniform ways, has multiple advantages:

- It will improve healthcare quality, by making it possible for a physician to integrate accurately all of a patient's medical information.
- It will improve healthcare quality and decrease costs, by making it possible for third-party innovators to compete to create widely applicable services and tools serving patients, providers, payers, public health officials, and researchers.
- It will provide much stronger privacy protection than available under current approaches, allowing persistent privacy assurances (including applicable patient preferences) to be attached to different kinds of information and using data-level encryption to prevent access of data by unauthorized persons.
- It will not require universal patient identifiers, nor will it require the creation of Federal databases of patients' health information.
- It will simplify the regulatory burden on providers, by decreasing the focus of meaningful use regulations on *ad hoc* list of data items.
- It will help U.S. industry leapfrog to the front of the pack internationally in health IT, by providing exchange standards that can be more broadly adopted by others.
- It will facilitate public health and medical research, by providing a secure way to de-identify data.
- It will not require that existing systems be replaced, but only be modestly upgraded or augmented by "middleware."

In short, the approach is designed to create robust ecosystem to support the needs of patients, providers, payer, researchers and the Nation.

Creating the ability for uniform exchange in an existing marketplace is a coordination problem; it is a public good that calls for Federal leadership in coordinating standards for health metadata and in creating economic incentives to adopt the standard. The definition of meaningful use and the rewards for being a meaningful user (and penalties for not being one) can be, if properly implemented, powerful mechanisms for doing this.

Finally, one must keep in mind that achieving the truly transformative effect of modern health IT infrastructure on the healthcare sector will also require that economic incentives are in place to improve the quality of care and reduce costs.

**Recommendations**. The final chapter of this report offers guidance to ONC and CMS and also makes an itemized set of specific recommendations. We urge ONC to augment its current "bottom-up" approach with a process that can generate "top-down" design choices that are carefully balanced between the goals of convergence and diversity. This is an appropriate government role and requires a more aggressive approach than has been taken in the early stages. We also discuss how ONC might, by standardizing a universal exchange language whose semantics is intrinsically extensible, unburden itself of a potentially never-ending and intrusive government role in the harmonization of health record meanings across all private sector products. An open, extensible language will allow products to compete, balanced with other competitive features, on the basis of the breadth of their abilities to understand multiple semantic realms. ONC's clinical document architecture standard (CDA) is an important step in the right direction, but needs more focus on data transmission, on innate privacy features, and on the enabling requirements of a more robust marketplace in new and innovative health IT products.

As regards CMS, we suggest specific ways in which the meaningful use process could be used to better advance more strategic national goals in health IT. Apropos of the much-needed overhaul of CMS's antiquated IT infrastructure, we emphasize the importance of not replacing one inflexible architecture with another and briefly suggest what a modernized, versatile infrastructure might look like. Fortunately, CMS now has new leadership, with the appointment of an administrator. A solid technical plan, with the necessary resources, will be now required for success.

Although ONC and CMS both lie organizationally within U.S. Health and Human Services (HHS), the dimensions of health IT are broadly consequential across multiple Federal departments, including Veterans Affairs (VA) and Department of Defense (DoD). Among our recommendations, we therefore suggest that the Chief Technology Officer of the United States in coordination with the Office of Management and Budget and HHS, develop within 12 months a set of metrics that measure progress toward an a operational, universal, national health IT infrastructure that has the desirable features that we have discussed. Focusing these metrics on operational progress, as distinct from research, prototype, and pilot efforts, will enable a more accurate continuing assessment of whether Federal efforts in health IT, including both executive initiatives and legislative mandates, are in fact supportive of the President's goal of increasing the quality, and decreasing the cost, of healthcare.

# PCAST Health Information Technology Working Group

Working Group members participated in the preparation of an initial draft of this report. They are not responsible for, nor necessarily endorse, the final version of this report as modified and approved by PCAST.

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2. Dr. Varmus resigned from PCAST on July 9, 2010 and subsequently became Director of the National Cancer Institute (NCI).

# I. Introduction and Overview

## Introduction

Improving the quality and decreasing the costs of healthcare are among the Nation's highest priorities. In 1960, healthcare expenditures represented about 5 percent of the United States' gross domestic product (GDP).[3] Today they represent about 16 percent—the largest share of GDP spent on healthcare among all major industrialized countries. Yet on critical measures of healthcare outcomes, such as life expectancy, infant mortality, and the number of physicians per capita, the United States ranks behind many other countries.[4] Our expenditures are not producing the results we should expect.

Information technology has the potential to transform healthcare as it has transformed many parts of our economy and society in recent decades. **Health information technology**[5] can allow clinicians to have real-time access to complete patient data, and provide them with support to make the best possible decisions.[6] It can help patients become more involved in their own care, which is especially important in managing chronic conditions like diabetes, asthma, or heart disease. It can enable a range of population-level monitoring and real-time research such as the detection of developing epidemics, health risks in the environment, or adverse events caused by medications. It can improve clinical trials, leading to more rapid advances in personalized medicine. It can streamline processes and reduce administrative overhead, as it has in other industries. It can lead to the creation of new, high-tech markets and jobs. Finally, it can help support a range of economic reforms in the healthcare system that will be needed to address our country's long-term fiscal challenges. As David Blumenthal, the National Coordinator for Health Information Technology, has written, "Information is the lifeblood of modern medicine, [and] health information technology is destined to be its circulatory system."[7]

Despite this great promise, however, the impact of IT on healthcare has so far been modest. Currently, almost 80 percent of physicians—the majority in small, independent practices—lack even rudimentary digital records.[8] Of those who do use electronic systems, most do not make full use of their potential functionality. The sharing of health information electronically remains the exception rather than the rule. The market for new products and services based on health IT remains relatively small and undeveloped compared with corresponding markets in most other sectors of the economy. While recent Federal initiatives have made some important advances toward changing this situation, healthcare has taken only the first few steps toward an electronic future.

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3. Agency for Healthcare Research and Quality. 2010. Health Care Costs Fact Sheet. See www.ahrq.gov/news/costsfact.htm
4. Anderson, G., and P. Markovich. 2009. *Multinational Comparisons of Health Systems Data, 2009*. New York: The Commonwealth Fund.
5. Terms in bold-faced type the first time they appear in this report are defined in the glossary.
6. Chaudhry, B., J. Wang, S. Wu, M. Maglione, W. Mojica, E. Roth, S. C. Morton, and P. G. Shekelle. 2006. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. *Annals of Internal Medicine*, 2144:742-752.
7. Blumenthal, D. 2010. Launching HITECH. *New England Journal of Medicine,* 362:382-385.
8. National Center for Health Statistics. December 2009. Electronic Medical Record/Electronic Health Record Use by Office-based Physicians: United States, 2008 and Preliminary 2009.

## The Origins of This Study

Given the importance of healthcare to the Nation's future, the President asked his Council of Advisors on Science and Technology how health IT could improve the quality of healthcare and reduce its cost, and whether existing Federal efforts in health IT are optimized for these goals. In response, PCAST formed a working group consisting of PCAST members and prominent experts in both healthcare and information technology.[9]

The working group held meetings in Washington, D.C., on December 18, 2009, and in Irvine, California, on January 14-15, 2010, as well as additional meetings by teleconference. The viewpoints of researchers, policy analysts, and administrators from government, healthcare organizations, and universities were presented and discussed. Additional analysis of the current state of health IT implementation among the 80 percent of physicians who practice outside of large integrated healthcare organizations was performed by the Science and Technology Policy Institute (STPI).

A draft report developed by the working group was submitted to the Health and Life Sciences committee of PCAST. That committee submitted the draft to several outside reviewers, who made valuable suggestions for improvements. From the working group draft, the additional input, and its own discussions, the Health and Life Sciences committee produced the present report, which was discussed and endorsed (with some modifications) by the full PCAST in public session on July 16, 2010.

## Analysis of the Problem

Several identifiable barriers in the healthcare system currently discourage innovation and vigorous competition in the market to create effective health IT systems.

First, the diffusion of IT within healthcare has been slow and oriented toward administrative functions. **Electronic health records** that contain patient information captured in clinical visits, through lab and imaging studies, and likely in the future from genetic tests, are a cornerstone of health information technology. Many healthcare providers, however, do not have the economic incentives and technical expertise to purchase and use EHRs. Physicians who do adopt EHRs often find they are spending extra hours each day to type in orders, notes from patient visits, or measures to be reported to CMS without receiving commensurate benefits. In addition, the fee-for-service payment model prevalent in U.S. healthcare does not create strong incentives to coordinate care, share information, or avoid unnecessary treatments, all of which are potential advantages of using EHR systems.

Second, the current structure of health IT systems makes it difficult to extract the full value of the data generated in the process of healthcare. Most electronic health records resemble digital renditions of paper records. This means that physicians can have trouble finding the information they need, and patients often wind up with poor access to their own health data and little ability to use it for their own purposes. Electronic records often do not include links to relevant information such as recent research findings or data on best practices that physicians and patients could use to make the best possible decisions. For reasons we discuss below, market innovation has not yet adequately addressed these challenges to the **usability** of electronic health records.

9. The working group members are listed in page 7.

Third, standards and infrastructure are lacking that would allow information to be easily shared across organizations. Relevant information does not seamlessly move with patients who receive care from multiple providers. This leads to duplication and hinders coordination of care. The lack of data exchange also means that researchers and public health agencies have limited access to data that could be used to improve health systems and advance biomedical research. Present Federal initiatives, described below, have the effect of encouraging the development of local and regional **health information exchanges** (HIEs) that involve agreements to exchange data among clusters of organizations. These exchanges are hampered by the administrative burdens of developing agreements and by a lack of financial incentives to increase coordination and efficiency. It is also unclear how these exchanges might scale to a national level.

Fourth, patients are concerned that the storage of their health information in electronic form will make it easier for employers, insurers, government, or malicious electronic intruders to improperly access their records. This concern may make them unwilling to participate in health IT systems or grant consent for their information to be used in research, even though the aggregation of patient data to compare treatments and providers is a major benefit of health IT. Data can be **anonymized** by removing all personal identifiers from the data. But patients also may want to be re-contacted if analysis of their data reveals a problem with a medication they are taking or a treatment that could benefit them.

Some large healthcare organizations have overcome at least some of these barriers and successfully adopted EHR systems. The **VistA** system adopted by the Veterans Health Administration (VHA) has helped the Nation's largest integrated health system provide a highly regarded level of information technology supporting better care. Kaiser Permanente's HealthConnect system links all of Kaiser's nearly 9 million members to all of its more than 14,000 physicians and their hospitals, rehabilitation centers and long-term-care facilities, so that Kaiser physicians can retrieve data on any patient who has received services anywhere in its network. Other leading hospitals and clinics also employ electronic record systems that allow them to consolidate patient health data generated within their organization.

These successes, however, also illuminate the limitations mentioned above. Even the most sophisticated organizations generally do not have efficient means to exchange health information with other providers. When exchanges occur, they often take place through limited or pre-formatted messages, such as electronic prescription information, or through comprehensive patient care summary documents, which cannot easily be searched for timely information such as that needed in an emergency. In addition, the systems employed by these large organizations are engineered to meet the specific needs of the organization that owns them, so they do not provide an open and accessible platform for market innovation that might lead to improvements in usability or functionality.

The main objective of this report is to argue that if health information technology is to have a truly transformative effect, the Federal Government should push ambitiously toward a national health data infrastructure in which patient data are readily available to providers in real time, can be accessed in **de-identified** form by researchers and public health agencies, and in which a market for applications that enhance EHR usability and patient involvement can flourish, enabling a "network effect" that can spur further adoption. The report describes a technological approach that could lead to this vision being realized, while at the same time strongly protecting privacy (including, where applicable, respecting the persistent privacy preferences of patients), and also describes some of the accompanying economic and regulatory steps that are required.

## The Present Federal Landscape

Recent Federal legislation offers a promising start toward these objectives. The Health Information Technology for Economic and Clinical Health Act, a part of the American Recovery and Reinvestment Act of 2009,[10] authorized expenditures on the order of $20 billion (with estimates ranging from $9 billion to $27 billion) to promote the adoption and use of EHR technologies connected through a national health information network. Under HITECH, hospitals and physicians who make "**meaningful use**" of interoperable EHRs can qualify for extra payments through Medicare and Medicaid.

Responsibility for developing policies that implement the overall **HITECH Act** lies primarily with the Office of the National Coordinator for Health Information Technology; however, ONC also works closely with the Center for Medicare and Medicaid Services which is responsible for promulgating policies that relate to Medicare and Medicaid payment for meaningful use of EHRs under HITECH. Both ONC and CMS recently released final rules to implement the first phase of the HITECH Act, which begins in 2011. The ONC rule specifies the standards, implementation specifications and other criteria for EHR systems and technologies to be certified under HITECH and thus eligible for the Act's incentive programs while the CMS rule specifies how hospitals, physicians, and other eligible professionals must demonstrate their meaningful use of these technologies in order to receive Medicare and Medicaid payment incentives.

Both sets of rules strongly indicate that standards and criteria for achieving meaningful use of EHRs will grow more rigorous in subsequent phases (2013 and 2015) as the technology continues to evolve and providers gain experience and sophistication in its use. For example, to qualify for meaningful use incentive payments in 2011, CMS will require providers to be able to electronically transmit medication orders, record patient information and problem lists, demonstrate use of decision support tools, test systems to exchange health information with other providers, and submit a small number of clinical quality measures; by 2015, CMS expects that to qualify for meaningful use of EHRs, providers will need to demonstrate greater use of decision support tools, higher levels of information exchange, and actual improvement in care coordination and patient outcomes.

The ONC also has moved to take a number of other useful actions in the short time since passage of **HITECH**. The ONC director and his staff have sparked needed awareness in the provider community, galvanized the experts and industry stakeholders, and created a momentum for change through open policy committee processes, several pilot frameworks, and the support of research in key areas. In addition, they have directly funded regionally based support systems for physicians and other providers, and supported several new programs and research initiatives designed to promote the use of health IT and the exchange of health information. ONC has distributed over $564 million to states and state-designated entities to enlist their leadership in facilitating health information exchange within their jurisdictions and across state lines. Moreover, ONC is sponsoring many demonstration projects that build useful momentum and develop valuable experience and buy-in. These have helped to create the prerequisite conditions where Federal leadership, leading to rapid progress, is now possible. Further discussion of ONC's initiatives and successes is in Chapter Three.

10. P.L. 111-5, "American Recovery and Reinvestment Act of 2009" (ARRA), 111 th Congress.

**Despite this progress, a major finding of this report is that achieving the President's goals depends on accelerating and redirecting current Federal work laying the groundwork for health information exchange.** While the 2011 rules are an appropriate initial step, the approach underlying these rules will not suffice to ensure that the various activities and experiments being supported by ONC will converge into an effective healthcare IT ecosystem that serves patients and providers. Going forward, the critical issue will be to ensure the creation, dissemination, and use of a universal exchange language for healthcare information that enables health IT data to be shared across institutions, along with network infrastructure that enables a patient's data to be located and accessed across institutional boundaries, subject to strong, persistent, privacy preferences[11]. **ONC should move rapidly to ensure the development of these capabilities; and ONC and CMS should focus meaningful use guidelines for 2013 and 2015 on the more comprehensive ability to exchange healthcare information.**

We also have an important concern about CMS. CMS is the largest recipient of electronic health information (including data quality measures and measure sets) from hospitals and providers documenting their use and the effects of health IT. **CMS will require major modernization and restructuring of its IT platforms and staff expertise to be able to engage in sophisticated exchange of health information and to drive major progress in health IT.** This should be a major priority for CMS's new leadership, and should be funded as appropriate for an essential component of the Nation's healthcare quality and affordability agenda. A recently initiated National Research Council study of CMS's IT capabilities should result in recommendations that will avoid replacing one inflexible architecture with another (a common trap in Federal IT acquisitions), but a successful outcome is at best several years away.

Several other agencies within HHS have potentially important roles in health IT. The Agency for Health Care Research and Quality (AHRQ) is a small but increasingly important research agency supporting health services and delivery system research. Approximately 80 percent of its FY 2009 budget of $372 million is invested in grants and contracts focused on improving healthcare.[12] The Food and Drug Administration (FDA), while not currently regulating EHRs, currently does receive voluntary reports of death and injury associated with EHR malfunctions. FDA officials have suggested possible future regulatory strategies that could include mandatory adverse event reporting, or even classifying EHRs as medical devices, which would make them subject to pre-market regulation.[13] Other agencies with operational experience, such as the Centers for Disease Control & Prevention (CDC), or individuals in the Commissioned Corps of U.S. Public Health Service, might have roles to play in the management or operation of a future national health IT infrastructure.

11. Foreshadowing discussion later in this report, a more technical description of the common framework is: (1) a universal extensible language for the exchange of health information based on "metadata-tagged data elements," (2) a standard for a minimal set of metadata that specifically enforce privacy safeguards on each individual piece of data, and (3) the development of a secure national infrastructure, based on the technology of today's web search engines, for locating and assembling all of a patient's information for clinical encounters and (when de-identified) for public health purposes.

12. AHRQ web page at http://www.ahrq.gov/about/ataglance.htm

13. Healthcare IT News (February 26, 2010) at http://www.healthcareitnews.com/blog/should-fda-regulate-ehr-safety

## Structure of this Report

Chapter Two gives a more thorough description of the benefits that could be realized by developing electronic health records to their full potential and integrating health information technology more completely into the healthcare system. The main features of the **data-centric** approach that we recommend are introduced with an initial discussion of **metadata**-tagged data elements.

Chapter Three describes in more detail the current state of health information technology, starting with the historical adoption and use of electronic records, and emphasizing the barriers that have arisen. The discussion focuses on specific cases that yield "lessons learned," both positive and negative. Also discussed are the successes and challenges facing the two key agencies ONC and CMS. The chapter concludes with a list of technical and market-related criteria against which to test proposed solutions.

Chapter Four outlines a technological approach based on the use of tagged data elements that could achieve many, if not all, of the key objectives. This chapter is somewhat more technical, although its general argument should be understandable by all readers. The deficiencies of solutions that require standardized records, or which rely on **service-oriented architectures**, are also noted.

Chapter Five summarizes today's privacy framework and indicates the ways in which it is inadequate for the future. Technologies are discussed that can be combined to achieve best-practice security along with persistent privacy protections.

Chapter Six discusses economic and regulatory issues, in particular how to reconcile the "public good" aspects of a national health IT infrastructure with the need to create vibrant, competitive markets. This chapter describes some of the main steps that are needed to complement the technological approach described in Chapters Four and Five, and relates health IT initiatives to the broader economics of healthcare.

Chapter Seven outlines some of the research opportunities that will be enabled by future health IT, and what are the requirements on that infrastructure so that the maximum benefits of that research can be achieved.

Chapter Eight brings together this report's recommendations and guidance to key Federal agencies. We offer guidance of both a general and specific nature to ONC and CMS, and also suggest what a longer term roadmap should look like. Among our key recommendations is that the Chief Technology Officer of the United States should oversee the development of a set of metrics that measure progress toward a national health IT infrastructure that is operational and universal (as distinct from experimental and pilot programs).

**This chapter's bottom line:** Health information technology has the potential to improve the healthcare system in numerous ways. Yet Federal efforts are not optimized to achieve the President's goals of improving the quality of healthcare and reducing its cost. Challenges differ by agency, but they include the need for more focus on the convergence of plans and the modernization of existing Federal IT infrastructure.

# II. The Potential of Health IT

## Introduction

In this chapter, we describe some of the potential benefits that could be realized from developing EHRs to their full potential and integrating health information technology more completely into the healthcare system. The benefits we describe might accrue at the level of individual clinical visits, at the level of healthcare organizations, at a broader regional and national level, and finally to patients wishing to have more information and more control over their own health and interactions with the healthcare system. We provide a series of "use cases" that illustrate the various levels at which information technology can improve healthcare delivery and the healthcare system.

We also note that formidable hurdles need to be overcome if these benefits are to be realized. The hurdles are both technological and economic. A key point is that current electronic health records, which are based on traditional paper records and exist largely within closed health organizations, cannot realize many of the potential benefits we have described. In order for health data to be broken down, indexed, transmitted across organizations, re-assembled, and aggregated, a more flexible technological approach is desirable. This approach is sketched below and described more fully in Chapter Four.

Later chapters expand on some of the other challenges that must be overcome to realize the potential benefits of health IT. Some early applications of IT in healthcare have had unexpected costs and consequences, and, despite the existence of commercial products and innovative demonstrations and pilot systems, the movement to electronic health records has been slow. The economic incentives to adopt and effectively utilize health IT have been weak, and the organizational structure of the healthcare system is itself highly fragmented. Current privacy regulation also creates complications for providers wishing to adopt and utilize IT. In short, there remain many barriers to achieving the potential of widespread and secure access to accurate, personalized, and comprehensive health data.

## Potential Benefits of Health IT: An Overview

As medical practices and technologies have advanced, the delivery of sophisticated, high-quality medical care has come to require teams of healthcare providers, including primary care physicians, specialists, hospitalists, nurses, and technicians. Each member of the team tends to have specific but inevitably limited direct interactions with the patient. Every health provider has a somewhat different view of a patient, depending on the expertise the particular specialist brings to the medical team, and no one provider knows everything. In effect, the patient has fragmented into disconnected facts and clusters of symptoms. To prevent the most basic medical errors, some facts are elicited over and over again, to the frustration of patients and healthcare providers alike: "Do you have any drug allergies?" "Have you had any surgeries?" "Are you taking aspirin or blood thinners?" This frustrating repetition works, albeit inefficiently, if the patient is cognitively intact and well informed, but not all patients fit that description, especially in the event of a serious or acute illness.

Health providers need views of the patient that are less fragmented than at present. A cardiologist, for example, needs immediate access to a patient's most recent and significant cardiograms, cardiac imaging studies, and lab tests. He or she also needs to know about a family history of heart disease, concurrent illnesses being cared for by other specialists, past medical events, recent medications, and activity and nutrition changes. A nutritionist needs to know about a patient's serum cholesterol and also about life changes, such as a new job or the illness of a spouse, that may have caused a sudden change in the patient's diet. Health IT can integrate and organize patient information, and facilitate its instantaneous distribution among all participants in the healthcare system, so that providers and patients can obtain complete up-to-date views of each patient. In simple terms, health IT has the potential to put the patient back together again to allow more coordinated care.

Health IT also has the potential to generate valuable new information to improve workflow, safety, and efficiency within healthcare organizations. In industries such as manufacturing, retailing, and financial services, the efficiency gains from information technology were realized only when companies made complementary organizational changes. Today, some health organizations already use IT to track quality metrics, deploy reminder systems and checklists for physicians and other caretakers, and provide rapid feedback for the organization when changes are made. The widespread adoption of health information technology could allow these efforts to spread throughout the healthcare system.

The aggregation of data across organizations offers further possibilities. If the data gathered by healthcare providers and the decisions made at the point of care by providers and patients were gathered and aggregated, they could reveal patterns of illness in a community or nationally, identify potential epidemics at very early stages, enable comparisons of different treatments or medical devices in large and diverse populations, and evaluate the effectiveness of specific treatments and make information about hospitals, physicians, and other providers more comprehensive and accurate. Healthcare providers could use the information generated from these data to provide up-to-date and accurate guidance for patients, while healthcare recipients could draw on the data to prevent illness and obtain the best possible treatments. Data used to be an incidental byproduct of healthcare. In the future, timely information derived from high-quality data should be at the center of efforts to analyze, understand, and improve the healthcare system.

The next sections expand on these potential benefits of health IT, in part through simple "use cases." Readers may, and probably should, find some of these cases rather easy or obvious. Indeed, what is surprising is that today they are generally not possible in most care delivery environments.

### *Table 1. The Potential Benefits of Health IT*

The ability to capture, store, exchange, and analyze medical information in electronic form could improve U.S. healthcare in many ways.

• **Quality of care for individual patients**. Patients will receive better medical care if they and their healthcare providers have access to complete and accurate electronic health records that aggregate information across time and organizations. Given the fragmented nature of the U.S. healthcare system, such integrated health records are now often not available. Such records could improve diagnoses, prevent errors, and save time.

• **Engagement of patients in healthcare**. The participation of patients in their own healthcare could substantially improve their care, especially in the management and treatment of chronic conditions such as obesity and diabetes. Access to electronic personal health information and interfaces that make it easy for public and private clinical organizations to share health information with each other and with patients could enable healthcare providers and patients to collaborate in informed decision-making.

• **Clinical studies of medical interventions**. Sound medicine needs to be based on empirical evidence of how well particular interventions work for patients. While some questions can only be answered through **randomized clinical trials**, a tremendous amount could be learned through the ability to integrate the combined experience of millions of patients. Aggregated de-identified information could enable a wide range of studies on such topics as the efficacy of prevention strategies, the frequency of particular complications in particular settings, and the response of individuals to specific drugs as a function of **genotype**.

• **Improved population-based knowledge.** Aggregated health information can provide invaluable tools for identifying and tracking medical events such as epidemics and adverse events related to treatment.

• **Development of new tools for medicine**. In most industries (such as retail consumer goods, shipping, and financial services), the availability of electronic information has led to an outpouring of creative tools that have increased quality and enabled new kinds of services. Healthcare could benefit greatly from such tools. Examples include home-based monitoring devices that could directly transmit data to physicians, systems that could help increase patient compliance with drug regimens, and computerized decision support systems able to incorporate the most up-to-date clinical knowledge.

• **Increased administrative efficiency**. In most industries, electronic information also has led to a decrease in administrative costs as many processes became automated. In healthcare, administrative tasks (such as filling out forms and processing billing requests) represent a significant fraction of healthcare costs. Health IT could streamline these tasks and significantly decrease costs.

## The Value of Patient-Specific Data to Patients

Electronic health information should enable patients to have full and accurate information about all medical evaluations, to track the management of their own conditions, to schedule and change appointments as appropriate, and to exchange email with providers. This would give patients and families more direct engagement with their care, create an avenue for communication with healthcare providers, and identify treatable symptoms early to avoid unnecessary emergency room visits or hospitalizations.

**Use Case 1:** A patient on warfarin, a blood thinner, strains his calf muscle during a tennis match and cannot remember whether it is safe to take Advil or Motrin. He types "Advil" into his personal health record list to see if there are any potential interactions with the list of medications in his record. Indeed, taking either Advil or Motrin would significantly increase his risk for serious bleeding. He emails his physician, who recommends cold packs and acetaminophen. The next day a discoloration and increased swelling occurs. He sends another email to the physician's office, where he is connected to a nurse practitioner who recommends a blood coagulation test. He is able to select times online for the test, for follow-up with the physician, and for possible further tests and physical therapy.

Electronic health information also can improve coordination of care by ensuring that every specialist, in every setting, has the same accurate and up-to-date information about a patient. This is especially important with patients who are seeing multiple specialists, with patients making transitions between care settings, and especially in emergency settings. This kind of data availability will reduce medical errors, reduce unnecessary tests, and reduce the chance that a patient's physician would not know about an unrelated but relevant condition being managed by another specialist.

**Use Case 2:** A 70-year-old woman with a newly diagnosed lung mass suspicious for lung cancer discovered on a CAT scan in a small community hospital is referred to a large academic center in a metropolitan area two hours away. The patient's local hospital automatically makes available her electronic health record, enabling the cancer surgeon to pull up the CAT scan images and radiologist report at the patient's consultation. She doesn't remember all her medications, but her electronic record has recently been updated and verified. She may need a lung biopsy, and her record notes that she has an unusual cardiac arrhythmia that has been treated by a cardiologist in the past but that she is no longer taking medication. The biopsy is positive for lung cancer, and she will need both surgery and radiation. She is able to receive some of this treatment closer to one of her children, who lives in another state 1,200 miles away, with real-time communication electronically between her oncology team and her primary care physician. During this time, she is weakened and falls, sustaining a hip fracture. She is taken to the emergency room, where all her information is immediately available to sort out the otherwise confusing picture of cardiac arrhythmia, anemia from cancer treatment, and recent surgical scars.

## The Value of Patient-Specific and Aggregated Data to Physicians

For the majority of U.S. physicians, electronic health information will for the first time enable them to query and analyze the "denominator" of their patient population—the full range of patients for whom they and their colleagues are responsible. This will make it possible for the physician to identify areas where patients are receiving less than optimal care—for example, how many patients with hypertension have their blood pressure under control, or how many patients with diabetes have their blood sugar measurements in the target range and have had appropriate screening tests.

This same clinical information is also essential to meet the growing number of demands for reporting of clinical quality measures for accountability and payment purposes. These demands are currently both expensive and cumbersome for most physicians, and to the degree that most of these data come from insurance companies, the data are limited to claims-linked information and are inevitably delayed and incomplete. Most physicians are very interested in and responsive to accurate evidence. Being able to interrogate one's own data for rates of performance on quality measures could lead to significant healthcare improvements.

**Use Case 3:** A general internist decides to seek approval for her practice to be designated a patient-centered medical home (PCMH) under Medicare because she cares for a large number of patients with chronic illness, including diabetes, heart disease, and hypertension. This requires her to submit a large number of data entry forms and quality measures, including descriptions of her patients, their disease profiles, and their demographics. Her office staff is able to do this easily by extracting the information from her EHR system, and she receives the designation. Her office is also able to file quality of care and utilization reports on a regular basis to 10 other payers apart from Medicare, and create reports that aggregate her patient population across all payers. This allows her to identify gaps in preventive measures or diabetes and hypertension control and create reports to maintain specialty board certification and hospital privileges. When she identifies areas for improvement, she implements changes in her practice and later re-measures. For example, she and her partners have increased the rate of elderly patients who received preventive falls assessments, and were able to do the follow-up measures electronically because they share EHR data with the two retirement homes and several nursing homes in the region. In doing this, they drew on patient-specific risk profiles and guidelines available electronically from the National Institutes of Health and the American Geriatric Society decision support programs.

Payers and consumers are increasingly including the results of patient surveys in performance measures used for payment, public reporting, and improvement. A fully functional electronic healthcare information system would enable physicians to contact patients directly, to solicit patient feedback related to specific conditions, and to compile actionable feedback to the practice.

**Use Case 4:** A small group practice provides online access to each patient's medical record and communicates regularly with its patients via email. The practice has recently implemented an open access scheduling system and is curious to learn how patients feel about the change, so they email all patients with a recent office visit a web link to complete a focused satisfaction survey. They also participate in the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey authorized by Medicare but would like to add more specific questions related to patient's own conditions such as: "Did the nurse follow up with you about managing your new glucometer?" "Did your questions get answered?" They are able to personalize aspects of this survey and at the same time have only the needed aggregate data reported to payers.

As the use of quality measures increases, a question looms about how much real impact these measures will have on outcomes that are meaningful to patients. The combination of more efficient and accurate physician reporting with population-based outcome data could dramatically enhance critically important research about which of the measures link with desired patient outcomes, which of them lead most directly to improvement, and how to streamline the measurement and reporting process to reduce the time and financial burden on physician practices and still produce measures relevant to patient values.

**Use Case 5:** A group of cardiology clinics in the Southwest, separated by significant distance, decides to work together to improve the care of patients who recently experienced a myocardial infarction (heart attack). They link information from each clinic's electronic medical records to track progress, learn what quality interventions work best, and create composite measures that help to distinguish what constitutes the best overall care. They are able to identify which sites have the best outcomes in certain areas, and they learn from each other how to apply these findings through webinars engaging all the staff in each clinic.

Having electronic health information about the entire population of patients served by a given practice or provider enables queries about groups of patients who suffer from a specific condition, are eligible for spec ific preventive measures, or are currently taking specific medications. Among other things, this population-based view enhances the ability of the practice to identify and work with patients to manage specific risk factors or combinations of risk factors. It also can detect patterns of potentially related adverse events and enable patients at risk to be quickly and correctly notified. For example, when a previously unidentified medication risk comes to light (as in the case of Vioxx), it is easy for the practice to identify all the patients taking that medication and to contact them immediately. If fully linked to the patient's personal health record, this function would also apply to over the counter medications. Similarly, when a needed vaccine (such as H1N1) is available, the practice can identify the patients at greatest risk and communicate with them efficiently. Outreach, patient education, and notification about particular risks are made possible by this kind of system.

**Use Case 6:** A family physician embeds electronic reminders that alert her when the patient she is seeing during an office visit needs preventive care. Each fall, the clinic queries the electronic record to see which patients will need an influenza vaccine and to automatically generate a reminder email and/or text message sent to the patient. When an unusual pandemic strain appears, with different risk groups, the database can be queried to identify and communicate with those patients who are at highest risk.

## The Value of Population Data for Research and Public Health

If real-time concurrent clinical data about every healthcare encounter were stored electronically, such data could be combined, without personal identifiers, from a regional or national population to allow enormous improvements in the ability to track public health issues and to develop prevention and amelioration strategies in a timely manner.

For example, natural epidemics such as H1N1 influenza are currently tracked through a combination of voluntary reporting by physicians and emergency rooms to various public health authorities and to the Centers for Disease Control and Prevention. Social networking and use of the Internet recently have been shown to add significantly to this capability.[14] But neither of these methods is impeccably accurate and truly comprehensive or able to pick up nuances of epidemics from current clinical data. A fully functional health information network that was widely used, interoperable, and able to be aggregated with a reasonable degree of accuracy and reliability would dramatically improve the ability to track known epidemics, to identify new ones, and to identify at an early stage other threats to public health such as bioterrorism or environmental exposures.

With sophisticated modeling expertise, this same database would enable **comparative effectiveness research** by tracking groups of patients taking comparable treatments for similar conditions. The results of these virtual clinical trials would be more representative of real-life patient populations, far less costly to conduct, and quicker to identify information relevant to the care of specific patient groups. Furthermore, as medicine is connected more closely to genetically linked traits and susceptibilities, this kind of tracking will accelerate the ability to provide patient-specific information to physicians and patients to individualize treatment decisions.

**Use Case 7:** A physician treating a patient with rheumatoid arthritis using TNF (tumor necrosis factor) inhibitors enters the patient into the database of a national clinical study. Because the patient's clinical and genetic information are both known, the physician is able to use specific characteristics to predict outcomes and reduce toxicity without relying on the traditional trial and error process. This information is available to all physicians and patients and is continually updated.

14. Brownstein, J. S., C. Clark, B. S. Freifeld, E. H. Chan, M. Keller, A. L. Sonricker, S. R. Mekaru, and D. L. Buckeridge. 2010. Information Technology and Global Surveillance of Cases of 2009 H1N1 Influenza. *New England Journal of Medicine,* 362:1731-1735.

This de-identified but clinically rich database would also enable **post-marketing surveillance** for FDA-approved medications, which now depend on voluntary reporting by physicians and healthcare organizations. An efficient way to track patient populations taking new medications, including other prescribed or over-the-counter medications simultaneously being administered, adds tremendous power to the ability to pick up adverse events or medication interactions as early as possible. As genetic information becomes more routinely available, this kind of post-marketing research capability will enable more accurate prescribing. This is especially important for medications such as biological (or cell-based) therapies and cancer chemotherapies where potential toxicities are significant and current research methods necessitate exposing large numbers of people to toxic side effects when they might not benefit from the treatment.

**Use Case 8:** An FDA Commissioner is able to launch a real-time assessment of every patient taking newly approved drugs and aggregate clinical patterns to identify adverse side effects of medications. A robust post-marketing electronic registry allows much earlier detection of important adverse events for discrete subpopulations of patients and at negligible additional cost to FDA.

Population-based clinical data will enable communities, states, and regions to track their own health statistics in a more timely, reliable, and credible manner. As we consider the potential of setting health goals for communities as well as for the Nation, these data would provide a continuous measure against which all stakeholders (healthcare providers, community groups, consumer and workforce advocates, businesses, and government) could engage around setting targets and tracking progress. Congress has established a process to develop national priorities for improving healthcare in the United States, engaging all the relevant Federal agencies plus multi-stakeholder public-private collaborations.

**Use Case 9:** For a particular year, ambitious new goals are set to improve health measures. Communities, regions, and states are able to provide comprehensive and accurate annual reports on each of these goals, identifying gaps where special focus is needed and key areas for focus in coming years. This process does not require extensive additional data gathering by state and local public health entities. Rather, it uses the flow of de-identified information generated by regular population health and healthcare activities.

## Realizing the Potential of IT: A Data-Centric Approach

The use cases above only scratch the surface of what might be possible if market innovation in information technology were to take off. A number of barriers, however, stand in the way. First, current electronic health records largely employ proprietary formats that are not directly exchangeable from one system to another. Second, it is difficult for data to be disaggregated, searched, and indexed because the context

(what we will refer to as the metadata) for individual entries in an EHR is often implicit at best.[15] Third, current EHRs generally exist institutionally within closed healthcare organizations or disconnected small practices rather than being accessible in appropriate form to patients, to other healthcare providers, and in de-identified or aggregated form to public health agencies and researchers. Strong economic incentives and regulatory initiatives are needed to overcome these obstacles. The new economic and regulatory programs launched by HITECH may not be sufficient.

In order to foreshadow later chapters of the report, it is useful to engage in a brief discussion of the EHR itself. A first point to convey is that in virtually all of our use cases, the "user" of the data does not need to be, and indeed should not be, scanning through the entire health record. Instead, the user needs to be looking at an application layer that accesses and presents a limited amount of information from a given health record or set of records. We refer to the ability of applications to access and utilize data relevant to a variety of specific tasks as a data-centric approach. Fortunately, data mining and presentation is something that computers, augmented by communications networks and distributed data storage, are very good at. Unfortunately, it is not something that current EHR systems are optimized for. Instead, many of them function as something closer to an electronic version of the paper record, and communication across systems is sorely lacking.

We will argue in this report that to achieve even the more modest goals set out in this chapter will require an infrastructure and a "universal exchange language" that allow data to be shared and communicated for different purposes among diverse EHRs and other applications. We also believe that there is a natural technological approach which will facilitate a move in this direction and which, over time, will also lead to beneficial changes in the way that EHRs are structured. This approach begins with the observation that the best way to manage and store data for advanced data-mining techniques is to break it down into the smallest individual pieces that make sense to exchange or aggregate. We will refer to these kinds of data as "**tagged data elements**," because each unit of data is accompanied by a mandatory "**metadata tag**" that describes the attributes, provenance,[16] and required privacy protections of the data. Modern, networked computers are particularly good at indexing, finding, and retrieving data that are discrete and "close to the surface," even when the pieces are distributed widely over many computer systems and data-stores. So storing data in this fashion can create an environment in which clinicians can access a **patient-centric** record tailored for each medical encounter, and in which health organizations, researchers and public health agencies can aggregate data for a broad variety of uses.

We expand on these points in Chapter Four by arguing for an *evolutionary transition* from traditional EHRs to a tagged data-element model, *and a more rapid transition for the more limited purpose of data exchange*. In the model we will propose, data can easily be aggregated and de-identified, and data do not depend on a single provider or a single vendor for use. The entities needed to facilitate this type of information-rich environment could be viewed as part of the national health infrastructure, like hospitals and clinical laboratories, regulated, but typically not operated by government entities , allowing data to be drawn safely for uses in multiple arenas. Embracing this outcome is an important and essential step toward leveraging the true power of information technology to improve healthcare.

15. For example, given an entry containing a laboratory test result, one might deduce the name of the physician who ordered the test from a case note with a corresponding date (context present, but implicit); but, for the case of an equipment recall, one might not at all be able to deduce the brand of medical equipment used (missing context).

16. Provenance includes information about the data's source and the processing that the data have undergone.

## Conclusion

Information technology, along with associated managerial and organizational changes, has brought substantial productivity gains to manufacturing, retailing, and many other industries.[17] Healthcare is poised to make a similar transition, but some basic changes in approach are needed to realize the potential of healthcare IT.

The most significant change is that all healthcare should be organized around the needs and specific characteristics of the patient, not around those of the hospital, doctor's office, insurance company, or EHR vendor. Medicine has become an information-rich enterprise, and a larger and more seamless flow of information will result in a transformation of care, organized around the patient, wherever he or she may be. The healthcare system will be driven by information and at the same time will generate information that can be used to improve healthcare. The potential for individualized care, higher quality, lower costs, and enhanced safety is immense.

The best way to give clinicians a unified, patient-centric record tailored for each medical encounter is to store, maintain, update, and exchange the data as small, distributed, metadata-tagged elements. The **data element indexing** and access services needed to facilitate this type of information-rich environment can be viewed as part of the national health infrastructure, like hospitals and clinical laboratories. Embracing and promoting this outcome is an essential step toward leveraging the true power of information technology to improve healthcare.

**This chapter's bottom line:** Improved health IT can directly affect, and improve, clinical encounters between doctor and patient, healthcare organizations, clinical research, and the monitoring of public health. For this to happen, we must be able to "disassemble" the information in electronic health records and then "reassemble" it in various ways.

17. Brynjolfsson, E, and L. M. Hitt. 1998. Beyond the Productivity Paradox: Computers are the Catalyst for Bigger Changes. See http://ebusiness.mit.edu/erik/bpp.pdf

# III. Health IT Today

## Introduction

Traditionally, electronic records and information technology have played a limited role in healthcare delivery. There are a number of reasons for this, both economic and technological. In this chapter, we describe some of the historical barriers to health IT adoption, and the current Federal initiatives that are beginning to change the health IT landscape. In doing this, we touch on some of the lessons that can be drawn from the experience of early IT adopters, predominantly large integrated healthcare organizations, as well as the historical and current state of EHR technology.

The final part of this chapter discusses nascent attempts to promote data sharing through local and regional health information exchanges. Data sharing and exchange through a national health IT infrastructure is essential to realize many of the potential benefits described in the current chapter. This requires the ability to access, assemble, and present data that are potentially being generated across a range of organizations. This capability is by and large lacking in the current environment. Moreover, current approaches to data exchange and aggregation, which are often bilateral or document-based, do not, in our view, present a clear path to scalable national solutions that would trigger transformative innovation and use of health IT. In this sense, there is potentially a large gap between the current path and the potential for IT to improve health and healthcare.

## Historical Barriers to EHR Adoption

Although the promise of EHR systems was recognized decades ago,[18] even today the great majority of physicians rely on paper records and use electronic data mainly for billing purposes. According to the CDC's National Ambulatory Medical Care Survey (NAMCS, 2009) only 6.9 percent of physicians reported having an extensive, fully functional electronic record system. Only 20 percent reported having even a basic electronic record system.[19] At first glance, this is surprising given that computers and information technology are so completely embedded in most industries. One would be shocked to hear of a leading manufacturer using paper records to track production or inventories, or of a financial services firm relying primarily on faxes and ordinary mail to exchange information with clients and partner firms. Indeed, healthcare providers have long used computers and IT for billing and communication with payers. Why has the broader adoption and utilization of information technology in healthcare been so slow?

At least part of the explanation lies in the organizational and economic structure of healthcare. Most physicians practice in small groups and are reimbursed for care on a fee-for-service basis. Physicians operating in this type of environment cannot easily internalize many of the potential benefits of electronic records and health IT, such as improved sharing of patient information, greater coordination of

18. E.g., Garwin, R. L. 1968. Impact of Information-Handling Systems on Quality and Access to Health Care. *Public Health Reports*, 83(5):346-351.

19. See http://www.cdc.gov/nchs/data/hestat/emr_ehr/emr_ehr.htm Primary care physicians and those practicing in large groups, hospitals or medical centers, and the western region of the United States were more likely to use electronic health records.

care, and aggregation of data.[20] They also have little incentive to undertake the substantial investment or money and time to install and adapt to electronic records, particularly when this involves a large fixed cost that cannot be spread across a large number of patients or physicians.

The situation has been compounded by a number of additional factors. Lacking demand from providers, the market has been slow to provide IT products geared toward small organizations. As we discuss below, even the advanced systems geared toward hospitals and large healthcare providers lack capabilities that seem rather obvious, such as extensive clinical decision support, or the ability to easily exchange data with other providers who share responsibility for the same patients. In addition, privacy and liability concerns may be a deterrent for some organizations, or at least for data-sharing initiatives.

Not surprisingly, the healthcare organizations that have adopted electronic health records tend to be large organizations that can shoulder the financial burden of installing customized systems and can internalize the benefits associated with such systems. These systems also tend to have different financial incentives than are prevalent in the broader healthcare system. Some are paid on a capitated basis (a fixed amount per patient per year), so they have an incentive to provide care efficiently and reduce duplication or extraneous services when possible. However, some tens of thousands of small physician practices have also adopted electronic health records. These physician adopters tend to be younger and more technologically savvy than their peers. Below we discuss some of the lessons that can be gleaned from the experiences of these early adopters.

## Limitations of Present-Day EHRs

The most commonly cited reasons for not adopting EHRs include the cost of installing and maintaining a system (including both financial and workflow disruption costs) and the lack of perceived benefits in terms of enabling higher quality, more efficient care. A frequent complaint is that electronic health records do not make the physician's job easier. In particular, few EHRs deliver the intelligent cognitive or decision support that one might hope for. Even where decision support is available, physicians often do not take advantage of it. This section describes some of the cost and "usability" concerns around current EHR systems, and how a robust technology market could alter the situation.

***Workflow Disruption and Documentation Burden:*** Present-day EHRs often require a substantial increase in physician time devoted to documentation. Physicians may complain that they are spending extra hours to type in orders and notes from patient visits. Healthcare systems can hire staff to enter data into the EHR during the office visit, but this is cumbersome and not economically feasible for small practices. Speech-to-text transcription systems exist, but so far they are useful only for specialties with circumscribed and highly specific vocabularies. Physicians often are left to design their own "templates" to reduce the data entry burden. Streamlined data entry via checklists, customizable templates, and other structured means is an area of opportunity for software and systems designers.

***Lack of Decision Support Functionality:*** Many EHRs were developed as electronic facsimiles of existing paper records. They were created largely without the assistance of experts in human factors and design and they do not fully leverage the ability of computers to retrieve and analyze data to provide useful

20. A growing literature demonstrates a positive return on investment for EHRs in small practices, but the larger part of the benefit is not captured.

guidance, safety checks, and decision support. There have been some useful advances in this area, such as modules that cross-check for drug interactions, provide warnings about allergies, or generate reminders for preventive services. Nevertheless, this is an area ripe for innovation. Recently, the National Research Council proposed a comprehensive research agenda for the development of new approaches to EHRs that would provide cognitive support for clinicians and draw on human factors engineering.[21] As just one example of the potential, research over the past decade has raised the possibility that diagnostic errors may be far more extensive than therapeutic errors. As much as 15 percent of all diagnoses may represent clinically significant errors.[22] Clinical decision support that could assist physicians in making effective diagnoses might represent a significant opportunity if it could be integrated with the electronic record.

**Technology-Enabled Diagnoses**

Imagine a patient with the history of hepatitis C who presents to a primary care physician complaining of an itchy rash. When the physician dictates or types the words "new rash" into the record, the record instantly reminds the physician that hepatitis C has associations with certain diseases, including a condition known as lichen planus that triggers an itchy rash. The decision support system can remember all of the associations between patient clues and medical diagnoses. It then becomes the job of the clinician to navigate the evidence and assess the situation with the richer information that is instantly available. In another example, imagine a veterinarian presenting with new symptoms. The decision support engine would immediately display diseases associated with veterinarian exposures. Such functionality is feasible today, but the burden and costs of deploying the record, and the use of "first generation" decision support by vendors, have hindered critical innovations needed to reduce diagnostic and therapeutic errors.

***Lack of a Platform for Innovative Applications:*** Many healthcare systems use enterprise systems customized to fit the needs of the particular provider. Other organizations rely on idiosyncratic "legacy" systems that often were initially used primarily for billing or pharmacy refills. Neither type of system provides an open and robust platform for software developers to build applications to improve data entry processes, provide decision support, or other functionality. The fact that existing systems often use record formats based on messages and page formats also makes it harder to access, retrieve, and analyze individual data elements. In addition, existing systems typically are not interoperable, so that data cannot easily be shared or aggregated across organizations. Although we discuss below some new technologies that may improve this situation, these limitations stand in the way of innovation that could help to alleviate some of the usability problems described above.

21. Stead, W. W., and H. S. Lin, Eds. 2009. Computational Technology for Effective Health Care: Immediate Steps and Strategic Directions. Washington, DC: National Academies Press. http://www.nap.edu/catalog.php?record_id=12572

22. Schiff, G. D, and D. W. Bates. 2010. Can Electronic Clinical Documentation Help Prevent Diagnostic Errors? *New England Journal of Medicine,* 362:1066-1069.

***Concerns about Security and Privacy:*** Finally, a major concern with healthcare information, as with financial and other highly sensitive personal data, involves security and privacy. The Privacy and Security Rules issued under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 provided the first broadly applicable Federal protections for health information. These Rules, along with multiple state laws, create a complex network of laws and regulations that address patient privacy and consent for the use of identifiable personal health information. The resulting regulatory framework, in current implementations, imposes significant costs on healthcare providers. Moreover, although HIPAA has usefully raised awareness of the need to protect health information, the Rule has become obsolete in many ways given advances in technology. A recent Institute of Medicine (IOM) report concluded that the law needs to be fundamentally reconsidered to reflect new information technologies and to enhance personalization and the quality of care.[23] Chapter Five expands on this point and discusses how emerging capabilities in metadata, encryption, and identity systems enable promising new ways to protect Internet-based information that were not envisioned when HIPAA was passed.

## Lessons from Early Adopters

The healthcare organizations that have adopted electronic health records are mainly large integrated health systems that can internalize the benefits of EHRs as well as fund the initial investment and ongoing maintenance. Although these organizations are not necessarily representative of the broader healthcare system, their experience provides some important lessons.

### *The Kaiser and VA Experience*

Two of the Nation's largest healthcare systems—the Veterans Health Administration (VHA) medical system and Kaiser Permanente—were among the earliest adopters of integrated EHR systems.

The VHA's adoption of its VistA system is credited with playing a major role in enabling the Nation's largest integrated health system to provide a highly regarded level of information technology supporting better care.[24] For example, the use of electronic reminders and performance measurement to improve pneumonia vaccination rates probably saved the lives of 6,000 veterans with emphysema.[25] VHA's vaccination rate became the national benchmark as pneumonia hospitalizations were halved even while VHA's patient population doubled—all while reducing taxpayer costs by $40 million.[26] VistA also has enabled the VHA to reduce medication errors to a rate of 7 per million prescriptions written, well below the national average of 1 error in 20.[27] VistA has been made available in open source but lacks the flexibility of other commercial systems, so it is not widely adopted except by some safety net organizations. It currently does not connect easily with other systems or with **personal health records** (PHRs,

23. Nass, S. J., L. A. Levit, and L. O. Gostin, Eds. 2009. Beyond the HIPAA Privacy Rule: Advancing Research, Improving Health Through Research. Washington, DC: National Academy Press. http://www.nap.edu/catalog.php?record_id=12458

24. Asch, S. M., et al. 2004. Comparison of Quality of Care for Patients in the Veterans Health Administration and Patients in a National Sample. *Annals of Internal Medicine,* 141:938-945.

25. VistA: Winner of the 2006 Innovations in American Government Award. 2006. See http://www.innovations.va.gov

26. VA Receives 2006 Innovations in Government Award. 2006. See http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1152

27. VistA: Winner of the 2006 Innovations in American Government Award. 2006. See http://www.innovations.va.gov

discussed below). Nor is it strong at creating searchable databases that web-based models promise. A descendent of VistA, the Armed Forces Health Longitudinal Technology Application (AHLTA), contains medical records of nearly 10 million military service personnel and their families. However, VistA and AHLTA have diverged to the extent that they are no longer cross-compatible.

Kaiser Permanente's HealthConnect system is based on the Epic EHR, the most widely used of current vendors. Kaiser's implementation connects all 8.6 million Kaiser Permanente members, over nine states and the District of Columbia, to 14,000 physicians[28] in Kaiser's 431 medical offices and 36 hospitals.[29] Physicians can retrieve data on any patient who has received services within their network. Kaiser has used the system to improve preventive care and the management of chronic conditions. Specialists are alerted if a patient is overdue for preventive screening (such as mammography), and often the test can be scheduled for that same day. Kaiser's system also produces quality measures and feedback for physicians, medical centers, and hospitals,[30] and is able to aggregate population-level data to track adverse events and trends. It was the first to identify the link between Vioxx and increased risk of heart attack and to remove the drug from its formulary.[31] It can also track early cases, predicting epidemics, such as influenza, across its offices.

An additional feature of Kaiser's IT system is that it allows patients to access online data and communicate with their physicians using secure messaging. More than 3 million Kaiser patients are registered for this feature, and over 100,000 access the system on a given day.[32] Kaiser attributes this part of the system with improving both quality and efficiency of care delivery. Findings from a 2009 study showed that patients' use of secure messaging and scheduled phone "visits" enabled by HealthConnect led to a 26.2 percent decrease in total office visits over four years.[33] Over the same four years, most measures of healthcare effectiveness and patient satisfaction improved significantly. Despite this useful functionality, however, Kaiser's system is a closed one that does not communicate easily with other systems or networks. Only recently have Kaiser and the VA begun to collaborate to share data about patients who use both systems, and efforts so far are limited to one geographic area (San Diego). Kaiser also is exploring further interactions with health information exchanges in some regions.

### *Experiences at Other Organizations*

The experiences of some other health systems help to illustrate the use of EHRs and the variety of issues involved in deploying IT in very different organizational and economic environments. In each of them, one can see the advantages to the patients within that system, but also the limits to models that are enterprise based rather than based on Internet technology.

The Palo Alto Medical Foundation (PAMF) is a highly-regarded multi-specialty group in Northern California that is affiliated with Sutter Health. In 1999, it deployed an Epic electronic record system similar

28. R. Kahn. 2010. Kaiser Permanente Completes Electronic Health Record Implementation. Available at http://xnet.kp.org/newscenter/pressreleases/nat/2010/030310ehrcomplete.html

29. Fast Facts about Kaiser Permanente. Available at http://xnet.kp.org/newscenter/aboutkp/fastfacts.html

30. Weissberg, J. Perspective: Electronic Health Records in a Large, Integrated Health System: It's Automatic....NOT! At Least, Not Yet. National Quality Measures Clearinghouse.

31. Kweder S. 2004. Vioxx and Drug Safety. Available at http://www.fda.gov/NewsEvents/Testimony/ucm113235.htm

32. Chen, C., T. Garrido, D. Chock, G. Okawa, and L. Liang. 2009. The Kaiser Permanente Electronic Health Record: Transforming and Streamlining Modalities Of Care. *Health Affairs,* 28: 323-333.

33. Ibid.

to Kaiser's.[34] Physicians can pull up notes written by other PAMF physicians, access lab and imaging results, and send messages to patients. Physicians and administrators also have access to population-level quality measures. PAMF has used IT to alter the scheduling system so that many routine visits are scheduled just one or two days in advance. Because PAMF does not own its own hospitals and recently merged with two other large groups in the Sutter system, it has been attempting to make its systems compatible with its partners and integrate data fully across its component groups. Even today, however, it has not achieved full integration.

Geisinger Health System is a prominent health system in central Pennsylvania that encompasses both Geisinger's own health plan and affiliated clinicians. Geisinger has extended its EHR to include the private practice physicians in the community, allowing them to access information about their patients hospitalized at Geisinger Hospitals, and allowing hospital-based physicians to get access to records from the community practitioners. Geisinger maintains a corporate research center that aggregates data from all the providers in the system to produce clinically based measures of quality of care, help physicians establish benchmarks, and monitor quality for external reporting. The distributed aspect of Geisinger's system involves additional challenges such as the standardization of data elements and data systems that are integrated into central data repositories. It has been easier for Geisinger to do this because they it is essentially the sole hospital provider in a large geographic area, and it does not face the competitive forces that might deter community physicians from signing onto a EHR system that only provided information from one hospital system and not others where their patients might receive care.[35]

### *Lessons and Challenges*

The experiences described above demonstrate how health IT can be successfully deployed and used, but they also reveal some of the challenges that remain.

A first point is that each of the organizations above has developed a system specifically tailored to its own needs. Each system has been expensive to deploy and requires substantial resources to maintain, as well as a significant and sustained effort to extract and utilize the information for organizational and care process improvements. While the organizations we have described also realize corresponding benefits, this kind of enterprise solution is inappropriate for small physician groups. Also, the patchwork nature of organizational solutions does not provide a scalable model for the effective flow of information centered around a patient, wherever that patient may be, or for a market for innovative electronic information solutions to everything from patient empowerment, to patient specific clinical decision support, to real time aggregated clinical data for robust quality assessment and public health purposes.

Second, the systems we have discussed are not mutually interoperable, meaning that patient information cannot easily be shared between providers with different systems or in different networks without a significant up-front investment to make this possible. Interoperability is important to improve and coordinate care delivery. Currently in the United States, most patients receive care from a variety of providers. One recent study found that the typical Medicare patient receives care from seven physicians

34. "Sutter Health and Affiliated Palo Alto Medical Foundation Praised by U.S. Health and Human Services for IT Innovation." 2005. See http://www.sutterhealth.org/about/news/news_pamf-ehr.html

35. Academy Health. "HIT and HSR for Actionable Knowledge: Description of Partnering Health Systems. Partner: Geisinger Health System." See http://www.academyhealth.org/files/HIT/Geisinger%20Health%20System_1wfs.pdf

spread across four organizations in a single year.[36] The lack of interoperability at the network level means that physicians do not easily have access to complete records for patients, nor does there exist a "master record" that is complete at any point in time. Chapter Six goes into more detail about the economic incentives for interoperability and how they can be better structured in the future.

## Health Information Exchanges

Data exchange and aggregation are central to realizing the potential benefits of health IT. We have already seen the limitations of current systems in this regard. In this section, we describe some nascent efforts to create health information exchanges that allow for a degree of local and regional data sharing. We also discuss why these exchanges do not provide an obvious or immediate path toward a national health IT infrastructure.

**Health Information Exchanges** are entities often built on a series of often bilateral legal agreements between different, often proprietary information systems to be able to share certain kinds of data. Many HIEs were developed for the purpose of aggregating health measures at the community level, such as those supported by the Robert Wood Johnson Foundation (RWJF) in its Aligning Forces for Quality initiative.[37] Within this RWJF-funded group and in other instances, these HIEs have been termed regional health information organizations (RHIOs). Originally conceived in response to the fact that physicians, hospitals, insurers, and other healthcare entities have been reluctant to share data beyond their corporate boundaries, they are typically state or regional entities set up to facilitate health information exchange in a region or market area. Their primary responsibility historically has been to establish "trust relationships" among these entities in order to enable the broadest possible health data exchange. They also facilitate the governance, data-sharing agreements, scope, technology, and financial models needed to support that exchange.

Conceptually, HIEs might be considered the mirror image of the enterprise EHR model. Their purpose is to locate all currently available electronic information on a patient from any source, in that community or region, and present it in an integrated format to any physician who is authorized to view it. Current electronic sources for these data are national and regional laboratories, pharmacies, and clinical claims data. The physician sees, therefore, information from other physicians caring for their patient, records on medications, lab test results, and, as it is made available, copies of hospital discharge summaries and eligibility and claims status. However, HIEs have been limited by the administrative burdens of obtaining data-sharing agreements at every practice and every hospital or nursing home. They also have been hampered by a lack of financial incentives to develop more coordinated and efficient use of resources (including information resources), as described later in this chapter. In addition, the level of clinical detail in these contractual agreements does not match the richness of information available from a clinical record. Nevertheless, they do provide the treating physician with the information that generally is most important to know about a patient, which can make a very big difference in patient outcomes. As regards privacy and security, HIEs demonstrate the reluctance of providers to share data with users they do not know—generally, users outside the communities in which providers reside.

36. Pham, H. H., D. Schrag, A. S. O'Malley, B. Wu B, and P. B. Bach. 2007. Care Patterns in Medicare and Their Implications for Pay for Performance. *New England Journal of Medicine,* 356(11):1130-1139.

37. Robert Wood Johnson Foundation. Aligning Forces for Quality. See http://www.forces4quality.org/welcome

It is important to note that participation in an HIE does not require the physician to participate in any proprietary system or to invest in a fully functional EHR. The information summary for a patient can be presented through a browser or computer screen "dashboard" in the physician's office, faxed, or deposited into an EHR if the physician has one. Most HIEs provide a portal through which physicians can "plug into" an EHR to view information. While ultimately physicians would be expected to exchange, not simply view, patient health information, some have argued that HIEs provide an important "on ramp" for small practices and independent physicians and their staff to integrate the use of health IT into their practices prior to full EHR implementation.

Nevertheless, HIEs have drawbacks that make them ill-suited as the basis for a national health information architecture. One major concern is their durability. As a Federal strategy to support health information exchange, HIEs began in 2005-2007 with a small amount of Federal demonstration funding to states; a few also received private grant support. Barriers to their success were substantial, including complex governance, the lack of a sustainable business model, continuing provider reluctance to share data, the lack of readiness to accept and use data in many organizations and practices, and technical limitations in knitting together the many disparate IT systems within most medical communities. As a result, only a handful of the original HIEs have managed to establish exchanges that functioned beyond the initial funding and limited scope of their initial pilots. Recent legislative support for new state-designated HIEs and requirements for information exchange and reporting will clear away a few of these hurdles, but the lack of a clear business case for communities to sustain HIEs over time remains a daunting challenge.

Interoperability also remains a concern. HIEs are subject to differing regional and state-based governance frameworks. Also, limitations result from a lack of standards to connect multiple proprietary systems. There is no guarantee that a patient who has received care in two or three hospitals, has recuperated in a nursing home, and is now receiving home care and seeing several different specialists will necessarily have all her data available to a treating physician during an office visit or at an emergency event such as a fall and hip fracture.

## New and Emerging Technologies

A number of new technologies offer significant potential for addressing the challenges described in the preceding sections. In this section, we describe three of them: cloud-based EHR products that are suitable for small providers, personal health records aimed at patients, and middleware products designed to make legacy systems interoperable. This discussion provides background for the next chapter of the report, which explains the technology issues associated with creating a health data platform that can facilitate innovation and broader transformation in healthcare.

### *"Cloud-Based" Technologies for Small Providers*

As discussed above, the enterprise solutions used by early adopters are not obvious solutions for the smaller healthcare organizations that still make up a large fraction of the U.S. healthcare system. Small organizations need low-cost off-the-shelf products and services that can allow them to capture the benefits of health IT without having to undergo a costly customization and maintenance process. The incentives created by HITECH have already led to substantial innovation and competition in this area.

The new products often rely on **cloud-based** technology that allows software to be run and data to be stored on remote servers. The cloud model reduces individual maintenance responsibilities and allows even small organizations to benefit from the scale economies in data storage and processing. In this model, much of the responsibility for maintaining security is shifted from the small health care organization to the cloud-based service provider. It is also advantageous from the perspective of promoting data exchange because data from many organizations are stored and processed in a more uniform way. In the future, more extensive cloud-based solutions and services are likely to provide small or under-resourced practices with everything from general practice management to advanced decision support to analytical tools for public health reporting and basic clinical research.

### *Personal Health Records*

PHRs are patient-controlled repositories of individual health data. They may contain excerpts or summaries of physician records generated from clinical encounters, claims data, lab and imaging results, prescription information, and (importantly) patient-entered data. Some PHRs, such as those offered by Dossia, Google, and Microsoft are available via the web, while others are software packages that allow consumers to store and maintain data on personal computers, mobile phones, or other digital devices. PHRs can include functions such as decisions support, appointment making, referral requests, medication refills, and bill paying. Patients also can contribute their own data to the PHR and can determine what data will be accessible to clinicians and others.

To date, most PHRs are not standards based, and few support an easy way to transport records among different EHR products. However, Google and Microsoft, the two largest vendors of web-based PHRs, recently agreed on mechanisms to enable the free exchange of information between their respective PHR systems, and others may follow.

An important feature of PHRs is that they are patient controlled and "travel with" the patient. In this sense, they represent a route to interoperability. A patient could schedule a visit with a new physician, or a specialist, and allow access to his or her PHR. PHRs can also allow increased patient involvement in their own healthcare by enabling them to input their own data, research health issues, and potentially meet and share information with patients who have similar conditions. Of course, one question about this type of technology is how much interest patients will actually have in utilizing these capabilities. They seem to have particular promise for patients with chronic conditions.

### *Data Aggregation "Middleware"*

An important feature of today's environment is that there is relatively little standardization in the health data captured and stored by different providers of healthcare services. Although a great deal of data already exist in the form of claims data, prescribing information, lab and imaging results, and clinical records, much of this data is trapped in different, incompatible databases. The last few years have seen the emergence of new **middleware** products designed to extract data from disparate legacy systems and put them in a compatible format. Examples include products and companies such as dbMotion, ICA CareAlign, Medicity MediTrust, Microsoft Amalga, Oracle HTB, and Orion Health. These technologies can play a role in making the transition from the current environment with little interoperability and document-based data exchange to an environment where data can be easily accessed and queried and assembled for a broad variety of uses.

## The HITECH Act and Shifting Incentives

The discussion so far has highlighted barriers to the effective use of information technology in healthcare. Recent legislation, however, has started the Nation on what is potentially a new trajectory. In 2009, the **HITECH Act** (part of the American Recovery and Reinvestment Act, or ARRA) authorized expenditures on the order of $20 billion (with estimates in the range $9 billion to $27 billion) over five years to promote the adoption and use of EHR technologies that would be connected through a national health information network. The legislation sets forth a plan for the "meaningful use" of health IT to improve the quality of care and enable changes in delivery systems essential to healthcare reform.

The HITECH Act attempts to create incentives for all hospitals and eligible providers, not just those associated with large systems, to adopt and use electronic information. A centerpiece of the Act is to put in place strong financial incentives for hospitals and physicians to adopt and meaningfully use electronic health records. Physicians who adopt electronic records by 2014 can qualify for Medicare bonus payments of up to $44,000. Beginning in 2016, physicians who have not adopted electronic records will be penalized in the form of reduced Medicare reimbursements. Similarly, Medicaid providers can receive up to $63,750 over the five years. These payments and penalties depend on the provider meeting the requirements for meaningful use.

The definition of meaningful use under HITECH involves both ONC and CMS, but CMS is the principal rule-making body since payment will be linked to the reporting of meaningful use measures. The statute leaves CMS broad discretion, requiring only that the definition include e-prescribing, the ability to exchange information with other healthcare providers to improve care, and the reporting of clinical quality measures to CMS. With input from several Federal advisory committees, CMS has proposed to phase in meaningful use criteria in three stages. Stage 1 criteria, to take effect in 2011, focus on electronically capturing health information in a coded format, implementing decision support, sharing information with patients, testing the ability to exchange information, and initiating the reporting of clinical quality measures to CMS. Stage 2 criteria, to take effect in 2013, would require more robust exchange of information and other high value uses of EHRs. Stage 3 criteria, to take effect in 2015, would require physicians to demonstrate the use of EHR technology in ways that improve the outcomes of care. The broad goal is to gradually acclimate providers to workflow changes and practice improvement opportunities that, ideally, will accompany the adoption of technology.

Responsibility for implementing many other parts of the HITECH Act resides with the Office of the National Coordinator, discussed in the introductory chapter. In particular, ONC is responsible for developing policy guidance and a broader future vision for health IT. As we discuss below, it has already begun a series of important initiatives to further IT innovation and standards in a variety of areas. It also must work together with CMS and other Federal agencies. Indeed, as we now discuss, the division of authorities and responsibilities poses significant challenges.

## Opportunities and Challenges for ONC and CMS

In the short time since the HITECH Act was signed, ONC has moved forward on several important initiatives. Perhaps the closest to this report is ONC's recasting of the Nationwide Health Information Network project. The NHIN is composed of standards and services that enable secure exchange of

health information over the Internet, combined with a strong policy and trust framework that enables organizations to share health information with strong consent and governance to improve healthcare delivery while strongly protecting privacy and security. As we elaborate in Chapter Four, we believe that this initiative could benefit from a more aggressive focus on a universal, extensible exchange language and the development of associated national infrastructure.

The ONC has also moved forward in the important area of **clinical decision support** and enhancing usability of electronic record systems. With AHRQ and the Office of the Secretary, it has established a Federal "collaboratory" whose members now number more than 150 across more than 15 Federal agencies. The collaboratory has developed an inventory of federally supported CDS efforts, promoted sharing of best CDS practices, and identified needs and strategies that have resulted in new projects sponsored by ONC, AHRQ, and other agencies. Notable among these new projects is an effort to develop generalized representations of important medical logic (rules) that enables these rules to execute in the same way even if installed in different vendor systems. The ONC also has awarded a contract to the RAND Corporation to advance CDS. Work performed under the contract will advance the Nation toward a CDS knowledge repository, including the implementation of best practices and tools for sharing CDS interventions. It also will address the "alert fatigue" problem (the problem of too many inessential "pop-ups") by, for example, identifying those drug-drug interactions that are of highest priority. Another ONC initiative aimed at improving EHR usability is a collaboration with the National Institute of Standards and Technology (NIST) to develop usability testing programs that may become a part of EHR certification.

In addition to these efforts, ONC administers HITECH funding for Strategic Health IT Advanced Research Projects and has awarded four cooperative agreements totaling $60 million. An award to the University of Illinois at Urbana-Champaign addresses the challenges of developing security and risk mitigation policies and the technologies necessary to build and preserve the public trust as health IT systems become ubiquitous. An award to the University of Texas Health Science Center at Houston addresses the challenge of harnessing the power of health IT to integrate with, enhance, and support clinicians' reasoning and decision-making, rather than forcing them into a mode of thinking that is natural to machines but not to people. An award to Harvard University focuses on the development of a platform architecture that will facilitate substitutable applications—enabling the equivalent of the iTunes App Store for health—as well as supporting the electronic exchange and use of health information in a secure, private, and accurate manner. And an award to the Mayo Clinic College of Medicine focuses on strategies to make use of data that will be stored in EHRs for improving the overall quality of healthcare, while maintaining privacy and the security of the data.

CMS plays a rather different, yet pivotal, role in the national health IT effort, in large part due to its broader centrality in the Nation's healthcare system. As the Nation's largest payer, CMS has substantial leverage over healthcare providers. For example, it is often argued that the fee-for-service payment system used by CMS tends to reward volume over patient-centered goals like coordination and **personalization**. As noted above, some of the leading adopters of health IT, such as Kaiser and the VA, are systems with very different financial structures. Recent healthcare legislation (the Patient Protection and Affordable Care Act, or PPACA) supports many initiatives to reform healthcare payment and to advance CMS projects such as Medical Homes and Accountable Care Organizations, which aim to create incentives for coordination and more efficient care. As we discuss in Chapter Six these types of innovations can significantly complement health IT efforts.

Even more directly related to EHR adoption and use, CMS exercises substantial influence over the type of data that providers must collect. For instance, payment reforms based on quality of care measures require providers to collect and report these measures. This type of data plays a key role in current attempts to define meaningful use, where the idea is to create consensus "measures of quality," the collection of which can be translated into requirements for "meaningful use" incentive payments.

One concern with this approach, however, is that most quality measures depend on strict specifications that limit the flexibility to describe complex care coordination and functional outcome goals. Indeed, at this point, most are related only to individual specific conditions. The reason for this is that many of the validated, existing quality measures reflect medicine's traditional focus on treating particular illnesses, rather than on care coordination and health maintenance. Furthermore, most EHRs were designed around billing codes, not around rich clinical information that would give a more patient-centered view of the context and the true outcomes of care, especially as it occurs over longer periods of time. Legislation allows the Secretary of HHS to approve alternative pathways for these CMS payments. Thus, if more robust clinical data were available and easier for a sophisticated system to gather and report, the use of these data ought to be encouraged.

A second concern is the ability of CMS to receive and process any complex forms of clinical data. The historically underfunded IT infrastructure of CMS has not kept up with the constant new legislative demands for new programs, especially those requiring quality-of-care data for numerous **value-based purchasing** programs. The culture and structure of CMS, and the demanding time frames of each legislative mandate, have led to multiple separate data platforms and different administrative approaches to each of them. Thus, even within CMS, it is not currently possible to aggregate data, and (for example) physicians are required to double-enter specific codes to be eligible for quality incentive payments. Through certification standards for EHRs, ONC is trying to require that EHR vendors supply a short cut for physicians to do this, but even if this occurs, the specific data elements will not provide a full clinical picture of patient care, and will therefore provide limited constructive feedback to providers about areas for improvement and about the value of the aggregated data.

CMS has not been able to invest in the infrastructure needed for the enormous scope of its growing database and quality-of-care requirements. For example, a 2002-2003 data modernization plan that would integrate data across CMS programs was not funded until 2006, and now proceeds only slowly and incrementally. CMS recognizes that this work is far from complete. In planning stages, CMS has high level concepts for a transformed and modern payment system and an Enterprise Data Environment that could, if appropriately implemented, contribute to the goals of this report. However, lacking funding, implementation work has been stalled. Congress now recognizes that CMS must upgrade its own IT systems in order to handle clinical and other performance information and to ensure program integrity, and it has begun to authorize these important upgrades. Notably, PPACA charges CMS to accelerate work on the CMS Integrated Data Repository to incorporate into the model data from all Federal health programs. It also directs CMS to enter into data sharing agreements with the Department of Defense, the VHA, and the Social Security Administration.

While we have not investigated these issues further, it seems likely to us that a complete overhaul of CMS's IT infrastructure will be needed in the foreseeable future, not because of future health IT requirements but simply for it to comply with existing legislative mandates. The National Research Council has

recently begun work on a study of the CMS information system capability, with a preliminary report due by December 2010 and a final report due at the end of 2011. Because CMS's operational mission of payment processing must proceed without interruption, and because it is starting from a technologically outmoded base, it seems likely that any rebuilding of CMS's infrastructure will be a difficult and lengthy process.

This is an ideal time for the leadership of CMS to assess the overall capability of CMS to take advantage of modern computing and to set in place a plan to upgrade systems, break down silos, and reduce unnecessary barriers to state-of-the-art computing capability. Federal IT projects frequently incur cost overruns and schedule slippages,[38] and it will be a significant management challenge for CMS to avoid the fate of other government IT modernization and software development projects.[39, 40] There is clearly a danger that rapid and otherwise achievable progress in health IT, as envisioned by ONC and (even more aggressively) by this report, could be forestalled or derailed if it becomes tied to CMS's formidable IT challenges.[41] This must be avoided.

## Conclusion

The state of health IT today can be summed up as a mix of "the good, the bad, and the ugly." This diversity, and especially the fact that perhaps 80 percent of physicians still do not use electronic records at all, except possibly for billing functions, creates a dilemma. Given the difficulty of bringing the healthcare system forward into the computer age, should we focus on small incremental steps? Or, having seen the remarkable adoption rates and advances of Internet-based technologies in other sectors, should we push for a more radical advance that risks leaving some providers behind?

Fortunately, there is a bridge between these two extremes. It is the fact that the Internet-based technologies create a platform for "disruptive innovation," meaning innovations that upset the status quo and can broadly expand markets. Cloud-based technologies and PHRs are potential examples of disruptive technologies in health IT. These types of technologies might allow the 80 percent of physicians who are non-digital to leapfrog some of the existing limitations of EHR systems directly into more modern technologies. Indeed this is precisely what we want to happen, and it is a direction in which ONC and CMS could concentrate their efforts.

38. GAO. 2009. "Social Security Administration: Effective Information Technology Management Essential for Data Center Initiative," GAO-09-662T.

39. See, for example, GAO, 2008, "Information Technology: Agencies Need to Establish Comprehensive Policies to Address Changes to Projects' Cost, Schedule, and Performance Goals," GAO-08-925; GAO, 2008, "DOD Business Systems Modernization: Progress in Establishing Corporate Management Controls Needs to Be Replicated Within Military Departments," GAO-08-705; and GAO, 2008, "Environmental Satellites: Polar-Orbiting Satellite Acquisition Faces Delays, Decisions Needed on Whether and How to Ensure Climate Data Continuity," GAO-08-518.

40. Elm, J.P., Goldenson, D., El Emam, K., Donitelli, N., and Neisa, A. 2008. Survey of Systems Engineering Effectiveness—Initial Results. Carnegie Mellon University/SEI, CMU/SEI-2008-SR-034, at http://www.sei.cmu.edu/library/abstracts/reports/08sr034.cfm

41. Kibbe, D. C. 2010. Should Doctors Reject the Government's EHR Incentive Plan? *Family Practice Management,* 17:8.

In setting up a roadmap for how we might move in this direction, it is useful to specify a clear set of mid-term goals. These should include:

1. Universal access by clinicians and patients to the current frontier of EHR functionality.
2. A robust platform for developers to create user interfaces, decision support, storage, and archiving services that will be broadly available to end-users and will not require major capital investments.
3. Seamless, user-transparent, cross-organizational data exchange.
4. Innate, strong privacy protection on all data, both at rest and in transit.
5. Efficient means for the aggregation of de-identified data for public health and research purposes.

As already indicated in Chapter Two, we believe that there is *at least one* technical approach that can achieve all of these requirements. The approach that we favor, based on the exchange of metadata-tagged data elements, is described in detail in the next chapter.

**This chapter's bottom line:** Despite success stories from some early adopters, the current level of IT use in healthcare is uninspiring.[42] Recent initiatives, particularly by ONC, are shifting the incentives and may stimulate substantial EHR adoption. But a substantial advance and concentrated focus are needed to develop a scalable, national health IT infrastructure. New technologies can assist in taking the required steps.

42. There are exceptions, however. For example, in Massachusetts, 50% of all providers have comprehensive EHRs, and 33% of all medications are electronically prescribed.

# IV. Technology for an Integrated Health IT Ecosystem

## Introduction

The current health IT landscape is dominated by enterprise systems based on proprietary formats. These systems lack ability to communicate and aggregate health information in the ways needed to serve patients, doctors, and researchers. The systems have been designed primarily to enable point-to-point communication of administrative information rather than clinical data. Importantly, the nature of current systems makes it difficult for innovators to develop new tools to improve the use of health information. There are few policies or governance models to drive innovations, such as research, advanced clinical decision support, or benchmarking. In short, there is no fuel for an ecosystem of economically self-sustaining healthcare innovation.

The overarching goal is to have a national health IT ecosystem in which every consumer, doctor, researcher, and institution has appropriate access to the information they need, and in which these groups are served by a vibrant market of innovators. At the end of the previous chapter, we listed a set of technical and market-related requirements for enabling this overarching goal. Here, we look at several possible technological approaches and describe in some detail an approach that, we think, has the greatest likelihood of rapid forward progress.

## Earlier Models for Enabling Data Exchange

Over the last 20 years or so, an era dominated by vertically integrated, proprietary EHRs, one approach has been to seek to create **standardized health records**. Because the medical system has long relied on filling in paper records, it was natural to assume that exchange or reuse of data would be impossible without establishing standardized record formats that would be comparable across providers. However, we believe that any attempt to create a national health IT ecosystem based on standardized record formats is doomed to failure. First, there is too much diversity and incompatibility for any kind of *a priori* standard to emerge. With so many vested interests behind each historical system of recording health data, achieving a natural consolidation around one record format for any particular subset of data would be difficult, if not impossible. Second, systems based on fixed records are inherently limited in their functionality. Consider, for example, a health record in which all types of blood test information are always stored. When a new type of blood test is developed, it is difficult to expand the record to include it. Moreover, it is difficult to exchange only parts of such an electronic record according to a patient's choice (for example, blood glucose measures but not HIV status).

A second approach to health IT, spurred by the emergence of the Internet, has focused on service-oriented architecture (SOA) as a way to solve the problems inherent in standardized record formats. SOA essentially involves using software policies, practices, and frameworks to enable one user to access sets

of "services" on another party's computers and data.[43] For example, two hospitals, using two different systems, might create bilateral arrangements that enable them to run "services" on each other's systems to execute transactions or access data. The approach could be expanded to small networks, and even to networks of networks.

As an analogy, one might consider two libraries with completely different systems for filing books. Each library's users have no idea how to find books in the other library. But if each library sets up a "service desk" with an actual librarian, then the other library's users can get what they need by lining up at the service desk for assistance. This analogy also makes clear one of the big limitations of SOAs, namely scalability. A library's own users can all be looking for books on the shelves at the same time; but users from the other library must queue for the librarian "service."

There have been extensive efforts to implement the above approaches in local and regional HIEs that seek to connect multiple organizations. By 2009, there were more than 190 HIE initiatives in the United States—although only about one-third were fully operational.[44] These HIEs report lower costs, improved outcomes, reduced staff time spent on process-oriented work, and increased data exchange—demonstrating the benefit of health information exchange. But despite these benefits, these approaches fall far short of what is needed. Most HIEs are based on standardized record formats or integrated care systems that cannot readily scale. Others link a range of proprietary systems. If a patient moves between two hospitals even within an HIE, critical tests done at the first hospital must often be repeated.

Most HIEs face the administrative burden of requiring adoption of legal agreements at each provider organization to share data. In addition, HIEs that began as pilot projects do not appear to be spreading or scaling up beyond their initial scope because they were launched without significant attention to long-term business models, a problem that the meaningful use incentives may not overcome. Most HIEs, moreover, are not currently interoperable across regions and markets to other HIEs, and thus remained closed and proprietary even as patients seek and require care outside their confines.[45] Because each HIE system is different, there is little incentive for entrepreneurs who make middleware and other innovative tools to serve this marketplace.

While such systems can surely be incrementally improved, we believe that such approaches will not solve the fundamental need for data to be universally accessed, integrated, and understood while also being protected. In a sector as fragmented and rapidly evolving as healthcare, we believe it is impossible to build a national implementation of SOA solutions and directories that could be used and scaled indefinitely into the future. (To draw a loose analogy, the approach is like trying to enable free trade among hundreds of entities by negotiating a huge number of bilateral trade agreements. Or it is like trying to promote dialog among speakers of a thousand different languages by training one million translators, each knowing a pair of tongues, instead of enabling them to speak a common language. The idea is laudable but impractical.) Moreover, the approaches will not overcome the barriers to entry for innovators wishing to develop new solutions. We believe that a steady supply of such innovators in the ecosystem is essential for increasing quality and decreasing cost.

43. Sprott, D., and L. Wilkes. January 2004. Understanding Service-Oriented Architecture, *Microsoft Architect Journal.*

44. eHealth Initiative. 2009. Migrating Toward Meaningful Use: The State of Health Information Exchange.

45. However, a few interesting examples of HIEs working across state boundaries are starting to emerge.

## Universal Exchange Using Metadata-Tagged Data Elements

The best way to achieve a national health IT ecosystem is to ensure that all electronic health systems can exchange data in a universal exchange language. The systems themselves could be designed in any manner desired — they could accommodate legacy systems that prevail or new recordkeeping systems and formats. The only requirement would be that the systems be able to send and receive data in the universal exchange language.

We believe that the natural **syntax** for such a universal exchange language will be some kind of extensible markup language (an **XML** variant, for example) capable of exchanging data from an unspecified number of (not necessarily harmonized) **semantic** realms. Such languages are structured as individual data elements, together with metadata that provide an annotation for each data element.

With some risk of oversimplifying, let us give an example. Imagine that an elderly patient has lived in several different cities and, over the years, has had mammograms done at various hospitals and clinics. Her physician now needs to retrieve images of her breast tissue over the previous decades to determine whether a current lump is of concern. In a health IT ecosystem where tagged data elements make up a universal language, the data elements the doctor could retrieve about this patient would include the mammograms themselves from all of the various places the patient has sought treatment regardless of provider network, geographic location, or whether the patient remembers them. The physician would be able to securely search for, retrieve, and display these privacy-protected data elements in much the way that web surfers retrieve results from a search engine when they type in a simple query.

What enables this result is the metadata attached to each of these data elements (mammograms), which would include (i) enough identifying information about the patient to allow the data to be located (not necessarily a universal patient identifier), (ii) privacy protection information—who may access the mammograms, either identified or de-identified, and for what purposes, (iii) the provenance of the data—the date, time, type of equipment used, personnel (physician, nurse, or technician), and so forth.

Most of the time, the metadata will not be needed by the physician; this information will be invisibly in the background. Occasionally, as in the case of a false positive or false negative in a particular image, the physician may want to dig deeper: The metadata will be there.

The metadata will also be important for researchers who may have access only to de-identified data. They might use it, for example, to determine whether a certain type of imaging equipment for breast cancer is yielding excessive numbers of wrong diagnoses. This could result in improvements or recalls of particular devices and improvements in software.

## Data Element Access Services

In the example above about retrieving multiple mammograms, we assumed more than simply a universal exchange language. We also assumed the existence of certain national infrastructure for *finding* health data, and for controlling access to it. (Importantly, though, we have *not* assumed a national repository for *storing* health data, which would be a more difficult and politically problematic issue.) We call this infrastructure, collectively, **data-element access services**. The services would include those

associated with crawling, indexing, security, identity, **authentication**, **authorization**, and privacy. As proposed, these DEAS and their components would have no right to *use* the data being exchanged; in fact, they would probably not even see the data.[46]Rather, they would act much like today's web search engines, but with additional levels of responsibility for exposing only those data elements authorized by applicable privacy rules and policies (including a patient's persistent privacy choices) and only to authorized, authenticated users. A patient would have the right to restrict the types of data elements indexed at all, or could opt out of the DEAS completely (although such a choice might negatively impact that patient's future care). We discuss privacy protection and security in more detail in Chapter Five.

Today, when a user views a web page, the data that make up the various parts of the page (text, images, ads, audio, video, etc.) are dynamically aggregated in real time from numerous computers in a range of *physical* locations and are then presented to the user as a single *logical* entity: the web page being viewed. The individual elements are not routed through any central server or repository. Rather, a set of access services enables the browser to query many distant computers simultaneously. Similarly, for health IT, a query submitted to the data-element access services would result in the seamless, dynamic aggregation of all the data requested. For example, a doctor's request for patient information could involve an indexing system identifying all the physical locations on the network of the data; real-time aggregation of the data; and analysis, translation, and presentation by the software application that the doctor is using.

The health IT ecosystem we envision does not require the existence of a uniform patient identifier. Instead, it could use associations of intrinsic patient-related information to link the appropriate data to specific patients**.** This method is used now to create patient record locators within local closed systems and regional health exchanges, but as employed today, it can be plagued by human error.[47] Since an automated system can use many more than the two factors (such as name and birthdate) now often used, it can be correspondingly more accurate.[48] Indeed, "identity resolution" is an established technology, with commercial offerings available.[49] For greater accuracy and convenience in the record-keeping associations, some patients (e.g., those named "John Smith") might elect to index their records by an email address or a reference to a personal health record account, but this would be optional.

How should DEAS be brought into existence and operated? There are several viable options: Individual states (or self-formed groups of states) could establish and operate DEAS. Federal funds might be used in the manner of a "race to the top," to support the best state's proposals, or to create an additional interoperating and intercommunicating DEAS for use by Medicare providers. DEAS could be established in large health delivery networks (including those operated by the Federal Government, such as the Veterans Administration). They could emerge from a more aggressive push toward achieving interoperability among existing HIEs. Or, their growth could be left to the private sector, perhaps seeded by some start-up funds in response to requests for proposals.

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46. As a privacy choice, a patient might choose to hide even *the existence* of certain data from the DEAS, for example the fact that he/she had received treatment at a particular facility. In making such a choice, the patient would understand that his/her own future physicians would be unaware of this data, with possible negative effect on their ability to deliver the best care.

47. World Health Organization 2007"Patient Identification", Patient Safety Solutions, vol. 1, solution 2, at http://www.ccforpatientsafety.org/common/pdfs/fpdf/presskit/PS-Solution2.pdf

48. Markle Foundation 2005 Linking Health Care Information: Proposed Methods for Improving Care and Protecting Privacy, at http://www.connectingforhealth.org/assets/reports/linking_report_2_2005.pdf

49. See, e.g., J. Jonas, 2006, Threat and Fraud Intelligence, Las Vegas Style, *IEEE Security and Privacy*.

As a matter of engineering, fewer DEAS providers is better, since communication between DEAS in response to queries is an additional overhead, but this must be weighed against socio-technical, governance, and policy forces favoring a more distributed network of DEAS.

In any case, all DEAS would need to be interoperable and intercommunicating in conformance to a single Federal standard, and would need to be audited for compliance with privacy and security policies. In response to a HITECH mandate, ONC has already begun a process for establishing governance of the NHIN.[50] This process might also explore how best to operate DEAS.

## Advantages of the Tagged Data Element Approach

Because of its multiple advantages, we advocate a universal exchange mechanism for health IT that is based on tagged data elements in an extensible markup language. If there were another equally good solution, it should also be considered; we have collectively been unable to think of one.

Tagged data elements can be combined for a single patient to produce the equivalent of an EHR, and organized around the needs of that patient at the time of care. At the same time, the data can be analyzed and combined with links to other information to provide physicians with clinical decision support, delivering patient-specific information to their fingertips to make the best possible decision for a patient given all of the information available. Tagged data elements from aggregated populations can also be combined to analyze comparative effectiveness of aspects of healthcare and improve efficiency and quality.

Since the language of metadata-tagged data elements is extensible, not fixed, it can itself evolve in response to the development of new applications and new medical knowledge. As already mentioned, extensible exchange languages exist today and are already used within health IT in specialized niches—and are used widely in other sectors. A main finding of this report is that the time is ripe for such a language to be declared as a universal exchange language for health IT, and that doing so will catalyze a large number of immediate and longer term advances.

Tagged data elements can be extracted by special software (known as middleware) from existing clinical systems. Or they can be produced from enhanced versions of those systems, or by completely new and innovative applications. In this way, all data could be exchanged among all systems no matter the origin or internal record formats of the data, and without the necessity of replacing existing legacy software.

A universal data exchange language can scale up to any level. It can allow retrieval by patients and physicians of information from different providers, in different parts of the country, to improve safety and coordination. It can deal with the diversity and complexity of both the underlying business and clinical systems. New types of data and associated metadata can be added at any time, since new data elements do not have to fit into a particular format. Data can be converted to whatever form best supports their intended use, from clinical diagnosis to medical research. This approach can create a fully interoperable, less costly, more effective national health IT ecosystem.

The availability of a universal exchange language can dramatically accelerate the entry of third-party innovators, because they can create applications that rely on uniformly described data elements and can access a larger market. These new applications could include cloud-based subscription services for individual doctors, small healthcare practices, long-term care facilities, large practices, and hospitals to

50. Government Health IT. June 25, 2010. ONC to issue "rules of the road" for NHIN Exchange. See http://www.govhealthit.com/newsitem.aspx?nid=74064

handle practice management (e.g., registration, scheduling, and billing); sophisticated medical systems (e.g., decision support, integrated lab ordering, medication management, allergy tracking); integrated medical-image management; **integration engines** to facilitate data exchanges with personal health records and other types of EHR in the cloud; and population health management (e.g., analytical tools for public health reporting, clinical research, and outcomes analysis).

The approach that we describe is consistent with existing market trends. Innovative companies are emerging that can access data from existing records and rearrange, store, and exchange the data as desired. Other companies are offering advanced software applications, information, and other services via the Internet. PHRs allow patients to store and monitor all of their health information and research their conditions using the full range of electronic resources.

The approach described does not require the creation of a uniform patient identifier or a national repository for healthcare data. The data, protected by strong **encryption**, can be stored on existing legacy systems or in the rapidly evolving "cloud" of distributed data stores.[51] Data involving a particular person can be stored in many different places and then aggregated, just as individual web pages are constructed from elements stored on many different computers. Specialized and secure search engines can crawl and index the metadata while actual access to the underlying data remains constrained by privacy protections.

This system can provide much greater security and privacy protection than can the current system. The attached metadata would describe the use and access provisions of the data, in accordance with law, policy, or the patient's privacy preferences where applicable. For example, in a circumstance where consumers give their consent for particular uses of their data and prohibit other uses, this information would be encoded in the metadata. For example, privacy restrictions embedded in the metadata could permit a physician to send a pharmacist the data required to fill a prescription and permit de-identified data to be used for clinical research, but restrict other uses of the data. Privacy considerations are discussed in greater detail in the following chapter.

**This chapter's bottom line:** A universal language for the exchange of health data is needed. An extensible markup language, where individual pieces of data can be tagged with context-setting metadata, is a straightforward solution and is superior to other proposed architectures.

51. Currently installed systems that do not encrypt data "at rest" can be upgraded evolutionarily over time, but would be required to encrypt data "in transit" when it is shared with another system.

# V. Privacy and Security Considerations

## Introduction

A key advantage of the tagged data element approach is that it will allow a more sophisticated privacy model, one where privacy rules, policies and applicable patient preferences are innately bound to each separate tagged data element and are enforced both by technology and by law. In this chapter, we briefly review the present situation as regards the privacy protection of medical information, and then explain the technology building blocks that will enable better approaches.

## The Present Framework

American ambivalence about integrating health IT into the healthcare system is rooted in significant part to concerns about privacy and security. Even though a large majority of Americans believe that electronic health records will improve the coordination and quality of care,[52] many Americans also believe that there is a reasonable likelihood that unauthorized users will view such records.[53] For example, a 2006 survey for the Markle Foundation found that 88 percent of Americans believe digital records will reduce the number of unnecessary or repeated tests and procedures they undergo.[54] However, this survey also found that 80 percent of respondents were "very concerned" about theft or fraud, 77 percent were equally concerned about use of their records for marketing purposes, 56 percent were worried that employers would see their health records, and 53 percent expressed concerned that insurers would, too. A solution to this perceived privacy problem must underpin any overhaul of the medical-data ecosystem.

Concern about the privacy of medical data is predicated on a range of factors. First is the potential for discrimination—in access or economic terms—that might influence health insurance or employment. Second, for some consumers there is a sense that medical data are "different" than other personal data. From this perspective, financial data involve something an individual has, whereas medical data involve what an individual is. Third, the use of personal medical data by others is potentially exploitative. People may be comfortable with having their de-identified data used for beneficial purposes like disease research, but not if they believe that commercial interests may use such information to try to sell them something or otherwise exploit it. Finally, Americans harbor deep-seated fears about possible government access to *any* personal data.[55]

The HIPAA Privacy and Security Rules, which went into effect in 2003, establish a Federal floor of protections for health information. The Privacy Rule, as amended by HITECH, regulates the use and disclosure of identifiable health information held by health plans, including employer-sponsored; health clearinghouses; and health care providers who engage in certain administrative electronic transactions (such as

52. NPR, Kaiser Foundation, and Harvard School of Public Health. March 2009. Cost, Privacy Top Health Care Concerns.

53. Electronic Privacy Information Center. Medical privacy public opinion polls.

54. Lake Research Partners and American Viewpoint. November 2006. Survey Finds Americans Want Electronic Personal Health Information To Improve Own Health Care.

55. McGraw, D., J. X. Dempsey, L. Harris, and J. Goldman. 2009. Privacy as an Enabler, Not an Impediment: Building Trust into Health Information Exchange. *Health Affairs,* 28(2):416-27.

submitting claims electronically (collectively called "covered entities") and their business associates.[56] In general terms, the Privacy Rule permits, but does not require, the disclosure of identifiable health information for treatment, payment and various health care operations without the express written permission of the patient. The Rule also permits the disclosure of identifiable health information for research and public health without patient permission, as long as a number of other specific, detailed conditions are met. As a Federal floor of protection, the Privacy Rule does not supersede state laws that are more stringent, such as those that require patient consent to exchange health information for treatment purposes.

## The Need for Strong, Persistent Privacy Protections

To build and maintain the public's trust in health IT requires comprehensive privacy and security protections that are based on fair information practices and set clear rules on how patient data can be accessed, used and disclosed, and that are adequately enforced. An individual's right to have some meaningful choice in how their information is shared is one important component of a comprehensive set of protections. Where such choices are provided, either in law or by policy, they must be persistently honored.

A patient cannot make meaningful privacy choices unless he or she understands the flows and uses of information and can therefore make informed choices. That is not the reality today. In practice, the current consent model mandated by HIPAA rarely allows fully informed choices. HIPAA allows many common disclosures (for example, for treatment, payment, and healthcare operations) without any consent at all. Some other disclosures are allowed unless the patient specifically opts-out. Some particular transactional flows of data require patient approval, but patients have little real information about those flows or the uses to which they will be put. As seen by the patient, HIPAA protection is often little more than "sign here to acknowledge that you understand your rights under HIPAA," which, of course, few patients do.

Some provisions of HITECH are intended to remedy this situation and give patients more control over the flow of their health information. For example, patients now have the right to restrict a provider from disclosing identifiable health information to a health plan when the information relates to treatment for which the patient has paid out of pocket. In general, however, patients have limited control over the way their health information is shared.

An exchange language based on tagged data elements allows for privacy rules and policies to be more effectively implemented; it also allows for more finer grained individual privacy preferences to be more persistently honored[57], and it can potentially allow patients to make better informed, persistent privacy choices not just in the rush of a medical encounter but reflectively and in an informed manner. For example, in circumstances where patient consent is required by law, policy, or practice, as part of enrolling with a primary care physician, a new patient might be asked questions like these: Do you want your primary care physician to be able to see your complete medical record, including from other places that you have been treated in the past? Do you want this to be automatic for places where you may be treated in the future? Do you want your physician to be able to consult with other physicians and

56. 45 CFR Parts 160 and 164. Summaries at http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html

57. See, for example, Health IT Policy Committee, Privacy and Security Tiger Team, transcript of Consumer Choice Technology Meeting (June 29, 2010), at http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=2833&PageID=19477

share relevant records with them at his or her discretion? If you are brought to a hospital emergency room, do you want them to be able to access your medical records without asking you? What if you are unconscious? Do you have a personal health record, and do you want your medical information to be automatically synchronized with it? Are there parts of your health history that you do not want disclosed to another doctor, such as treatment for mental illness? Do you want to be notified (or have your physician notified) when research using your data suggests new options for your own care?

There are pros and cons to the different possible answers to the questions in this example, and patients, in consultation with their physicians or other counselors, must understand these. For example, a physician must be able to know when a patient has chosen to withhold data and may not ethically be able to treat a patient who withholds medically necessary information. As a general principle, the more information that patients consent to make available in clinical situations, the more likely they are to benefit from better diagnosis and treatment options, especially those that may depend on their specific personal histories or genetic makeup.[58] Similarly, in sharing their information for research purposes, patients participate in a social contract that benefits everyone in general, but may also (with the help of an enabling health IT infrastructure) benefit themselves directly. Privacy and security protections need to be seen as enabling population research, not unnecessarily limiting it.

While face-to-face counseling on privacy choices should be available whenever choice is either required by law, policy or practice, most patients will probably educate themselves on the issues and make privacy choices through a web interface, where they will also be able to change their choices at any time. An important point is that, when patients have a meaningful opportunity to choose, a patient's choices will be persistent, that is, continuing until changed. Most patients ideally will have elected privacy choices at a time when they are healthy and competent. This is truer to the principal of informed consent than is a rushed signature at the time of a medical emergency, or when the patient's physical or mental competency is compromised.

## Deleterious Effects on Medical Research and Care

The HIPAA Privacy and Security Rules, as well as sometimes more stringent state laws and regulations, were intended to enhance the privacy of health information. However, they have had the unintended consequence of freezing its exchangeablity. The complex mandates of both HIPAA and state laws and regulations leads organizations to equate protection to sequestration, with little or no provision for either access based on roles (for example, the needs of an emergency room physician) or for legitimate secondary uses of data (for example, epidemic tracking), although HIPAA itself actually does allow disclosures in many such cases.

Even before HITECH, some organizations' interpretations of HIPAA had proved detrimental to medical research and, potentially, care. For example, a 2005 study by the University of Michigan found that implementation of the HIPAA Privacy Rule was followed by a drop from 96 percent to 34 percent in the percentage of follow-up surveys completed by patients being monitored after a heart attack.[59] The report concluded that the Privacy Rule "significantly decreases the number of patients available for outcomes

58. The need to have an unbiased second opinion may be an exception to this principle.. Henriksen K. and H. Kaplan, H. 2003. Hindsight bias, outcome knowledge and adaptive learning Quality and Safety in HealthCare 12:ii46-ii50,

59. Armstrong, D., E. Kline-Rogers, S. M. Jani, et al. 2005. Potential Impact of the HIPAA Privacy Rule on Data Collection in a Registry of Patients with Acute Coronary Syndrome. *Archives of Internal Medicine,* 165:1125-1129.

research and introduces selection bias in data collection for patient registries." Similarly, a 2006 study by the U.S. Government Accountability Office found that healthcare providers were "uncertain about their privacy responsibilities and often responded with an overly guarded approach to disclosing information to ensure compliance with the Privacy Rule.[60]

It seems likely that the modifications to HIPAA enacted in Subtitle D of the HITECH Act—in particular those that require covered entities to track all disclosures to associates[61]—will further stifle innovation in the health IT field while offering little additional real-world privacy protection. The limitations of HIPAA and the HITECH provisions (sometimes referred to as HIPAA II) should be reformulated so that they ensure both patient privacy and patient benefit from medical research, in a world where medical data are increasingly in electronic form and where there is a growing need for real-time or near-real-time aggregated data to improve healthcare. A recent report from the Institute of Medicine suggests that these policies need a major overhaul to enter the electronic age.[62]

## Data Security: How Good Is Good Enough?

An exchange language based on tagged data elements enables a fine-grained model for addressing privacy, including honoring a patient's privacy preferences. However, this model is only as good as the level of security applied to the data itself. If an unauthorized user can compromise data security, and not get caught in doing so, then he can also compromise any patient privacy model.

In data security, the perfect is often very much the enemy of the good. It is important that criteria for electronic security measures not be overspecified to the point of impossibility. A useful point of comparison is the degree of security inherent in old-fashioned paper records stored in folders in a medical file room. These paper records are completely secure against large-scale, remote electronic "phishing" to sift through the records to find particular nuggets of information. File rooms seem *in practice* to be fairly secure against massive compromises even by physical means: breaking and entering to steal large numbers of paper medical files would not be a difficult criminal exploit, but it occurs virtually never.[63]

By contrast, paper records provide much less protection against unauthorized compromise (e.g., by copying) of the medical record of a single, targeted individual. We can infer from publicized cases that this happens regularly (for example, in the case of celebrities[64]). While private investigators cannot in most cases obtain a third party's medical records legally, they appear to have a significant ability to do so nonetheless. There is no reason to think that paper records are more secure than electronic records in the scenario of targeted individuals, since the exploit is typically enabled by suborning an insider with access to both paper and electronic records, or by social engineering (e.g., wearing a doctor's gown and walking into an unattended file room). In fact, paper records lack intrinsic security that is provided

60. J.F. Wilson. 2006. Health Insurance Portability and Accountability Act Privacy Rule Causes Ongoing Concerns Among Clinicians and Researchers. Annals of Internal Medicine 145(4):313-316.

61. Public Law 111-5 (2009), especially Sec. 13405 (42 USC 17935), at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/hitechact.pdf#page=39

62. Nass, S. J., L. A. Levit, and L. O. Gostin, Eds. 2009. Beyond the HIPAA Privacy Rule: Advancing Research, Improving Health Through Research. Washington, DC: National Academy Press. http://www.nap.edu/catalog.php?record_id=12458

63. But see, for example, PI Newswire, "Medical Records Found in DMV's Dumpster," June 3, 2010, at http://www.pinewswire.net/2010/06/medical-records-found-in-dmvs-dumpster

64. For examples, see "Celebrity Medical Records in Massive UCLA Breach" at http://www.huffingtonpost.com/2008/08/05/celebrity-medical-records_n_116968.html, and "Exposed: Clooney's Medical Records" at http://abcnews.go.com/GMA/story?id=3711136&page=1

by even the most elementary electronic security protections. There is no way to tell if a paper record has been read or copied, for example. By contrast, an electronic system with basic authentication (by username and password) and auditing (of file accesses) preserves a record of who accessed what.

We can draw several conclusions: A health IT infrastructure needs to provide *significantly better* security than traditional paper records in all respects. It must be designed with *very strong* technical protection against remote, bulk attacks that compromise large numbers of records, because paper records do not have this vulnerability. The security of a single individual's information needs both technical protection and also protection by regulation and criminal law. Technical protection alone cannot prevent the suborning of otherwise authorized individuals, but it can greatly raise the bar by making them likely to get caught.

In today's healthcare sector, there is an astounding range of security practices in handling electronic data, ranging from excellent to poor. Importantly, there is little consistency in security practices. Sloppy practices have led to system failures at multiple levels, such as the massive compromise of personal data in a stolen laptop computer[65] or a burglarized hard disk drive.[66] In a well-designed system, as one example, it should be technically impossible for any individual to aggregate large numbers of records in an exportable format, and there should be multiple layers of real-time auditing to be sure that it is not in fact happening. We next turn to the question of whether it is possible to design appropriate protections for the privacy of electronic health records.

## A Health IT Architecture for 21st-Century Privacy and Security

We believe that a universal exchange language based on tagged data elements will allow the design of much better privacy and security protection than currently exists for either paper or electronic systems, for two principal reasons. First, the ability to tag an individual piece of data with privacy-related information, as part of its metadata, enhances privacy safeguards. Second, because tagged data element exchange protocols are designed to be efficient for the rapid exchange of small pieces of data, it is feasible to use security protocols that involve multiple exchanges of challenge and response. We illustrate these points in this and the next subsection.

How would this all work behind the scenes technically? Here we review briefly some of the technologies that can be combined to produce a well-designed system for protecting patient privacy, and indicate some of the design choices that will need to be made in creating such a system.

Encryption is the basic technology of making data completely unreadable unless it is brought into contact with a separate, smaller piece of data called the encryption **key**. Each piece of data can have its own key, or multiple pieces can have the same key. There can be several different keys that unlock the same data—for example, one for ordinary use and another (kept somewhere else) for rare emergencies.

A likely design decision would be that all patient information should always be encrypted either when stored or transmitted. Encrypting all "data at rest" (stored as on hard disk drives) protects against physical

65. InformationWeek January 30, 2008. "Laptop Stolen With Personal Data On 300,000 Health Insurance Clients," at http://www.informationweek.com/news/security/showArticle.jhtml?articleID=206100526

66. WBBM Chicago May 27, 2010. "Nearly 200,000 Are Potential ID Theft Victims," at http://cbs2chicago.com/investigations/ID.theft.2.2.1719905.html

data breaches like misappropriation of hardware from healthcare IT data centers. Encrypting data "on the wire" (transmitted over networks), and authenticating the endpoints of every network connection, help defend against various network attacks, such as eavesdropping and misdirection of sensitive data to unauthorized parties.[67]

Another design decision could be to specify that a key for patient information is never stored (or even present) on the same computer system that holds its corresponding patient data. That would enforce technically that there be a *transaction* whenever data are to be used: the data must come from one computer system, and the key from another. The two computer systems can be physically distant, and managed by different organizations, so as to make insider threats much less likely. Transactions (which can themselves be encrypted) can be monitored and audited by a security infrastructure that is also independently managed.

Crucially, each encrypted datum carries metadata governing its specific use and access. These metadata are inseparable from the data and are inviolable, protected by a **digital signature**. While metadata are themselves likely encrypted (another design choice), their keys are, by design, known to an authorized set of secure search engines so that, for example, all the records of a particular patient can be located. However, the search engine has no access to the (differently encrypted) actual patient data.

Identity is also a crucial aspect of security. Determining the identity of a principal is commonly called authentication. Except for patient-consumers, all of the principals in the health IT system can be authenticated using physical credentials (such as smartcards), biometrics (such as fingerprints), and a secret such as a password. Requiring two of these three methods, a possible design choice, is termed "**two-factor authentication.**" Credentials could be issued to healthcare professionals by participating institutions and medical-certification agencies. Whenever data are accessed, an audit mechanism records the actions taken by principals, along with the information used to authorize those actions. Credentials can be revoked when necessary.

An authenticated principal has the right to perform actions in the system. Some rights might come from the identity of the principal (e.g., a patient has the right to see her records), while others might come from the role held by the principal (e.g., an emergency-room doctor has the right to see the medical record of an unconscious patient). Determining the rights of an authenticated principal is commonly called authorization. In the healthcare security system, a range of designated, authorized roles can be pre-consented, and anybody who presents the role credential will get appropriate access for a particular situation. This credential does not attach to the individual; it attaches to each specific role. For example, when an emergency-room doctor leaves for home, his or her role-based authorization is deactivated.

Finally, an audit mechanism records the actions taken by principals in the system along with the information used to authorize those actions. A secure audit mechanism must provide strong protection so that audit records cannot be tampered with or deleted. For example, an audit system must record any access, modification, or deletion of a patient's health records and any changes to the associated authorization policies. In case of an error in a patient's health record, the audit mechanism would reveal the

67. While the breach notification requirements of HITECH provide significant incentives for encryption, they do not require it.

principal who introduced the mistake and the authorization information for that access. Strong audit mechanisms can be implemented using cryptographic and other techniques.[68] Patients should have the right to review audit records pertaining to their data.

A well-designed combination of encryption, authentication, authorization, and, for research uses, de-identification can yield a health IT infrastructure that is secure, and where all principals are auditable. It can have strong protection against bulk data theft (for example, using real-time audit mechanisms on top of all the other controls), and be significantly better protected against insider threats to individual patient privacy than present paper or EHR-based systems. As already noted, technical security, no matter how effective, must also be augmented by administrative, civil, and criminal penalties. Because technical measures can never be perfect (especially against insider threats), it is ultimately these penalties that deter willful misuse by individuals or negligence by institutions. What well-designed technical measures can do is to make data compromises very difficult to perpetrate, and thus very rare.

## Privacy Protection of Metadata-Tagged Data Elements

By way of example, let us look somewhat more closely at how the general technologies described above might be combined in an infrastructure based on tagged data elements. For the purposes of this example we will make an arbitrary set of design choices, not necessarily those that might be made after a careful systems study. Suppose that the data elements in question are, as in a previous example, the mammogram history of a particular patient, Abigail.

In a first scenario, suppose that Abigail's physician, Dr. Jones, queries to bring up all of Abigail's previous mammograms. The data element access services (DEAS) described in Chapter 4 first check that Dr. Jones has properly authenticated herself to the system and that she is in a role (e.g., primary care physician) that allows her to issue queries of this type. It then assembles (based on Abigail's name, date of birth, present and previous addresses, and so forth) a list of locations at which Abigail has medical records and has given prior consent for them to be locatable (assuming that rules or policies are in place requiring such consent).[69] If Abigail has consented to have the nature of her medical records also indexed (e.g., that some locations hold mammogram records, while others hold blood test records) then the list of locations can be pruned to a smaller number; otherwise the DEAS has no medical information and does no pruning. The DEAS now sends the locator information list (analogous to the web's "https://" universal record locators) to the EHR system on Dr. Jones's computer. That system, not the DEAS, then fetches the actual tagged data elements, each one containing a previous mammogram. It is important to note that the DEAS never has access to the mammograms themselves (the clinical data), and has access to even a description of the clinical data (the fact that it is a mammogram) only with patient consent. While most patients may elect a default choice that allows more efficient indexing and location of their records, the DEAS is designed to also serve (albeit with reduced efficiency) patients who choose to impose greater privacy restrictions on their data.

68. Markle Foundation (2006) Implementing a Trusted Information Sharing Environment: Using Immutable Audit Logs to Increase Security, Trust, and Accountability. at http://www.markle.org/downloadable_assets/nstf_IAL_020906.pdf

69. Abigail has chosen to exclude from indexing, for example, that as a teenager she was once treated for a drug overdose.

Can Abigail's mammogram images now be displayed? No, because they are still encrypted. For each data element, Dr. Jones's computer now queries another service of the DEAS for the required decryption keys. These requests include, again, Dr. Jones's own authentication data and role. They now also include the digitally signed (and therefore unforgeable) patient privacy preferences that accompany each mammogram as metadata. The DEAS examine whether Dr. Jones's credentials and role are consistent with Abigail's privacy choices. If they are, the DEAS send back the individual keys, and Dr. Jones's computer displays the mammograms. If they are not, then an explanatory message is sent and the mammograms are not displayed. In either case, the entire transaction is summarized in an audit record that goes, in real time, to a layer of security checking designed to look for anomalous signs of misuse. Such signs might include the collection of more patient records by a single supposed clinician than can plausibly make sense in that clinician's role, or a pattern of requests from a single facility for data on patients with whom they have no previous relationship and for whom they cannot supply any required evidence of patient interaction.

Notice that, in this and all scenarios, data and key are brought together only in the clinician's computer, and only for the purposes of immediate display; decrypted data are not replicated or permanently stored locally. Note also that the multiple data storage locations never had access to the keys, so compromise of their data, even by an insider with physical access, is impossible. Similarly, the DEAS that managed the keys never saw the data.

In a second scenario, suppose that an NIH researcher, Dr. Garcia, is studying the comparative effectiveness of two different mammography techniques. His credential and role identify him to the DEAS as authorized to receive only de-identified data from patients. When Dr. Garcia queries for data, he receives 100,000 locator records for mammograms meeting these criteria. However, these locator records are different from those returned to Dr. Jones's in the first scenario. Their unforgeable digital signature specifies that they may only be used to locate de-identified data. When Dr. Garcia's computer now sends out for the 100,000 mammograms (and their accompanying metadata), they come back de-identified, and they contain a digital signature that so certifies. Dr. Garcia's new DEAS queries for the individual decryption keys must now contain (i) his own authentication and role as researcher, (ii) the digitally signed privacy requirements and preferences (where applicable), and (iii) the certification that the data have already been de-identified. Only if everything matches do the DEAS provide Dr. Garcia's computer with the decryption key for each piece of de-identified data.

These examples are intended only as illustrations. In fact, the computer exchanges would be even more complicated than indicated. The fields of computer security and data protection are sophisticated and highly developed. While the web will continue to be full of reports of data compromises in badly designed systems, or systems subverted by bad management practices, there is no reason that a national health IT infrastructure should be designed and managed at less than state-of-the-art best practice. Our judgment is that such best practice can yield much better privacy and security for health IT than today's scattered approach, and also can be much more enabling of secondary data uses such as public health and research.

**This chapter's bottom line:** The tagged data element approach allows for a sophisticated, fine-grained model of implementing strong privacy controls (including honoring patient-controlled privacy preferences where applicable) and strong security protection.

# VI. Economic and Regulatory Issues

## Introduction

Many economic and regulatory steps need to be taken to realize the technological opportunities described in this report. This chapter offers a succinct discussion of some of the main issues. An important consideration here is that many aspects of health IT, particularly those associated with data exchange and aggregation, have "public good" characteristics. Because the benefits of a networked health infrastructure will be distributed widely, while costs are borne locally, market forces may fail to generate appropriate incentives for providers to invest in interoperability or to allow their data to be indexed and accessed. The public good nature of the problem calls for coordinated leadership to implement standards for interoperability and to enable indexing and retrieval of patient records. At the same time, policy makers need to create market conditions that reward information exchange, and enable market innovation to deliver the IT services and applications that can ultimately have a major effect on healthcare systems.

The technological approach described in Chapters Four and Five relies on two key elements. The first is the adoption by providers of interoperability standards that enable data to be shared across institutions. The second is the creation of network infrastructure and administration that enable distributed data to be indexed and accessed subject to appropriate data access restrictions. Both have the public good features mentioned above, in much the same way as investments in transportation or communications networks. We argue that Federal leadership exercised by ONC and CMS can play an important role in furthering both interoperability investments and network infrastructure development.

## Standards and Incentives for Interoperability

As described in Chapter Four, one way to enable scalable data exchange and new application development is through the adoption of *standardized metadata* that enable patient data to be indexed, queried, transmitted, and re-assembled for different uses. This route to interoperability does not mean that every provider has to adopt a standard health record format or reconfigure its approach to inputting and managing patient records. Indeed, we pointed out that technology already exists and is offered by a variety of middleware providers that enables existing systems to become interoperable in this fashion.[70]

Nevertheless, the economic environment poses substantial roadblocks for investments in interoperability. There is not yet a recognized standard for health metadata, and healthcare organizations and technology providers considering adoption of a standard face a coordination problem. Even for the healthcare systems that are leaders in using information technology, there is little private incentive to focus on widespread interoperability unless other providers are making the same investment and there is a clear path toward productive data exchange.

70. Halamka, J. November 11, 2009 *The Magic of Middleware*. Life as a Healthcare CIO, at http://geekdoctor.blogspot.com/2009/11/magic-of-middleware.html

Furthermore, the economic incentives of healthcare providers may not be strongly aligned with making patient data exchangeable. Healthcare providers with their current closed data systems may view their data at least partly as a proprietary strategic asset. A hospital may have an incentive to exchange data with local clinicians, improving patient care and tethering the clinicians more closely to the hospital. But the incentives become less clear if the hospital is contemplating exchanging data with competing hospitals or with providers who are not local and with whom it shares few patients.

The local and regional health information exchanges discussed in Chapter Three have gone some distance toward promoting data transfer between institutions. But these models in their current form do not use a tagged data element approach that enables parties to flexibly assemble and re-assemble data elements in different ways to respond to different types of patient encounters, address population questions, track drug effects or epidemics, or enable clinical research. Moreover, as described earlier, local and regional exchanges will not provide a clear route toward national interoperability if they adopt different standards or settle on different governance models for regulating data access.

Federal leadership, therefore, has a clear role to play in coordinating standards for health metadata and in creating economic incentives to adopt the standard. The definition of meaningful use and the rewards for being a meaningful user (and penalties for not being one) are powerful mechanisms for doing this. Current work on meaningful use already has begun to incorporate interoperability standards. The initial recommendations by the Health IT Standards Committee that were transmitted to ONC in March 2010 do describe data exchange standards that providers must adopt to qualify as meaningful users, but they are far less ambitious than the objectives laid out in this report. In the next chapter, we will make some specific recommendations for how these standards can be developed over time so that the lever of meaningful use can help promote an effective architecture for widespread data exchange.

We emphasize that there is a potential concern with pushing too many requirements into meaningful use. The concern is that this will create too onerous a burden for many healthcare providers, especially smaller physician offices that already may lag behind in adoption. However, the initial experience with meaningful use suggests that providers of the IT systems have a strong incentive to compete by ensuring that their products qualify under meaningful use. If meaningful use is expanded in a moderate way to require standardized metadata, technology providers likely will incorporate the standards into their products, and competition between technology firms will rapidly bring down the costs of middleware that will allow legacy systems to meet the standard.

## Creating a Data Exchange Infrastructure

The second component to the technological model we have outlined is the network infrastructure that links healthcare providers, patients, labs, researchers, and other stakeholders and enables qualified users to query distributed data stored by partners in the network. In thinking about the development of such an infrastructure, an important economic point is that communication networks are very often characterized by increasing returns. One reason is user externalities: the more parties sharing data in a network, the more valuable is membership to any given party. A second is the spreading of fixed costs. On a per-member basis, the costs of creating an indexing and data retrieval service may be large if only a few providers are participating in the network, but many of the costs are fixed and hence decrease on a per-member basis with increasing participation.

Current efforts at health data networking are at relatively small scale. As we have described, they consist of local and regional health information exchanges and narrower initiatives between particular institutions (hospitals and affiliated local physicians, or Kaiser Permanente and the Veterans Health Administration). The ONC is offering important support to these efforts—for instance, through cooperative agreements with all 56 states and territories to lead and promote health information exchange and through its Beacon Community grants program, which provides funding to 17 communities to build systems by which hospitals, clinicians, and patients use technology to improve health.[71] An important strategic question, however, is whether local experimental projects are the appropriate approach if the end goal is a national infrastructure.

One way to achieve this is to ensure that pilot projects are scalable and employ sufficiently flexible and interoperable technology. There are several ways in which Federal agencies might take this approach. One possibility is that CMS, the VHA system, or the Department of Defense (DoD) could initiate scalable pilot exchanges using the type of tagged data element model described in Chapter Four. The ONC also could use its grant funding to promote exchanges with the same type of flexible and scalable architecture. Finally, meaningful use guidelines that require providers to expose certain data to qualified users over approved networks are a powerful incentive mechanism. We make specific recommendations about meaningful use in the final chapter.

Regardless of how the network takes shape, an essential piece of the approach described in Chapter Four is a service that would index data available to the network and allow approved parties to locate a patient's data and assemble data elements, in both cases subject to access regulations. We termed this the data element access services model. The provider or providers of these services do not need to physically possess or store patient records in a central repository. But the providing entity does need to index data stored in a distributed fashion and retrieve and transmit data elements in response to qualified user queries, in much the same way that Internet search engines index data on the web and assemble data elements in response to queries.

The economic and regulatory issues around this service require careful consideration. Because privacy concerns are paramount with patient data, any provider of indexing and retrieval services must be able to maintain the trust of patients and clinicians. While such services might evolve in response to market forces, it seems likely that, at a minimum, regulatory oversight by ONC will be important for preserving patient trust. For instance, one possible regulatory requirement might be that providers of indexing and retrieval services have no commercial interest in the data and operate in ways that seek to maximize benefits for patients and the general public.

Compared with the broader costs of health IT adoption, the costs of creating indexing and retrieval services are likely to be low provided that the network reaches sufficient scale. Nevertheless, if the entities providing the service are prohibited from making commercial use of the data, they will need a funding mechanism. One possibility would be for the Federal Government to provide initial funding. Ultimately a variety of models might work. Funding could come from small charges on queries or from a small fee assessed to insurers on the basis of their enrolled members. One potential advantage of having payers, rather than providers, be the source of funding is that payers are in the best position to pass the costs

71. Office of the National Coordinator. May 26, 2010. Beacon Community Program. Available at http://healthit.hhs.gov/portal/server.pt?open=512&objID=1805&parentname=CommunityPage&parentid=2&mode=2&cached=true

on to the general population, who ultimately will have to bear the costs for any technology investment. Also, obtaining funding from payers would not impose a direct financial burden on providers, labs, or pharmacies whose participation would be important for making the system valuable.

## A Regulatory Structure for Data Access

The national health IT infrastructure we envision would also require a carefully considered system to control access and ensure patient consent. As described in Chapter Five, an important benefit of the tagged data element approach is that different data elements can have different levels of security. This means that a single system can allow a treating physician to access a complete patient record, a payer to access summary statistics from a physician, and a researcher to access de-identified data to enable clinical research on different treatments.

With a tiered system for data access, applications used by providers, patients, and researchers might be assigned roles that enable them to retrieve and use different types of data. Patients and providers could then consent to share data for certain purposes but perhaps not for others. For instance, they might consent to allow data to be accessed by other providers for direct clinical care or allow certain data elements to be accessed by researchers in other than de-identified form. But they might prohibit access to firms seeking to market pharmaceuticals unless they wanted to be targeted for advertising.

There are inherent trade-offs in formulating a regulatory policy for data access. Patients with privacy concerns and providers with an economic interest in maintaining proprietary data may prefer a tighter policy that limits data sharing and the ability of third parties to develop applications that make use of networked health data. On the other hand, such applications have the potential to yield substantial general benefits in terms of increasing the quality and consistency of care, informing patients, and facilitating research. In this sense, ensuring data access has some of the same public good aspects as interoperability and network investment—in particular, widespread general benefits and more targeted costs to privacy. It is important to keep this trade-off in mind in formulating regulatory policy.

## Competition to Supply Technology

So far, we have focused mainly on the government's role in bringing about a national health data infrastructure. In our view, however, one of the advantages of moving in this direction is to invigorate market innovation. Indeed, developing a networked infrastructure likely will involve the expansion of several of the nascent technology markets mentioned in Chapter Three. These include the markets for cloud-based electronic record and clinical decision support systems tailored to smaller providers, for middleware products that allow disparate legacy systems to be made compatible, and for new applications that enable patients and providers to leverage newly available data.

The economic incentives created by ARRA have already generated substantial innovation and competition in cloud-based electronic record products. More than 300 companies are offering some form of EHR product for physicians. Competition among these companies already has led to more affordable systems and improved products. Some of the companies in this market also are offering guarantees that physicians who adopt their system will qualify for meaningful use payments.[72] These cloud-based

72. Stytz, M., et al. 2010. Electronic Patient Health Record Technology: Status and Challenges. Washington, DC: STPI.

products are likely to become increasingly powerful as data exchange increases because physicians in smaller practices will be able to take advantage of data integration and tools that currently are available only to physicians in large integrated practices. This market therefore has an important role in ensuring that all physicians and patients benefit from advances in health IT and data exchange.

As noted above, moving from the current system to a tagged data element architecture will require that existing systems be upgraded to achieve interoperability. If providers have sufficiently strong incentives to upgrade, either because of the benefits of data exchange or because of meaningful use requirements, large EHR vendors are likely to move to interoperability. For organizations with legacy systems, we observed earlier that middleware products already exist that can extract data from existing systems and put them into tagged element form. The products might also provide an alternative for clients of large vendors who want a competitively priced alternative to upgrading their current system. To ensure that providers have multiple options, it is important that Federal policies are consistent with this market remaining competitive and innovative.

One further technology issue that arises in envisioning the future path of health IT relates to the problem of data storage and aggregation. Providers using electronic records are currently adding roughly 80 megabytes of data per person per year.[73] This rate is likely to increase as imaging and genetic data expands over time. As datasets expand, there could be substantial efficiencies in archiving large amounts of data in aggregated repositories. Indeed, this may be one advantage of cloud-based products. As we emphasized earlier though, the networked environment we envision is not dependent on the *physical location* of data storage. In this sense, it is consistent with a scenario under which data remain physically located with individual providers and labs, and one where technology evolves to favor a regime where data are stored in more aggregated forms.

## Innovation and Markets for Applications

Transforming large amounts of linked data into information that improves healthcare delivery and benefits patients and other stakeholders will require a sophisticated layer of application software. Chapter Three described in some detail the limitations of today's EHR systems that could be remedied with innovative applications. But because providers currently create and store data in many different ways and typically in closed systems, there is no common data "substrate" that application developers can use. Furthermore, short of individual time-consuming sales, there is no easy way to make data-centric products available to providers or patients.

An important advantage of the technological approach we have described is that it would enable new markets where firms compete to provide services and tools to patients, healthcare providers, payers, public health officials, and researchers. These tools might include products for patients to gather information about diseases using their personal health data, to input data from home health monitors, or to compare healthcare providers. Providers might benefit from improved tools for data entry, clinical decision support, or e-prescribing. Commercial products could also emerge to serve the general health system. For example, providers could benchmark their patient population and outcomes with peer provider organizations, enabling new forms of quality measurement.

73. John Halamka, personal communication, based on 2000-2010 Beth Israel Deaconess Medical Center data.

Many of these tools might function by combining individual data with a broader reference database. Analogous products are common on the Internet. Map-based products that provide directions or help consumers locate businesses or services combine individual information (a person's location and interest) with an underlying population database (maps with GPS coordinates, traffic data, and inventories of businesses). Personal finance tools use a combination of individual financial data and broader publicly available data on financial markets. The Internet also offers a model for market creation. As increasing amounts of data have become available (real estate transaction prices, financial market data, search and browsing data, and social network data), companies have emerged to build applications that use the data and market these applications to consumers and businesses.

One set of applications might address the problems with usability of EHRs described in Chapter Three. One way to understand some of the usability challenges is that current systems do not necessarily format information in a way that reflects the decision-making and information-flow processes of medical care. The problem is acute if a patient is seen by several providers who have to exchange clinical notes or lab results in document form. A system based on tagged data elements, coupled with the ability to query remote data stored by other providers, can allow for new software products that would deliver the data that the physician and patient require at the point of care, including the ability to intelligently retrieve information for advanced clinical decision support (evidence-based guidelines, genetic information, clinical trial access, and so on).

Patients also stand to benefit from applications that would allow them to collect information on treatments and physicians or share information with those who have similar conditions. For example, with the infrastructure we have outlined, a patient with a new diagnosis might be able to search instantly for the local specialist who has seen the most patients with similar conditions and prognoses. While it is possible that many patients may be uninterested in this form of engagement or these types of tools and will prefer to rely on a physician's advice, there are likely to be a large set of patients, particularly those with chronic health problems, who are interested. Patients with chronic illnesses already benefit from being able to search the Web or share information through discussion boards and social networking sites. Many might have a strong interest in applications that would allow them to access information culled from underlying health records.

A further class of applications might help users compile and aggregate population-level data on health outcomes, physician performance, or population health. These applications could be geared toward provider organizations, insurance companies, public-health companies, and researchers, broadly defined.

## The Broader Economics of Healthcare

A central point to keep in mind in thinking about the future of health IT is that the mere adoption of EHRs, and even the creation of a technological infrastructure for data exchange, is unlikely to have a truly transformative effect on the healthcare sector unless the appropriate economic incentives are in place to improve the quality of care and reduce costs. Indeed the same organizational and economic factors that have blunted the incentives to adopt IT will also affect the incentives of healthcare providers to use IT as they begin to adopt EHRs. In this sense, it is difficult to separate health IT issues from broader

economic issues relating to the healthcare system. While addressing the broader economic structure of the healthcare system is far beyond the scope of this report, it is useful to highlight a few of the issues and mention some current Federal initiatives that may complement health IT efforts.

To see the issues we have in mind, consider the common claim that EHRs can eliminate duplication and reduce healthcare costs. While it may be true that, for instance, networked EHRs could allow access to recent lab tests, one also needs to remember that in the healthcare system, one person's costs are another person's income. There often can be a fine line between duplication and a useful safeguard, and to the extent that providers have strong financial incentives pushing in one direction, the mere installation of IT systems may not reverse behavior.

Taking this example up a level, it is widely understood that the dominant fee-for-service model does not provide much incentive to streamline care, and also that the fragmented organizational structure of healthcare makes it challenging to move away from this model, because each small practice or hospital is a "tub on its own bottom" financially and therefore is not rewarded for interactions with other providers. This puts some of the major potential benefits of health IT, such as the ability to coordinate care across physicians, or to share and aggregate data from clinical encounters, somewhat at odds with the prevailing economics of the healthcare system. From this perspective, it is clear that the vision of health IT we have described needs to be supplemented by a broader set of reforms in payment and healthcare organization to realize the full potential of these technologies.

Several of the CMS initiatives funded under the Patient Protection and Affordable Care Act (PPACA) are notable in this regard, because they potentially complement health IT efforts. One such initiative is the primary care medical home model, which would put the patient and primary care physician at the center of a virtual organization that is paid a fee to coordinate all care the patient receives from specialists and other providers. In this model, the primary care physician would need to be able to exchange patient information seamlessly with other providers and assemble a complete record of the patient to successfully coordinate care. Another is the accountable care organization model, which would group hospitals and physicians into larger organizations that would contract with payers to care for an entire population. In this model, physicians and hospitals would need to share patient data and information to coordinate care, reduce unnecessary emergency room and hospital use, engage patients and families to enhance self-care, and track patient outcomes in a continuous manner. Both of these models would seem to require the type of coordination and data exchange that health IT can provide.

Advances in health IT are also likely to facilitate many proposed innovations in healthcare payment. Many of these innovations, and particularly those authorized as pilots under the PPACA, revolve around either pay-for-performance or bundled payments. With pay-for-performance, providers would be rewarded or penalized for patient outcomes relative to some quality benchmark. Bundled, or episode-based, payments would shift payment away from fee for service toward payment for all treatment following a diagnosis or for a set of procedures and subsequent care.

## Estimating Costs

PCAST has not performed a detailed analysis of the system-wide costs associated with implementing the recommendations of this report. However, some general comments on costs are in order here. Overall, the approach recommended in this report is expected to *improve* healthcare quality, *decrease* the cost of health IT systems (due to increased competition) and lay the foundation for systemic reforms to increase the efficiency of healthcare. These benefits are likely to be distributed widely throughout the healthcare system and persist over a long period of time. The transition costs to achieve these savings are expected to be small, both compared to the broad societal benefits and to the overall $20 billion scale of the Federal health IT effort. These costs will be borne more narrowly, at least initially, by EHR vendors, healthcare providers, and government agencies. It is useful to distinguish several components of cost:

1. **An initial cost for developing standards for the universal exchange language and its associated privacy and security protocols.** Based on this group's examination of a range of analogous activities from other sectors of the economy and a survey of the literature and colleagues, we estimate the engineering cost of developing the actual standards to be in the range of $20 million to $40 million.

2. **For healthcare providers with installed EHR systems, a cost to upgrade their systems, or to add middleware, so as to enable the exchange of data by means of the new protocols.** Based on the current cost of middleware products, we estimate the incremental cost might be 5 to10 percent of providers' current EHR costs. On the other hand, this estimate may be overstated, because a nationwide move to adopt the new communication protocol would likely result in significant competition to supply upgrade products, which would place price discipline on incumbent EHR providers. We estimate that to upgrade their products, existing EHR vendors might have to make one-time engineering investments on the order of $5 million to $20 million per vendor, based on estimates of private investment in companies now offering products with similar levels of controls and privacy. The duplication inherent in these costs can be reduced by the Federal Government developing, and putting into the public domain, reference implementations for key processes (such as security functions).

3. **For healthcare providers with no current EHR system, the additional cost associated with the new requirements of the universal exchange language.** We expect this cost to be minimal or absent. The proposed approach will likely to result in a more competitive and innovative market for EHR solutions, for example cloud-based products that are well-suited for smaller providers.

4. **Capital and operating costs to the government associated with the infrastructure for indexing and searching patient healthcare data, and for related trusted security processes**. Here, we note that multiple companies such as Google, Microsoft, Yahoo, Baidu, and some that preceded them, have made private investments in building and provisioning search systems for the entire Internet, which dwarfs the quantity of information in health IT. We estimate the proposed costs as being on the order of $100 million to $300 million per year, probably ramping up from the lower figure as the use of these services ramps up correspondingly, producing greater national cost savings. Included in the costs is an assumption of 0.1 GB per person, which would today be $0.20 per person per year, a total of $62 million in storage costs. One possibility is that the Federal government would bear the cost for the initial capital investment, and that the costs ultimately would be borne by either all users of the service, or by healthcare payers, including the government in its role as a payer.

**This chapter's bottom line:** Some aspects of the new health IT infrastructure will enable new, competitive, entrepreneurial markets. Some other aspects are "public goods" and will require government leadership. The benefits of health IT affect, and are affected by, other aspects of healthcare reform, especially payment models.

# VII. Health Data and the Research Opportunity

## Introduction

Today, most information about the effectiveness of therapies such as drugs derives from small-scale observations of a handful of patients (often a few hundred, sometimes fewer) in clinical studies. The most convincing clinical studies incorporate design elements, such as randomization of subjects to alternative treatments, to reduce the impact of unmeasured confounders on the treatment effect. These studies are appropriately considered to produce the highest quality evidence regarding a particular agent's efficacy, but they also suffer from well-recognized problems.

***Efficacy, not effectiveness*:** Clinical research studies usually focus on highly selected and often non-representative patients. They are designed to detect differences in the main outcome of interest, which means they are often too small to pick up less common but potentially important outcomes (such as serious adverse events) and are too brief to capture fully the long-term consequences of different treatment strategies.

For efficiency's sake, the studies often exclude patients with complex medical histories or many illnesses. This is problematic in that the treatments are needed by patients with complex illnesses where multiple different conditions make the range of choices greater than the usually simple comparison of a single trial.

***Out of date before they are even finished:*** Today's clinical research studies are not carried out in real time. Instead, they take years to design, fund, launch, and complete. Sometimes, by the time they are completed the question under investigation is obsolete. For instance, it is quite common for multiple clinical trials in cancer to be occurring simultaneously. New drugs can then be approved that have never been compared with each other, so the physician and patient do not have any way of knowing which is best. They only know that each is better than some other drug that is no longer used.

***Burdensome and costly:*** Today's clinical research enterprise is, at best, a sidecar loosely tethered to the clinical care enterprise. What is done in clinical research has its own expense structure and funding stream. The oversight of research is separate and apart from the oversight for clinical care. Its participants—both patients and investigators—are involved in sometimes redundant or repetitive activities. For instance, data often are collected twice for patients in clinical research studies: once for the patient's chart, and again for the research database.

***Narrow focus:*** Most research focuses on a narrow set of questions regarding therapeutic choices. Yet many important questions in healthcare stretch far beyond the choice between drug A or drug B. For example, healthcare research needs to evaluate operational aspects of the delivery system and evaluate arrays of therapeutic choices side by side. Ideas for new directions for research can and should come from observations about health trends independent of specific hypotheses.

## The Potential for Real-Time, Real-World, and Comprehensive Data

Numerous questions that clinical research is poor at addressing today could be answered using large datasets gathered through ongoing medical care, particularly if the data were available in near real time. A list of questions that could be addressed illustrates the promise.

***Syndromic surveillance and public health monitoring:*** Our infrastructure for monitoring public health is spotty and slow, depending on individual offices reporting data locally or regionally. Health IT and real-time data on the use of the healthcare system have the potential to address this deficiency. Today, the ability to follow cancer trends, asthma and other environmentally sensitive conditions, antibiotic resistance, or flu-like symptoms requires additional infrastructures layered on top of the healthcare delivery system (such as cancer registries or emergency room reporting).These infrastructures are costly and incomplete. In many cases, they also are unable to produce details related to the entire population (the denominator) against which this information should be compared.

Routine collection of data could eliminate redundancy, be far more comprehensive, and overcome the denominator problem. Case ascertainment (such as detecting new cases of cancer or new cases of antibiotic resistance) would grow naturally out of data capture during routine clinical care. Moreover, the denominator (or denominators) would grow out of the same resource. For instance, it would be straightforward to assess the prevalence of antibiotic resistance across all cultures of a certain bacterium in a geographic area during a certain period of time. Those data could be married to data on prescriptions of different antibiotics in ways that cannot be achieved today.

There are working examples of such real-time data collection. New York City monitors pharmacy purchases as a way of capturing early signs of flu-like symptoms.[74] This activity is important for routine decisions about vaccinations and also for such factors as bio-terrorism preparedness. Current search engines also can identify a flurry of inquiries about flu, but they cannot identify whether the queries resulted from symptoms or from media exposure.

***Adverse event monitoring:*** An ongoing concern for drug and device safety is the lack of a routine system of data collection for adverse events. The Food and Drug Administration mostly relies on *ad hoc* reporting of events. It does not have a good way to estimate the relative frequency of atypical events among all patients exposed to a drug or device or to separate association from causation. With extensive use of health IT and aggregated data, the data would be sufficiently rich to identify patterns and to separate events caused by particular drugs and devices from those that occur purely by coincidence.

Many examples of such event detection exist. The most frequently cited is the linking of Vioxx to cardiovascular events—something achieved through analyses of data captured by Kaiser Permanente and reported by several insurers as well.[75] Other examples include the detection of cardiovascular complications associated with the diabetes drug Avandia and with several calcium channel blockers used for treating high blood pressure.[76] Yet these represent relatively rare cases of adverse events detected

74. USA Today. October 25, 2009. "R.I. Tracks H1N1 with Electronic Data," at http://www.usatoday.com/news/nation/2009-10-25-rhode-island-flu-tracking_N.htm

75. Kweder S. November 18, 2004. "Vioxx and Drug Safety." Available at http://www.fda.gov/NewsEvents/Testimony/ucm113235.htm

76. Nissen, E., and K. Wolski. 2007. Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes. *New England Journal of Medicine,* 356(24):2457-2471.

through clinical databases. Other serious adverse events, such as those observed in randomized trials measuring the effect of erythropoeisis stimulating agents on cancer progression, were not detected in administrative data even though the effects were large, because there was not enough clinical detail in the information. This limitation could be overcome by greater data availability.

***Assessments of dissemination and utilization:*** The gap between knowledge and the delivery of care, branded as the "quality chasm" by the Institute of Medicine a decade ago, remains a serious concern. The shortfalls disproportionately affect members of minority groups and individuals who lack insurance.[77] Currently, numerous redundant and sometimes conflicting systems aim to monitor utilization and quality as a way to mitigate these problems. Through programs such as quality measurement and reporting, chart review, and auditing, providers are increasingly being asked to report on what they are doing. This set of approaches, although conceptually attractive, has many problems. Any quality measurement collection involves large costs and burden. It also involves choosing the quality measures before creating a structure to capture the measures, which means both that the domains of quality that can be assessed are logistically limited and that the speed of change is sub-optimal.

The potential of data to monitor quality and the use of evidence-based approaches is immense. At scale, health IT will provide insight into the quality of care in all settings without actually having to design systems to report a particular element. The initial standards for meaningful use emphasize this potential benefit. If clinical systems capture sufficient data about patients, including both their eligibility for particular treatments and their contraindications, along with physician orders, e-prescriptions, and other delivery data, continuous quality monitoring and feedback could become part of routine care rather than the add-on it is today.

***Comparative effectiveness research:*** Perhaps the greatest potential of the data that can be captured using health IT lies in the potential to fuel comparative studies of diagnostic and therapeutic approaches. Comparing treatment and management approaches in a way that can easily be accessed by both physicians and patients could improve patient outcomes and reduce healthcare spending. Funding for comparative effectiveness research is already growing. Electronic health information, in the easily accessible form enabled by metadata-tagged data element collection, aggregation, and security standards, would enable this kind of research to advance much more rapidly than with the traditional, institutional EHR model.

## Supporting Research Uses

The uses described above, although they all hinge on data collected through EHRs, require somewhat different types of data, falling broadly into one of three categories: Effective **syndromic surveillance** and other public health monitoring could be achieved through collection of data that are already regularly recorded in patient charts but are not currently aggregated. *Separation of adverse events from coincidence and ascertainment of quality measures* may require more detailed information than is currently routinely captured in most patient charts today, but likely possible to capture within the system that we envisage. However, *comparative effectiveness studies*, particularly those that build in some experimental design or

77. Alliance for Health Reform. March 2006. "Racial and Ethnic Disparities in Health Care." Available at http://www.allhealth.org/publications/pub_38.pdf

require additional data elements or assessments, would require more data than are routinely captured and also would require a framework of two-way interaction with the clinician and patient. We will illustrate this in an example below. And there are many other types of clinical research, not just clinical trials, in which two-way interactions between research and clinicians are desirable.

Methodological issues will need to be considered as data from EHRs become available for research studies of increasing sophistication. Practicing physicians are busy, not necessarily trained in research, and not always ideal collectors of patient data for research. Patients, exercising their right to opt in or out of studies, will cause data to be collected from incomplete, or incompletely defined, populations. Effects like these complicate the design and validation of research results. But the availability of data in quantities orders of magnitude larger than today will allow subtle and sophisticated experimental designs, more than compensating, we think, for the data's complexities.

### *Linking Patients to Clinical Studies*

To see the potential for interactive data collection in EHRs to lead to the enrollment of patients in clinical trials, consider an oncologist who, upon seeing a patient with a new diagnosis of cancer, could be asked by the interactive program to upload detailed information about disease type, stage, other conditions, and performance status. Depending on that information, lists of eligible ongoing studies could be presented to the treating physician and patient, and enrollment in the study could occur during that visit. As an intermediate step, a more intensive data collection could be initiated, along with patient enrollment into a registry when enriched data are needed to address a particular question.

The value of such a system is clear. More information generated in clinical care could be used to accelerate learning, and many biases that exist in observational data could be overcome through the use of several types of experimental designs (such as randomization or block assignment). Providers and the patients would know all of the available opportunities to participate in clinical trials, and the physician could manage the patient through the process, with real-time data exchange to and from the research team. Not all providers would be authorized investigators in any trial, but electronic access to every available study would include the real-time ability to query the study about its appropriateness for the interested patient and any additional information. Much of this could be done without the patient having to transfer care to another provider.

Committing to only one level of data collection at a national level would be a mistake. A lot can be achieved based on clinical data gathered during routine care only, while some research requires additional data gathered during healthcare encounters. Other research may require experimental designs that entail additional steps such as informed consent, data categorization, follow-up questionnaires, and the like. To accommodate different levels of data collection, the infrastructure should be designed while considering the tradeoffs of collecting research-quality data against possible burdens. These burdens include a higher level of training for the providers involved and possible additional costs and processes required for high-quality research data, but the burdens can be limited and the advantages enhanced

with access to a tagged data element environment. The implied trade-offs are matters of policy, to be codified only after careful consultation with all stakeholders, and to be justified not by the abstract desirability of research, but by explicit consideration of how research feeds back to better patient care.

***Some opportunities and challenges in observational data:*** Observational data first uncovered the cardiovascular side effects of Vioxx, long before randomized trials demonstrated the same findings. Likewise, the apparent benefits of some unusually effective cancer treatments, such as Gleevec for chronic myelogenous leukemia, were apparent based on outcomes of studies using single specified therapies, well before randomized trials documented the actual size of the beneficial effect.[78] Yet observational studies can be hindered by biases that can be hard to detect, and sometimes findings are disproved by randomized trials or observational studies that contain more granular data. For instance, numerous observational cohort studies suggested that beta-carotene supplementation would reduce the risk of developing lung cancer, but randomized trials of the intervention showed the opposite effect.[79] A recent observational analysis of radiation treatment for women with DCIS (ductal carcinoma in situ, an early stage breast cancer) suggested that delays in radiation reduced overall survival, even though the underlying disease has a very low mortality rate and randomized trials of radiation for it had shown no mortality benefit.[80] The potential, and the limitations, are one motivator for providing an infrastructure that will eventually allow more than one approach to EHR-driven research.

### *Real-Time Patient Benefits from Comparative Effectiveness Research*

Making patient clinical data available to researchers clearly has long-range benefits to patients. Until now, this has been a linear process with a timescale of years, since it requires performing the research, submitting it for peer review, publication, and ultimately the adoption of new clinical practices that benefit future patients.

Health IT can make it possible to get benefits to patients much faster. Indeed, patients could benefit directly from a research study to which they are concurrently contributing.

If patient progress and outcomes were routinely captured in data and made available in near real time, partial data can be used in sophisticated ways to assign treatments to new patients in optimal ways. These data also could be used to personalize treatment for patients already enrolled in a study.

78. Cohen, H., G. Williams, J. Johnson, J. Duan, J. Gobburu, A. Rahman, K. Benson, J. Leighton, S. Kim, R. Wood, M. Rothmann, G. M. Chen, M. Staten, and R. Pazdur. 2002. Approval Aummary for Imatinib Mesylate Capsules in the Treatment of Chronic Myelogenous Leukemia. *Clinical Cancer Research,* 8(5):935-942.

79. National Cancer Institute. Beta-Carotene Supplements Confirmed as Harmful to Those at Risk for Lung Cancer. Available at http://www.cancer.gov/clinicaltrials/results/final-CARET1204

80. Gold, T., T. Do T, and W. Dick. 2008. Correlates and Effect of Suboptimal Radiotherapy in Women with Ductal Carcinoma in Situ or Early Invasive Breast Cancer. *Cancer,* 113(11):3108-3115.

A patient-physician interaction in an *adaptive comparative study* might proceed along these lines:

1. Using the physician's diagnosis, the physician's computer identifies a comparative effectiveness study relevant to the patient's condition and advises the physician.
2. The physician asks the patient whether he is interested in participating. The patient is advised that, by participating, he will receive a treatment recommendation based on, literally, today's best weighted judgment of all the accumulated data. However, the recommended treatment might not be the brand name drug that he expects.
3. The patient agrees to participate in the study.
4. Through the physician's computer and the physician, the patient is asked if he wants to allow the study to access his personal genotype data, in which case a more personalized treatment recommendation might be made.
5. The patient agrees to this.
6. The study recommends a treatment, for example a prescription which is sent through the physician's computer (with patient and physician concurrence) to the patient's local pharmacy.

This example demonstrates a synergistic combination of three health IT opportunities, each potentially revolutionary. The first is real-time decision support to the physician based on evidence-driven best practice. The second is the real-time interaction of that decision support with completely current clinical data, without months or years of lag. The third is seamless integration of the clinical setting with the enrollment of patients into the clinical and comparative studies that will generate the next round of new data. Importantly, because these studies are adaptive (that is, they assign patients to treatments not arbitrarily, but rather based on the partial accumulated study data), they are consistent with the physician's duty to give each patient the treatment believed to be best for him or her on the basis of the most current evidence.[81]

81. W. H. Press. 2009. Bandit Solutions Provide Unified Ethical Models for Randomized Clinical Trials and Comparative Effectiveness Research. *PNAS*. 106:22387-22392.

**This chapter's bottom line:** A national health IT infrastructure will enable new kinds of research and will also create opportunities for the faster coupling of research to clinical practice.

# VIII. Guidance to Agencies

## Introduction

In this final chapter, we discuss what needs to be done if rapid progress toward the realization of a national health IT infrastructure is to be achieved. Because of the complexity of the issues, we give recommendations at several levels of specificity. First, as an example, we sketch a possible roadmap for getting all the way to the transformative future that we envision. Next, in narrative format, we give some overall short-term guidance relevant to the two key agencies, ONC and CMS. In the next chapter, we give a list of specific recommendations to several agencies that can (and, we think, should) be tracked by senior policy makers within the Executive Office of the President as to progress achieved.

## A Feasible Roadmap to the Future

An important feature of the tagged data element model advocated in this report is that there is a natural transition path from present EHRs and from existing demonstrations of information exchange. As an illustration, we sketch a possible way—though by no means the only possible way—in which that transition might unfold. Key to this roadmap is its leveraging of universal data exchange, and the network effect, to spur EHR adoption.

First, HHS would define by regulation the most basic features of the tagged data element exchange. This would include the specification of an extensible markup language, most likely a variant of the existing language XML. ONC's clinical document architecture standard is important foundational work for this. However, additional focus is needed on aspects that relate to data transmission, to innate privacy features, and (perhaps most importantly) to facilitating the disaggregation of complex records into the smallest possible data elements, suitable for use by a broad range of new health IT products in a new, entrepreneurial marketplace. The universal exchange language is more than just an extensible wrapper for the exchange of documents, each in its own fixed format. It needs to facilitate (if not directly require) the exposure of the underlying semantics of individual data elements for new uses, including many not anticipated by the original data producer.

Also defined from the start would be a minimal initial set of requirements for the metadata that will accompany each piece of data. These might include, for example, the patient's name and birthdate, the applicable privacy rules and policies, including any patient's pre-consented privacy choices (e.g., "data may be used in research but only when fully de-identified"), an identifier of the originating physician or institution, a provenance within that institution (for example, a reference to a type of equipment or standard clinical procedure), and a time-stamp. Since the language is extensible, only a minimal set of metadata needs to be standardized at this stage; more will naturally evolve at later stages of adoption or as features added by individual software vendors.

A part of the specified metadata—for example, the patient name and birthdate—would be specified as "indexable" items that are made visible to authorized data element access services for indexing and data locating as they become available in stages of the transition.

Next, ONC and existing standards groups would publish mappings of existing vocabularies and content standards (for example, the HL-7 vocabulary standards for electronic exchange of healthcare information[82] and the ICD-9 and ICD-10 international disease classifications[83]) into the adopted markup language.[84] This straightforward step immediately expands the semantically meaningful realm of tagged data exchanges to include data that are coded in these existing standards. It incorporates these standards into the new architecture, leveraging the work done by thousands of people for decades.

In parallel, vendors of existing EHRs would be encouraged to rapidly publish mappings of their existing exchange mechanisms into the extensible markup language. For example, if a product is now able to exchange prescriptions, whole medical records, or other information, the vendor should easily be able to map that exchange at the existing level of aggregation into the markup language. This is only a first step toward an infrastructure of fully tagged data elements, because the individual data units are not yet the smallest pieces that make sense to exchange and aggregate. However, it is an important step, because it immediately allows the development of middleware that is able to exchange and display information from multiple vendor systems. It also is an important first step toward creating the kind of competitive marketplace that we envision. Data from patient-controlled personal health records can likewise easily be mapped into the new framework.

Many, if not all, of the meaningful use exchanges that are posited for the near future can and should also be mapped into exchanges of tagged elements within the framework of the markup language. Also important is a standard metadata markup for physicians' clinical summary records and case progress notes. There is no requirement at this stage for any exotic natural language processing or coding of these items. Their textual contents are exchangeable data elements in their own right whose exchange can add valuable clinical context.

After only these steps, we would already begin to see the value added of a single framework for tagged data element exchanges. At this point in the transition, the data are not yet in the smallest pieces that make sense and are not yet accompanied by all the metadata that will ultimately be needed. But the data will already have become universally exchangeable and universally privacy-protected, and the data will already incorporate large, widely recognized semantic realms. This is where the power of emergent markets, and the network effect, will first be felt.

Next in the transition sequence, ONC would define standards for the surfacing of metadata for use by the data element access services—that is, for finding and requesting patient clinical data (e.g., data relevant to a particular patient who presents in an emergency room) and also research data (e.g., anonymized data for a particular study by a state public health agency). In parallel, ONC (or another agency under ONC's policy direction) would would encourage the development of intercommunicating and interoperable DEAS. The DEAS will initially be much like any of today's web search engines, but they will be secure and specialized to privacy-protected data exchanges within the health network.

82. "Health Level Seven International" at http://www.hl7.org/

83. World Health Organization. "International Classification of Diseases (ICD)" at http://www.who.int/classifications/icd/en/

84. The United States Health Information Knowledgebase (USHIK), maintained by AHRQ, maintains metadata on many healthcare-related data standards that could be considered for rapid incorporation. See http://ushik.ahrq.gov/index.html

This is the point at which patients and clinicians would see tangible benefits from "putting the patient back together." Aided by new software applications, physicians will start to see tailored, unified views of all of a patient's interactions with the healthcare system, seamless across institutional and geographical boundaries.

In parallel, both as the market for health IT becomes more competitive and also to meet new government or payer requirements, vendors of existing EHRs would start to break down their data exchanges into smaller, more elemental units. For example, a regulatory requirement for metadata that includes the model and calibration of the instrument used in a specific lab test will cause the data to be exposed as tagged elements, rather than as part of an unwieldy integrated EHR. If there are new entrants into the EHR business, they should see a competitive advantage in producing systems that use metadata-tagged data elements by original design. At the same time, existing vendors, or unrelated middleware vendors, will provide add-on software to expose existing EMR information in an exchange interface where it appears as tagged data elements, regardless of how it is internally represented. The feasibility of such middleware is demonstrated by the fact that, as we have noted, in special cases it already exists today.

Over time, deliberatively and by appropriate processes, ONC and CMS would require (by means of the meaningful use or certification regulatory mechanisms) that smaller meaningful units of tagged data, and more extensive metadata tagging, be exposed at the interface, so as to be encouraging the development of new software applications and new benefits to the physician and patient. We will have gotten to this point by incorporating into the new framework, and then incrementally upgrading, health IT systems that exist today. Also, by creating a universal framework, new markets will be created for innovative software applications whose internal representations of the data, and thus capabilities, may be amazingly different from those available today.

## Guidance on Necessary Design Choices

The development of a complex information infrastructure, such as that required for health IT, requires many design choices at many levels, and with appropriate ordering in time. Early conceptual design choices may have large, and even unanticipated, effects on later implementation-related choices. An important concept is that every choice *limits* the possible design space of subsequent choices. Sometimes this is desirable, because it forces convergence to desired goals. Other times, and especially early in the design process, it is important that design choices *preserve* a wide range of subsequent design options. Good systems design consists of finding the golden path between the extremes.

One often hears it said that "government should not dictate IT architectures," and we agree. The word "architecture" implies a series of decisions extending far down into the design process. What government *does* need to dictate, or at least facilitate the early standardization of, are those early design choices that will enable interoperability. These choices do not specify architectures, but rather "high-level protocols," or "data exchange languages," or even just common ways of thinking about the problem from a global perspective. Here government, both by its convening powers and by its regulatory authorities, has a crucial role to play, for the reasons already discussed in Chapter Six.[85]

85. The crux of the argument in Chapter Six is that this is a public good problem. Market incentives are lacking for private firms to invest in universal exchange capabilities, because they cannot appropriate the benefit.

ONC leadership recognizes (as do we) that complete interoperability in the entirety of the domain of healthcare is a massive undertaking. This has led to an approach that is iterative and incremental, focused on producing the specific, limited solutions that bring the greatest immediate value. The problem with this seemingly sensible approach is that it can result in a set of ad hoc solutions, rather than in high-level design decisions that could be both convergent and preserving of a wide range of possible subsequent design options. A key example, previously discussed, is the rapid establishment of a universal, extensible exchange language. As a more general statement, we think that ONC needs to augment its current multi-faceted approach with a process that can generate design choices at a national level that are carefully balanced between the goals of convergence and diversity. This is an appropriate government role and requires a more aggressive approach than is visible at present.

As a related issue, ONC's current approach has the effect of postponing the development of a genuinely universal "syntax" (that is, the formatting of data that are exchanged and the details of exchange protocols) until after the government has harmonized the "semantics" (that is, the clinical or operational *meaning* of the data, or its human understanding) from many different health IT-related realms. This approach implies a focus on achieving some harmonization between taxonomies for diagnosis, for test results, for genetic information, for billing codes, for the particulars of medical instrumentation, and so forth. We urge reconsideration of this approach.

A large body of experience in other domains suggests that creative and entrepreneurial energies are best unleashed by standardizing a syntax that is broadly extensible into different semantic spaces. A much-studied historical example[86] is the language XML ("extensible markup language") and its many off-shoots. If an XML-like universal exchange language for health IT were even minimally standardized, then many existing semantic taxonomies could immediately be mapped to it. Would these be instantaneously harmonized? No. But there would be immediate market incentives toward harmonization, because vendors could compete on how broadly their products "understand" the existing semantic spaces. Rather than a never-ending, Sisyphean government approach to harmonization, the existence of an extensible standardized syntax would promote a market-driven, largely nongovernment, ongoing process. This is a case where government needs to define a (syntax-based) approach that opens the market to new players, and then largely get out of the way.

As mentioned, ONC's CDA is a foundational step in the right direction. However, the thrust of CDA seems largely that it be an extensible wrapper that can hold a variety of structured reports or documents, each with vocabulary-controlled metadata. While this shares many features with the universal exchange language that we envisage, it lacks many others. In particular, it perpetuates the record-centric notion that data elements should "live" inside documents (albeit metadata tagged). We think that a universal exchange language must facilitate the exchange of metadata tagged elements at a more atomic and disaggregated level, so that their varied assembly into documents or reports can itself be a robust, entrepreneurial marketplace of applications. In a similar vein, we view the semantics of metadata tags as an arena in which new players can participate (by "publishing"), not as one limited to a vocabulary controlled by the government.

ONC's cautious approach on these two issues is understandable: the problem itself is inherently complex, and the Office is under pressure from parties who would like the bar for receiving payments under

86. Gray, J., "A Conversation with Tim Bray." February 16, 2005. http://queue.acm.org/detail.cfm?id=1046941

ARRA to be set low. However, we are concerned that this direction, pace, and actions are not currently sufficient to achieve, in the necessary time frame, the President's goal that the Nation have a health IT system adequate to support efforts to increase the quality and decrease the cost of healthcare. Some additional guidance for ONC relates to its support of CMS and is discussed in the next section.

## Guidance on Meaningful Use Requirements

Earlier we discussed the broad discretionary powers given to CMS, under ARRA, to define what constitutes meaningful use of EHR technology. In Chapters 4 and 5, we outlined a vision of what ought to be achievable, over the mid- and long-term, as a state-of-the-art national health IT infrastructure. Here, we put these pieces together to suggest what CMS should be doing now.

To accelerate the adoption of a universal exchange language, HHS should specify that meaningful use measures reported to CMS be captured in a tagged data element format.[87] To meet these criteria in the short term, some healthcare providers with legacy EHR systems would probably add middleware to extract and operate on data-level clinical information. Large vendors of EHR systems would likely offer upgrades to meet the CMS requirements.

Such a meaningful use data policy would accomplish several things. First, it would advance EHR technologies in the direction of being able to generate data needed to support other aspects of meaningful use, for example, advanced clinical decision support. Second, this substrate of data will catalyze a host of new IT applications for physicians and hospitals to improve the quality and efficiency of care. Third, this policy eliminates the incentive for vendors to "hard wire" into EHRs the specific quality measures currently required to qualify for meaningful use, instead motivating them to provide a flexible framework into which specified reporting items can be easily inserted. This is important because meaningful use measures will change over time as the art and science of quality measurement improve and as more clinically meaningful measurement constructs become available. If providers are required to pay for expensive system upgrades as new measures are implemented, their support for both the technology and for quality assurance programs will quickly dissipate. Moreover, providers need flexibility in their EHRs to respond to the unique quality-reporting requirements of different health plans and to satisfy licensure, certification, and accrediting organizations with the least possible added burden.

To support this type of meaningful use policy, ONC should issue reference standards with which EHR, software, and middleware vendors would need to comply. The original set of standards for EHR certification[88] implementing HITECH relies heavily on existing standards for the interoperability of health information technologies, including those established and/or promoted by the Health Level 7 standards organization (HL7), NIST, and Integrating the Healthcare Enterprise (IHE). These standards were chosen in an attempt to provide a "minimum set of transport, content, and vocabulary standards required to drive or enhance the predictability of data exchange when used in EHR technologies, in order to drive adoption". We would like to see ONC focus on enabling and accelerating health information exchange at the level of the datum, rather than the message or document, while developing a corresponding

87. Although the reported data consists of aggregated counts, not individual patient data, a tagged metadata format can also be applied to this type of data.

88. Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology at http://HealthIT.HHS.gov/standardsandcertification

reference implementation to verify interoperability. This conceptually straightforward approach to certification would allow flexibility and continued innovation in quality measurement and reporting without adding an extra administrative burden.

For its part, CMS's approach to innovation in quality assessment will need major structural and technical overhauls, and to share the visionary and strategic goals of ONC and the President, so that it advances the state of the art in both clinical practice and health IT. Now, for Stage 1 of meaningful use, CMS will require a set of objectives/measures for eligible professionals and 23 for hospitals. In selecting clinical quality measures for physicians, CMS chose to use a subset of measures from its Physician Quality Reporting Initiative. These measures are highly specified and can be submitted to (and received by) CMS only through specific, limited, technical methods.

PCAST has two concerns with this approach. The first concern is that although isolated, condition-specific measures such as "percent of patients with blood pressure under control" are relevant to population health, they are not adequate to assess the broad range of competencies required for physicians and healthcare organizations to deliver safe and effective care. There is good evidence that real improvements in quality will result only from generating and acting on data that reflect the multidimensional aspects of the clinical practice.[89] Today, large integrated group practices can often generate more sophisticated quality metrics and feedback to physicians than what CMS plans to require. It would be unfortunate if CMS were to re-focus these organizations on less effective measures. As another example, some medical specialty boards and health plans are creating comprehensive assessments of a physician's skills in a particular clinical area.[90] These assessments might combine clinical data elements from a physician's practice with results from a test of knowledge, a review of clinical practice systems, and patient experience surveys, all while testing the psychometric properties of new or different combinations of these various data elements. Such innovation in quality measurement and feedback should lead to innovation in practice improvement cycles comparable to other modern engineering standards.[91] CMS should develop a roadmap for expanding its quality measures to reflect improvements in both information technology and methods of quality assessment.

Our second concern is that clinical quality reporting to CMS is limited to the technical specifications of a single designated consensus body, the National Quality Forum (NQF). This in turn limits both the scope of kinds of measures and the technical specifications that CMS is able and willing to accept. The law contains language allowing an alternate pathway for measures if justified by the Secretary of HHS, but that pathway has not been used. We think that wider use of this alternate pathway provision would allow for more innovation and more meaningful quality assessment than is possible using only computable data that have been electronically "defined" for some other purpose. Moving to a tagged data element environment would allow much greater flexibility of quality assessments. It also would require improvement in CMS's ability to receive more complex data as described above. With new resources and the charge from the PPACA, CMS should ensure that this flexibility is built into its future rulemaking.

89. Leatherman, S., and A. Epstein. 2010. *Performance Measurement for Health System Improvement*. Cambridge, UK: Cambridge University Press.

90. Darves, B. June 2008. "Ensuring—and Tracking—Physician Competence." New England Journal of Medicine Career Center. at http://www.nejmjobs.org/career-resources/ensure-physician-competence.aspx

91. Gawande, A. 2009. *The Checklist Manifesto: How to Get Things Right*. New York: Metropolitan Books.

CMS's attempt to synergize the **Physician Quality Reporting Initiative** and meaningful use programs and reduce the reporting burden on physicians is a very reasonable approach during the first years of implementation, and is required by legislation. Going forward, however, quality improvement information will be richer, more secure, and timelier if gathered and delivered through Internet-accessible systems.

CMS needs to take specific actions that will demonstrate the value of tagged data element exchange. Adjusting fee-for-service payments based on currently reportable quality measures may spur at least some providers to become more sophisticated users of health IT. But it will not bring healthcare closer to the vision described in Chapter Two if the goal is only to achieve higher scores on specific measures. In Chapter Six, we discussed how CMS demonstrations projects such as the primary care medical home and accountable care organization models would shift the payment focus toward coordinated, integrated care. These models are potentially highly complementary to investments in health IT. CMS could further this connection and perhaps make these models more likely to succeed by requiring that demonstration sites have EHR technologies capable of more than reporting specified measures. These capabilities should include delivering and retrieving metadata-tagged, patient-centered, and patient-authorized information with other networks and sources such as PHRs and public health data aggregators. In addition, it will be important for CMS to document and publicly share what is learned about the contributions of such exchanges to the effectiveness of these new models and the results they achieve.

CMS needs a more aggressive program to support the growth of clinical decision support and secondary data uses. Chapter Three discussed the many problems with the "usability" of EHRs from the clinician's perspective. Most of today's systems do not format information in such a way that it reflects the decision-making and information-flow processes of medical care. Instead, their information display is codified in a series of "pages" that can hamper care while providers work through an electronic version of their written record. Software is needed that is more flexible and can deliver the relevant data that the physician and patient require at the point of care, including the ability to intelligently retrieve information for advanced clinical decision support (such as evidence-based guidelines, genetic information, and clinical trial results).

Federal policies also could seed the development of applications that can improve the capabilities of Federal and public health agencies to leverage large stores of electronic data to advance national health system objectives. Specifically, the Department of Health and Human Services should jumpstart an applications market through both requests for proposals and technology transfer agreements for the secondary use of EHR data. This market could result in the development of a very wide range of applications, including software to support pilot projects for benchmarking, coordination of new ONC objectives toward tagged data element ecosystems with entities developing adverse event and syndromic surveillance networks, tools and training to enable the gathering and input of research-quality data within a fully functional EHR, and the development of a test network for comparative effectiveness research.

Finally, we return to the serious challenge posed by CMS's antiquated IT infrastructure, and the pressing need for its modernization, as has already been recognized by CMS leadership. CMS needs to ensure that it does not replace one inflexible architecture with another. While it is outside of our charge to anticipate the conclusions of a recently initiated National Research Council study of CMS information

system capability, we would be surprised if a modern solution did not include most of the following elements: (1) a hardware infrastructure based on continuously upgradeable commodity data center technology; (2) a distributed, redundant, reliable storage system that logically presents as a unified, global file system; (3) a software infrastructure based on standard tools and APIs for distributed computing; (4) data consistency maintained by well-understood distributed transaction management protocols; (5) a well-specified protocol stack (most likely with remote procedure calls on top of TCP) and carefully specified interface formats. As discussed in Chapter Three, Federal IT projects of this magnitude frequently incur cost overruns and schedule slippages, and can take many years to complete. Rapid and otherwise achievable progress in health IT, as envisioned by ONC and (even more aggressively) by this report, could be forestalled or derailed if it becomes tied to CMS's formidable IT challenges.

# IX. Recommendations

A number of specific recommendations for the short- and mid-term follow from the discussions contained in this report.

The Chief Technology Officer of the United States should:

- In coordination with the Office of Management and Budget (OMB) and the Secretary of HHS, and using technical expertise within ONC, develop within 12 months a set of metrics that measure progress toward an operational, universal, national health IT infrastructure. Research, prototype, and pilot efforts should not be included in this metric of operational progress.
- Annually, assess the Nation's progress in health IT by the metrics developed, and make recommendations to OMB and the Secretary of HHS on how to make more rapid progress.

The Office of the National Coordinator should:

- Move more boldly to ensure that the Nation has electronic health systems that are able to exchange health data in a universal manner based on metadata-tagged data elements. In particular, ONC should signal now that systems will need to have this capability by 2013 in order to be deemed as making "meaningful use" of electronic health information under the HITECH Act.
- Act to establish initial minimal standards for the metadata associated with tagged data elements, and develop a roadmap for more complete standards over time.
- Facilitate the rapid mapping of existing semantic taxonomies into tagged data elements, while continuing to encourage the longer-term harmonization of these taxonomies by vendors and other stakeholders.
- Support the development of reference implementations for the use of tagged data elements in products. Certification of individual products should focus on interoperability with the reference implementations.
- Set standards for the necessary data element access services (specifically, indexing and access control) and formulate a strategic plan for bringing such services into operation in an interoperable and intercommunicating manner. Immediate priority should be given to those services needed to locate data relating to an individual patient.
- Facilitate, with the Small Business Administration, the emergence of competitive companies that would provide small or under-resourced physician practices, community-based long-term care facilities, and hospitals with a range of cloud-based services.
- Ensure that research funded through the SHARP (Strategic Health IT Advanced Research Projects) program on data security include the use of metadata to enable data security.

The Centers for Medicare & Medicaid Services should:

- Redirect the focus of meaningful use measures as rapidly as possible from data collection of specified lists of health measures to higher levels of data exchange and the increased use of clinical decision supports.
- Direct its efforts under the Patient Protection and Affordable Care Act toward the ability to receive and use data from multiple sources and formats.
- In parallel with (i.e., without waiting for) the NRC study on IT modernization, begin to develop options for the modernization and full integration of its information systems platforms using modern technologies, and with the necessary transparency to build confidence with Congress and other stakeholders.
- When informed by the preliminary and final NRC study reports, move rapidly to implement one or more of the options already formulated, or formulate new options as appropriate, with the goal of making substantial progress by 2013 and completing implementation by 2014. CMS must transition into a modern information technology organization, allowing integration of multiple components and consistent use of standards and processes across all the provider sectors and programs it manages.
- Exercise its influence as the Nation's largest healthcare payer to accelerate the implementation of health information exchange using tagged data elements. By 2013, meaningful use criteria should include data submitted through reference implementation processes, either directly to CMS or (if CMS modernization is not sufficiently advanced) through private entities authorized to serve this purpose.
- By 2013, provide incentives for hospitals and eligible professionals to submit meaningful use clinical measures that are calculated from computable data. By 2015, encourage or require that quality measures under all of its reporting programs (the Physician Quality Reporting Initiative, hospitals, Medicare Advantage plans, nursing homes, etc.) be able to be collected in a tagged data element model.

The Department of Health and Human Services should:

- Develop a strategic plan for rapid action that integrates and aligns information systems through the government's public health agencies (including FDA, CDC, NIH, and AHRQ) and benefits payment systems (CMS and VA).
- Convene a high-level task force to align data standards, and population research data, between private and public sector payers.
- Convene a high-level task force to develop specific recommendations on national standards that enable patient access, data exchange, and de-identified data aggregation for research purposes, in a model based on tagged data elements that embed privacy rules, policies and applicable patient preferences in the metadata traveling with each data element.

- As the necessary counterpart to technical security measures, propose an appropriate structure of administrative, civil, and criminal penalties for the misuse of a national health IT infrastructure and individual patient records, wherever such data may reside.
- Appoint a working group of diverse expert stakeholders to develop policies and standards for the appropriate secondary uses of healthcare data. This could be tasked to the Interagency Coordinating Council for Comparative Effectiveness Research.
- With FDA, bring about the creation of a trusted third-party notification service that would identify and implement methods for re-identification of individuals when data analysis produces important new findings.

Other or multiple agencies:

- AHRQ should be funded to develop a test network for comparative effectiveness research. The FDA, and also other HHS public health agencies, should enable medical researchers to gain access to de-identified, aggregated, near-real-time medical data by using data element access services.
- HHS should coordinate ONC activities with CDC, FDA, and any other entities developing adverse event and syndromic surveillance networks.
- The Department of Defense and the Department of Veteran Affairs should engage with ONC and help to drive the development of standards for universal data exchange of which they can become early adopters.

# Appendix A: Expert Input

Expert Input into Health Information Technology Report. PCAST is grateful for the input of these individual experts. Listing here does not imply endorsement of this report or its recommendations.

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# Appendix C: Glossary

**Anonymize**–Removing all personal identifiers from data

**Authentication**–Determining the identity of a principal

**Authorization**–Determining the rights of an authenticated principal

**Clinical decision support**–Bringing relevant information to the clinician, at the right time and place, to enable optimal health care

**Cloud-based**–A technology that allows software to be run and data to be stored on remote servers

**Comparative effectiveness research**–Research that informs clinical decisions by comparing evidence on the benefits, harms, and effectiveness of different treatments

**Data element access services**–Services that are associated with crawling, indexing, security, identity, authentication, authorization, and privacy

**Data-centric**–A focus on the specific data relevant to a given task

**Data element indexing**–Process and infrastructure for locating data elements, similar to today's web search engines

**De-identified**–Data with all patient identifying information removed, but with the possibility of providing information back to the patient under specified circumstances

**Digital signature**–Cryptographic method for ensuring that data cannot be altered except by the person who created them.

**Electronic health record**–An electronic record of health-related information for an patient that contains information captured in clinical visits, lab and imaging studies, and other information important to the patient's medical past

**Encryption**–Technology of making data completely unreadable except by a person in possession of the corresponding "key"

**Genotype**–The genetic makeup of a specific human being

**Health information exchange**–The mobilization of electronic healthcare information across organizations within a community, region, or hospital system

**Health information technology**–Technologies that manage and transmit health information for use by providers, consumers, payers, insurers, and all the other pertinent groups

**HITECH Act**–An act passed by Congress in 2009 that authorizes expenditures of approximately $20 billion over five years to promote the adoption and use of electronic health record technologies that would be connected through a national health information network

**Integration engines**–An application of a universal exchange language that can facilitate data exchanges with personal health records and other types of EHRs in a cloud

**Key**–A piece of data that can unlock and make readable cryptographically protected information

**Meaningful use**–Still pending an official definition from CMS, but ARRA requires that the definition include e-prescribing, the ability to exchange information with other healthcare providers to improve care, and the reporting of clinical quality measures to CMS

**Metadata**–Information that characterizes data, such as contextual information

**Metadata tag**–A tag accompanying each piece of data describing the attributes, provenance, and required security protections of that piece of information

**Middleware**–Software used to extract and reformat data elements from existing clinical systems

**Patient-centric**–Healthcare organized around the needs, capabilities, and desires of patients, with the goal of optimizing care in part through greatly improved uses of data

**Personal health record**–An electronic record of health information that is maintained, controlled, and shared by a patient-consumer

**Personalization**–Tailoring medical care to be optimized for the unique individual characteristics of the particular patient

**Physician Quality Reporting Initiative**–Established under the 2006 Tax Relief and Health Care Act, the initiative provides physicians with a financial incentive to voluntarily provide CMS with a report on three or more chosen quality measures that applies to their Medicare patient base

**Post-marketing surveillance**–A system by which to identify adverse events that did not appear during the drug approval process

**Primary care medical home**–A model of care that places the patient and primary care physician at the center of a virtual organization that is paid a fee to coordinate all care the patient receives from specialists and other providers

**Randomized clinical trials**–A type of clinical trial in which participants are randomly assigned to different forms of treatment

**Semantics**–The clinical or operational meaning of data

**Service-oriented architecture**–An approach to health IT that involves using software policies, practices, and frameworks to enable one user to access sets of "services" on another party's computers and data

**Standardized health records**–Health records that follow a standardized format that is comparable to all other formats and can be accessed by all necessary parties

**Syndromic surveillance**–Surveillance using health-related data that precedes diagnosis and signals a sufficient probability of a case or an outbreak to warrant a further public health response

**Syntax**–The formatting of data that are exchanged, as well as the details of the exchange protocols, including privacy protection and other important aspects

**Tagged data elements**–Data accompanied by metadata describing the attributes and privacy protections of the data

**Two-factor authentication**–The use of two of the following three in determining the identify of a principal: physical credentials (such as smartcards), biometrics (such as fingerprints), and a secret (such as a password)

**Universal exchange language**–A common language and format in which all electronic health systems can exchange data

**Usability**–The ease with which physicians and other healthcare providers can learn to use electronic records, capture data from clinical encounters, and then make use of the data to improve care delivery

**Value-based purchasing**–The concept that buyers should hold providers of health care accountable for both the cost and quality of care

**VistA**–An integrated system of software applications that directly supports patient care at Veterans Health Administration facilities

**XML**–Also known as extensible markup language, a set of rules for encoding documents in machine-readable form

# Appendix D: Abbreviations

**ACO**–Accountable Care Organization

**AHRQ**–Agency for Health Care Research and Quality

**ARRA**–American Recovery and Reinvestment Act

**CDA**–Clinical Document Architecture

**CDC**–Centers for Disease Control & Prevention

**CDS**–Clinical Decision Support

**CMS**–Centers for Medicare & Medicaid Services

**EHR**–Electronic Health Record

**FDA**–Food and Drug Administration

**HIE**–Health Information Exchange

**HHS**–U.S. Department of Health and Human Services

**HIPAA**–Health Insurance Portability and Accountability Act

**HL7**–Health Level 7, Inc.

**IHE**–Integrating the Healthcare Enterprise

**IOM**–Institute of Medicine

**ONC**–Office of the National Coordinator

**NHIN**–Nationwide Health Information Network

**NIST**–National Institute of Standards and Technology

**PCIP**–Primary Care Information Project

**PCMH**–Primary Care Medical Home

**PHR**–Personal Health Record

**PPACA**–Patient Protection and Affordable Care Act

**RHIO**–Regional Health Information Organizations

**SHARP**–Strategic Health IT Advanced Research Projects

**VHA**–Veterans Health Administration

President's Council of Advisors on Science and Technology

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