

Early Glimpses of the Learning Health Care System: The Potential Impact of Health IT



The Health IT for Actionable Knowledge project examines the experiences of six large health care systems that have used data from electronic health records and other information technology to conduct research and analysis related to health care delivery. This document is one of five reporting the results of this AcademyHealth initiative. Each report draws on examples from these early-adopting health systems to explore a range of issues relevant to the conduct of health services and other research using electronic clinical data. The six health system partners in this effort are Denver Health, Geisinger Health System, Kaiser Permanente, the New York City Department of Health and Mental Hygiene's Primary Care Information Project, the Palo Alto Medical Foundation Research Institute, and the Veterans Health Administration. AcademyHealth gratefully acknowledges the generous support of the California HealthCare Foundation in funding this project, and the U.S. Agency for Healthcare Research and Quality (AHRQ) for providing seed funding.

Summary

In addition to collecting and storing patient information for use in individual clinical encounters, electronic health records (EHRs) provide data for new types of research and analysis to be undertaken in delivery settings. EHRs enhance research capabilities by providing data that captures patient outcomes, is proximate to the point of care, and is available in near real-time. With such data, research becomes an important tool in the iterative innovation process referred to as the “learning health care system.” Among the types of inquiry in delivery systems facilitated by EHRs are quality improvement (QI) analysis, health services research (HSR), analysis to identify opportunities for workflow efficiency, training and research involving simulations, collaborative research with other organizations, public health research, and new types of clinical and basic scientific investigation. The ability to analyze EHR data in delivery systems has begun to blur traditional distinctions between research, especially HSR, and QI, creating new opportunities for multidisciplinary innovation in care delivery and the development of new research methodologies. At the same time, using EHR data for such inquiry requires particular sensitivity to hardware and software capabilities, data quality, and differences between cultures of research and health care delivery.

Introduction

The Health Information Technology for Economic and Clinical Health (HITECH) Act provisions of the 2009 American Recovery and Reinvestment Act (ARRA, P.L. 111-5) aim to make EHRs and the electronic exchange of medical information the norm in American health care. The Office of the National Coordinator for Health Information Technology (ONC), the office within the U.S. Department of Health and Human Services (HHS) with primary responsibility for implementing HITECH, is focused on achieving widespread adoption and initial “meaningful use” of EHRs by health care providers and on helping to establish standards that will support the secure exchange of electronic health information.

However, the potential of EHRs goes beyond recording medical information about particular patients for use in clinical encounters. EHR data can be aggregated in various ways and for several purposes. In some cases, the availability of electronic data enhances activities traditionally undertaken in health care delivery settings such as clinical research, quality assurance and improvement, and public health surveillance. In

the case of health services research, EHRs make the analytic skills that have heretofore been used mainly in academic pursuits both possible and valuable for the near real-time delivery of health care and for the management of organizations that provide that care.¹

This report discusses how EHR data are changing the ways in which we define and conduct “research” on health care and the important new opportunities these electronic capabilities create for health care providers. It is based on a series of meetings and case studies of six early health IT-adopting health systems in the United States conducted by AcademyHealth between 2009 and 2011 as part of its Health IT for Actionable Knowledge project. Three of these organizations—Kaiser Permanente, Geisinger, and the Veterans Health Administration (VHA)—are emblematic of the integrated health care delivery systems that were the earliest adopters of health information technology (health IT). Another two of the organizations studied, Denver Health and the New York City Department of Public Health’s Primary Care Information Project (PCIP), are public health and safety net providers. The sixth organization, the Palo Alto Medical Foundation (PAMF) and its Research Institute, began as a large multi-specialty medical group that has merged with other organizations in northern California to become an integrated regional delivery system. Their collective experiences offer insights into how the health care system as a whole might fully leverage EHR data as health IT is more widely adopted and used.

How Does Health Information Technology Change the Potential for Research on Health Care?

Electronic health records, introduced in the 1960s, actually had their roots in research. With a grant from the U.S. Public Health Service, Kaiser Permanente tested the first computer-based medical record, which it designed to support both patient care and health services research.² The VHA’s first EHR system was also designed by researchers within the organization, who piloted and studied a prototype EHR during the early 1980s. One reason for the historical link between research and EHR development may be the fundamental ways in which electronic data expands the capabilities of researchers while it simultaneously changes the way patient care is documented. In particular, EHRs facilitate the availability of data in three important ways:

- *The availability of clinical data including outcomes data.* Traditionally, electronic data for health services research was largely limited to administrative claims (health care records submitted to insurers and other payers by providers for reimbursement purposes), primary data collected specifically for research purposes, and vital statistics and data on reportable diseases collected for public health purposes. Claims data include procedures

and diagnoses. While the coding used in claims is intended to reflect the actual clinical situation for a patient, it is also a tool in providers’ strategies to maximize reimbursement, potentially at the expense of clinical precision and detail. Vital statistics and surveillance data used by public health officials, another source of data for researchers, also lack clinical detail. Although clinical laboratories increasingly report results electronically, providers traditionally store this information as part of patients’ paper records. More detailed clinical data collected directly from patients retrospectively for research is often expensive and may suffer from patients’ inaccurate memories. Abstracting clinical information from paper medical records is expensive and requires appropriate training.

By contrast, EHRs provide potentially ready access to detailed clinical data.³ Although work remains to be done to establish the relative accuracy of EHR data for particular purposes, EHRs provide researchers with greater flexibility in obtaining clinical data for a relatively small incremental cost compared to other sources of such data.⁴

- *The availability of data proximate to the point of care.* Information collected and stored electronically can be aggregated, analyzed, and provided back to the point of care with ease. Having integrated EHRs proximate to care is not only helpful to the care of individual patients, but it is also useful to support provider decisions, ensure quality of care, compare provider performance, and manage resources at or near the point of care. Traditionally, providers have had limited information available in the clinical care setting—they have had paper records for individual patients, and those records did not necessarily contain or provide ready access to documentation for all test results or care provided to a patient. Paper records also do not allow providers, at the point of care, to compare across patients or understand how their care might differ from their colleagues. This information has the potential to improve patient outcomes.
- *The availability of data in near real-time.* Creation and preparation of electronic data for research traditionally takes time. Administrative data belongs to payers. For Medicare, there is a lag of two or more years before claims data are available to researchers. Similar delays can exist for data from private insurers, if they choose to make claims available to researchers at all. Clinical abstraction of paper records and retrospective collection of data from patients also take time. Furthermore, academic incentives that reward accuracy and certainty over speed add to the technological barriers that hinder the quick availability of data and research results.⁵

Health IT as a Tool for Rapid Learning and Innovation

For health care executives and clinical leaders, the most important opportunity presented by EHR data may be its central role in what some experts are calling a “learning health care system.”⁶ This strategy uses electronic data to drive a “process of discovery as a natural outgrowth of patient care, ensuring innovation, quality, safety, and value and serving to reduce the gap between clinical care and research.”⁷ In an iterative, rapid-learning cycle, health care organizations systematically collect and analyze data, use evidence to identify opportunities to improve care, implement innovations, evaluate the outcomes, and develop new hypotheses to test. The potential improvements to health care in a learning system are seen as coming from multiple domains, including quality measurement and improvement, clinical research, and analysis of the comparative effectiveness of alternative treatments.⁸

A 2009 Institute of Medicine (IOM) workshop exploring the application of rapid-learning principles to cancer care focused on the variety of information tools that will comprise a national infrastructure for innovation. These tools include interoperability among data systems for health information exchange, patient registries, databases like the Food and Drug Administration’s Sentinel system (which collects data about adverse events associated with FDA-approved products), Web-based consumer information like the National Library of Medicine’s MedlinePlus, and the National Cancer Institute’s open-source Cancer Biomedical Informatics Grid (caBIG) described later in the box on page 4. At the base of this infrastructure for rapid-learning, however, are the EHRs maintained by individual patients’ health care providers.

A related framework for understanding technological change⁹ highlights many of the types of research undertaken in health care delivery organizations that are discussed later in this report. In this framework, innovation in health care is seen as existing on a spectrum that ranges from basic investigation to applied technological development and diffusion. Improvements in health care delivery begin with basic biomedical research findings which are translated into an understanding of the clinical safety and efficacy of potential treatments or other medical technologies in a controlled environment through animal studies and human trials. This knowledge is, in turn, translated into a more thorough understanding of what types of patients are likely to benefit, and in what type of setting, through comparative effectiveness and health services research under “real world” conditions. Finally, in order to improve population health, this knowledge is scaled up and implemented more broadly across the health care system with ongoing quality measurement and improvement.¹⁰

Figure 1: **Translational R&D and the Organization of Research at Geisinger**



Source: Geisinger Health System

The emergence of clinical research informatics as a specialized sub-discipline of the general field of biomedical informatics underscores the centrality of health IT to each of these types of knowledge translation and the research activities that make them possible.¹¹ Because EHRs are a major source of research informatics, health care delivery organizations are becoming an institutional home to the full spectrum of research translation activities. The organization of research activities at Geisinger Health Systems among its three research centers, as illustrated in Figure 1, reflects this translational model of research within a health care delivery organization.

Research in Health Care Delivery Organizations

The six health systems profiled as part of AcademyHealth’s Health IT for Actionable Knowledge project engage in activities that illustrate the range of research and analytic capabilities facilitated by health IT. Covering the full spectrum of innovation activities that comprise a learning health care system as described in the previous section, the experiences of these organizations also demonstrate how health IT helps break down traditional definitions and boundaries between different types of research and analysis. This section discusses each of these types of research activities, beginning with those that can most directly and readily improve the value of health care services delivered and moving toward those whose potential to improve care lies mainly in the future.

Quality Improvement. Health care delivery organizations have long devoted resources to assuring and improving the quality of care they deliver. The goal of QI is to eliminate the overuse, underuse, and misuse of health care services. In its 2001 report, *Crossing the*

Quality Chasm, the IOM identified the health care industry's lag in taking full advantage of information technology as a barrier to improved quality.¹² The access to outcomes data (in addition to the process information that has hereto dominated QI) and its real-time or near real-time availability, both of which are facilitated by EHRs, greatly enhance health care organizations' ability to address quality issues. All six of the health systems studied in the Health IT for Actionable Knowledge project report developing systems to collect and assess quality measures and provide immediate feedback to providers at the point of care through electronic "dashboards" and similar tools. Researchers can also use QI measures to study what affects the outcomes that clinicians believe are important, rather than the researchers creating their own measures over and over again. This both speeds the research process and makes the findings more relevant.

Health Services Research. According to the Agency for Healthcare Research and Quality (AHRQ), HSR "examines how people get access to health care, how much care costs, and what happens to patients as a result of this care. HSR seeks to identify the most effective ways to organize, manage, finance, and deliver high quality care; reduce medical errors; and improve patient safety."¹³ Five of the six health systems examined for the Health IT for Actionable Knowledge project provide examples of the diverse ways delivery systems are integrating HSR into their organizational structures and missions.¹⁴ In each case, the growth in HSR activities is linked to the capabilities for electronic data collection, storage, and analysis made possible by EHRs. In summary:

- Denver Health's HSR department started as a unit within the CEO's office. Originally conceived as a way to identify and disseminate best practices and other lessons learned about the organization and delivery of care in a municipal safety-net institution to the larger research and delivery system world, this group has been an active participant in the Accelerating Change and Transformation in Organizations and Networks (ACTION) project, a contracted partnership between AHRQ and 15 alliances of delivery systems with robust electronic data capabilities, broad clinical and research experience, and a proven ability to move research findings into practice.¹⁵ The HSR unit has subsequently been moved to the Department of Patient Safety and Quality, reporting to the Chief Quality Officer. Topics for research and analysis are both internally and externally generated and funded. Members of the HSR department also provide internal consultation to other Denver Health staff on issues related to research methods. Denver Health's EHR uses Seimens' software.
- The U.S. Department of Veterans Affairs Veterans Health Administration (VHA) maintains an internally funded Health Services Research and Development (HSR&D) service to undertake research

National Cancer Institute's Cancer Biomedical Informatics Grid (caBIG)

Between 2004 and 2010, the National Cancer Institute (NCI) has invested more than \$350 million in the Cancer Biomedical Informatics Grid (caBIG), a collaborative IT infrastructure for data collection, integration, analysis, and dissemination across NCI centers and programs designed to facilitate the discovery of new approaches to detection, diagnosis, treatment, and prevention of cancer. Begun as an attempt to develop standards for interoperability and analytic tools for cancer researchers and as a forum for comparing data related to gene expression related to cancer research, caBIG was expanded in 2007 to an initiative to develop a comprehensive open-source "enterprise" system to support all aspects of cancer research. Plans for this system have included an EHR and cloud computing.¹⁶

Because of caBIG's ambitious scope and significant budget, NCI Director Harold Varmus, M.D., created a working group to review the program upon his appointment in July 2010. The group's report underscored some of the potential problems in developing broad health IT systems from scratch. The working group affirmed the relevance of caBIG's original goals. In particular, caBIG "moved the cancer research community beyond messaging systems and limited structured vocabularies" to an "infrastructure that allows data to be harmonized across cancer centers."

However, it strongly criticized the program's effort to expand beyond those goals to develop "an overly complex and ambitious software enterprise of NCI-branded tools," especially for managing clinical trials. The report concluded that these NCI tools duplicate established commercial software, have not been widely adopted, and do not provide benefit commensurate with the upfront and on-going investment they require. The working group saw the lack of independent oversight and non-peer-reviewed funding decisions as key to caBIG's difficulties. In addition to recommending that NCI correct these short-comings in its process, the working group suggested that caBIG return to its original goals.¹⁷

on patient care, care delivery, health outcomes, cost, and quality in the VHA. In addition, the service supports the training of clinician and non-clinician researchers through post-doctoral career development awards. HSR&D research occurs throughout the VHA's medical centers, with locations specializing in particular types or topics of research. HSR&D developed their first EHR as a mechanism for collecting and storing patient data for research. As it has evolved as a key tool in providing care, the VHA has also enhanced the ability to

use EHR data for quality improvement by developing regional and national data warehouses and creating VA Informatics and Computing Infrastructure (VINCI), a secure virtual environment to improve researchers' use of VHA data while ensuring patient privacy and data security. The VHA uses EHR software it created itself.

- Kaiser Permanente (KP) is actually three distinct organizations: Kaiser Foundation Health Plan, Kaiser Foundation Hospitals, and the Permanente Medical Groups. Together, they operate eight regional health care organizations from Hawaii to Washington, D.C. The two California regions (North and South) account for two-thirds of the KP membership and nearly all the Kaiser Foundation Hospitals. KP was a pioneer in capitated health coverage in the United States, and its core product offerings are still full-service HMO plans. In response to the evolving health care marketplace, however, KP now also offers a variety of high-deductible and self-funded plans to purchasers. Most of the KP regions have dedicated research units that undertake both internally and externally funded studies. These research units include the Division of Research in the Northern California region, the Department of Research and Evaluation in Southern California, the Institute for Health Research in Colorado, and the Center for Health Research which includes the Georgia, Hawaii, Northwest and Mid-Atlantic regions. In addition, the KP Center for Effectiveness and Safety Research (CESR), founded in 2009, represents a national network of research across all eight Kaiser regions. HSR, which includes both institutional- and investigator-initiated studies, represents a significant portion of the more than 1,000 researchers and staff and the \$140 million annually (in 2010)¹⁸ devoted to research by KP. One distinctive feature of KP as a venue for HSR is that it functions as a capitated insurer and payer as well as a provider of care, which gives the organization a particular incentive to achieve greater value for each dollar in care delivered. KP's EHR uses Epic software.

- Geisinger is an integrated health care delivery system serving 31 of Pennsylvania's 67 counties, mainly in the central and northeastern parts of the state. The system sees about 350,000 primary care patients and about 700,000 specialty care patients each year. Scientific investigation at Geisinger is built upon a translational research and development model in which research is part of a continuum running from basic research to clinical trials and outcomes research to the implementation of new knowledge into clinical practice. The Center for Health Research, started in 2003, houses HSR as well as epidemiologic and community health research. The Clinical Innovations team, often in collaboration with the Center for Health Research, implements new models of care, and Geisinger Ventures seeks commercial partnerships to develop and market Geisinger innovations for the larger health care system. Spending for HSR is

The HMO Research Network (HMORN)

Three of the health systems examined as part of AcademyHealth's Health IT for Actionable Knowledge project (Geisinger, KP, and PAMF) are members of the HMORN. In addition to serving as a forum for researchers at member organizations to share ideas and best practices, the HMORN provides the infrastructure to carry out collaborative studies in epidemiology, comparative effectiveness, and other health services research. Support for HMORN research can come from the health plans themselves or from external sources, including the NIH Collaboratory established by the NIH Common Fund to facilitate the translation of research findings into patient care.

Key to the HMORN's research infrastructure is its ability to draw on the EHRs of its member health plans. The HMORN has created a virtual data warehouse (VDW) consisting of patient level administrative and EHR data. Using a set of standards established by an HMORN-wide working group, member health plans have created a parallel set of databases of pre-defined variables. Creating the databases ahead of time helps assure the efficiency of the process and the quality of the data. Maintaining the data at each health plan minimizes threats to data security and privacy. The VDW comprises demographic, health plan enrollment, encounter, procedure, diagnostic, provider, cancer/tumor, pharmacy, vital sign, and laboratory data. Because multi-center research adds to the regulatory complexity of obtaining approval to use data, the HMORN has also established streamlined procedures for creating data use agreements and for IRB review.¹⁹

not broken out separately from the \$16 million in total research spending at Geisinger, about 55 percent of which is supported by external or endowment funds (i.e., not clinical practice or other reimbursed care). Geisinger has its own capitated health plan covering 230,000 individuals, about half of whom get most of their care from Geisinger. Like KP, the role of insurers may increase the value of HSR and general research since the health system has a larger incentive than do providers without insurance risk to seek greater value through improved quality and efficiency. Geisinger's EHR uses Epic software.

- The Palo Alto Medical Foundation Research Institute (PAMFRI), which was founded in 1950, has long conducted HSR including some of the earliest studies on the cost of care in the 1960s.²⁰ PAMFRI is the dedicated research unit of the Palo Alto

Medical Foundation (PAMF), a multi-specialty group medical practice of more than 900 physicians and about 600,000 patients in four northern California counties. PAMF introduced an EHR using Epic software in 2000, and since 2008, all of PAMF uses this one system. PAMFRI reinforced its commitment to HSR by recruiting a senior health services researcher from academia to become the organization's director in 2008. Through close working relationships with clinical and executive leaders of PAMF, health services researchers at PAMFRI identify and address practical research questions with the intent of improving quality and efficiency of care. With appropriate privacy and patient protections, researchers have access to a regularly updated copy of the EHR database. Though some work is internally supported, researchers seek external funding as appropriate. Regardless of the source of support, the researchers give priority to questions that can result in publishable, generalizable knowledge. Of the \$9.6 million budgeted for HSR in 2012, 69 percent is from external sources with the remainder from other income, gifts, return on investments, and PAMF itself.²¹

The Use of Lean Process at Denver Health

In 2005, with initial support from AHRQ, Denver Health introduced the Lean method for rapid-cycle improvements to eliminate waste from the process of delivering health care. Based in part on the quality improvement theories of statistician W. Edwards Deming, Toyota first developed Lean for application to automobile manufacturing. The Lean process attempts to distinguish those steps in an organization's work flows, or "value streams," that add value for patients from those that do not. In adapting Lean to health care delivery, Denver Health relies on Rapid Innovation Events (RIEs), in which staff examine a particular value stream, find opportunities for greater efficiency with the goal of eliminating 50 percent of the waste, and implement appropriate changes, all within a one-week period. Managers and clinical staff participate in several RIEs each year. Administrators and clinicians throughout the organization who receive special training to become Lean Black Belts are responsible for identifying additional opportunities to eliminate waste. A key component of the Lean process is the identification of metrics and data with which to evaluate the impact of changes to a given workflow. Between 2005 and 2009, the Lean process generated \$42 million in financial benefit to Denver Health with \$8.8 of that amount attributable to the Black Belts alone. The program has gained momentum over time with over half of the \$42 million realized in 2009 alone.²²

A separate report written under the auspices of this project, "HSR Agenda Setting: Lessons from Three HIT-Enabled Health Systems," examines the HSR function at Denver Health, Geisinger, and PAMFRI in greater detail. In particular, it examines the history, placement, and role of HSR in each health system, how each organization determines what HSR questions to pursue, and the sources of HSR funding.²³

Research and Analysis for Efficiency Improvements. EHRs and related health IT can also help support delivery organizations' efforts to increase value by making the process of care more efficient. In recent years, Denver Health has adopted the Lean methodology, an approach originally developed by the automotive manufacturer Toyota, to reduce waste and improve the health care experience for patients. In an analysis of their Lean experience undertaken for AHRQ, Denver Health cites the benefit of information technology to provide the data needed for baseline and on-going monitoring.²⁴ The box to the left discusses the use of Lean at Denver Health in greater detail. In the course of the Health IT for Actionable Knowledge project, Geisinger, KP, PAMF, and the VHA all also cited the importance of clinical and administrative electronic data to support efforts to reduce waste.

Simulation in Research and Training. Simulation in health care has emerged as a significant tool for minimizing medical error, improving health outcomes, and creating efficiency. For some health care services in which experimenting on or learning from real patients puts those patients' well-being at risk, simulation can offer an effective alternative. Simulations can be used for training or to explore alternative clinical or management decisions. They can take several forms, varying in complexity, approximation of reality, and technological format. They can present the patient cases or other situations in verbal format, using actors or dummies in a realistic setting, or with computers. Outcomes can be determined by established rules and probabilities or by expert evaluation.²⁵ Data from EHRs can facilitate simulations by providing the knowledge base to identify areas where simulations may improve provider performance and provide the basis for understanding the likely outcomes of simulated actions. In the past several years, research involving simulation has become a funding priority for AHRQ.²⁶ Several of the health systems examined for this project, including Geisinger, KP, and the VHA, have developed simulation capabilities for training, evaluation of technology, and research.²⁷

Collaborative Research. Another trend among delivery systems with EHRs is their increasing involvement in research that spans multiple organizations. Collaboration in clinical, health services, or other research drawing on patient experiences among different health care organizations can increase sample sizes and provide opportunities to examine a greater diversity of patient populations. One key to such collaboration is the ability to understand,

harmonize, and possibly exchange data among different organizations' EHRs. Another key is the ability for individual researchers to bridge cultural or other differences across organizations and among themselves. As discussed later in this report, these requirements can present significant challenges.

All regions of KP share common EHR software, although data are not routinely shared across those regions. Efforts of the KP Center for Health Research, which undertakes studies that can span the health plan's northwest, southeast, and Hawaii regions, represent one such effort. Similarly, each VHA medical center uses the same EHR but maintains its own database of patient records. However, the creation of regional and national data warehouses has facilitated research involving more than one medical center. The Health Maintenance Organization Research Network (HMORN), a consortium of 19 health care delivery organizations including KP, Geisinger, and PAMF, provides a more extensive example. At the core of HMORN is a virtual data warehouse comprising a set of standardized data formats and coding conventions used by HMORN members. These conventions allow each plan to extract standardized data files for use by researchers in particular studies. The box on page 5 discusses the role of electronic data in HMORN activities in greater detail.

Research to Support Public Health Functions. EHRs also provide a new tool for those charged with public and population health. By electronically querying the EHR systems of individual providers, the New York City PCIP has been able to conduct near real-time syndromic surveillance, in which the city is able to measure the number of patients presenting at their physicians' offices with particular symptoms (e.g., flu-like symptoms) to be able to track the potential spread of infectious disease or environmentally-triggered health problems by neighborhood. In addition, PCIP can track progress toward achieving city-wide goals for prevention such as for immunizations, disease screening, or chronic disease management. Such information provides a potential tool for identifying and addressing public health needs more quickly than do more traditional, labor-intensive reporting and primary data collection. It also suggests that EHRs provide an opportunity for primary care providers to pursue public health objectives when treating individual patients. A separate Health IT for Actionable Knowledge report, "Using Health Information Technology to Improve Health and Health Care in Underserved Communities: The Primary Care Information Project," examines New York City's experiences in greater detail.²⁸

Clinical Research. Clinical research, especially research testing the safety and effectiveness of new pharmaceuticals, other therapies, and diagnostics, has long had its own infrastructure including tools for the collection, storage, and analysis of research data.

Five of the health systems partnering on this project participate in clinical trials. The New York City PCIP, part of a public health department, does not.

Much clinical research, especially studies sponsored by pharmaceutical or medical device companies, have been managed by firms known as clinical trial organizations (CTOs) or contract research organizations (CROs) that have traditionally collected and analyzed research data with their own software and computer systems. The adoption of EHRs by hospitals and other delivery organizations participating in clinical research provides an opportunity to integrate data for research and care functions. Five of the six partnering health systems for this project carry out clinical research.²⁹ The extent to which data collection, storage, and analysis for clinical research is integrated into these systems varies across and within institutions. In general, clinical research studies managed by outside CTOs/CROs tend to have their own electronic data systems while research studies initiated and managed internally are more likely to integrate their data collection and management to some degree with the EHR, for example by collecting needed patient data directly from the EHR or storage or analysis of research data behind the same electronic firewall that protects EHR data.³⁰ Among health systems examined as part of this project, the VHA is currently building capacity to leverage its EHR in the conduct of clinical trials sponsored by industry or other outside funders.³¹

Although such integration provides potential efficiencies, it also presents many of the technological, methodological, and governance issues briefly described below. A separate report from AcademyHealth's Health IT for Actionable Knowledge project, "Finding Value in Volume: An Exploration of Data Access and Quality Challenges," explores issues of data infrastructure, data quality, and data governance as experienced by the six health systems in greater depth. As described in the box on page 4, a recent initiative of the National Cancer Institute, the Cancer Biomedical Informatics Grid (caBIG) illustrates both the potential and challenges of using integrated electronic systems to support clinical research.³²

Basic Research, Genomics, and Phenomics. Basic scientific investigation to better understand human physiology, genetics, disease, and the basis for potential new treatments has traditionally been the purview of universities, academic medical centers, and to the extent that it provides the basis for potential new diagnostic tools or treatments, the laboratories of pharmaceutical and biotechnology firms. Computer informatics is a key tool in gene sequencing and related genomic research, even though the EHR *per se* is of limited value to basic science.³³

At the same time, however, EHRs can be particularly useful in translational research that tries to bridge basic biological understanding and human health. Phenomics, the study of an organism's physical and biochemical characteristics and how changes in genetic make-up and environmental factors affect them, is an example of this type of scientific investigation. Such research is ultimately intended to be the basis for personalized medicine, defined as "the tailoring of medical treatment to the individual characteristics of each patient."³⁴ In the delivery of care, a link to a patient's genetic information known to be associated with particular health conditions may help clinicians provide appropriate care. Such research links data from biological samples, especially genetic material, with clinical data recorded in patients' EHRs.

Several of AcademyHealth's partners on the Health IT for Actionable Knowledge project are leveraging their EHRs for phenomic and genomic investigation, including a large project by KP's Northern California region in collaboration with the University of California, San Francisco. With \$25 million in support from the National Institutes of Health, KP is creating a large data repository of more than 400,000 health plan members to support studies of genetic associations with drug metabolism and response, disease progression, development, and recurrence, environmental information, as well as characteristics of patients' lifestyle and behavior.³⁵ The VHA is also creating a large genomics cohort called the Million Veterans Program, which makes use of that health system's EHR.³⁶

New Opportunities and Challenges

The availability of electronic data gives health systems new ways to use research to better understand their organizations and the care they provide, but at the same time, these new capabilities have significant implications for the research process itself.

The Blending of HSR and QI. As more health services researchers take advantage of EHR data to work directly with delivery systems, the line that has traditionally distinguished HSR from other types of measurement and analysis that support health care administration and care has become less relevant. In the case of QI, for the purposes of privacy and human subject protections, the traditional distinction is that QI is part of the management of health care delivery systems, while research is performed in order to produce generalizable knowledge.³⁷ However, for health services researchers who work in delivery organizations, their research agendas are often intertwined with the work of their QI colleagues. For example, as described by one delivery system-based health services researcher providing input to this project, his HSR agenda includes assessing and describing the generalizable lessons that can be gleaned from practice changes initiated by QI professionals, and raising, from a research perspective, questions whose answers could be readily applied by the operating organization. The QI community is also increasingly focused

on systematically evaluating processes for assuring and improving quality as evidenced by the emergence of new fields of inquiry like improvement science and other attempts to evaluate and learn from actual innovations in QI. As discussed earlier, both health services researchers and QI professionals make use of EHR data that is available in near real-time close to the point of care.

The health systems examined as part of the Health IT for Actionable Knowledge project noted several benefits and implications of this blurring of QI and research:

- Regular interactions among health services researchers, experts in operations research, QI professionals, clinicians, IT specialists, and other professionals at these institutions yield multidisciplinary interpretations of problems and data, and are key to developing innovative approaches to achieving better cost and quality outcomes.
- The presence of researchers on the front lines of care delivery has introduced approaches to methodology that can run counter to traditional academic norms. As described by one delivery system-based health services researcher, academic rewards are often weighted towards sophisticated or new methods and dramatic answers to what are often narrowly defined questions. In delivery systems, however, greater value is given to more widely applicable results produced more quickly. Health services researchers involved in this project also noted that there can be differences in the necessary level of certainty for academic and health services research. They suggested that this difference may be related to the degree of control maintained over the results. In traditional academic research, the researcher has little control over how results are used once they are openly published. In addition, academia generally rewards the use of sophisticated methodological approaches. As a result, the peer-review process puts substantial emphasis on achieving a high level of certainty and identifying limitations. By contrast, delivery system researchers retain significant control over how their results are used. If analysis suggests a particular course of action, the organization can implement it. If a particular innovation does not work, the organization can abandon it or try an alternative. Everything else being equal, having such control over how research is used may reduce the level of certainty necessary to act.
- Even if the standards of evidence for delivery system research can vary from those expected in academia, researchers who work on the front lines of health care have noted the need for new analytic methods and inquiry appropriate to the use of EHR data.³⁸ Methodological challenges include finding new ways to deal with biases and confounding variables common to research not based on randomized controlled trials (RCTs) and developing better approaches to replicating results from one setting to another or scaling interventions up from a pilot phase to full implementation.

Data Infrastructure. A key potential benefit of delivery system research involving EHR data is the ability to link data across health care organizations. The six health care systems that participated in the Health IT for Actionable Knowledge project cited several reasons why such interconnectedness is desirable. Examining data from more than one organization or site of care can increase sample sizes, making it easier to detect hypothesized effects. In addition, multiple locations can create opportunities to examine natural experiments or isolate geographic or institutional factors related to outcomes of interest. One health system cited the ability to link to data beyond their own organization as an important tool in recruiting the best health services researchers. Another health system saw the ability to link to other organizations' data as an opportunity to learn about the benefits and drawbacks of the hardware and software systems that other health systems have chosen to inform their own organization's future purchasing decisions.

In order to use data from different health care delivery organizations, however, there has to be an infrastructure that allows different computing systems to interact and exchange data. Even when two organizations use the same software, it is possible that they record data in different fields or define particular variables differently. Such variation can occur even within a single organization. In order to use data from different systems, there need to be standards established before the research is undertaken, or researchers need to invest resources to understand and harmonize the data so observations are comparable.

Deciding what data to collect can also present difficulties. Data needs for research can differ from those for clinical care or administrative operations. For example, most clinical care can occur even if necessary information is in free-form text notes or scanned images of non-digitized records. Data in these formats, however, represent a significant hurdle for research. In addition, for retrospective study, the variables needed for HSR or QI may not be in the EHR. Even for prospective research or analysis, clinicians only have a finite amount of time to record data during a patient encounter, presenting potentially difficult choices about what pieces of information are most important to collect.³⁹ Even if the data needed for a particular study is not readily available, electronic systems generally create large amounts of data not previously available. The volume reflects both the number of observations (i.e., patients) in a database as well as the number of data elements available for each of those observations. Health systems participating in this project noted that the potential for large volumes of data to overwhelm researchers underscores the value of advance planning and the involvement of researchers in the initial design and implementation of data infrastructure.

Data Quality. Although EHRs facilitate the use of data for research and analysis, they often require more time and resources to clean than do administrative or other data used by researchers in the past. Health

systems researchers involved in this project pointed out that this need does not reflect less accuracy in EHR data than in traditional research data; rather, EHR data provides better opportunities for researchers to analyze its quality and clean it as necessary.

Threats to the quality of EHR data can arise from several sources. There can be inconsistencies in how often or in what fields different clinicians enter data.⁴⁰ As mentioned in the discussion of data infrastructure, there can be variation in how different clinicians interpret particular variables. Another potential difficulty derives from the use of open text fields in which clinicians can record notes in free form as opposed to using defined fields. Informaticians are developing software for Natural Language Processing (NLP), which attempts to electronically interpret free-form text in order to extract useful information. However, such software is still in development and varies in its effectiveness.

As with methodological rigor, accuracy is desirable, but the level of data quality necessary can depend on its use, particularly when achieving greater accuracy requires additional time and resources. For clinical or administrative decision-makers on the front lines of health care delivery, the cost of not having timely information may be greater than the benefit of achieving greater confidence in the accuracy of the data. For traditional research, the incentives are often reversed. Working out what level of data accuracy is needed for what purpose is an on-going process for researchers.⁴¹

A separate Health IT for Actionable Knowledge report examines issues related to data infrastructure and data quality in greater detail.⁴²

Data Governance. As suggested above, the regulatory requirements for human subjects and privacy protection are different, and generally more restrictive, for research uses of data than they are for QI activities, which are considered part of patient care. The blurring of lines between research and QI has created some uncertainty about appropriate data governance. While the basic concepts and rules, including the "Common Rule,"⁴³ have not changed, discussions with the six health systems examined in this project suggest that compliance with those rules may become more complicated. For example, if a researcher wants to explore a change in clinical care, this typically requires a full IRB review and informed consent by the patient/subjects. If a clinic wants to change its care, it is considered QI and no IRB review or informed consent is required. What happens, however, if a researcher wants to evaluate the clinic's decision to change practice? Is IRB review required? If an IRB does not review the researcher's effort, many journals will refuse to consider the resulting papers for publication. If the IRB is asked to review the intervention, is a full consent required of the patients, even if may impede workflow and make the clinic unwilling to make the change?

Discussions with different health systems also suggest that there is institutional variation in how they interpret and implement human subjects guidelines. For example, one health system participating in the Health IT for Actionable Knowledge project requires all investigation to be reviewed by their IRB. However, the organization has made the IRB process relatively simple for minimally-risky inquiry. Another health system, citing a lengthy and cumbersome review process and IRB members generally unfamiliar with non-clinical research, reported a more liberal interpretation of what analysis requires IRB review. Researchers from all of the health systems agreed that in light of new research capabilities created by health IT, the rules, guidance, and processes related to human subjects and privacy protection need updating, especially as they apply to HSR and other non-clinical trial research.

A separate Health IT for Actionable Knowledge report, “Legal and Policy Challenges to Secondary Uses of Information from Electronic Clinical Health Records,” looks specifically at issues related to data governance.⁴⁴

Bridging Cultural Divides. Undertaking HSR and other research in health systems also requires sensitivity to the differences between traditional academic culture and that of health care delivery. The need for faster turn-around and the acceptability of more uncertainty in the results in delivery system research have already been mentioned. Another difference is the degree of collaboration expected in the research process. In traditional academic HSR, the scientific culture is more oriented toward the individual researcher.⁴⁵ Typically, an investigator identifies an interesting question, finds appropriate data, secures external funding, and when satisfied with the validity of the results, disseminates them through peer-review publication and scientific conferences. Academic researchers may “partner” with a delivery system, but this is usually to obtain access to *their* data and many researchers feel that as long as they abide by the data use agreement, they have fulfilled their obligation to the delivery system. Although one project may beget another, it is far more common that at the end of the project (or even the completion of the data transfer) there is no further communication with the delivery system.

In contrast, researchers who choose to work *within* delivery systems have strong reasons to nurture their relationship to the organization, even if their work is totally externally funded. Data by itself is useful; data with access to the people who created it, who can explain its nuances, and who can provide additional information is extraordinarily valuable and offers the researcher a competitive edge in external funding. Providing such data and the access to the human capital behind it is costly to the delivery

system, but is a cost well worth bearing if the organization can see some returns from its collaboration with the researchers. The implications of these cultural differences include:

- Health services researchers in the organizations examined as part of the Health IT for Actionable Knowledge project stressed the importance of researchers developing both personal relationships with clinicians and administrators and an understanding of the incentives and pressures they face in order to identify research projects of value to the organization. They also stressed that personal relationships with clinicians can be key to understanding how they record information in the EHR and in interpreting research results.
- The graduate programs that train new health services researchers could serve the field by developing new curricula and practical experiences that familiarize young health services researchers interested in working in or with delivery systems with how these organizations operate. For mid-career researchers, there would also be value in developing learning experiences that provide a hands-on understanding of delivery system operations and the organizational values that underlie those operations.
- A commitment by delivery systems to HSR can also require adjustment for clinicians and administrators. For providers and administrators already facing competition for their time and attention, the potential benefit of research and working with researchers may not be immediately apparent. Devoting resources to research can be seen as taking resources away from patient care. One area where this tension has played out at some of the health systems examined as part of the Health IT for Actionable Knowledge project has been in access to data and IT professionals. The experience of these same health systems, however, suggests that leadership and a vocal commitment to research from the corporate suite can help other professionals in the organization appreciate its value.

Conclusion

The experience of the six institutions examined as part of AcademyHealth’s Health IT for Actionable Knowledge project confirms the potential value of electronic data systems for multiple uses beyond patient record keeping. However, by examining only six health systems, this project can only provide a flavor of the benefits, costs, risks, and challenges associated with secondary, analytic uses of EHRs. More effort is needed to identify and disseminate best practices and to know how to translate them for the great diversity of delivery organizations that will eventually have the capacity to use their EHR systems for more than just documenting patient

care. Nonetheless, the experience of these early health IT-adopting entities can serve to sensitize both researchers and health care delivery organizations to the ways in which electronic data changes the way research and analysis of health care is evolving.

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Acknowledgements

AcademyHealth gratefully acknowledges the time and expertise provided in the preparation of this report by the researchers, clinicians, IT professionals, executives at the health systems participating in AcademyHealth's HIT for Actionable Knowledge project – Denver Health, Geisinger Health System, Kaiser Permanente, the New York City Department of Health's Primary Care Information Project, the Palo Alto Medical Foundation Research Institute, and the Veterans Health Administration. Any errors are AcademyHealth's.

Endnotes

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