Health Information Technology in the United States, 2015:

Transition to a Post-HITECH World

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Table of Contents

List of Exhibits

Introduction to the 2015 Annual Report

Major Content Areas

Chapter 1: Research, Policy, and Progress

In chapter 1, the authors review the work of the HIT adoption initiative, noting the highlights and milestones of the past eight years. The authors begin in the pre-HITECH era and end with the current estimates of HIT adoption among physician and hospitals. The most recently available survey data finds approximately three-quarters of U.S. nonfederal acute care hospitals have at least a basic electronic health record (EHR) system. While this represents a significant increase from the prior year, many fewer hospitals appear to be ready to meet Stage 2 meaningful use criteria and may be subject to penalties.

Chapter 2: Health Information Exchange: Community HIE Efforts

A key motivation for the recent large national investment in EHRs was to enable better information sharing across health professionals that would result in high-quality, efficient, and coordinated care. Prior to the passage of the HITECH Act, most health information exchange (HIE) activity was local and regional, emerging in various health care delivery markets where stakeholders, such as health care delivery organizations, payers and state governments decided to pursue it. With the passage of the HITECH Act in 2009, and the subsequent creation of the State HIT Cooperative Agreement Program, there was a more concerted federal effort to increase HIE. Despite this investment, HIE efforts have persistently struggled with challenges to financial viability and sustainability. In this chapter, the authors present recently collected data from a national survey of HIE efforts. Findings suggest that HIE efforts operate in the vast majority of states and should, in theory, be broadly available to health professionals within those states. In addition, HIE efforts appear to be supporting the exchange of a board range of types of clinical data, with a particular focus on summary of care records, discharge summaries, and test results. In addition, HIE efforts are working to support new models of care and payment, suggesting that HIE efforts are adapting to meet the needs of the changing health care delivery system. However, the survey also finds substantial challenges. These challenges encompassed technical, financial, governance, human resources, privacy and security, and patient consent. Moving forward, it will be important to understand whether there is some prioritization of these barriers and then understand whether there is a set of policy remedies that are feasible.

Chapter 3: Evaluating HITECH: Successes, Barriers, and Future Opportunities

In this chapter, the authors review the results of major HITECH programs, including the Regional Extension Center program, State Health Information Exchange Program, Health Information Technology Workforce Development Program, the Beacon Community Cooperative Agreement Program, the Strategic Health Information Technology Advanced Research Projects, and the Global Assessment Monitoring the National Implementation of HITECH. Collectively, the evaluation of these efforts finds while HITECH helped to initiate significant progress with regard to the adoption and use of HIT in the United States, in general, it fell short of achieving its overarching goals to establish a highly effective and efficient health care system enabled by the advanced use of HIT. A number of factors contributed to these shortcomings characterized by a combination of both broad and program-specific challenges. Overall, the ambitious goals of HITECH, while optimistic, overlooked barriers that were beyond the scope of the legislation and the programs it authorized. As the nation continues on the path to optimize the use of HIT, successes, barriers, and lessons learned through the HITECH cooperative agreement programs will continue to shape these efforts.

Chapter 4: Big Data: A Realistic Assessment of its Applications to Health Care

In this chapter the authors discuss big data in the commercial marketplace, drawing on the literature and interviews with subject matter experts. The authors focus on the role of big data in the health care system, exploring definitions, challenges, limitations, and potential uses. The authors present several real-world applications that clinical organizations are implementing using big data technologies. Findings from this research suggests that there is indeed a strong potential for big data to transform the health care system, as long as concerns about data security, data sharing, the development of analytic capabilities, collaboration among stakeholders, and consumer engagement are addressed. This is a worthy agenda for federal agencies, health professionals, payers, vendors, and other key stakeholders to pursue during the next few years.

Chapter 5: Why Payment Reform and HIT Interoperability Must Follow the Same Innovation Route

In this chapter the authors argue that two forces have the potential to break through the current institutional impediments to providing a fluid and meaningful exchange of useful health information data: 1) the growing movement of payment innovation, and 2) the emergence of interoperable software architectures that can make data liquid and fungible.

Chapter 6: Roadmaps for the Future of National Health Information Technology Infrastructure

In this chapter, the authors profile and compare three of the most influential reports that speak to the development of our country's HIT infrastructure, and shaped current efforts, led by ONC, to bolster this infrastructure by specifically focusing on a key challenge: the lack of robust interoperability. These reports are: 1) the *Report to the President Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward*; 2) *A Robust Health Data Infrastructure*; and 3) the 2014 report from the JASON Task Force. The review suggests that ONC's current approach to work toward nationwide interoperability has been heavily shaped by the ideas developed in these reports.

Chapter 7: Coordinator's Corner

In an effort to provide insight on how the national investment in HIT has, has not, and can catalyze broader efforts to transform health care delivery, the authors asked David Brailer, David Blumenthal, Farzad Mostashari, and Karen DeSalvo to reflect on their time as the National Coordinator for Health Information Technology. Their reflections are synthesized in this chapter.

Chapter 1: Research, Policy, and Progress

Samantha Penoyer and Catherine DesRoches

The inaugural edition of the *Annual Report on Health Information Technology in the United States* was released in 2006.[1] At that time, the technology landscape was very different than today. The iPhone® had not yet been released. Facebook had just become available to the general public and Twitter was in its infancy. Today the landscape is markedly different. Ninety percent of Americans have cell phones and of these, 64 percent own a smartphone.[2] The explosion of applications and new mobile technologies has altered the way Americans communicate and share information across the spectrum. These mobile devices are used extensively for communication, searching for information, and sharing data. Recent research by the Pew Research Center indicates that Americans are also using these mobile technologies to research health questions or concerns and track their personal health information including diet, exercise, and key indicators such as blood pressure.[3] This change in the use of mobile technologies over the past nine years has been accompanied by an increased use of health information technology (HIT) in physician offices and hospitals.[4] Unlike the growth in mobile technologies, which was spurred by consumer demand, the growth of HIT proceeded more slowly and was advanced through significant policy changes and public investment.[5]

The HIT adoption initiative has been tracking the landscape of Health Information Technology adoption before, during, and after this period of policy activity and public investment. In this chapter, we review the work of the initiative, noting the highlights and milestones over the past eight years. We begin in the pre-HITECH era and end with the current estimates of HIT adoption among physicians and hospitals.

Pre-HITECH: Establishing Definitions, Developing Capacity for Measurement, and Monitoring and Determining Baseline

Prior to the implementation of HITECH, adoption of HIT was less rapid than anticipated, which was surprising given the expectation that HIT would increase quality of care.[6] Understanding the rate of HIT adoption, the characteristics of health professionals and hospitals adopting HIT, and the barriers that existed were critical to inform policy development and to spur HIT adoption. To answer these questions, it was imperative to establish definitions for key elements of the aforementioned research questions: electronic health record (EHR) and adoption.

An environmental scan of the EHR definition landscape revealed slightly differing definitions from organizations and from national surveys.[7] For example, the International Organization for Standards (ISO) offered a global definition about the capacity of an EHR, while the Institute of Medicine (IOM) detailed core functionalities and key elements included in each. An expert consensus panel (ECP) reviewed these definitions and those included in high-quality national surveys and through a modified Delphi process, determined that the following functions are essential for a basic EHR: health information and data, results management, order entry management, and decision support. The ECP suggested that as EHR adoption becomes more widespread, interoperability and exchange of information should be included to determine adoption beyond a basic EHR.[8]

A measurable definition of adoption, along with measures definitions of EHR functionalities was critical to answering the research questions. “Adoption” is a process that captures the acquisition, installation, and use of EHRs. The first step–acquisition–includes researching, budgeting, and investing in an EHR system. Next, installation includes the stages of hardware and software deployment. Finally, use means not only having systems usable but also that health professionals are actually using the EHR functions, or in different units in the inpatient setting. All three steps must be completed for the EHR to be considered adopted.[9]

Finally, to begin monitoring HIT adoption among health professionals who serve vulnerable populations, the ECP developed recommendations for: (1) the definition of vulnerable populations, and (2) ways to identify health professionals who serve them. The ECP determined that racial and ethnic minority populations and low-income patient populations were the highest priority for monitoring EHR access. The ECP identified Community Health Centers (CHCs), public hospitals, and physicians serving high volumes of patients that meet the definition of vulnerable were identified as health professionals who served vulnerable populations.[10]

At that time, valid and generalizable EHR adoption estimates were difficult to determine due to a lack of national surveys with adequate sample size, response rates, and high-quality content. Once these definitions were established, baseline EHR adoption rates were estimated using nationally representative data. These baseline estimates were unique at the time because they were based on physician and hospital adoption of the individual electronic functionalities determined by the ECP to be a necessary component of a functional electronic health record system (see Exhibit 1). Using these definitions, roughly 4 percent of physician practices reported having a fully functional EHR, while 13 percent reported having a basic EHR.11 Adoption of a fully functional EHR was largely driven by practice size after controlling for a wide range of variables. In the inpatient setting, only 1.5 percent of hospitals had a comprehensive EHR and an additional 7.6 percent had a basic system.[12]

Exhibit 1: **Electronic Functionalities Required for Basic and Comprehensive EHRs in Physician Offices**

Practice has an electronic system for:	Basic EHR	Comprehensive EHR
Health information and data		
Patient demographics	X	X
Patient problem lists	X	X
Medication lists	X	X
Clinical notes	X	X
Notes including medical history and follow-up		X
Order entry management		
Orders for prescriptions	X	X
Orders for radiology tests		X
Prescriptions sent electronically		X
Orders sent electronically		X
Results management		
Viewing laboratory results	X	X
Viewing imaging results	X	X
Electronic images returned		X
Decision support		
Drug interaction warnings		X
Out of range test levels highlighted		X
Reminders regarding guideline-based interventions or screenings		X

Source: DesRoches, CM, Campbell, EC, Rao, SR, et al. 2008. “Electronic Health Record Adoption in the Ambulatory Setting: Findings From a National Survey of Physicians.” *New England Journal of Medicine*, vol. 359, pp. 50–60.

Exhibit 2: **Electronic Functionalities Required for Basic and Comprehensive EHRs in Hospitals**

Hospital has an electronic system for:	Comprehensive EHR*	Basic EHR with clinician notes+	Basic EHR without clinician notes+
Electronic Clinical Documentation			
Patient demographics	X	X	X
Physician notes	X	X	
Nursing assessments	X	X	
Problem lists	X	X	X
Medication lists	X	X	X
Discharge summaries	X	X	X
Advanced directives	X		
Results viewing			
Lab reports	X	X	
Radiology reports	X	X	
Radiology images	X		
Diagnostic test results	X	X	
Diagnostic test images	X		
Consultant reports	X		
Computerized Health Professional Order Entry			
Laboratory tests	X		
Radiology tests	X		
Medications	X	X	X
Consultant requests	X		
Nursing orders	X		
Decision Support			
Clinical guidelines	X		
Clinical reminders	X		
Drug allergy alerts	X		
Drug-drug interaction alerts	X		
Drug-lab interaction alerts	X		
Drug dosing support	X		

* Comprehensive EHR requires presence of each functionality in all clinical areas.

+ Basic EHR requires presence of each functionality in at least one clinical area of the hospital.

Source: Jha, AK, DesRoches, CM, Campbell, E., et al. 2009. “Use of Electronic Health Records in U.S. Hospitals.” *New England Journal of Medicine*, vol. 360, p. 1628.

The major barriers reported at that time among hospitals and physician practices were financial. Available data revealed the financial burden of adopting an EHR was reported more often as the predominant barrier by small, under-resourced health professionals, which are more likely to serve vulnerable patients. More than 90 percent of CHCs cited that lacking the capital to invest in EHR systems as an important or very important obstacle for adoption, which is likely due to CHCs' reliance on Medicaid payments and public grants rather than other, higher third-part payments. Policy recommendations to address these barriers included financing and operational support to facilitate adoption and continue supporting the maintenance of EHR systems.

HITECH: Policy Implementation

In response to the slower-than-expected adoption of HIT, Congress included the Health Information Technology for Economic and Clinical Health Act as part of the American Recovery and Reinvestment Act (ARRA) of 2009. This marked the start of major policy implementation to spur the advancement of HIT across the United States. HITECH provisions aimed to address the financial and technological barriers reported by health professionals who were slow to adopt EHR systems. A variety of programs described in detail in chapter 4, were implemented under HITECH to ease the burden of these barriers on health professionals and spur advancement of HIT:

- Strategic HIT Advanced Research Projects (SHARP) Program
- HIT Workforce Development Program
- Beacon Community Cooperative Agreement Program
- Health Information Technology Extension Program
- State Health Information Exchange Cooperative Agreement Program

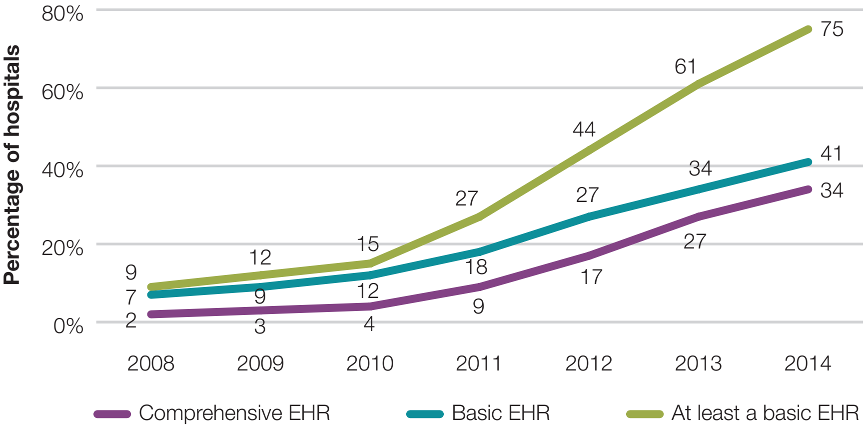
In addition to these programs, HITECH authorized the Centers for Medicare & Medicaid Services (CMS) to provide financial incentives to health professionals who participate in Medicare or Medicaid. The Medicaid program provided incentives to health professionals who attested to adopt, implement, or upgrade their EHR system, which addresses the initial financial investment barriers cited prior to HITECH. Subsequent years of the Medicaid EHR Incentive program would provide incentives to meaningful users of EHR systems. Unlike Medicaid, the Medicare EHR Incentive program does not provide incentives for adoption, implementation, or upgrading EHR systems. Rather, it began by providing incentive payments for meaningful users of EHR systems and, in subsequent years, will penalize health professionals that are not meaningful users of EHR systems. By the time HITECH was implemented, about a quarter of physicians and just over 10 percent of hospitals had at least a basic EHR system.[13,14] However, very few hospitals and physicians could meet the criteria for Stage 1 meaningful use incentive payments.

Was HITECH Successful in Increasing EHR Adoption?

Hospitals

A recent report by the Office of the National Coordinator for Health Information Technology, details findings from the American Hospital Association's annual survey of EHR Adoption.[15] The finding showed that by 2014, 75.5 percent of hospitals had adopted at least a basic EHR, a substantial increase from 58.9 percent in 2013 (Figure 1). Between 2013 and 2014, basic EHR adoption rates increased from 33.4 percent to 41.1 percent, and comprehensive EHR adoption rates increased slightly more, from 25.7 percent to 34.4 percent.[16] When compared to the percentage of hospitals with a basic (7.9%) or comprehensive (1.5%) system in 2008, it is clear that the nation's hospitals have made significant progress toward the goal of universal EHR adoption.

Exhibit 3: **EHR Adoption Among U.S. Hospitals, 2008–2014**



Source: Dustin C, Gabriel M, Searcy T. "Adoption of Electronic Health Record Systems Among Non-federal Acute Care Hospitals 2008–2014. ONC Data Brief, no. 23." Office of the National Coordinator for Health Information Technology: Washington DC; Adler-Millstein, J, DesRoches, CM, Furukawa, MF., et al. 2014. "More Than Half of U.S. Hospitals Have at Least a Basic EHR, But Stage 2 Criteria Remain Challenging for Most." *Health Affairs*, 33(9): pp. 1664–1671; Authors calculations.

EHR Adoption by Hospital Type

Additional analysis of the AHA data by the authors found, as in prior years, hospitals were more likely to have at least a basic EHR if they were large (49.9% comprehensive, 35.3% basic, and 14.7% less than basic, $p < 0.001$); a major teaching hospital (56.7% comprehensive, 30.5% basic, and 12.7% less than basic, $p < 0.001$); not-for-profit (40.6% comprehensive, 37.2% basic, and 22.2% less than basic, $p < 0.001$); and urban (37.6% comprehensive, 40.8% basic, and 21.6% less than basic, $p < 0.001$) (Exhibit 2). There were also differences by region, with the Midwest having the highest proportion of comprehensive EHR adoption (38.6%) and the Northeast having the highest proportion of basic EHR adoption (45.7%, $p=0.008$ across categories).

Data Exchange

Seventy-six percent of hospitals reported exchanging data with outside health professionals, including ambulatory health professionals and other hospitals in 2014, up from 62 percent in 2013 and 41 percent in 2008, the year the survey began including this measure. This data could include laboratory results, radiology reports, clinical care summaries or medications. This rate of exchange varied by state, ranging from 100 percent of hospitals in Rhode Island and Delaware to 42 percent in Nevada.

Exhibit 4: **Hospitals Exchanging Data With Outside Health Professionals or Hospitals, 2014**

State	Percentage	State	Percentage
United States	76	Missouri	65
Alabama	76	Montana	63
Alaska	86	Nebraska	69
Arizona	79	Nevada	42
Arkansas	79	New Hampshire	88
California	68	New Jersey	83
Colorado	80	New Mexico	82
Connecticut	77	New York	76
Delaware	100	North Carolina	78
District of Columbia	66	North Dakota	85
Florida	82	Ohio	86
Georgia	83	Oklahoma	72
Hawaii	91	Oregon	87
Idaho	58	Pennsylvania	87
Illinois	79	Rhode Island	100
Indiana	85	South Carolina	81
Iowa	66	South Dakota	80
Kansas	60	Tennessee	69
Kentucky	82	Texas	66
Louisiana	77	Utah	76
Maine	67	Vermont	80
Maryland	88	Virginia	93
Massachusetts	85	Washington	70
Michigan	78	West Virginia	71
Minnesota	83	Wisconsin	80
Mississippi	55	Wyoming	67

Source: Swain M, Charles D, Patel V, Searcy T (April 2015). "Health Information Exchange Among U.S. Non-Federal Acute Care Hospitals: 2008–2014. ONC Data Brief, no. 24." Office of the National Coordinator for Health Information Technology: Washington, D.C.

Hospital Participation in the CMS EHR Incentive Program

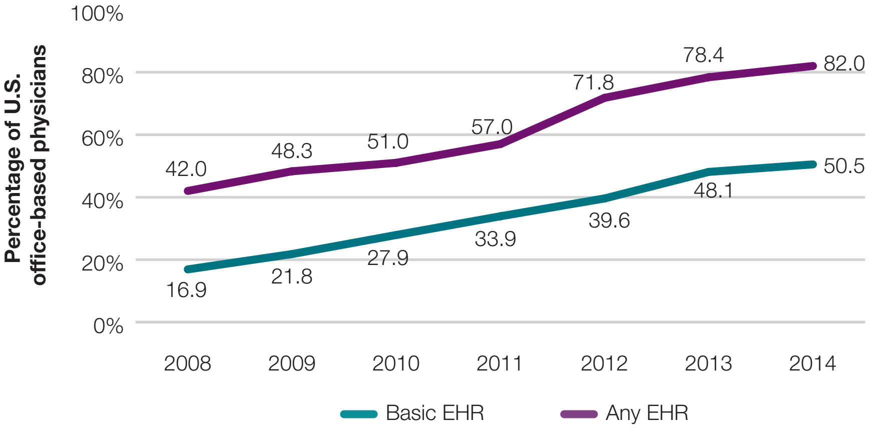
Recent data from CMS on the proportion of eligible hospitals attesting to and receiving payments for achieving meaningful use suggest that the nation's hospitals are still facing challenges to implementing and using an EHR system in a way that will improve care. This data shows 4,379 hospitals attesting to meaningful use at least once in the five years since the inception of the payment program. However, the data for Stage 1 can be difficult to interpret because CMS releases an "ever paid" and "ever attested" number. This approach may overstate the number of hospitals currently participating in the program, as hospitals are required to attest to meaningful use every year.

The current data on Stage 2 attestation does not suffer from the same complications as Stage 1 because 2014 is the only year that CMS has reported on Stage 2 thus far. In 2014, 1,826 hospitals successfully attested to meeting Stage 2 criteria (approximately 38% of all hospitals registered for the meaningful use incentive program)–far fewer than the 4,379 ever attesting to Stage 1. This reduction in the number of attestations suggests that even those hospitals that have met Stage 1 criteria may be facing significant challenges in achieving Stage 2.

Physicians

The National Ambulatory Medical Care Survey EHR supplement conducted by the National Center for Health Statistics, regularly collects nationally representative data on the rate of EHR adoption among U.S. office-based physicians. The most recent data from this survey, collected in 2014, suggest that approximately one-half (51%) of U.S. office-based physicians have a basic EHR. The percentage of physicians with a basic EHR varies from 74 percent in North Dakota to 29 percent in New Jersey (Exhibit 5).

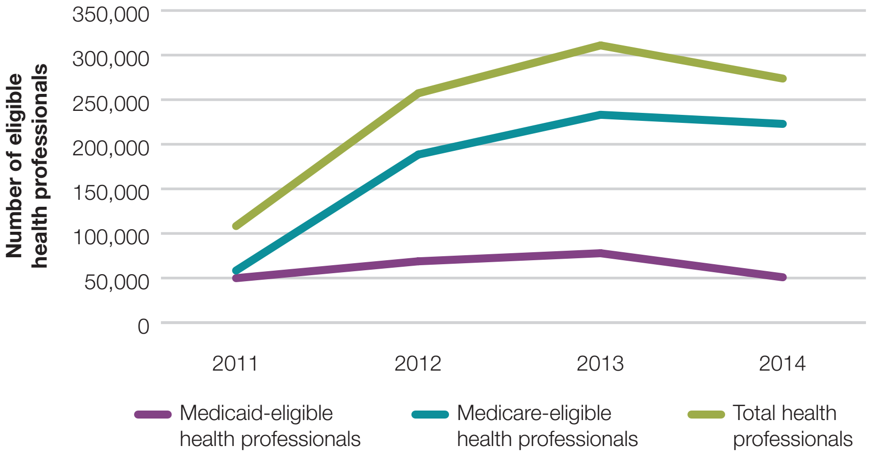
Exhibit 5: **EHR Adoption Among U.S. Office-Based Physicians, 2008–2014**



Source: National Center for Health Statistics. *NAMCS EHR Supplement*, 2014.

Data on meaningful use attestations and payments to health professionals through CMS' EHR Incentive program suggest fairly robust participation with 305,124 eligible health professionals successfully attesting to meeting meaningful use standards by July 2015. However, similar to U.S. hospitals, health professionals appear to be having difficulty achieving the more stringent Stage 2 criteria. Of the attesting health professionals noted above, only 20 percent (59,918) had successfully attested to Stage 2.[17] Moreover, overall participation in the program declined between 2103 and 2014 for eligible health professionals in both the Medicare and Medicaid EHR Incentive Programs (Exhibit 6).

Exhibit 6: **Meaningful Use Payments to Eligible Health Professionals by Program Year**



Source: Centers for Medicare and Medicaid Services. July 2015. *EHR Incentive Data Health Professional Summary*. Available at: www.cms.gov/EHRincentiveprograms.

Post-HITECH: Policy Impact

The lasting impact of HITECH remains to be seen. As the incentive programs progress to more advanced functionalities in later stages of meaningful use, and as the penalty phases of the programs begin, health professionals will have to continue moving toward health information exchange, patient engagement, and quality measurement. While the impact of HITECH is not yet clear, the pace of adoption of technologies by the public is likely to continue at a rapid pace. Consumer engagement with technology is likely to bring further pressure to bear on health care organizations as patients seek ways to use these devices to track and transmit their own data and interact with health care health professionals. In the following chapters of this report, we review what is known about the effect of HITECH and explore the possibilities of a post-HITECH future.

Endnotes

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Chapter 2: Health Information Exchange: Community HIE Efforts

Julia Adler-Milstein, PhD, Jennifer Gilbert, and Ashish K. Jha, MD, MPH

Introduction

A key motivation for the recent large national investment in electronic health records (EHRs) was to enable better information sharing across health professionals that would result in high-quality, efficient, and coordinated care.[1] Electronic health information exchange (HIE) can also facilitate improved patient access to their own health information and the ability to draw on multiple sources of clinical data for public health surveillance, research, and other population health management activities.[2] Indeed, there has been little disagreement on the need for HIE or the potential value from enabling HIE to occur. What has been less clear is the best approach to HIE and the associated role for federal and state policy efforts.

Prior to the passage of the HITECH Act, most HIE activity was local and regional, emerging in various health care delivery markets where stakeholders, such as health care delivery organizations, payers, and state government, decided to pursue it. With the passage of the HITECH Act in 2009, and the subsequent creation of the State HIE Cooperative Agreement Program, there was a more concerted federal effort to increase HIE. However, neither meaningful use (MU) criteria nor the requirements of the State HIE Cooperative Agreement Program specified how HIE must occur. Meaningful use criteria focused on HIE use cases, such as electronic exchange of lab results, ePrescribing, and summary of care record exchange following a care transition.[3] Each state received money under the Cooperative Agreement Program to ensure that all health professionals in their state had the ability to meet the meaningful use criteria that required HIE.[4]

The result has been a proliferation of efforts to enable HIE, including growth in the number and scope of local and regional efforts, as well as new state-level efforts created with funding from the HIE Cooperative Agreement Program.[5] However, HIE efforts have persistently struggled with a set of challenges, spanning varied domains from technical to governance to financial sustainability. It is therefore important to continue to monitor progress of HIE efforts across the nation, and in particular, assess whether they operate in the majority of health care delivery markets, enable the exchange of key types of clinical data and support key HIE use cases, and whether they are financially sustainable, particularly now that the funding from the State HIE Cooperative Agreement Program has ended.

Therefore, in this chapter, we present recently collected data from a national survey of HIE efforts. The data speak to the overall progress toward nationwide HIE, as well as the gaps and barriers. We conclude with a set of policy recommendations for how to ensure that current efforts to promote HIE can thrive and the United States can realize the large anticipated gains from better availability of clinical data.

Methods

We sought to survey all organizations in the United States that facilitate exchange of clinical data between independent entities (organizations with no shared financial or governance relationship). We relied on our list of 202 efforts that were potentially engaged in facilitating HIE from four prior national HIE surveys that we conducted between 2007 and 2012.[5–8]

Our survey instrument included two parts. The first asked respondents screening questions to determine whether, as of December 1, 2014, the organization was facilitating clinical data exchange among independent entities or at least pursuing it as a goal. Respondents that met these criteria were prompted to complete the second part of the survey, which asked for organizational demographics (numbers and types of stakeholders involved in data exchange, governance), types of data exchanged, ability to support meaningful use criteria, funding sources, and barriers to development. The survey was administered between December 2014 and May 2015. We determined that 44 organizations on our initial list (22%) did not meet inclusion criteria, most often because they were a defunct HIE organization or had been misclassified in our source data as an HIE effort when in fact they were a participant in an HIE effort. Of the 158 remaining HIE efforts, we received responses from 127, a response rate of 80 percent. We classified the 127 respondents as either "operational" if they were actively facilitating exchange of clinical data between independent entities of any type, or "planning" if they were pursing clinical data exchange but not yet exchanging data.

Key Findings

Number of HIE Efforts and Growth

We identified 106 operational HIE efforts and 21 efforts that were in the planning phase. The most highly represented type of organization was Health Information Organizations (HIOs), (51% of the sample selected this designation), followed by State HIEs or State-Designated Entities (an organization that runs HIE efforts on behalf of a state), for which 25 percent of the sample selected this designation (Exhibit 7).

Exhibit 7: **Types of Organizations**

Type of Organization	Frequency	Percentage (Denominator = 127)
Health Information Organization (HIO)	65	51.2%
State HIE or State-Designated Entity (SDE)	32	25.2%
Health Care Delivery Organization (e.g., hospital, IDN, IPA, ambulatory practice)	17	13.4%
Community-Based Organization	11	8.7%
Nongovernmental Organization (NGO) or Policy/Advocacy Group	7	5.5%
Public Health Department or Agency	6	4.7%
Technology Vendor	6	4.7%
State Medicaid Agency	3	2.4%
Academic Institution	3	2.4%
State Government (other than state Medicaid or public health)	2	1.6%

Note: Respondents could identify as more than one type of organization.
Source: Authors' analysis of survey data.

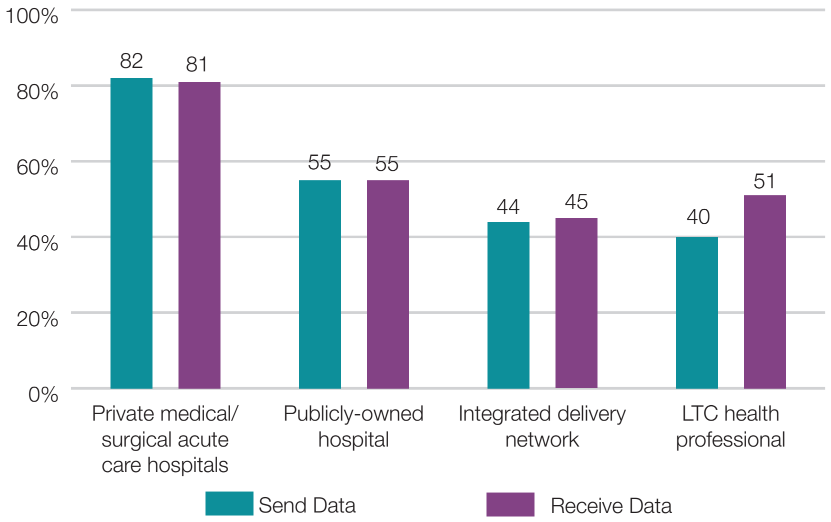
Many operational efforts had been actively exchanging clinical data for five or more years (40%). The next largest group of respondents became operational more recently and had been exchanging data for three–four years (23%). This suggests that a group of efforts was able to become operational with the new support for HIE under HITECH. More than three in five efforts operated as established, independent organizations and the remaining operated from within another organization (e.g., a hospital or an integrated delivery network).

Eighty-four percent of states had at least one operational HIE effort in the state, and 68 percent of states had at least one operational effort that reported covering the entire state. For 30 percent of states, the effort covering the entire state was a State or SDE effort. For the 56 percent of states with one or more operational local/regional HIE efforts that did not cover the entire state, on average, these efforts covered 12 percent of hospital service areas (HSAs) in the state.

Types of Participants

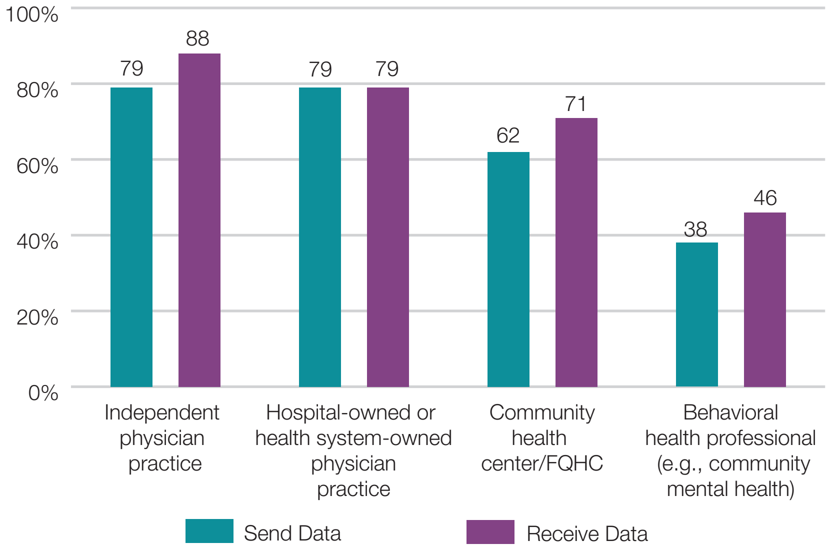
Among operational efforts, the most commonly reported stakeholders to send and receive data in inpatient facilities were private medical and surgical acute care hospitals (in 82% of operational efforts) (Exhibit 8). In terms of ambulatory facilities, the most commonly reported stakeholders to send and receive data were independent physician practices (in 88% of efforts) (Exhibit 9). Within other stakeholder categories, the most commonly reported participants involved in data exchange were public health departments (56% receive and 44% send) as well as independent labs and imaging centers (Exhibit 10). Payers were involved in data exchange in approximately one-quarter of operational HIE efforts.

Exhibit 8: **Engagement in HIE Efforts Among Inpatient Health Professionals**



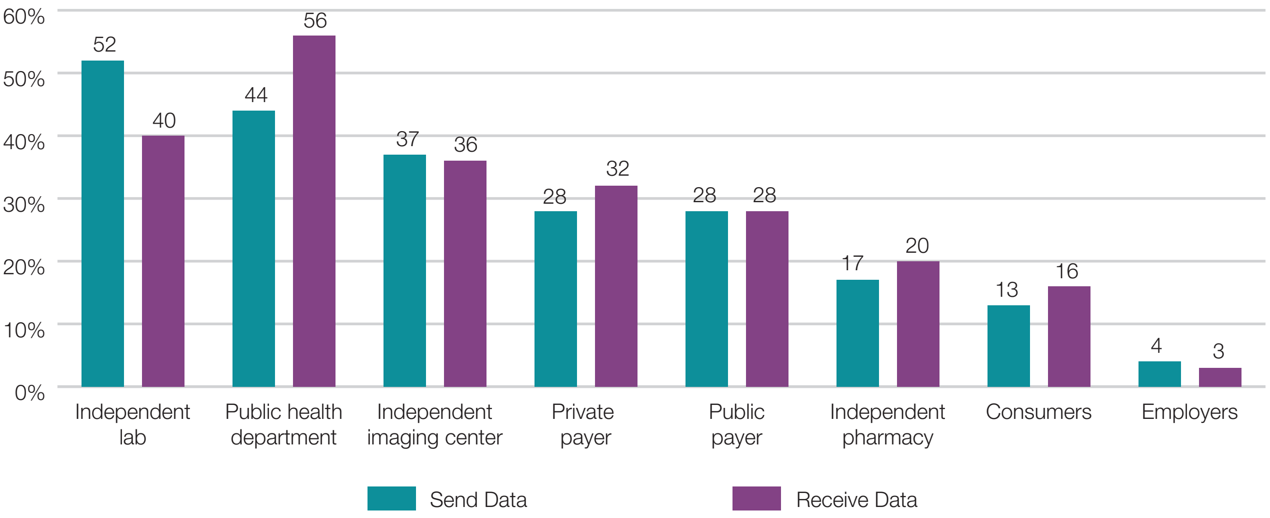
Source: Authors' analysis of survey data.

Exhibit 9: **Engagement in HIE Efforts Among Ambulatory Health Professionals**



Source: Authors' analysis of survey data.

Exhibit 10: **Engagement in HIE Efforts Among Other Stakeholders**

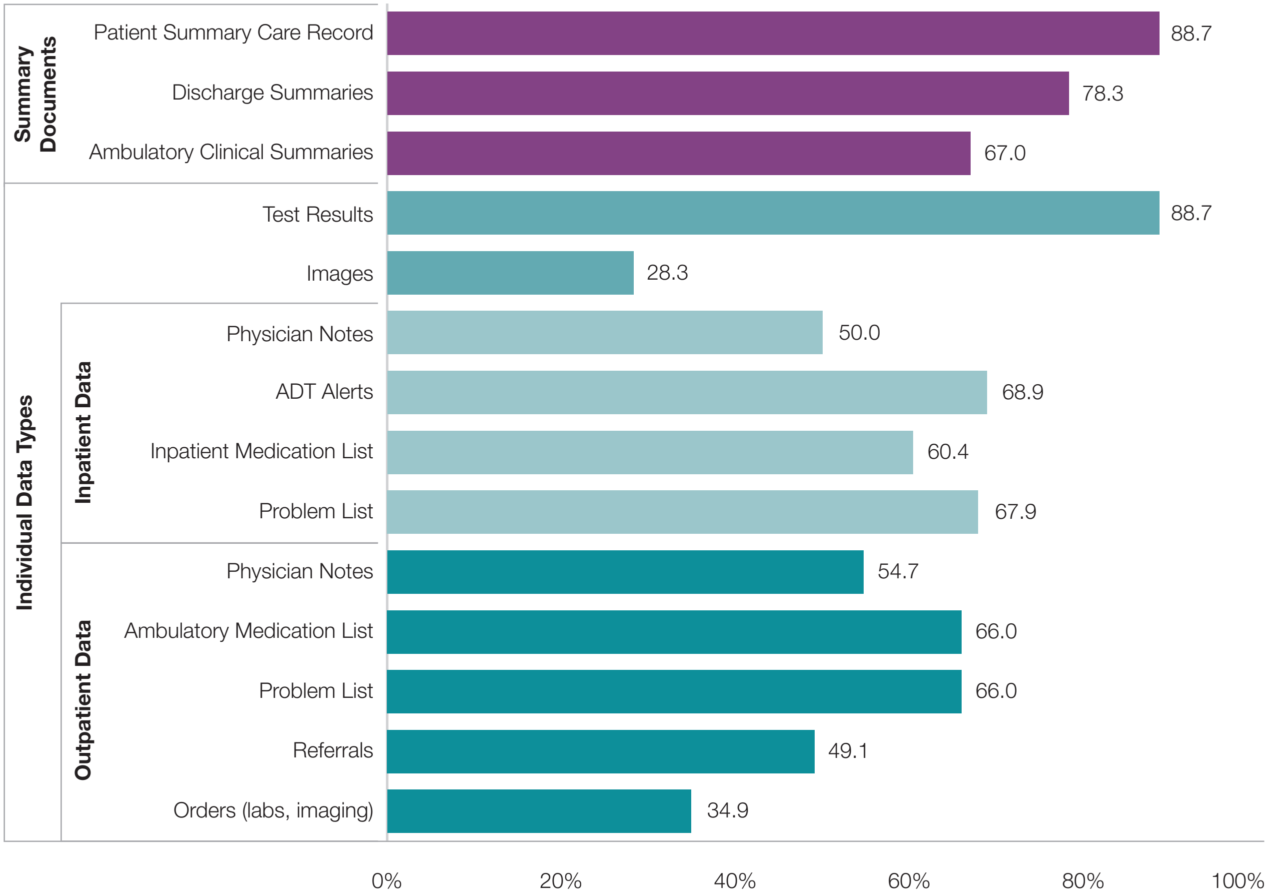


Source: Authors' analysis of survey data.

Types of Data Exchanged and Use Cases

Among the three types of summary documents, patient summary of care records were exchanged by 89 percent of operational HIE efforts, followed by discharge summaries (78%) and ambulatory clinical summaries (67%) (Exhibit 11). Among individual types of data, test results were the most common type of data exchanged (89% of efforts) followed by admission-discharge-transfer (ADT) alerts (69%) and inpatient problem lists (68%). Images were least often exchanged (28%).

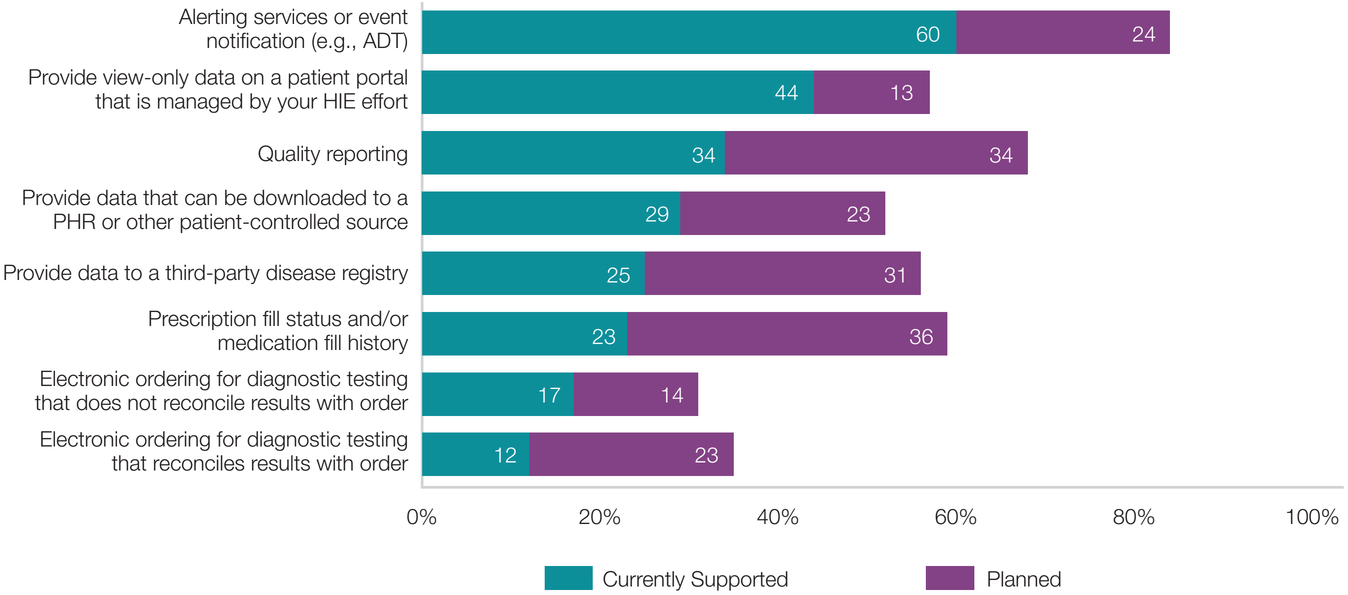
Exhibit 11: **Types and Frequency of Data Exchanged by Operational HIE Efforts**



Source: Authors' analysis of survey data.

Over half of operational HIE efforts offered alerting services or event notification (60% currently supported and 24% planned) (Exhibit 12). Other commonly supported HIE use cases were patient portal management (44% currently supported, 13% planned), quality reporting (34% currently supported and 34% planned), and providing data to patient-controlled sources (29% currently supported and 23% planned) and to third party disease registries (25% currently supported and 31% planned). Less commonly supported HIE use cases included electronic ordering for diagnostic tests that would not reconcile results with the order (17% currently supported and 14% planned) as well as those that would reconcile results with the order (12% currently supported and 23% planned).

Exhibit 12: **Supported Use Cases**



Source: Authors' analysis of survey data.

Approaches to Exchange

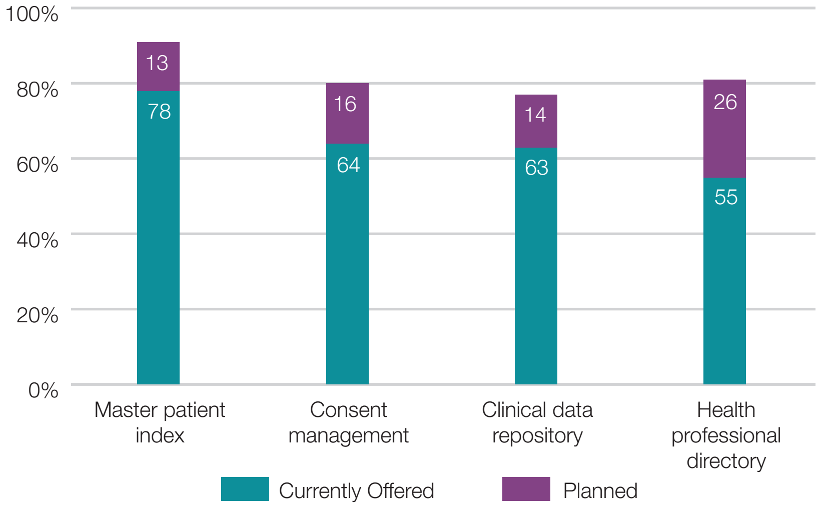
HIE efforts can use a range of technical approaches to support data exchange and HIE use cases. Each approach carries different implications for how information is accessed and used. HIE efforts typically offered more than one approach to accommodate different types of data or different preferences for how to exchange data from participating stakeholders.

The most common technical approach was a query model, in which users actively search for available data for a given patient (81% of operational efforts). This allows a health professional to search for prior information about a patient when needed, and avoids the complexities associated with determining who should receive a given piece of data, such as a test result, which may be relevant to multiple different health professionals. A drawback of the query-based approach is that many health professionals may not be aware that the data are available or may not take the time to search.

The second most common technical approach was a push model, in which one-directional electronic messages are sent through an interface directly into an EHR (80%), followed closely by a push approach in which electronic messages are sent to an inbox outside an EHR (79%). In contrast to a query model, this approach does not require that health professionals seek out data. However, the value of the data is limited because it is directed to specific users and therefore not broadly available. The second type of push model also has workflow implications as a health professional must log in to a separate system in order to see the message and data it contains.

In terms of more general components that enable HIE, nearly all operational efforts had or were planning to build a master patient index (78% currently offered and 13% planned) (Exhibit 13). The majority of HIE efforts offered consent management (64% currently offered and 16% planned), had a clinical data repository (63% currently offered and 14% planned), and had a health professional directory (55% currently offered and 26% planned).

Exhibit 13: **Components Included in HIE Efforts**



Source: Authors' analysis of survey data.

HIE and Meaningful Use

When we assessed the degree to which HIE efforts are enabling participating health professionals to achieve core Stage 2 meaningful use criteria, we found that a small subset (9.4%) supported eight core HIE-related functionalities (Exhibit 14). The majority of efforts enabled health professionals to transmit summary of care records for transitioning patients (77% of operational efforts); transmit laboratory test results as structured data (63%); as well as submit immunization data to immunization registries (59%); and submit lab results to public health agencies (52%). The three Stage 2 criteria least often supported were secure electronic messaging (45%); supporting patient ability to view, download, and transmit data (34%); and ePrescribing (16%). For menu measures, 20 percent of operational HIE efforts supported electronic submission of reports to cancer registries and 15 percent supported electronic submissions of reports to noncancer registries.

Exhibit 14: **HIE Efforts' Support for Meaningful Use**

HIE-Related Stage 2 Meaningful Use Criteria	Core or Menu	Percentage of Operational Efforts
Transmit a summary of care record for patients referred or transitioned to another health professional or setting	Core	77.4%
Transmit clinical laboratory test results as structured data for integration into EHRs	Core	63.2%
Submit electronic immunization data to immunization registries or immunization information systems	Core	59.4%
Submit electronic data on reportable laboratory results to public health agencies	Core	51.9%
Submit electronic syndromic surveillance data to public health agencies [a]	Core	50.0%
Enable health professionals to use secure electronic messaging to communicate with patients [b]	Core	45.3%
Support participating health professionals' ability to enable patients to view, download, and transmit their health information	Core	34.0%
Generate and transmit permissible prescriptions electronically (ePrescribing) [c]	Core	16.0%
Percentage of Operational HIE Efforts That Support All Core Measures		**9.4%**
Submit electronic reports of cancer cases to public health central cancer registry [d]	Menu	19.8%
Submit electronic reports of cases for a specialized registry other than cancer [d]	Menu	15.1%

Notes:

a Core for eligible hospitals and Menu for eligible professionals

b Core for eligible professionals only

c Core for eligible professionals and Menu for eligible hospitals

d Menu for eligible professionals only

HIE Efforts' Engagement in Health Reform

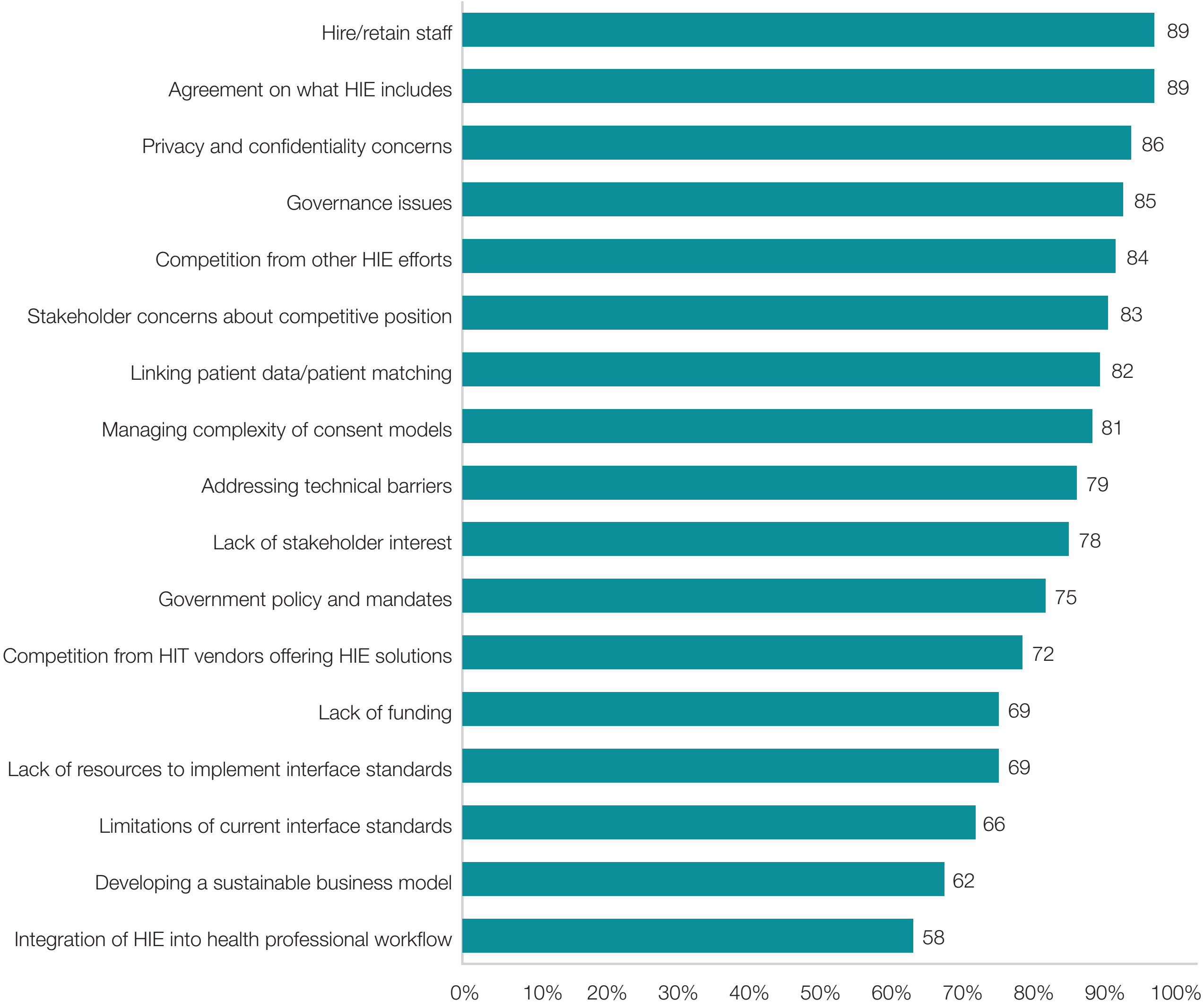
There are several ways in which HIE efforts could engage in health reform efforts and offer services that are in demand beyond support for MU. The first is through using exchanged data to support quality reporting. By aggregating data from multiple sources, more comprehensive and reliable quality measures can be created, which can be used for performance measurement, public reporting or pay-for-performance. Over half of operational HIE efforts (59%) reported being able to use exchanged data to profile participating health professionals on standard quality metrics. Of those that have the capability, nearly half (45%) are currently doing so, but only 14 percent of those who are currently doing so report the measures publicly.

HIE efforts were more engaged in new approaches to care delivery and payment. Fifty-six percent of operational efforts reported that they are supporting Accountable Care Organizations (ACOs) and 55 percent are supporting Patient Centered Medical Homes (PCMHs) while 16 percent are supporting other kinds of delivery system reform efforts. An additional 26 percent are not currently supporting reform efforts but plan on doing so in the future. Only 4 percent are not currently supporting these kinds of efforts and are not planning on doing so in the future.

Barriers to Development

We asked HIE efforts to characterize the degree to which potential barriers slowed their development. The three most common barriers for operational HIE efforts were: (1) the ability to hire/retain staff (cited as a substantial or moderate barrier by 89% of efforts); (2) lack of agreement on what "HIE includes" (89%); and (3) stakeholder concerns about privacy and confidentiality (86%) (Exhibit 15). Additional barriers cited by more than 80 percent of operational efforts included governance issues (85%); competition (84%); stakeholder concern about competitive position (83%); accurately linking patient data/patient matching (82%); and managing the complexity of consent models (81%). Even barriers cited least often: technical barriers; lack of stakeholder interest; and addressing government policy and mandates; funding; lack of resources to implement interface standards; limitations of interface standards; developing a sustainable business model; and integration into health professional workflow were still cited by more than half of efforts.

Exhibit 15: **Barriers to Development**



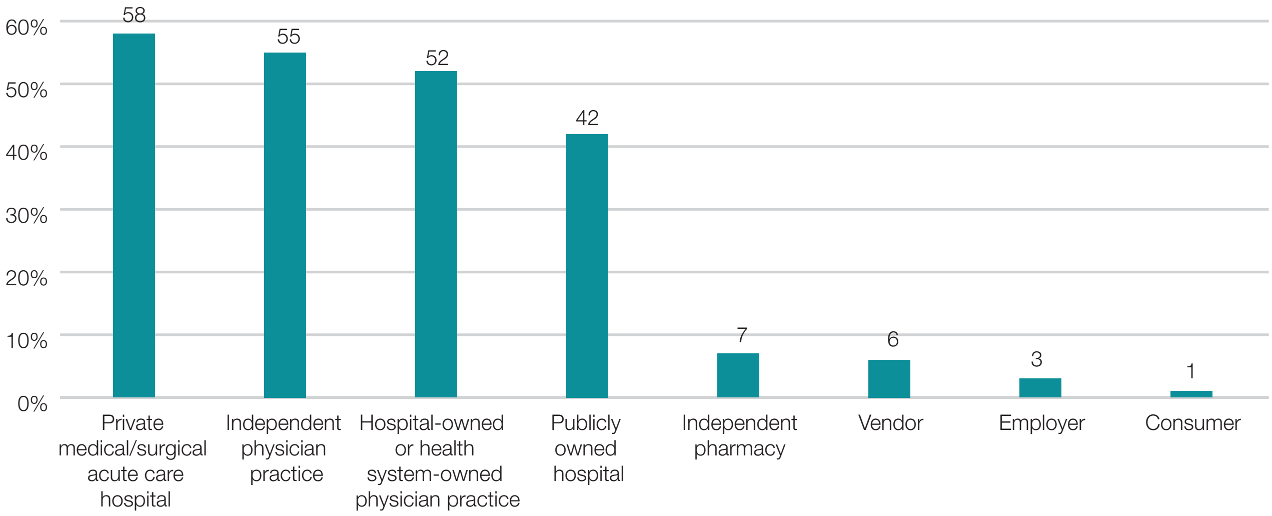
Source: Authors' analysis of survey data.

Financing and Current Financial Sustainability

Given persistent and pervasive challenges associated with financial viability and identifying sustainable business models, we examined current sources of financial support, as well as asked respondents about which source of support was most substantial. Assessment fees was most often cited as the most substantial source of support for operational HIE efforts (34%), followed by membership or subscription fees (14%), and state funding (13%). For HIE efforts in the planning stage, state funding was most often cited as the most substantial source of support (24%) followed by membership or subscription fees (19%) and usage/transaction fees (19%). For operational HIE efforts that reported receipt of membership or subscription fees, these fees made up an average of 57 percent of their total revenue. Assessment fees made up an average of 45 percent of total revenue on average, followed by federal funding (43% of total revenue) and state funding (23% of total revenue).

The four most commonly reported stakeholders paying to participate in operational HIE efforts were private medical/surgical acute care hospitals (58% of operational efforts); independent physician practices (55%); hospital-owned or health system-owned physician practices (52%); and publicly owned hospitals (42%). The four least commonly reported stakeholders paying to participate in HIE efforts were independent pharmacies (7%); vendors (6%); employers (3%); and consumers (1%) (Exhibit 16).

Exhibit 16: **Top and Bottom Four Reported Stakeholders Paying to Participate in HIE**



Source: Authors' analysis of survey data.

Less than half of operational HIE efforts (46%) and HIE efforts in the planning stage (38%) reported that they were able to cover operating costs with revenue from participants (our definition of a financially sustainable entity). Among those that did not meet our measure of financial sustainability, 24 percent of efforts reported that revenue from participating entities covered 0 percent of operating expenses. Thirty-eight percent reported that revenue from participating stakeholders covered 1–49 percent of expenses, and 38 percent reported that revenue from participating stakeholders covered 50–99 percent of operating expenses.

One-quarter of planning efforts and 36 percent of operational efforts that were not yet financially sustainable thought that they would become so in the future. For those that reported that revenue from participants did cover at least

100 percent of operating costs, we asked how long it took from the time they began exchanging information to the time it took for them to reach financial sustainability. On average, these respondents reported that it took 2.6 years to reach financial sustainability.

With the recent end of the State HIE Cooperative Agreement Program, the extent to which State HIE efforts and SDEs are sustainable is an important question, along with the extent to which their sustainability impacts the sustainability of local and regional HIE efforts. Among both operational and planning HIE efforts that were not State or SDE efforts, 30 percent reported that they believed that their State/SDE effort was sustainable, while 32 percent did not believe that the State/SDE effort was sustainable and 35 percent were unsure. In contrast, 78 percent of State/SDE respondents believed their effort was sustainable (6% thought their effort was unsustainable and 13% weren't sure).

In terms of the interdependencies between the sustainability of State/SDE and local/regional HIE efforts, a substantial proportion of both groups felt that State/SDE sustainability would have a moderate-to-significant impact on sustainability of local/regional HIE effort (60% among State/SDE respondents and 42% among local/regional HIE efforts). Among State/SDEs, 57% of respondents believed the sustainability of local/regional HIE efforts would have a moderate to significant impact on the sustainability of the state-level HIE effort. In general, local/regional efforts were split on the impact of the State/SDE HIE effort on their pace of development, with 40 percent reporting that their State/SDE sped up their progress, 30 percent reporting that their State/SDE slowed down their progress, and 27 percent reporting no impact.

Policy Implications

While many HIE efforts have existed for over a decade, the past few years mark a period of dedicated attention and substantial resources devoted to increasing HIE. The State HIE Cooperative Agreement Program was intended as a one-time infusion of support to develop sustainable approaches to HIE through state-level efforts, which should have been bolstered by growing demand for HIE by health professionals as they pursued meaningful use (and in particular, Stage 2 MU). A broader push for HIE should have come from payment and delivery system reform efforts; HIE efforts should be valuable in the context of these new models because they require better management of utilization and performance monitoring, for which better access to timely clinical data is essential.

Our data reveal where HIE efforts are robust and where they are struggling. Bright spots include the fact that HIE efforts operate in the vast majority of states and should therefore, in theory, be broadly available to the health professionals within those states. Also encouraging is the fact that HIE efforts support the exchange of a broad range of types of clinical data, with a particular focus on summary of care records, discharge summaries, and test results. In terms of HIE use cases, alerting services or event notification are commonly supported. Together, this suggests that widely recognized gaps in information due to care fragmentation and care transitions are beginning to be addressed. In addition, HIE efforts are working to support new models of care and payment. Given the relatively recent development of these models, the high level of engagement suggests that HIE efforts are responding to meet an important new need.

The challenges to the progress of HIE efforts are, however, substantial. Perhaps most telling is the fact that, across a wide range of barriers, all were cited by the majority of HIE efforts as a moderate or substantial barrier. This reveals not only how difficult it is to develop and sustain a robust HIE effort, but how difficult it is for policymakers to foster an environment in which HIE efforts can flourish. Developing legislation that simultaneously tackles technical, financial, governance, human resource, privacy and security, and patient consent domains is daunting and far more difficult than if there were a single, substantial barrier inhibiting HIE progress. Moving forward, it will be important to understand whether there is some prioritization of these barriers–that is, one or two that are particularly problematic– and then understand whether there is a set of policy remedies that is feasible.

Among all the barriers, our data delved into the continued challenges with financial sustainability. While lack of funding and challenges identifying sustainable business models have been consistently cited as barriers over time, these are likely to take a major toll on HIE efforts now that State HIE Cooperative Agreement Program funding has ended. A small but nontrivial percentage of HIE efforts reported that the state was their most substantial source of funding, and overall, funding from states accounted for 23 percent of revenue among local/ regional HIE efforts (on average). Further, a substantial proportion of both state HIE efforts as well as local/regional HIE efforts felt that the sustainability of state-level efforts impacted the sustainability of local/regional efforts. And, while state-level efforts were optimistic about their sustainability, only 30 percent of local/regional efforts were confident that their state HIE effort was sustainable. This gap is telling and suggests that specific policy efforts to ensure the states have strong sustainability plans are critically important. To the extent that states are unsuccessful in identifying ongoing support, we could see a number of local and regional HIE efforts struggle to be sustainable. Foreshadowing this issue is the fact that only one-third of efforts that are not yet financially sustainable thought that they would become sustainable.

Without comprehensive policy efforts that are implemented quickly, our results suggest that many HIE efforts will continue to struggle. This is likely exacerbated by the fact that new approaches to HIE are on the rise, including HIE capabilities offered by electronic health record vendors to connect those on the same vendor platform, and those focused on enabling connectivity within a set of defined health care delivery organizations that wish to strategically partner (referred to as enterprise HIE). While these approaches increase the extent to which HIE occurs, they can directly compete with state- and community-level HIE efforts, and enable HIE based on the interest of vendors and of health care delivery organizations, which likely differ from (and perhaps are even in contrast to) where patients receive care. This will limit the extent to which we fulfill the vision of broad-based HIE that allows information to follow patients electronically across care delivery settings. These challenges are widely recognized, and, as described in Chapter 6, the Office of the National Coordinator, as well as other groups are working to re-envision the national HIT infrastructure in ways that enable interoperability and HIE that is patient-centered. HIE efforts undoubtedly have a role to play and clarity on the national strategy is a key step in enabling HIE efforts to develop a strategy that enables them to be sustainable and create value.

Conclusion

There is little disagreement that improving the performance of our health care delivery system rests on the ability to electronically share information more readily and consistently, both across health professionals and for broader population health aims. However, there is also little disagreement that doing so is fraught with substantial obstacles, and there are many such obstacles that span an array of domains. This makes it difficult for policymakers to take action in ways that speed HIE progress, but the need to do so is evident in the fact that so many current HIE efforts report sustainability challenges. Our data suggest that much of the progress achieved in the past few years under the HITECH programs is at risk unless we identify the role for state, regional, and local HIE efforts in the evolving national HIT landscape. While several avenues look promising, including the ability of current HIE efforts to support new models of care delivery and payment, the next few years will be critical to ensure that they are able to do so successfully, and that all the key stakeholders have aligned incentives and supportive policies are in place.

Endnotes

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Chapter 3: Evaluating HITECH: Successes, Barriers, and Future Opportunities

Yael Harris, PhD and Llewelyn Brown, RN, MPA

Background

In 2008, The Office of the National Coordinator (ONC) for Health Information Technology released its second *ONC-Coordinated Federal Health Information Technology Strategic Plan: 2008–2012*, identifying several goals for advancing national health care priorities, including increased electronic health record (EHR) adoption and secure exchange of clinical data [ONC 2008]. The goals identified in the strategic plan closely aligned with the programs ultimately authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, which provided unprecedented financial and technical assistance to health professionals implementing EHRs, grants to states to establish or advance the electronic exchange of health information, and authorized the creation of programs designed to train and certify HIT professionals [ARRA 2009]. Exhibit 17 provides a high-level overview of the HITECH programs, providing context for each program's key objective, information regarding the approach and high-level metrics employed to assess progress. As required by HITECH, ONC funded an independent evaluation of each cooperative agreement program to identify challenges, disseminate findings and inform future health policy. This chapter provides background about the HITECH programs evaluated by ONC, synthesizes key findings from those evaluations, and describes implications relevant to future plans for addressing the nation's goals for leveraging technology to support health care improvement.

Exhibit 17: **Overview of HITECH Programs Related to Specific Objectives**

Program	Objective	Approach	Metric(s)
Meaningful Use Incentive Program*	EHR Adoption	Incentive payments to eligible providers for meeting specified adoption criteria	# of eligible providers meeting requirements Total Medicare payments
Regional Extension Center (REC) Program	Technical Assistance	Regionalized entities to provide assistance to small and underserved providers	# of providers adopting an EHR # of providers attesting to meeting meaningful use requirements # of providers receiving incentive payment
State Health Information Exchange Cooperative Agreement Program (HIE)	Information Exchange	State-level support to build or expand information exchange capabilities	% of providers in state e-prescribing % of providers in state receiving lab results electronically % of providers able to access electronic patient data from other providers or centralized repository
Health Information Technology Workforce Development Program (Workforce)	Establish a Skilled Workforce	Funding to community colleges to offer short-term training and universities to offer more advanced training; establishment of a curriculum and certification exam to support a set of defined HIT roles	# students enrolled in community college/university-based program # of students completing program # of graduates employed in HIT # of curriculum downloads # taking certification exam
Beacon Communities Cooperative Agreement Program (Beacon Communities)**	Effective & Widespread Use of HIT	Funding to communities to achieve high levels of adoption/interoperability toward specific outcomes	% EHR adoption in community % information exchange in community Demonstrated quality improvement (topics varied) Demonstrated cost savings (services varied)
Strategic Health Information Technology Advanced Research Projects (SHARP)**	Address Future HIT Challenges	Funding to research entities to address high-level issues: privacy and security, usability, patient-centered design, improved clinical quality	# products developed # peer-reviewed publications/poster presentations/white papers

CMS = Centers for Medicare & Medicaid Services

* No formal evaluation of the meaningful use program was funded by ONC. As such, there is no subsequent discussion of the incentive program in this chapter.

** The Beacon and SHARP programs were not explicit components of HITECH.

HITECH Program Design

Each of the HITECH programs was designed to address key challenges to realizing HITECH's ultimate goal of improved health care quality and efficiency through the widespread use of HIT [Blumenthal 2010]. The programmatic design employed for each of the HITECH programs varied in an effort to enable program flexibility while balancing the collective insights and expertise at the national, state, and local levels. Below, we discuss the design of each of these programs.

Regional Extension Center Program

The Regional Extension Center (REC) program was tasked with providing technical assistance to 100,000 small practices and health professionals serving vulnerable communities. RECs were modeled after the U.S. Department of Agriculture's Cooperative State Research, Education, and Extension Service, with the goal of providing "boots on the ground" technical assistance to geographically defined regions of the country. Staffing included both clinical and technical experts to support a range of services, including vendor selection, EHR implementation, attestation assistance, and quality improvement activities. A total of 62 cooperative agreements were awarded to entities covering non-overlapping geographic regions defined primarily by state boundaries. Many RECs established partnerships with other entities including fellow RECs, other HITECH grantees, and state and local health departments. In some cases, the same entity had been awarded more than one HITECH grant (e.g., acting as both the REC and State HIE) which enabled synergies. While some RECs offered publicly available education sessions, all RECs charged a fee for health professionals to receive individualized technical assistance and support. The cost structure and amount varied greatly depending upon the REC and the health professional. These fees were intended to ensure a health professional's commitment as well as to help offset the costs of services and lay the foundation for developing a sustainable model after depletion of HITECH funding.

State Health Information Exchange Cooperative Agreement Program

In March 2010, ONC awarded cooperative agreements to a total of 56 states, eligible territories, and qualified State Designated Entities (SDEs) to support the establishment or expansion of HIE efforts [ONC 2014a]. Grantees were given several options for governing HIE activities to carry out their core duties: administrative coordination, managing progress toward technical program goals, and convening all relevant stakeholders to support the program. This flexibility was intended to allow grantees to leverage existing infrastructure and organizational arrangements to expand information exchange capabilities.

Grantees pursued a variety of technical approaches for storing information and facilitating the ability of health professionals to request, send and receive information. States decided whether HIE participants were required to store data in centralized versus local repositories and weighed options to transfer information through directed exchanges, query-based exchanges or a hybrid approach. Directed or "push" exchanges support the ability to send and receive secure information electronically between HIE participants while query-based exchanges allow health professionals to request and receive patient information from other health professionals. For example, health professionals can use directed exchange to share laboratory orders and results and discharge summaries in a manner more secure than email [Dullabh et al 2014a]. Query-based or "pull" exchanges allow health professionals to search and retrieve stored information from a centralized database of health information.

Health Information Technology Workforce Development Program

The HIT Workforce Development Program employed a hybrid national and local approach in its design of four inter-related programs seeking to increase the number of professionals with HIT training. These programs included the development of a curriculum and supporting resources, the establishment of two training programs, and the creation of a competency exam. At the national level, ONC convened national experts to delineate a set of 12 distinct "roles" to ensure a well-rounded HIT workforce. These roles then informed the curriculum content, intended to support HIT training. In addition to being made publicly available, the curriculum was employed at the local level funded by community colleges that were encouraged to leverage these resources for use in short-term educational programs targeting one or more of six professional roles. While many community colleges enrolled students from the local community, most also offered courses online to support national education opportunities. In addition, nine four-year colleges and universities offered certificate or master's degree programs to provide training targeting the remaining six roles. To complement these efforts, a national competency exam was developed to demonstrate the capabilities of individuals with training or experience in HIT. The exam was offered for free to community college graduates while others were allowed to take the exam for a small fee.

Beacon Communities Cooperative Agreement Program

While not mandated under HITECH, the Beacon Communities Cooperative Agreement program, identified as a White House priority, was designed to complement the mandated HITECH programs, and, as such, was included in the collection of evaluations funded by ONC. As a result, 17 regionally based communities received funding to ensure the representation of a diverse population, unique health professional characteristics and innovative approaches to the use of technology. Collectively, the Beacon communities represented an extremely diverse population as demonstrated by high variability in the racial and ethnic mix of their residents as well as their socioeconomic circumstances. Exhibit 18 provides a visual illustration of the geographic distribution of the Beacon grantees. In order to realize their goals of enhanced chronic disease management and increased health care efficiency, all Beacon communities leveraged existing community-based resources, partnering with local health professionals, other HITECH grantees and non-traditional partners like local health departments, long-term-care health professionals, and accountable care organizations (ACOs). A subset of Beacons employed creative technical solutions such as patient dashboards, telehealth and mobile health.

Exhibit 18: **The Geographic Distribution of the Seventeen Beacon Awardees**

Source: Office of the National Coordinator. 2013. Strengthening Care Management with Health Information Technology, *www.healthit.gov/sites/default/files/onc-beacon-lg2-strengthening-care-mgmt-with-hit.pdf*.

Strategic Health Information Technology Research Projects

In contrast to the Beacon program, the Strategic HIT Research Projects (SHARP) established a set of discrete projects overseen at the local level with an emphasis on national dissemination of project findings. Each of the grantees was tasked with exploring one of four narrowly defined challenges related to optimizing the use of HIT: issues related to privacy and security; the need for patient-centered tools; HIT product usability; and using HIT to improve clinical quality. Each grantee established multidisciplinary teams led by nationally recognized academic or medical research institutions. At the request of ONC, in 2012, awardees narrowed the focus of their proposed work to target activities most likely to influence HIT in the short term and concentrate their efforts on market engagement to ensure the relevance of the final products.

Global Assessment Monitoring the National Implementation of HITECH

The Global Assessment Monitoring the National Implementation of HITECH was established to help ONC and policymakers better understand the national impact of HITECH, as well as the interdependencies of its multiple components and potential areas for future focus, including those outside the purview of the HITECH-funded programs. While it served many objectives, the ONC sought to use the Global Assessment contract as a vehicle to provide a broader understanding of the opportunities and challenges encountered during implementation of HITECH, as well as enabling a more detailed analysis of the lessons learned.

Program Results

A formal evaluation of each of the HITECH programs, as well as the Beacon communities and SHARP programs, helped to provide insights regarding each program's performance on key metrics, challenges encountered, and lessons learned. Some programs are still engaged in additional work using remaining HITECH funds; however, available data to date has been helpful in providing a general understanding of the preliminary impact of each of these programs. Here, we present a summary of the findings reported in the evaluations followed by a discussion of challenges and lessons learned. More detailed insights, particularly those targeting specific grantees, have been informed through case studies which helped to illuminate variations and unique lessons learned that varied across grantees which may not be readily transparent when looking at aggregated data.

Regional Extension Center Program

Overall results suggest that the REC program was highly successful in helping targeted health professionals (small primary care practices and safety-net health professionals) adopt and implement an EHR; however, helping all of these health professionals qualify for meaningful use incentive payments proved to be more challenging. Data reported to the ONC by the grantees indicated that, by January 2015, enrollment to receive technical assistance from a REC had surpassed the original goal of 100,000 health professionals by over 150 percent. This final sample included over 5 percent of all primary care practitioners, including over 50 percent of eligible primary care health professionals employed in rural communities. ONC data also demonstrates that RECs engaged a large number of safety-net health professionals, including Federally Qualified Health Centers and critical access hospitals. Over 90 percent of all health professionals who sought technical assistance from an REC were successful in adopting a certified EHR system; however, less than three quarters of these entities could effectively demonstrate the meaningful use of their EHR by August 2015 [ONC 2015a]. Exhibit 19 provides a summary of the REC's results in meeting each of its program goals.

Exhibit 19: **Regional Extension Center-Enrolled Providers' Adoption of Electronic Health Records, June 2015**

Providers by Practice Type	Total Enrolled	Percentage Live on an EHR	Percentage Demonstrating Meaningful Use
All Enrolled Providers	157,000	92%	74%
Practice Consortiums	24,468	96%	82%
Rural Hospitals	2,457	97%	78%
Small Private Practice (1–10 providers)	53,749	91%	75%
Private Practice (11+ providers)	1,029	67%	28%
Specialty Practice	3,088	68%	49%
Community Health Center	24,255	95%	68%
Rural Health Clinic	3,704	91%	69%
Public Hospitals	20,881	90%	72%
Critical Access Hospitals	4,452	94%	66%

NOTE: Primary Care Providers include practitioners of family medicine, general medicine, internal medicine, geriatrics, obstetrics/gynecology, and pediatrics.

Sources: Office of the National Coordinator for Health Information Technology. *Percent of REC Enrolled Providers by Practice Type Live on an EHR and Demonstrating Meaningful Use, Health IT Quick-Stat #37*, *http://dashboard.healthit.gov/quickstats/pages/FIG-REC-Providers-Live-MU-Practice-Type.php*. June 2015; *www.healthit.gov/provider-professionals/regional-extension-centers-recs*

As with any national program, the REC program demonstrated variability across its 62 grantees with some entities surpassing their targets, while others were less successful. Key barriers identified included vendor issues, such as technical assistance in product implementation and optimization, difficulties with the meaningful use attestation process, and practice-specific issues such as staffing and training. While many of these barriers were experienced by all health professionals working with the RECs, some communities faced greater hurdles. For example, health professionals treating a high volume of Medicaid patients were stymied in those states where the establishment of the Medicaid program was delayed. Practices in nonmetropolitan communities faced greater challenges in recruiting competent HIT professionals to support their system implementation. Under Stage 1 of meaningful use, health professionals could fulfill the information exchange requirements by demonstrating their capability to electronically transmit data. In spite of this, health professionals in regions that already had a robust architecture to support these activities were at a considerable advantage, as compared to health professionals practicing in states and communities without an operational system to support information exchange. Health professional satisfaction working with RECs has not been assessed across numerous communities; however, results from a survey of those working with the Arizona REC indicated that their experience was positive [Tang et al 2014].

State Health Information Exchange Cooperative Agreement Program

There is general public consensus that the State HIE program encountered a number of both anticipated and unforeseen challenges which hampered its efforts in ensuring access to electronic information exchange for all eligible health professionals. While successes were realized in several states, wide variation in the governance, funding and technical implementation of HIEs produced mixed results in the program as a whole. In general, states with previous experience establishing either a statewide or regional health information exchange were far more successful in supporting the active exchange of health data across a diverse set of health professionals and payers; however, markets with several large health systems, many of whom were already operating or in the process of establishing an HIE prior to HITECH, were more likely to encounter barriers [Dullabh et al 2014b]. Several states were hindered by financial limitations and state politics introducing roadblocks.

Mixed experiences with stakeholder buy-in were also present alongside uncertainties in funding for some HIEs. Respondents to a 2013 survey believed that the vast majority of publicly funded exchanges would not continue to be sustainable without significant changes in their business model. Respondents predicted that, going forward, successful models will need to rely on private funding either through insurers or health professional participation fees [PRWeb 2014].

Challenges with the administrative and financial structure of HIEs were reflected in the wide variation in implementation experiences. By the end of 2013, only 31 (out of 56) of the funded U.S. States and territories reported having the ability to support query-based exchange across the entire state[1] and ten additional states and territories reported that they could not even support query-based exchange within a narrowly defined geographic region [ONC 2014b]. In lieu of a publicly funded statewide information exchange, most states supported health professionals' use of the ONC-established DIRECT protocol, a set of standards policies and services to support a secure point-to-point exchange of data using the Internet. By the end of 2013, 47 States and territories reported that exchange through DIRECT was widely available to health professionals within the State [ibid].

By the end of 2014, interoperability service offerings varied greatly across states. Exhibit 20 details the top 10 services grantees offered or planned to offer, to health professionals. In addition to legislation to support HIE, many states established an "opt-out" consent model[2] to increase patient participation in the exchange.

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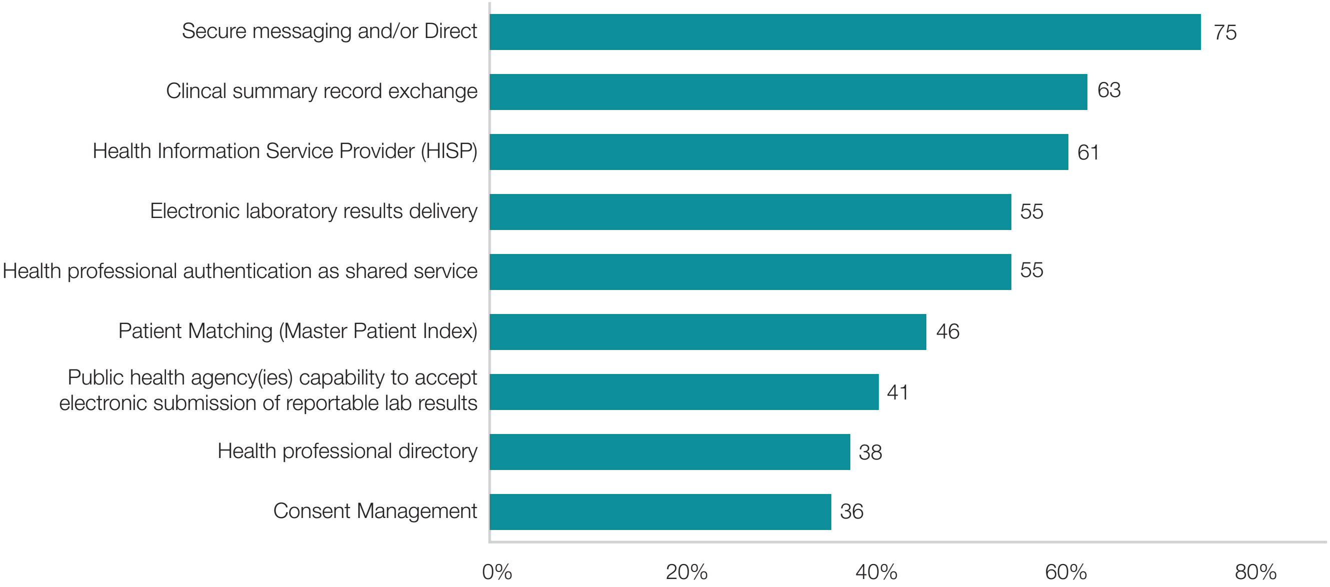
[1] Query-based exchange, or "pull" transactions, allow an entity to submit a request for patient information directly from the HIE.

[2] An "opt-out" consent model automatically includes patient data in the health information exchange unless s/he explicitly opts out of participation.

Exhibit 20: **Top Ten Services Grantees Plan to Offer or Support**

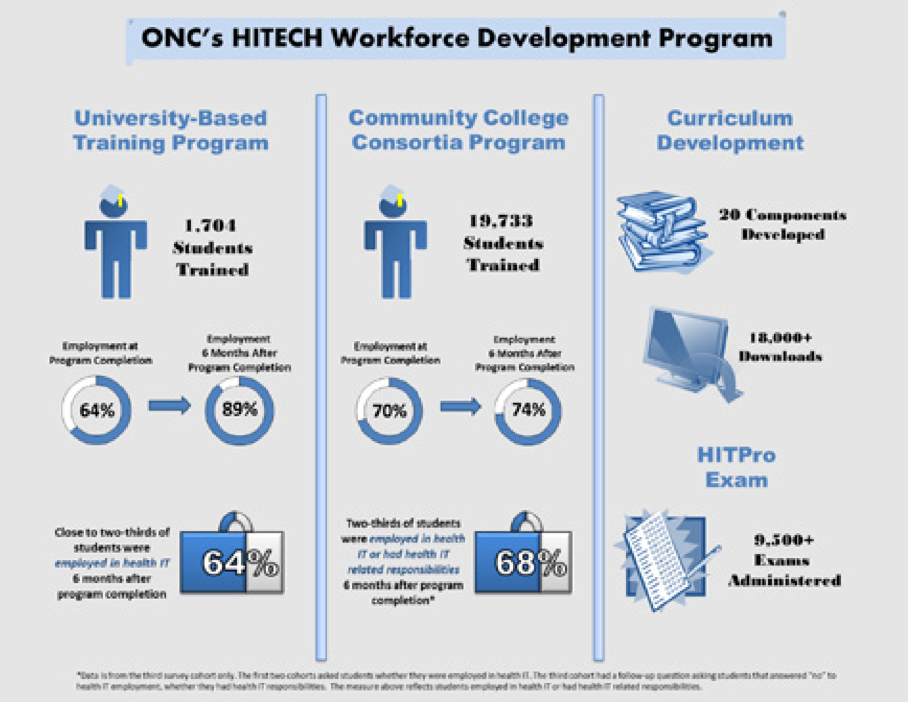


Source: Dullabh P, Ubri P, Loganathan S, Latterner M. *Evaluation of the state health information exchange cooperative agreement program: State approaches to enabling HIE* (typology brief). [August 2014b]. Available at *www.healthit.gov/sites/default/files/statehietypologybrief.pdf*

HIT Workforce Development Program

The Workforce program was generally successful in achieving its primary targets. As a result of the HITECH funding, ONC was able to publicly release a comprehensive curriculum developed by leading experts. As of March 2013, over 180,000 individuals had downloaded curriculum material from a public website [ONC 2014b]. Approximately 20,000 students completed all requirements for a HIT program at one of the HITECH- funded community colleges, exceeding the programmatic goal by nearly 200 percent [Lowell 2014]. A survey of employers for graduates of these programs indicated that graduating students had gained valuable skills and knowledge which they brought to their new jobs [ibid]. Over 1,700 students completed one of the university-based training programs, reflecting a completion rate of 80 percent across all enrollees and exceeding the program's identified goal. Within six months of graduation, approximately two-thirds of the graduates reported being employed in the field of HIT [ibid]. While early interest in the certification exam was lower than expected, by the end of the workforce grant program, over 9,500 individuals had taken advantage of the free vouchers made available to community college program graduates and other select professionals electing to sit for the certification exam [ONC 2014c]. A graphic illustrating the key accomplishments of the workforce grants is depicted in Exhibit 21.

Exhibit 21: **Overview of Workforce Development Program Outcomes**



Source: *http://dashboard.healthit.gov/quickstats/PDFs/Workforce-Development-Programs-Infographic.pdf*

In spite of these national achievements, success varied across the country. In large states like Texas, California, Florida and New York, over 1,000 individuals in each state completed a HITECH-funded program at either a community college or university. However, in seven states, several of which are extremely rural (Alabama, Arkansas, New Hampshire, New Mexico, Vermont, West Virginia, and Wyoming), fewer than 100 individuals across the entire state completed a program. There were also notable differences in the success of individual programs. For example, among the 4,700 students who enrolled in a program at one of the eight colleges within the Northwest Community College Consortia, over 80 percent successfully completed all requirements. In contrast, the Southern Community Consortia, comprised of a total of 21 individual colleges, successfully recruited over 10,000 students; however, less than half competed the six-month program [Swain and Lowell 2014].

Beacon Communities Cooperative Agreement Program

The work of the Beacon Communities is an ongoing process which will likely continue to yield valuable insights into the effective use of HIT and its potential to enhance community health and care coordination. Unfortunately, aggregate data on the impact of these investments on population health across the targeted communities is not available. Perhaps the greatest insights gained from evaluations of the Beacon Communities to date have been an enhanced understanding of the challenges that must be overcome to realize the program's goals of building a HIT infrastructure, fostering innovation, and leveraging these efforts to improve population health, reduce costs and improve quality [Rein et al 2012]. Many communities encountered technical challenges related to legal and market-based barriers to building a robust, broad-reaching health information exchange across a diverse community [ibid]. A number of communities also found that vendor capabilities could not support their care management goals and that a lack of standards for documentation created challenges with their use of HIT [Allen et al 2014].

Considering the distinct approach employed by each of the Beacons as well as the divergent nature of the targeted population and clinical conditions, it is not surprising that the experience and findings from each community was unique. Some communities that built upon a pre-existing architecture, such as the Central Indiana Beacon Community's use of the Indiana Health Information Exchange, were able to expand existing programs to demonstrate clear quality improvement results, such as increased preventive care screenings, better care management of a targeted chronic condition, and reduced re-admissions and emergency department visits [ibid]. Other communities had to invest time and resources in order to establish an infrastructure to support their proposed objectives. This introduced new challenges, such as securing stakeholder buy-in, defining roles, and developing relationships and trust.

Strategic Health Information Technology Research Projects

Overall SHARP success was measured by the number of "outputs" produced by the grant entity. By 2014, SHARP grantees had participated in 155 presentations showcasing their work. An additional 168 publications helped to broadcast research and findings to the public at large. Further outreach efforts included the development of applications and software, providing information and education through videos and technical reports, and hosting workshops. The primary goals of SHARP included broadly disseminating the work products, advancing the field, and facilitating future efforts in the identified areas. Within each of the specific SHARP teams, there were also area-specific accomplishments. These included the delineation of risks associated with the use of mobile devices, medical devices, and medical monitoring equipment; the creation of a prototype to ensure the security of shared patient data; the establishment of a framework to objectively measure EHR ease of use; the development of key standards related to data transport, clinical content, and data models; and the creation of an open-source solution to support the analysis of free text [Moiduddin et al 2014].

While all SHARP grantees experienced challenges related to coordination across internal partners as well as with external stakeholders, each also encountered its own unique barriers. The team working on issues related to privacy and security reported difficulty acquiring datasets to validate their findings while the team focused on enhancing usability-reported challenges related to securing participation by commercial vendors. The SHARP team tasked with establishing patient-centered applications and tools reported difficulty gaining buy-in from the HIT community, and the team working to advance clinical knowledge found that their clinical element models could not be universally applied, requiring ongoing refinements [ibid].

Global Assessment Monitoring the National Implementation of HITECH

HITECH was, and continues to be, an ambitious initiative characterized by broad legislative goals to be advanced through a variety of initiatives including the grant-funded programmatic efforts. As such, program- specific findings fail to properly portray the collective impact of these discrete activities on the nation as a whole in terms of realizing the intent of HITECH. The products of the Global Assessment, including quarterly reports, focused research, and case studies, helped to provide an in-depth conceptualization of the multiple components of the HITECH Act and their key dependencies, as well as delineating challenges that were not directly under the control of the collective HITECH programs but would likely impact the ability to realize the HITECH objectives [Gold et al 2012]. A quarterly report produced as part of the Global Assessment provided ONC with a synthesis of selected statistics, activities and publicly reported information relevant to various facets of the Act and its overall impact. Focused research on a select number of “special topics” helped to provide a more in-depth understanding of issues which had the potential to significantly impact HITECH’s ultimate success, while case studies conducted at the community level helped to better assess the impact of local context on health professionals’ incentives and capacity to achieve meaningful use as well as to understand variation in program implementation [Gold et al 2013a; Gold et al 2013b; Blavin et al 2014; Devers et al 2014].

Discussion

From the inception, there was a general acknowledgement that each of the HITECH cooperative agreements would require coordinated execution involving federal, state, and local authorities. Identifying a successful balance between administrative oversight and promoting individual grantee autonomy proved challenging. In addition, each of the HITECH cooperative agreements required early, and continuous, involvement of key stakeholders to secure buy-in and assistance in implementation. The diversity of these stakeholders, their individual investments in the programs’ success, and their complementary or competing priorities played a significant role in the overall effectiveness and impact of each of the HITECH grant programs. Each of these factors influenced the HITECH-funded cooperative agreement programs and affected their realization of the intended goals. Exhibit 22 provides a summary of some of the strengths and weaknesses identified through implementation of each of these programs.

Regional Extension Center Program

Since HITECH’s enactment, the percentage of health professionals using an EHR has grown dramatically [Charles et al, 2015]. While many of these accomplishments can be attributed to increased public awareness regarding HIT and the meaningful use incentive payment program, the RECs played a valuable role in advancing adoption by a subset of health professionals with limited resources. A report by the General Accounting Office (GAO) found that the assistance provided by the RECs significantly contributed to these health professionals’ ability to meet the meaningful use requirements [GAO 2013]. In spite of this evidence, a significant subset of health professionals working with RECs failed to achieve the requirements for Stage 1 of meaningful use, indicating that they will likely continue to struggle to keep up as the requirements for subsequent stages continue to escalate. This suggests that the transition from EHR implementation to effective utilization (as demonstrated by qualifying for meaningful use) is far more difficult than initially anticipated. In addition, some of accomplishments cited as evidence of the RECs’ success may not necessarily be attributable to the efforts of the RECs. For example, in reporting the total number of REC-assisted health professionals who achieved program goals for adoption and implementation, the numbers included health professionals, such as a large portion of community health centers that were already using an EHR prior to the passage of HITECH [Ryan et al 2014]. Anecdotal information, supported by case studies, suggests variability in performance by members of the REC team, including their subcontractors, resulting in differences in health professional satisfaction and success [Farrar et al 2014]. The future of the REC program remains unclear as many RECs failed to establish a sustainability model to ensure their continued operation following completion of the cooperative agreement program.

State Health Information Exchange Cooperative Agreement Program

Since the passage of HITECH, a number of states have expanded their HIE capacity and successfully promoted health professional adoption of the DIRECT protocol. Although meaningful use interoperability requirements played a significant role, the state grants were leveraged to support these activities. In spite of these achievements, the state HIE Cooperative Agreement Program, in general, fell short of its intended goals. As discussed earlier, as of January 2015, no states had successfully established the infrastructure to support bi-directional interoperability for all health professionals practicing in the state. While some states made significant headway in expanding their HIE capacity, other states were not able to fully optimize their grants, stymied by a number of both anticipated and unanticipated challenges encountered at the national, state, and community levels. By granting each state the autonomy to design and implement a personalized model, the federal government did not foresee the challenges associated with supporting these diverse approaches. As a result, the capacity to provide technical assistance through a federally funded contract vehicle was limited in the absence of a clearly articulated approach (or set of approaches) to achieve program goals. Technological barriers including incomplete national standards, inconsistent implementation of available standards and the absence of a demonstrated patient-matching algorithm remain barriers that cannot be resolved without federal leadership. At the state level, challenges related to leadership and coordination hindered progress. As discussed earlier, several states enacted legislation to advance health information exchange; however, the development and passage of new state laws contributed to further delays. One of the greatest barriers encountered was the need to engage stakeholders at multiple levels. Garnering buy-in from a diverse array of health care health professionals proved more challenging than anticipated, especially in areas where health systems had already established their own interoperable system. Health professional competition, market consolidation, and disagreement about the approach to ensuring sustainability created additional impediments [Dullabh et al 2014].

HIT Workforce Development Program

In spite of the recognition that the United States still requires significant growth in the number of HIT-trained professionals, the Workforce program stimulated efforts to begin to diminish this gap. Resources generated through this program are anticipated to continue to enhance this endeavor. Many community colleges continue to offer HIT programs and additional programs have been established at technical schools across the United States. All of the certification and graduate degree programs continue to operate and the curriculum developed through this program, along with supporting material is available for download from the Internet. The American Health Information Management Association has assumed management responsibility for the competency exam [Lowell 2014]. Perhaps the single greatest shortfall of the Workforce program was the lack of general awareness about the program and its opportunities. While student enrollment in the community college programs was high, knowledge of these programs among the public at large was limited. Enhanced coordination and outreach, working in partnership with career advisers, job placement programs, and potential employers, such as health care health professionals, RECs, state entities leading the implementation of information exchanges, and vendors, could have played a role in increasing public awareness of, and subsequent enrollment in, these programs. Likewise, few people outside those already employed in the field of HIT and schools already offering HIT programs are aware of the availability of the curriculum developed through this program. Broader outreach and communication regarding this free resource and its supplemental materials should be made available to the education community at large including high schools where students can gain an interest in pursuing a career in the field of HIT. The overall goal of the Workforce program was to increase the number of trained professionals to support adoption, implementation, and effective utilization of HIT. However, the lack of awareness of these programs, which limited enrollment, also hindered the subsequent ability of graduates to find jobs in this field. By the program's conclusion, a number of grantees hired career counselors to support these efforts, however a more concentrated effort to identify potential employers and encourage their active recruitment of program graduates might have proven more effective.

Beacon Communities Cooperative Agreement Projects

From its launch, the Beacon program encountered a variety of challenges which hindered the ability to demonstrate its impact. The decision to expand the number of awards from an initial 10 to a total of 17 communities necessitated the need to employ less rigorous selection criteria in order to ensure that the final set of awardees were geographically distributed across the nation and included culturally and geographically diverse communities. As a result, at the time of the award, a subset of the grantees lacked the infrastructure and high rates of adoption which were initially viewed as integral to programmatic success. Each community was granted broad discretion in its design and program implementation, including the set of goals through which they were expected to track their success. As a result, the types of metrics, data collection approach, and expectations for each of the grantees varied widely. Across communities, the ability to demonstrate progress was further stymied by difficulties in capturing and reporting the proposed performance metrics as well as concerns regarding the completeness and accuracy of the data that could be captured [Rein et al 2012]. The diversity of the approaches employed by each individual community limited the federal government's ability to provide technical assistance and program oversight.

In addition to failing to clearly articulate standardized metrics which could be used to demonstrate the effectiveness of each communities' unique approach, the Beacon program overlooked a critical opportunity to properly document the steps and processes undertaken which could then be leveraged by other communities as a roadmap. As such, the Beacons were not able to successfully achieve their potential in serving as paradigms for other communities across the United States. While the HITECH funds likely contributed to a more robust HIT infrastructure within the communities, most Beacons did not fully articulate a sustainability plan which could enable ongoing efforts toward realizing the potential of HIT even after HITECH funds were expended.

Strategic HIT Advanced Research Program

There is general agreement that the SHARP projects advanced our knowledge and ability to address critical challenges hampering the nation's ability to fully benefit from HIT. For example, the SHARP project that focused on improving EHR usability successfully established a framework to objectively measure EHR ease of use. The assessment tools designed by the grantee to identify usability barriers have since been employed by the National Institutes for Science and Technology (NIST) to inform their EHR usability guidelines [NORC 2014]. However, the broad-reaching scope for each of these projects initially compromised each project team's identification of short-term, attainable goals which could be employed to evaluate each project's impact. As a result, in spite of the progress realized by each of the SHARP project teams, there remains a general lack of public understanding and recognition of these accomplishments. The failure to conduct broad outreach to increase awareness and understanding of the SHARP program, in general, and specific to each of its distinct projects is a significant shortcoming that could have been remedied through enhanced public outreach and endorsement of the products produced using HITECH funds. To date, the SHARP program remains the least understood HITECH cooperative agreement program, belying its contribution to the field of HIT. Enhanced communication and promotion, specifically targeting those entities most likely to benefit from the findings, would not only have increased public awareness but also helped to proliferate the realization of the program objectives.

Exhibit 22: **Examples of Strengths and Weaknesses of HITECH-Funded Cooperative Agreement Programs**

Program	Strengths	Weaknesses
Regional Extension Centers	■ Broad coverage of all states and territories ■ Generated high enrollment among health professionals serving rural and underserved populations ■ Produced opportunities for negotiated discounts on EHR products ■ Enhanced clinician understanding and utilization of EHRs ■ Leveraged local expertise and experience	■ Composed of staff with varying levels of experience ■ Experienced delays in staff recruitment and training ■ Restricted ability of health professionals to select an REC that could best serve their needs ■ Some RECs unable to support the full range of certified EHR systems ■ Experienced challenges in securing vendor support ■ Encountered delays in some states regarding implementation of a Medicaid meaningful use program
State Health Information Exchange	■ Enabled flexibility to reflect state needs ■ Leveraged existing HIE infrastructure ■ Increased HIE awareness within state ■ Expanded adoption of DIRECT protocol	■ Limited by insufficient guidance on best practices ■ Lacked federal support in bringing stakeholders together ■ Overlooked the lack of national standards for data exchange ■ Introduced confusion regarding interaction of state efforts with DIRECT protocol roll-out ■ Failed to provide incentive for laboratory participation ■ Neglected the need to demonstrate proven governance models ■ Underestimated challenges in establishing effective sustainability plans ■ Diversity in approaches hindered provision of technical assistance ■ Limited oversight
HIT Workforce Development	■ Supported flexibility in employing curriculum ■ Enabled both onsite and remote learning opportunities ■ Funded community college programs across U.S. ■ Identified a range of workforce roles	■ Limited program awareness among general public ■ Curriculum not developed prior to first semester ■ Insufficient job placement assistance ■ Funded university-based programs already in development ■ Limited knowledge of curriculum availability
Beacon Cooperative Agreement Program	■ Enabled identification of customized goals ■ Encouraged creativity and innovation ■ Supported geographic and demographic diversity	■ Focused on geographic diversity rather than community potential ■ No coordination or consensus on defined program metrics ■ Difficulty capturing baseline and outcome data ■ Flexibility impeded ability to generalize findings ■ No plans for sustainability
Strategic HIT Advanced Research Projects	■ Addressed key barriers and challenges ■ Produced actionable deliverables incorporated into national efforts ■ Promoted technological innovation ■ Advanced HIT field	■ Established overly ambitious goals ■ Project evolution made it difficult to define clear goals ■ Difficulty translating findings into practice ■ Challenges coordinating large teams

Note: The Global Assessment is not included in this table as it was not a unique HITECH-funded program but rather an assessment of the overall impact of these programs.
Source: Authors' analysis of survey data.

Conclusion

While HITECH helped to initiate significant progress with regard to the adoption and use of HIT in the United States, in general, it fell short of achieving its overarching goals to establish a highly effective and efficient health care system enabled by the advanced use of HIT. A number of factors contributed to these shortcomings characterized by a combination of both broad and program-specific challenges. Overall, the ambitious goals of HITECH, while optimistic, overlooked barriers that were beyond the scope of the legislation and the programs it authorized [Gold 2012]. Other nations–many with a long-standing history of supporting HIT adoption–are still aspiring to realize the goals which HITECH anticipated could be accomplished in three years [Adler-Milstein 2014]. To compound these challenges, America faces tremendous impediments which many other countries do not have to overcome, such as competing, proprietary health care systems, the lack of a universal patient identifier, and tremendous regional variation in terms of policies, infrastructure, and culture. Other barriers, such as inconsistent implementation of interoperability standards, the upfront costs associated with the purchase of an EHR, the importance of information exchange with a wider array of health care entities, such as long-term-care health professionals and laboratories, and competing financial interests across health care organizations and EHR vendors, further challenged the ability to realize HITECH's ultimate intent.

The overall design of HITECH as an amalgamation of multiple programs compounded these distinct challenges. Rather than taking a holistic approach to address recognized barriers, the legislation authorized a number of discrete programs without clearly articulating the need to ensure effective coordination and communication across these programs. A prime example demonstrating inefficiencies resulting from this lack of program harmonization is the lack of integration between the REC and Workforce programs. While RECs initially reported difficulty in recruiting sufficiently trained staff, graduates of the community college programs reported challenges in securing a position in which they could employ their new skill set.

Implementation at the individual program level, while well-intentioned, often failed to adequately address recognized pre-existing barriers. In designing the Workforce program, the legislation acknowledged the shortage of a workforce to effectively support HIT. However, the failure to implement programs sequentially meant that health professionals were struggling to adopt and effectively utilize EHRs without the benefit of staff with the appropriate training. Similarly, while the meaningful use program established a baseline for operationalizing the use of an EHR, incentive payments were not made available until after health professionals made a significant financial investment in the purchase or upgrade of an EHR system.

Further design challenges were introduced in the execution of the cooperative agreement programs. The REC program established a series of steps whereby, once accomplished, the grantee would be able to draw down a portion of its funds. As a result, grantees had limited initial capital to support their recruitment efforts. This was particularly challenging for RECs that experienced greater challenges in terms of recruitment, as financial resources would have proven helpful to enable broader outreach and communication regarding the benefits of their assistance. Some of the barriers to successful health information exchange were well-recognized prior to implementation of the State HIE Cooperative Agreement Program. These included the difficulty in bringing diverse stakeholders to the table, establishing an effective governance model, and overcoming proprietary interests to enable data sharing. Some entities across the United States had identified solutions to successfully overcome these barriers. However, details on how these solutions could be effectively reproduced were not widely disseminated at the time of the state HIE awards. Within the Workforce program, the concurrent rollout of the community college program and funding to develop a HIT curriculum for use by these programs resulted in inefficiencies as the community college consortia each had to individually invent a curriculum which, subsequently, needed to be revisited in light of the final curriculum topics and resources.

In spite of these shortcomings and obstacles, HITECH enabled considerable progress with regard to the employment of HIT. As a result of the programs and activities enabled by HITECH, national adoption of EHRs has grown exponentially. The general public has a greater understanding of the potential of HIT and health professionals who previously resisted the transition to an EHR now have a greater appreciation of its value in supporting efforts to provide optimal, personalized care. Advanced uses of HIT have enabled progress in a number of areas, including population health management, real- time quality data feedback, and advancing the application of big data solutions to enable new insights into the provision of health care.

Perhaps the greatest contribution of HITECH was its assistance in delineating challenges that still need to be addressed in order to continue to advance the effective use of HIT. In 2014, the ONC released a revised Federal Health IT Strategic Plan which defined a set of broad strategies that will continue the work initiated by the cooperative agreement grantees. The strategies articulated in the plan build upon accomplishments to date while leveraging insights gleaned from implementation and execution of HITECH [ONC 2014d]. The 2015–2020 Strategic Plan emphasizes the need to expand the capacity of the HIT workforce by taking advantage of resources and lessons learned from the Workforce program. Similarly, future technical assistance to advance EHR design and deployment will be informed by successes and challenges faced within the REC and Beacon programs. Further, ONC acknowledges the critical need to continue to address significant gaps in the ability to exchange health information to meet the escalating requirements defined in the meaningful use legislation as well as those articulated in ONC’s Nationwide Interoperability Roadmap [ONC 2014e]. The Roadmap calls on stakeholders to devise strategies to fortify the technical foundations of health information exchange, such as standardized vocabularies and includes a new focus on supporting health information exchange for emerging health care areas such as biomedical research, mobile technologies, and telehealth, as well as additional health professional types, including post-acute care, long-term care, and behavioral health professionals. As the nation continues on a path to optimize the use of HIT, the successes, barriers, and lessons learned through the HITECH cooperative agreement programs will continue to shape these efforts. Ongoing discussion with grantees and the stakeholders with whom they interacted may continue to yield valuable information that will further augment these efforts.

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Chapter 4: Big Data: A Realistic Assessment of its Applications to Health Care

Yael Harris, PhD and Craig D. Schneider, PhD

Introduction

A "big data" revolution is under way in health care [Kayyali et al 2013]. There is tremendous excitement among some health care experts regarding the potential for big data to transform the health care system, while others are more skeptical. This chapter will present an assessment of the potential for big data in health care to meet expectations for improving quality of care and efficiency of care delivery.

The topic of big data and its potential "to transform everything" [Groschupf 2014] has generated "all the excitement and headlines …. The promise of big data, of course, is a treasure trove of high value: everything from predictive and prescriptive analytics to population health, disease management, drug discovery and personalized medicine (delivered with much greater precision and higher efficacy) to name but a few" [Munro 2013]. Our objective for this chapter is to go beyond the marketplace hype to identify current and potential real-world applications in health care.

Addressing the topic of big data is challenging. First of all, there are several definitions of big data, which we discuss in the next section. Second, big data is a dynamic subject—the field is evolving rapidly and the situation is changing every year [Abu-Jaber interview]. Third, the health care field is lagging behind commercial big data efforts [Shah and Pathak 2014]. Lastly, many commentators are viewing the possibilities of big data from a parochial perspective, rather than thinking about the potential system-wide impact.

It is important to recognize that big data is not merely a single large dataset. A useful metaphor is considering traditional data sources—even enormous databases such as the Medicare claims database—as "filing cabinets," while big data is more like a "conveyor belt" [Gantz and Reinsel 2011]. The filing cabinet, no matter how large, is static, while the conveyor belt is constantly moving and presenting new data points and even data sources.

Our research methodology for this chapter was to speak with seven subject matter experts by telephone and to conduct a literature review on big data in health care. The interview subjects are listed in the acknowledgements at the end of the chapter. In addition, Dr. John Halamka of Beth Israel Deaconess Medical Center shared *a paper on the subject* with us [Halamka 2014].

In this chapter we discuss big data in the commercial marketplace, and then focus on its role in the health care system. We then discuss the various definitions of big data and provide background on the relevant statutes and regulations that apply to big data in health care. Next, we explore the challenges, limitations, and potential for big data in health care and present several real-world applications that clinical organizations are implementing using big data technologies. We conclude the chapter with our observations and conclusions based on this research.

Big Data in the Commercial Marketplace

Only a few years ago, not many people had heard the phrase “big data,” but now “it’s hard to go an hour without seeing it” [Marcus 2013]. If one Googles the term “big data,” 880 million results are returned (as of December 2014); a similar search, by one of the authors, only two years earlier yielded 1.4 million results.

Those numbers pale in comparison to the scope of big data itself. Today, big data is measured in terabytes and petabytes, and is on the way to a yottabyte. According to the *Boston Globe*, “A yottabyte is a mind-boggling amount of data. A byte is eight 1s and 0s. A yottabyte is 1,000,000,000,000,000,000,000,000 (10^{21}) bytes. It’s the amount of data that the National Security Agency thinks it will need to store the information it’s gathering and processing in the name of intelligence. It is estimated that a yottabyte could store 9 billion years of Blu-ray-quality movies” [Laskow 2012]. The quantity of data is projected to increase by a factor of 10 between 2013 and 2020, from 4.4 trillion gigabytes to 44 trillion, doubling every two years [EMC 2014]. As of 2012, 2.5 exabytes (1 billion gigabytes) were being created each day, and this amount is projected to double about every three years. In fact, more data crosses the Internet every second than was stored in the entire Internet as of 1992 [McAfee and Brynjolfsson 2012].

This staggering volume of data is collected and stored in a variety of sources. They include social network profiles, social influencers such as blogs, activity-generated data from mobile devices, software-as-a-service and cloud applications, data that is publicly available on the Internet, Hadoop (software that supports big data analysis) applications, data warehouse applications, columnar and NoSQL applications that supplement Hadoop analyses, network and in-stream monitoring processing, and legacy documents from multiple archives [Brust 2012].

There are numerous examples of how these data sources are being used to improve performance in several industries. Google used big data to improve spell-checking software by mining trillions of searches by millions of users; Numenta’s product, Grok, provides advanced predictive analytics; physicists used big data to discover the Higgs Boson [Marcus 2013]; IBM’s Watson became famous for winning *Jeopardy!,* but is now being used by multiple companies, including by banks to detect fraud; Palantir Technology’s software is applied in both the intelligence community and in banking; and Amazon is well known for mining customer data and using algorithms to recommend purchases its shoppers might like [*Economist* 2012].

Big data is proliferating throughout the economy because “the big data of this revolution is far more powerful than the analytics that were used in the past. We can measure and therefore manage information more precisely than ever before. We can make better predictions and smarter decisions. We can target more effective interventions, and can do so in areas that so far have been dominated by gut and intuition rather than by data and rigor” [McAfee and Brynjolfsson 2012].

Big Data in Health Care

The promise of big data that McAfee and Brynjolfsson describe helps to explain the growing excitement regarding big data’s potential in the health care field. In 2011, 150 exabytes of health care data were created, and, similar to what we have learned about other industries, this number is growing at an annual rate of 40 percent [Corbin 2014], and will soon approach zettabyte and yottabyte scales [Cottle et al 2013]. Linking data from many sources and utilizing real-time data can help provide insights and answer key problems, and give greater value to the health care experience [Downing interview].

There are several drivers of the big data movement that are specific to health care, including: changes in technology that enable access to and utilization of big data sources; a government and system-wide acceptance of open source data and transparency; an increasing emphasis on patient-centeredness and patient engagement; consumer-directed health care; expansion of electronic medical records (EMRs) and health information exchange (HIE) due to the requirements of meaningful use; the importance of cost control; and the need to address population health and accountable care based on the growing value-based purchasing movement in Medicare, Medicaid, and the private sector. In addition, Tariq Abu-Jaber, former Vice President of Medical Informatics at Harvard Pilgrim Health Care points out that, due to value-based purchasing, the responsibility for predictive modeling is shifting from payers to health professionals, further driving the use of big data by health care health professionals.

According to John Glaser of Siemens, beyond the traditional medical data currently in use (EHRs and claims data), there are three additional critical sources of big data in health care, the first two of which are specific to the health care industry: (1) genomics (genes) and proteomics (proteins); (2) data generated by patient-held mobile devices; and (3) social media.

Genomics and Proteomics

One example of the potential benefits of genomics and proteomics is cancer treatment. "The greatest promise for the detection and treatment of cancer lies in the deep understanding of the molecular basis for disease initiation, progression, and efficacious treatment based on the discovery of unique biomarkers … we still need to measure what is happening in a patient in real time, which means finding tell-tale proteins that provide insight into the biological processes of cancer development" [National Cancer Institute 2014].

Patient-Generated Data

Recently developed patient-held devices, such as FitBits,® are now generating huge amounts of real-time data. By the end of 2015 it is projected that there will be 3 billion Internet Protocol-enabled devices, including about 5 million patients using remote health monitoring devices, plus an additional 150 million health care/medical apps [Feldman et al 2012].

Social Media

Social media related to health care is also growing dramatically. About one in five smartphone owners have at least one health app on their phone, with the most popular apps focusing on exercise, diet, and weight control. In addition, 30 percent of adults actively share information about their health on social media sites with other patients, and just under half with their doctors and hospitals [Honigman 2014]. John Glaser observes that this surge in information sharing by patients can provide timely feedback on the effectiveness, as well as side effects, of a particular prescription drug.

Another framework for thinking about big data in health care is envisioning data as information transmitted through five data collection streams. These five collection sources are: social media/Web data; machine-to- machine data (such as sensors and other remote devices); transactional data (from claims and billing activities); biometric data (from sources that include genomics, retinal scans, and radiology images); and human-generated data (stored in EMRs and physician notes) [Cottle et al 2013].

In the next section we discuss the definitions of big data, how they apply to health care, and how these frameworks fit into these definitions.

Definition of Big Data

The literature review and our interviews revealed multiple definitions of "big data." According to the American Association for Public Opinion Research, there is no "singularly pre-eminent big data definition" [AAPOR 2015]. This may be because, as John Glaser explains, big data is not a thing; instead, it refers to a category of activity– it is a broad umbrella that covers an array of topics. There are two distinct classes: the first class is the data itself and the changes in the characteristics of the data; the second class is analytics and what can be done with the data [Glaser interview].

Another of our subject matter experts, Juergen Klenk of Exponent, provided a similar and useful way of thinking about the definition of big data: there is a technical definition and a functional definition. The technical definition is focused on the distinction between data management and data analytics, and the functional definition addresses the question of: now that the data is stored and available for data analysis, what can we do with it?

Technical Definition

The most common definition of big data is that it embodies the "three V's"–volume, velocity, and variety. Some analysts also add a fourth V, for the veracity of the data.[1]

Volume–scale of the data: We have already discussed the staggering volume of data that is now available. To put this in perspective, as of 2012 about 2.5 quintillion terabytes of data were generated each day; as much data is generated in two days as was created from the beginning of civilization until 2003 [Shah and Pathak 2014].

Velocity–analysis of streaming data: There are now 18.9 billion network connections– about 2.5 for every human on the planet. Examples of velocity include cars with numerous sensors collecting real-time data, and the New York Stock Exchange capturing one terabyte of information every trading day [IBM 2014].

Variety–different forms of data: Social media is diverse and enormous–30 billion pieces of content are exchanged on Facebook every month, 400 million tweets are sent every day, and 4 billion hours of video are posted to YouTube each month. In health care, there are now 420 million wearable wireless health monitors [ibid].

Veracity–uncertainty of the data: Analysts have to incorporate and assess massive amounts of both structured and unstructured data that are being collected continuously. This means the data sources contain a significant amount of uncertain and imprecise data. Data "scrubbing" is no longer feasible to make the data certain and precise for analysis [Walker 2012].

Putting the four V's together in the health care space means that big data is information that is collected in some structured and nonstructured formats and, when analyzed, can provide new knowledge or business intelligence that would have been more difficult to acquire in the past [Downing interview]. One example involves using EHRs and other medical data to increase the volume, variety, and potential for data and analytics. An ideal situation for using big data is collecting data from multiple sources (clinical, genomic, outcomes, claims and social data) and coming up with predictive analytics based on the information stemming from all of these data sources [Bates et al 2014].

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[1] Some sources add other "V's" – value and (data) visualization.

Functional Definition

We have established that big data is not just a large dataset, but rather an approach to making connections between multiple large data sources [Abu-Jaber interview]. Brent James, of Intermountain Healthcare, proposes three functional uses of big data: (1) data mining of databases collected for other purposes; (2) real-time data streams applied to areas such as human genomics; and (3) using a data system for a specific targeted purpose that has clinical implications (interview).

Abu-Jaber points out that the original notion of big data reflected using novel sources of input data to solve problems, answer questions, and provide new insights. The challenge with big data is that the underlying data is highly complex, unstructured, and difficult to derive. In the past, we lacked the tools and technology to handle multiple sources of real-time data, and the data itself was difficult to format and unwieldy [ibid]. However, the data collection and analytic capacities within the United States have grown exponentially in recent years.

An example of this change in health care is the ability to use medical records and physician notes, which were in a textual data format and considered hard to work with–it was said that "you can't do anything with text." Today, however, programs like Python (an open-source programming language), R (a free statistical programming language), Hadoop, and natural language processing tools are allowing data to be searched quickly. This enables clinical organizations to identify unlimited and unstructured text in real time [ibid].

Now that we have provided context and definitions for big data, in the next section we discuss the statutes, regulations, and government policies that both enable and constrain big data in health care.

Policies, Regulations and Laws

A few key statutes and regulations have helped to lay the groundwork for the "big data revolution" and continue to shape and inform activities which support the use of big data to advance health care. Below we briefly describe several key laws that have served as major drivers in establishing "big data" as a vehicle to transform the practice of health care.

Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 required the Secretary of the Department of Health and Human Services (HHS) to develop regulations to ensure the privacy and security of personally identifiable health information. The *Standards for Privacy of Individually Identifiable Health Information* (the Privacy Rule) was released in 2000 to ensure the protection of individuals' health information while enabling the exchange of health information. The *Security Standards for the Protection of Electronic Protected Health Information* (the Security Rule), released in 2003, established a national set of standards to ensure the protection of health information being held or transmitted electronically.

HIPAA included components that laid the groundwork for today's potential for large-scale data analytics. Included in the HIPAA provisions were guidelines for supporting national standards for electronic health care transitions and code sets, as well as developing unique health identifiers for health professionals and employers. These standards have become the essential elements for the electronic transmission of health information, as well as a vehicle to standardize the classification of diseases, clinical procedures, medical services, and medications across health care health professionals. These changes created a revolution in the field of HIT and also raised awareness about the importance of–and challenges in–securing patient-identifiable data. As such, HIPAA, particularly the Administrative Simplification provisions, was key to laying the foundation for establishing inventories of health information data.

American Recovery and Reinvestment Act

The passage of the American Recovery and Reinvestment Act (ARRA) in 2009 specifically promoted the use of health care data by providing funding to support comparative effectiveness research (CER). The purpose of CER is to provide information that helps both health professionals and patients to select the treatment approach that best meets the individual's needs and preferences based on complete information regarding cost and effectiveness [Conway and Clancy 2014]. While several agencies were already conducting CER research, ARRA substantially increased these investments and expanded funding to accelerate this work. This focus on comparative effectiveness research has been a driving force for continuous efforts to standardize EHRs, increasing the ability to aggregate health information to support the comparison of treatment approaches.

ARRA also established the Patient-Centered Outcomes Research Institute (PCORI), a nonprofit corporation tasked with supporting "patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored and managed through research and evidence synthesis" [Manchikanti et al 2011]. PCORI funds research that uses big data derived from multiple sources to assess treatment options, improve health care delivery, reduce health disparities, and improve communication and dissemination of research [PCORI 2014].

In addition to providing over $150 billion to support the health care industry, ARRA played an important role in advancing the use of big data for health care. By emphasizing the importance of comparative effectiveness research, helping health professionals invest in EHRs, and promoting entities to fund ongoing research endeavors, ARRA increased the nation's reliance on large-scale data sets, as well as emphasized the importance of applying advanced analytics to help inform future investments of health care dollars.

Health Information Technology for Economic and Clinical Health Act

Perhaps the single most influential policy with respect to advancing the field of big data in health care was the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act. Included as a component of ARRA, HITECH authorized about $30 billion to expand the use of health information technology and establish the infrastructure to advance health care quality and efficiency. Below we focus on the programs which had a significant impact on the use of big data.

One component of HITECH that has likely had the biggest impact on the availability of health care data is the provision to support meaningful use incentive payments for eligible health professionals who meet certain criteria for the adoption and use of electronic health records. As a result of the HITECH Act, over $20 billion has been paid to eligible health professionals (both inpatient and outpatient) in order for them to implement EMRs into their health care systems

[CMS 2014] and the rate of adoption among both ambulatory and inpatient health care health professionals has grown exponentially (see Chapter 1 of this report for further details about current EHR adoption rates). The result of this upsurge in the use of EHRs has translated into a wealth of structured health information stored in electronic format.

An additional component of HITECH which had a tremendous impact on the use of big data for health care was the creation of the Beacon Communities Cooperative Agreement Program and the Strategic Healthcare IT Advanced Research Projects (SHARP) programs. The Beacon program, which we describe in greater detail in Chapter 3, funded a number of communities across the United States to advance the use of HIT and electronic exchange, and to develop innovative approaches to health care delivery. These grantees used information garnered from multiple, large-scale data sets in an effort to reduce costs and improve health care quality.

The SHARP[2] program provided funding to support research focused on addressing recognized challenges affecting the adoption and widespread use of HIT. A set of distinct research entities focused on key challenges limiting the use of health information data. Through efforts to advance privacy and security protections; harness the power of HIT to improve clinical decision-making; improve the usability of HIT; develop strategies that leverage existing data to identify best practices; and expand the interoperability of health data collected from multiple sources, SHARP served as a critical impetus to expand the capacity and utilization of big data. The SHARP programs not only helped to create larger, more robust data sets derived from multiple information channels, they also provided key insights that demonstrated the potential of big data to advance health care quality.

Patient Protection and Affordable Care Act

The passage of the Patient Protection and Affordable Care Act (ACA) in 2010 marked a landmark in the nation’s approach to health care. In addition to expanding health care coverage to millions of Americans, ACA’s provisions created new sources of electronic data. Through the establishment of health insurance marketplaces, ACA accelerated the transition to electronic aggregation of claims data. Increased insurance enrollment provided information on new patients previously not captured in electronic databases. The ability to link detailed electronic health insurance data to electronic health records has helped to create a robust inventory of health information to inform predictive analytics. As a result, health care organizations can now access and analyze more comprehensive sets of patient information. These by-products of the ACA have enabled health professionals, policymakers, and researchers to advance their use of large and diverse sets of health care data to support care coordination, outcomes-based reimbursement, and population health management.

The ACA also shifted health care payment models from a primarily fee-for-service approach to one where health professionals assume more risk. One notable example of these new health care delivery models is the establishment of Accountable Care Organizations (ACOs), whose focus is on care coordination and management to enhance patient outcomes at a lower cost. In order to achieve these goals, ACOs must use large sets of health care data to evaluate the most effective treatments, identify outliers, and track overall quality and financial performance.

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[2] Four SHARP programs were funded through HITECH. A fifth program was funded by the National Institutes of Health.

The use of payment incentive programs, also known as pay-for-performance, had already been in place at the time that the ACA was passed. However, the ACA expanded the number of these programs, establishing value-based purchasing programs as well as Medicare penalties for poor clinical outcomes. In order to support these efforts, the Centers for Medicare and Medicaid Services (CMS) has had to develop and apply complex algorithms to aggregated health care data capturing information on services and outcomes for patients across the United States.

Digital Accountability and Transparency Act

The Digital Accountability and Transparency Act (DATA of 2014) recognized the emerging value of health information by increasing access to federal spending across all programs. Prior to the passage of the act, there was minimal transparency regarding how federal dollars were being allocated and used. Through its requirement to establish standards for fiscal reporting, DATA is likely to enable more granular access to information to support research. Expanded access to data on federally funded programs will increase the research community's ability to access large sets of previously unavailable data. The wealth of these increased sources of information are likely to expand our ability to link multiple electronic records to provide new insights.

As we have suggested, these laws–HIPAA, ARRA/HITECH, the ACA, and DATA–established a foundation for the development and growth of big data in health care. In the next section we discuss the limitations and opportunities for applying big data analytics to the health care system.

Growing Role of Big Data in Health Care

Big Data Is Not a New Concept

While "Big Data" has become an increasingly popular concept and the focus of numerous articles, presentations, and news releases, our discussions with experts reveal that the concept itself is not a new one in the health care sector. Much of today's current big data efforts are actually the reincarnation or evolution of ideas that have been under development for several decades. In 1993, the Clinton Healthcare Reform Taskforce established a health information technology subgroup [Kolodner interview]. This entity–advised by national leaders in the field of HIT representing both the public and private sectors–recognized that perhaps the greatest benefit to be realized through nationwide implementation of HIT would be the advancement of medical knowledge through secondary use of the aggregate health data ("large data sets") captured in digital form.

As early as the 1990s, integrated delivery systems have been analyzing EHR data to support research to enhance patient care. Beth Israel Deaconess Medical Center has been using de-identified health record data since 1991 to support care coordination and management, quality measurement, and population health [Halamka 2014]. In 1996, Intermountain Healthcare established an initial structure for collecting data to support clinician care [James interview]. Within a year, the health system developed two data streams to help analyze clinical care targeting two conditions that comprised more than one-fifth of their patient volume–pregnancy and labor and ischemic heart disease. Through data analysis, Intermountain was able to increase patient outcomes while reducing overall costs [Parker and Vitelli 1997]. Based on these successes, the process was expanded to other prevalent health conditions.

The Amount of Health Information is Growing Exponentially

Big data is beginning to have a substantial impact at the state, health professional, and consumer levels. While the potential for big data has been in place for decades, only recently have increased sources of electronic information and improved technology allowed for exponentially growing statewide data repositories, and unprecedented data access and storage. The number of states that have created, or are in the process of establishing, all-payer claims databases (APCDs) demonstrates this growing wealth of electronically accessible information and interest in leveraging this data to increase knowledge [Peters et al 2014]. "APCD systems fill critical information gaps for state agencies to support health care and payment reform initiatives and to address the need for transparency in health care at the state level to support consumer, purchaser, and state agency reform efforts" [Porter et al 2014].

At the health professional level, the escalating adoption and use of EHRs has expanded data capacity and analytic capabilities to inform clinical care and health outcomes across a variety of health care settings. The next target for big data is establishing successful strategies to leverage this information to improve care, reduce costs, and inform clinical decision-making. As such, the key issue is not our ability to access the data but rather using the data to gain insights that we can implement in real time to impact payers, health professionals, and patients. The challenge is not about collecting data but turning this data into "actionable wisdom" [Halamka 2014].

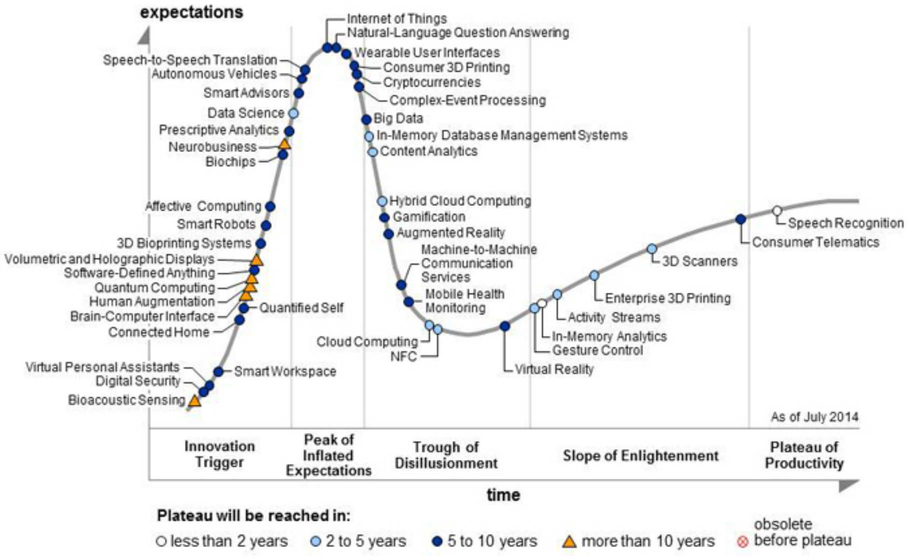
In addition to the plethora of available clinical and administrative data, as we described earlier, new sources of consumer-level information are being generated through social media, self-reported data via mobile devices, and telemetry data available through automated monitoring devices. This information provides useful insights into daily activity, behavior, and emotions, increasing our understanding of individual and group physical and behavioral health, as well as enabling our ability to monitor trends across different demographic and geographic populations. Analogous to the financial and commercial industries, this new information may help predict–and ideally impact–individual patient behavior.

Managing Expectations

While the use of big data has been growing in health care, the experts interviewed for this chapter cautioned that expectations and anticipation regarding the potential of big data should be tempered with restraint. Their perspective is in contrast to numerous articles suggesting that big data is going to be a panacea for the health care industry [Choucair et al 2015; Roski et al 2014]. From the use of genomic data to identify personalized medical treatment options to the ability to save billions of dollars through models for improved health care efficiency, researchers have touted the potential for big data to transform the practice of medicine [Wang et al 2014; Bates et al 2014]. While the potential is real, the reality may not meet expectations and some leaders in the field have expressed skepticism. The Gartner Hype Cycle (Exhibit 23) describes a "peak of inflated expectations" followed by a "trough of disillusionment." A prime example of this is the increasing skepticism among oncology researchers that access to large sets of genetic data will help find a "cure" for cancer [Mukherjee 2010].

While the overall potential for big data currently may be more hype than reality, John Halamka believes that the trajectory is still positive [Halamka 2014]. Realizing the potential of big data will require better comprehension of its strengths as well as continued efforts to understand its limitations. There is also a need to capitalize on the increased interest and high expectations through the development of better analytic models, and the need to structure inquiries to leverage the capabilities of available data and ensure that findings are not spurious. According to Brent James, using data without a clear analytic framework may generate statistically significant findings, but with a 95 percent confidence interval, 5 percent of findings will be wrong and the results will not be reproducible. As such, we need to embrace the new possibilities apparent in big data while avoiding the misconception that bigger data means better data or that big data is a panacea in solving all of our nation's health care challenges.

Exhibit 23: **Gartner's 2014 Hype Cycle for Emerging Technologies**



Source: Gartner's 2014 Hype Cycle for Emerging Technologies, August 11, 2014, *www.gartner.com/newsroom/id/3114217*

Limitations to Big Data

There are a number of reasons why health care lags behind other industries [Shah and Pathak 2014] in its use of big data. Across the literature, a number of barriers have been identified which restrict our ability to maximize the use of data. These can be categorized into the following high-level concepts: data protection and ownership, access and availability, quality, validity, and lack of effective data analytic approaches to optimize use of this information.

Data Protection and Ownership

Members of both the public and private sectors agree that one of the key obstructions to the use of big data in health care involves concerns regarding data security and who has the authority to de-identify and share this information [AAPOR 2015]. HIPPA established guidelines for the sharing of personal health information across "covered entities." However, as the nature of health care data, the volume of information, and the types of information which are available continues to evolve, these guidelines will likely need to be revisited. Even in cases where data has been de-identified, the potential to identify patients remains troublesome. This is a particular concern when dealing with data associated with a narrowly defined population such as persons with rare medical conditions or unique personal characteristics. As a result, health information can easily be attributed to a specific person in spite of the removal of personally identifiable information, such as name and date of birth. HHS has recognized this issue and at a recent health forum focused on minimizing disclosure risk due to the proliferation of publicly available data sets [Czajka et al 2014].

Another challenge that needs to be addressed is clarifying data ownership. In the past, patient-level information was shared in paper-based format, requiring the patient's written authorization to enable this data to be shared with other entities. However, with the advent of electronic health records, patient generated information, and even nonstructured data available through social media, determining data ownership has become less clear. In order to ascertain who has the authority to share this information and grant permission for re-use of the data, it is necessary to consider a wide array of potential data owners, including the subject of the information, the entity which collects that information, the individual who compiles and analyzes the information, the person who purchases the data, and the public at large [AAPOR 2015]. While these barriers are not technical, they will need to be addressed and eventually overcome [Kolodner interview].

Data Access and Availability

Another significant challenge that can limit big data's potential in health care stems from barriers related to accessing and sharing data across health professionals and health systems. A number of factors contribute to this impediment including financial concerns–health care health professionals, such as large health care systems, have a vested interest in not sharing their data [Klenk interview]. Data sharing is frequently compromised by personal interests; entities fear that in sharing their data they might miss a discovery and, thus, an opportunity to leverage their health information, whether for financial gain or professional recognition. They also fear that shared data may compromise their market share, thus reducing overall revenue.

The historical focus of the U.S. health care system has been on individual markets overlooking the global benefit of a shared data approach [de Brantes interview]. State and regional efforts to implement an all-inclusive model of health care data have been stymied by a lack of buy-in from individual health professionals [Adler-Milstein et al 2011]. Public funding to support the aggregation of data has historically been limited and, when made available, rarely produced sustainable data repositories that can support ongoing analysis and prediction activities [de Brantes interview]. When the limited public funding is expended, private investments are rarely available to support the long-term ability to maintain and continue to expand and utilize state and regional data inventories comprised of health information. Recent federal efforts led by the HHS Chief Technology Officer, such as *healthdata.gov*, have begun to address this challenge by supporting the transparency and accessibility of publicly available information [Downing interview].

Data Quality

The quality of health data has been a consistent source for concern. For years health care researchers have called into question the reliability of claims data [Green et al 1993; Lohr 1990]. The limited research on EHR data has also generated trepidation about the use of this data for predictive analytics [Tse and You 2011]. A number of factors can compromise data quality, including human error, variability in data capture and storage, and inconsistency or evolution of terminology and practice standards. This is further compounded by the fact that the information used in big data analyses are often secondary data, repurposed to answer questions for which the data was not initially intended [AAPOR 2015].

Inconsistencies in the way data is recorded significantly impact the quality of health data [Glaser interview]. The accuracy and comprehensiveness of the data recorded in a patient's clinical record may vary based on the type of health professional entering the information and his or her medical area of focus (Neri et al 2014). Since the majority of clinical health information is entered by humans, there is a higher likelihood of significant errors [Adler-Milstein and Jha 2013]. Incomplete and missing data fields, as well as widely varied clinical documentation can make it difficult to use health care data to draw conclusions or make predictions that will impact future care [ibid]. In addition, nonclinical elements such as race and ethnicity are frequently under-reported (missing) or inaccurately recorded. For example, a third-party analysis of EHR data at Beth Israel Deaconess Medical Center discovered wide variation in the recording of data elements related to health disparities [Halamka 2014].

Variance in how data are collected, captured, and stored can also impact its usability and value. There is currently little consistency in the way that information must be captured in an EHR, so differences in the wording or decision logic embedded in these tools can impact how data is captured [de Brantes interview]. Even software products that meet meaningful use certification requirements vary in the level of granularity of the data that is captured, as well as their use of standardized medical terminology [Kreda and Mandel 2014]. The resulting data not only calls into question its uniformity but–when trying to match data that has been stored using non-standardized definitions and approaches–the ability to link the data and the subsequent ability to "trust" the information within the resulting data set.

Data Validity

Diverse and imperfect strategies for de-identification and aggregation of health information not only make it harder to combine data across systems, but also introduce new errors that affect the validity of the final data set. Trying to minimize these inaccuracies and effectively integrate disparate sets of information squanders time and resources that could be better spent actively using the data to benefit health care. Even when data acquisition is inexpensive, the costs associated with "cleaning, curating, standardizing, and integrating" disparate sets of data can be significant [AAPOR 2015]. Francois de Brantes indicated to us that his team typically spends 90 percent of their time focused on data mapping and "scrubbing" to enhance data accuracy, leaving only 10 percent of their time to focus on using the data to drive clinical quality improvements, thus compromising the resource available to produce actionable insights.

What is frequently referred to as "big data" is usually an amalgamation of disparate sources of data, each of which introduces its own level of uncertainty and error. In a 2015 report, the American Association for Public Opinion Research further elucidated these challenges: "Big Data are typically aggregated from disparate sources at various points in time and integrated to form a data set… these activities introduce errors that may be variable, creating noise and poor reliability, or systematic, leading to bias and invalidity" [ibid]. Much of the resulting data has not been validated, leading to the potential to draw biased inferences [Downing interview]. Applying non-standardized algorithms to this data can lead researchers to draw conclusions which may be distorted by a considerable amount of noise. Without standardized algorithms and analyses to support the systematic analysis of big data, researchers are likely to generate spurious results or chase patterns that are not real [Adler-Milstein and Jha 2013]. The lack of a tested and validated algorithm has led to over- or under-estimation of diagnoses which can introduce significant error into analyses at both the individual and population level.

Lack of Effective Data Analytic Approaches

One of the most significant limitations to realizing the potential of big data in health care has been the lack of a strategic approach to data analysis. According to Brent James, the strategy of looking through large data sets to detect random findings is both “flawed and lazy.” While data mining might generate some information, these findings may not be clinically meaningful and could even distract efforts from more directed research that can impact patient care. Juergen Klenk adds that this approach is no more than “data dredging,” and that deciphering meaning from patterns and turning findings into meaningful action is challenging.

Effective data analysis can only be realized by the use of a multidisciplinary team working together to unlock key lessons from the data [James interview]. An effective team must apply both inductive and deductive reasoning to the available information, leveraging a combination of analytical and clinical skills. Effective integration and utilization of big data can best be accomplished through coordinated efforts by individuals who contribute different skill sets. According to the American Association of Public Opinion Research, in order to effectively use big data, it is necessary to convene a team characterized by the following four roles: a subject matter expert, an individual with formal training in research, a team member experienced in computer science, and a system administrator [AAPOR 2015]. One of the keys to Intermountain’s successful use of big data to reduce costs and improve quality has been their use of a strategic, team-based practice of embedding researchers into clinical development teams [James interview]. This model allows Intermountain to optimize the skill sets of professionals who embrace different approaches to data analysis, leading to more meaningful insights from the available data. Practicing clinicians may not necessarily bring skills in data analysis, but their clinical experience and knowledge of the medical process brings tremendous insights to the researcher team to support interpretation of data findings.

Even with an appropriate data analysis strategy, resource constraints may impair the ability to use big data effectively. For example, states that have established all payer claims databases (APCDs) may have limited resources to utilize the amount of data that is now available and maximize this information to inform policies and practices. In order to employ effective statistical analyses, it will be necessary to address a number of challenges which hinder the effective use of big data: heterogeneity, noise accrual, spurious associations, and accompanying endogeneity [Fan et al 2014]. Advocates of big data often underestimate the importance of acknowledging these limitations and recognizing the need to develop and test algorithms which can prove useful in evaluating the validity of available data. As stated by Greg Downing of HHS: “we need to go in with open eyes and a healthy skepticism.”

Opportunities and Applications

The real lure of big data is its potential to generate new knowledge [Murdoch and Detsky 2013]. Through access to data from multiple information streams, it is possible to not only enhance patient care but also accelerate our research capabilities to advance future health care endeavors. These benefits include improved outcomes, efficiency, and safety to support care at the individual, systematic, and population levels. As stated by Juergen Klenk, “no matter the stakeholder, big data has the potential to greatly improve the quality and cost of health care.”

Enhanced Clinical Care

The ultimate goal of big data is to use this information to benefit those from whom the information is derived [James interview]. In the past, research relied solely on primary data collection which generated valuable findings but could not produce timely insights based on the results. As one analyst describes it, traditional research is built for "comfort, not speed." The ability to capture and analyze data quickly can augment decision- making to produce rapid changes to best meet individual needs [AAPOR 2015]. Through the real-time use of patient-level data, it is possible to not only improve patient management, but to also identify and implement timely, targeted interventions to produce optimal outcomes. Clinicians are able to ask questions that can immediately impact care delivery, minimizing the time it takes to find the best treatment for a specific patient [Klenk interview]. One example of this is the use of clinical decision support systems which have helped improve the efficiency and quality of health care [Bates et al 1998].

Historically, the practice of health care involved responding to situations after they had occurred. Practitioners typically reacted to patient needs with access to limited information and knowledge to guide their decision-making process [James interview]. As health information becomes more ubiquitous with increasing access to multiple sources of data and meaningful presentations of this information, health professionals can better anticipate patient needs and events before they occur. One example of this is Kaiser Permanente's use of patient-level data to reduce emergency department visits. Information from the patients' medical record is used to generate a comorbidity score and a physiological stability score for the preceding 72 hours. This information is then combined with vital sign data generated by a patient monitoring device [Bates et al 2014]. This enables real-time care management to improve decisions and enhance outcomes and efficiency.

The expanding amount of longitudinal health data can yield findings that have the potential to benefit multiple patients across a wide array of conditions. Beginning in 1996, Intermountain Healthcare began building a data system to support clinical management and track intermediate and final costs and outcomes. The system is designed around the flow of care, and allows the clinician to identify the right risk factors [James interview]. Harvard Pilgrim Health Care is currently utilizing EMR data provided by contracted health professional organizations, as well as electronic claims submissions, to generate "close-to-real-time" utilization analytics. This clinical data is used to improve clinical care processes and programs (such as case and disease management) through the delivery of better targeted interventions [Abu-Jaber interview].

Access to timely data can also help clinicians learn from the experience of their peers. Big data enables clinicians to access information about treatment plans other clinicians have chosen when treating similar patients [Murdoch and Detsky 2013]. This peer-to-peer learning is a valuable asset, especially in areas where there are not well-established clinical guidelines or processes. At Beth Israel Deaconess Medical Center, clinicians no longer need to wade through sets of raw data; instead, they have the capacity to review suggestions in real time to optimize the care they provide to their patients [Halamka 2014].

Improved Patient Safety

Access to large quantities of data not only improves clinical outcomes through the ability to detect better treatment options, but also enables health professionals to predict and prevent adverse events or ineffective treatments [Glaser interview].

Specifically, in the field of pharmacology, the ability to harness large sets of historical data can provide more timely insights into medication safety and effectiveness [Manyika et al 2011]. This can reduce the time required for clinical trials, identify adverse events that can more easily be detected through population-level data, and reduce the cost of research by supporting the early detection of a new drug's lack of efficacy [ibid].

New sources of data, such as remote monitoring devices, can provide rapid feedback to prevent patient harms and detect unanticipated or adverse effects of treatment approaches. One example of this is the wireless transmission of blood glucose levels which can help a health professional identify out-of-range values and prevent a diabetic episode by revisiting medication dosages when necessary. Further, by tracking patient-reported information through social media, researchers can gain insights into any unanticipated harms associated with new medications, as well as unintended adverse reactions to common treatments such as immunizations or over-the-counter medications.

Data from electronic health records can also provide insights into treatment approaches that may be harmful. A study of patients undergoing inpatient surgical procedures at Department of Veterans Affairs medical centers found that employing natural language processing to electronic medical records resulted in increased sensitivity in the identification of postoperative complications as compared with administrative data [Muff et al 2011]. Use of large health data sets can also help to generate predictive models to determine relative risk of a particular approach, taking into consideration its overall benefit compared to potential harms [Klenk interview]. One example of this is the early detection of adverse effects associated with the painkiller Vioxx [Manyika et al 2011]. This information can help clinicians better understand effective treatment models and detect unnecessary treatments that may subject the patient to suboptimal care.

Increased Efficiency

Efficiency is often viewed as the ultimate metric of a high-performing health care system—one where clinical outcomes are optimized through the use of the most appropriate treatment modalities with minimized use of inappropriate or ineffective treatments. Using data on past procedures and outcomes can help clinicians find the best treatment approaches, not only improving quality of care but simultaneously improving cost management. This approach has been effectively employed by Intermountain, where teams of researchers evaluate patient care outcomes to look at how treatment decisions affect patient care in terms of both quality and cost. These analyses help to ensure that practitioners are making clinical decisions based on the most recent evidence. It also results in significant cost savings to the health care system as ineffective or minimally effective treatments are eschewed in favor of those with better demonstrated impact [James interview].

Big data can also help predict more efficient models of care. For example, Geisinger Health System currently analyzes its EHR data and other cost systems to identify potential improvements in efficiency [Moore et al 2013]. Payers have also found value in using multiple data streams to help reduce costs. Harvard Pilgrim is enhancing revenue and reimbursement processes by applying risk management and predictive models using a combination of both existing and new data sources to model the impacts of novel payment and contracting methodologies, in collaboration with network health professional organizations [Abu-Jaber interview].

Through access to large amounts of data, researchers can refine and test algorithms to support better diagnoses [Glaser interview]. Large amounts of data support the ability to analyze treatment impacts at the micro-level to incorporate factors such as patient age, genetics, and family history to better delineate those treatments with the greatest likelihood of success. The goal is to focus analytics on issues that have the most impact, such as cost-effectiveness research, and measure its success in terms of delivering high-quality, efficient health care.

Another emerging opportunity for increased efficiency is the use of data analytics to support program integrity. Memorial Healthcare System combines EHR data for patients in its network with utilization records and billing information. In addition to using this information to assess physician and hospital performances, data analytics applied to the aggregate data have proven valuable for comparing vendor data against internal and external databases to reveal fraud and conflicts of interest [Lanser-May 2011].

Strengthened Consumer Engagement

Over the past several decades, attention has shifted to increased data transparency with the goal of improving clinical quality. Initial efforts to use data to drive quality focused on the use of claims data to report on clinical outcomes such as hospital mortality [James 2012]. Over time, the use of this information has become more sophisticated, producing more detailed "report cards" on health professional information relative to a wider array of patient-level outcomes across multiple health care health professional types [ibid]. While patients were the initial targets of data transparency efforts, this information has had more of an impact on health professional behavior [ibid; Totten et al 2012].

With increasing amounts of health information, the focus has returned to identifying how to use data to help patients make more informed decisions about health care as well as to empower patients to become active participants in their care [Manyika et al 2011; Groves et al 2013]. The number and diversity of mobile health apps and other consumer-facing resources currently available in the marketplace demonstrates the growing focus on using technology and data to support patient engagement [Estrin and Sim 2010]. An interactive online system (mHealthCoach), exemplifies this growth in the use of big data to support consumer engagement. The primary goal of mHealthCoach is to educate patients to enable them to more effectively manage their treatment and care, specifically in regard to chronic care medication. Leveraging data from the Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Project (HCUP), the app allows health professionals and payers to message patients with a higher-risk of not adhering to care management protocols to support more proactive disease management [Groves et al 2013]. Asthmapolis, another mobile health app utilizes a phone's GPS tracking system, linked to inhaler usage, and combines this information with CDC data to come up with personalized treatment plans and prevention strategies based on trends seen across differing geographic areas. This data leads to the development of personalized treatment plans based on the patient's exposure to allergens in their neighborhood [Groves et al 2013].

Recent evidence suggests that today's patients are increasingly active in accessing health information online [Murdoch and Detsky 2013]. In addition, individuals are progressively more interested in using social media to share information and evaluate health care services and health professionals [Hensley 2014]. As such, the Internet serves as a valuable resource to support consumer engagement and patient activation in the care of a wide array of health conditions. *PatientsLikeMe*, a website which allows patients to share information about their health conditions, has partnered with the University of South Florida's Department of Internal Medicine to improve outcomes for patients with multiple myeloma. The organizations will exchange and publish information on their websites, which will give patients information and support while they contribute their health data for research [University of South Florida 2014]. By leveraging social media, it may be possible to increase consumer activation by establishing algorithms which let patients review aspects of a health professional's clinical experience or a health care protocol for a specific health condition that they find most relevant. This information could then direct the patient to appropriate online resources such as specialists and clinical trials, qualitative feedback other than from patients, and clinical outcomes on a set of self-selected indicators.

Expanded Potential for Personalized Medicine

The ability to link data on medications to genetic information offers tremendous potential. Each drug compound has a certain pathway which depends upon the medication, disease, and unique characteristics of the patient. However, to date, the interaction of these different pathways has not been well understood [Klenk interview]. Through the ability to link data on medical treatment and outcomes with individual patient characteristics, science can better support personalized medicine. Geisinger Health System has proactively embraced this approach in its current efforts to customize protocols for patients based on their genomic profile [Moore et al 2013].

Treatment of life-threatening diseases such as cancer might be revolutionized by the ability to use genomics to identify the most effective chemotherapy agents for each patient. This work is currently under way at Memorial Sloan Kettering Cancer Center, where they are leveraging the analytic capability of IBM's Watson computer to personalize cancer care by applying information about a specific patient to a knowledge database, and helping oncologists make the best treatment decisions. The results can incorporate the latest medical breakthroughs, and are enhanced by Watson's capability for cognitive computing to "learn" and thereby improve the accuracy of recommended treatment options [Bassett 2014].

Likewise, the pharmaceutical industry spends billions of dollars testing new medications for effectiveness on large, heterogeneous populations. By using data more effectively, the research and demonstration process can become more personalized, testing the effectiveness and safety of medications targeting specific subsets of individuals [Klenk interview].

Historically, data resided in silos which forced researchers to limit the scope of their research questions. Big data offers the potential to break down these artificial barriers to gain more insights into disease treatment [de Brantes interview]. One example of this is in the ability to better understand and treat cancer. Tumor registries serve as valuable public health tools to track the prevalence of different types of cancer; however, the information captured in these systems is often limited to counts of the number of patients with a particular type of cancer. The ability to augment this with information such as stage, treatment approaches, and patient-specific information (which may include contributing factors such as zip code, smoking status, or family history) can offer new insights into cancer treatment and help establish more accurate predictive models for at risk populations.

Increased Transparency and Information Sharing

Increased access to shared data is revolutionizing the practice of medicine. Since 1996, Intermountain Health care has accumulated two petabytes (2,000 terabytes) of data which has enabled it to longitudinally track thousands of patients. It is currently expanding the utility of this information by linking their database with other national collaborative networks. These rich data streams are being used to produce clinical findings which can be shared with all clinicians through the peer-reviewed literature [James interview].

The U.S. Department of Health and Human Services (HHS) has emphasized the importance of information sharing through its Open Data Initiative. By making multiple large data sets available to the public, HHS is promoting and enabling the use of big data throughout the health care system. In addition to focusing on data quality and ensuring that the data methodology is carefully described so that consumers can clearly understand what the data represents, HHS is also performing metadata tagging in order to improve the data tagging process [Downing interview]. More recently, the National Institutes of Health launched a Big Data to Knowledge Initiative. During the next seven years about $700 million will be provided to research ways to use data to improve health. For example, the University of California at Santa Cruz is examining genomic data to identify cancer-causing genes which may lead to development of drugs to target these genes, and the University of California at Los Angeles is studying cardiovascular disease to find protein markers that are correlated with the onset of cardiovascular problems [Healy 2014].

Advanced Population Health

A growing number of public health and policy officials are hoping to use big data to improve health care at the population level [Downing interview]. Through access to multiple clinical and claims data sources, the Health Care Incentives Improvement Institute is using multiple data streams to enhance public health data systems. Currently cancer care claims data does not include data elements that allow the analyst to confirm and classify reported cases of cancer, such as by stage or tumor size. Through the integration of multiple data sources, including clinical data, claims data, and lab results, the goal is to be able to make more appropriate inferences, classify cancer cases, and track case management [de Brantes interview]. These insights will help to detect potential environmental risk factors (e.g., contaminated water supply) as well as conditions that are more amenable to currently available treatments (e.g., cancer types which respond faster to treatment).

Massive databases, including information generated through social media, are currently used to support public health surveillance including detecting disease outbreaks, emerging infections, and patterns of patient harm [Murdoch and Detsky 2013]. Perhaps one of the most widely publicized examples of this is research led by the Johns Hopkins School of Medicine which demonstrated that, using key search terms, data from Google Flu Trends could effectively predict surges in flu-related emergency room visits one week before warnings came from the Centers for Disease Control and Prevention (CDC) [McAfee and Brynjolfsson 2012]. However, while Google searches between 2009 and 2001 enabled the CDC to more accurately predict flu incidence, more in-depth research revealed that case estimates produced by Google were highly exaggerated [Butler 2013]. Another example of how access to multiple sources of data in real time can improve health care is in the area of patient safety. Project

Artemis, a cooperative venture between the University of Ontario and IBM, is predicting nosocomial infections in the neonatal intensive care unit before the presence of symptoms arises [Cottle et al 2013].

Even online social networking tools such as Facebook and Twitter have been useful in supporting population health. Tracking Facebook postings, researchers at the University of Wisconsin demonstrated the value of social networking in detecting and improving mental health among a population of at risk individuals [Moreno et al 2011]. In Haiti, Twitter updates were found to be as accurate–and significantly more timely–than official reports in enabling public health officials to track the spread of cholera after the January 2010 earthquake [McAfee and Brynjolfsson 2012]. As such, big data in both standardized and nonstructured form has the potential to improve population health through disease tracking and detection, surveillance, awareness and public health response [Manyika et al 2011]. According to Tourangeau and colleagues, "found" data, such as a log of exercise captured from a personal, wearable device, may even improve information accuracy as it reflects real-time data capture rather than information gleaned through surveys which can be subject to recall bias [Tourangeau et al 2000].

Beth Israel Deaconess Medical Center (BIDMC) in Boston is applying big data for multiple use cases: delivering information to clinicians at the point of care, performance assessment, predictive analytics, and transparency and sharing with other organizations. Because of the richness of their approaches to using big data, on the next page we delve into a bit more detail on BIDMC's use cases.

Beth Israel Deaconess Medical Center: An Exemplar of the Use of Big Data in an Academic Medical Center

Providing information at the point of care: The voluminous data in an EMR needs to be filtered so that the clinician can identify what is particularly significant, and BIDMC applies decision support rules to assist clinicians at the point of care. For example, normal blood pressure readings might be data, but a sudden drop in a specific patient's blood pressure needs to be brought to the health professional's attention—this is useful information. Relating the blood pressure drop to a clinical event such as chest pain is knowledge. When the system suggests an intervention such as aspirin and oxygen, then that is wisdom that can improve patient outcomes.

The decision support process for radiology illustrates this model. When a doctor orders a radiology test, a query is sent to a decision support application that includes best practice rules from the American College of Radiology and the literature. The system recommends the most appropriate radiology test based on the evidence and the patient's medical record. Possible radiology tests are scored on a five-star scale to balance efficacy, risk, and cost. In this example, the clinician does not need to focus on raw data, but instead receives suggestions in real time to optimize patient care, and the prior authorization process is accelerated because the payer knows that the decision to order the test is evidence-based.

Performance assessment: BIDMC operates a Medicare Pioneer Accountable Care Organization (ACO) known as BIDCO. ACOs must achieve continuous wellness rather than only treating sickness. ACOs and other value-based payment models require new data systems that combine observations about the patient into a continuous view of his or her health care. BIDCO implemented a cloud-hosted EMR to physician practices that did not have a certified EMR, and required each clinician to send a summary of each visit to a database. Following submission, the EMR sends a transition-of-care summary containing all the data necessary to calculate quality and performance metrics to the statewide quality data center. Claims are sent to a financial data warehouse, and clinical and claims data are merged to enable analysis of quality, cost, and outcomes.

Predictive analytics: The integration of clinical and financial data enables BIDCO to conduct predictive modeling and analyze disease patterns. BIDCO uses these tools to determine the most appropriate setting for care and avoid hospitalizations and emergency department visits—in its first year as a Pioneer ACO, BIDCO achieved shared savings.

Transparency and sharing with other organizations: BIDMC also established the Clinical Query application to support comparative effectiveness research. This is a Web-based tool that allows for analysis and visualization of clinical data collected by BIDMC. The idea is to help researchers determine the statistical power of a clinical trial or the availability of data for research prior to launching the study. The query tool was developed with 20,000 medical concepts using software from the i2b2 project, which was initiated by Harvard Medical School to mine large clinical databases. For example, if the researcher has a hypothesis that there is an association between breast cancer and taking angiotensin-converting enzyme (ACE) inhibitors, s/he can analyze 2.2 million EHR records that have been downloaded into a standardized repository between 1997 and 2014, with 200 million data elements. This search finds about 2,400 patients with breast cancer who were taking ACE inhibitors.

ONC launched the Query Health Initiative to build on the i2b2 experience "to create a generalizable methodology to query heterogeneous big data sources stored in hospitals across the country." This approach protects patient privacy by keeping all patient-identifiable data within a secure data center and only reporting aggregate numbers.

Adapted from Halamka John D. "Early Experiences with Big Data at an Academic Medical Center," Health Affairs; *33:7, July 2014.*

Conclusion

This chapter has provided background on and a functional definition of big data, relevant laws and regulations, the limitations of–and the opportunities for–big data, as well as detailed several real-world applications. We conclude with some observations, strategies, and next steps that may help the health care system realize the potential of big data analytics.

Early innovators may have laid the groundwork for leveraging the massive amounts of information to drive practice changes, but more recently the key driver has been the changing health care marketplace, facilitated by the legislation we previously discussed. Improvements in technology and the accountable care movement have accelerated the adoption of big data applications by health care organizations.

Our interview subjects noted that access to lots of data is not new in health care. As Francois de Brantes pointed out, data in and of itself is useless–it is what we do with it that matters. What is important is not only obtaining access to big data, it is achieving insights from the data and creating reasonable inferences with the data that is the current challenge.

In order to fully meet the potential of big data, the health care system will have to resolve the following issues:

Data security: Big data in health care will, by necessity, include personal health information. The health care system must develop protocols that enable the sharing of data while protecting individual patient privacy. Although federal legislation such as HIPAA provides an important foundation for data security protocols, the health care and technology landscape is constantly evolving. As a result, stakeholders need to convene on a regular basis to update and revise privacy and security guidelines. HHS can play a useful role in initiating and facilitating such conversations.

Data sharing: In its draft 2015–2020 Federal Health IT Strategic Plan, ONC highlighted the value of big data and the need for collaboration [ONC 2014]. This plan outlined strategies to help address challenges that currently hamper the use of big data: (1) implementing consistent standards and reducing variability in terminology, vocabulary and coding; (2) leveraging federal regulations to encourage the adoption and use of common standards; (3) developing policies to enable people to manage and control their personal data; and (4) promoting the incorporation of usable electronic information to support clinical care. This framework is a worthy starting point to facilitate data sharing among health care organizations.

Analytic capabilities: There are three important aspects to the analytic capabilities for big data: (1) a sufficient number of well-trained analysts; (2) the resources to fund these analysts and their work; and (3) the implementation of effective analytic approaches. Health care has lagged behind other industries in the application of big data, in part, because the return on investment has not been apparent. The accountable care movement is leading to a change in this attitude as health professionals recognize the need to employ data analytics to advance health care efficiency. But sufficient resources and proficient expertise are not enough–as Brent James pointed out, the right questions have to be asked and analysts and their managers need to be thoughtful about the findings to ensure that results are not spurious.

Collaboration and Peer-to-Peer Learning: One approach to addressing development of well-trained analysts and effective analytic strategies is collaboration and peer-to-peer learning among health care organizations. New partnerships across the health care system will be necessary to establish a robust infrastructure that can support and sustain big data efforts–an example of an effective partnership to date is a collaboration between Intermountain Healthcare and 18 other integrated delivery networks. In addition to sharing data and analytic strategies, organizations need to share experience and expertise, including bringing together researchers with clinical expertise and those with analytic strengths. Current examples of such collaboration and peer-to-peer learning are the Medicare ACOs (see *innovation.cms.gov*) and the APCD Council and the National Association of Health Data Organizations which support state APCD development and analytic efforts.

Consumer Engagement: As a result of advances in data analytics and information sharing, patients have more information to inform their decision-making efforts. However, consumers need information presented in a meaningful way to help them make more informed decisions [Hibbard and Peters 2003]. New data presentation tools, such as online dashboards, mapping software, and smart boards that provide the capability to drill down on specific information can empower consumers by providing information in a practical and interpretable format. While these new tools are helpful, the most transformative impact of big data on patients and their families is social media. Although it seems that many patients have overcome privacy concerns in the way they use social media to discuss health care issues, health professionals, payers, and government agencies will need to resolve how to use this ubiquitous information to improve health quality and efficiency.

Hype or Reality?

Our review of the literature and interviews with experts lead us to the conclusion that there is indeed a strong potential for big data to transform the health care system, as long as these concerns–data security, data sharing, development of analytic capabilities, collaboration among stakeholders, and consumer engagement–are addressed effectively. This is a worthy agenda for federal agencies, health professionals, payers, vendors, and other key stakeholders to pursue during the next few years.

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- Brent James, MD, MStat, *Executive Director*, Institute for Health Care Delivery Research, Intermountain Healthcare
- Juergen Klenk, PhD, *Principal Scientist*, Exponent
- Robert Kolodner, MD, *Vice President and Chief Medical Officer*, ViTel Net

In addition, John Halamka, MD, *Chief Information Officer* of Beth Israel Deaconess Medical Center, shared a paper he has written on the topic of big data in health care.

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Chapter 5: Why Payment Reform and HIT Interoperability Must Follow the Same Innovation Route

Francois de Brantes, Douglas W. Emery and James Maldonado

In the January 2007 issue of the *Journal of Healthcare Information Management*[1], we argued that the American health care system is "*a dark, lumpy archipelago composed of tens of thousands of isolated corporate islands that, at least in terms of information, chop up patients into cloistered parcels and then zealously leverage the resulting fragments for economic advantage.*" The proposed pathway to link these corporate islands was the deployment of health information exchange organizations that, as quasi-public utilities, could enable the creation of digital feedback loops for any number of stakeholders, including patients.

Since then, the passage of the HITECH Act and the infusion of billions of dollars in subsidies have significantly increased the adoption of electronic medical records, a needed prerequisite to electronic health care information exchange. However, it can be argued the primary benefit of EHR adoption has been to convert analog clinical data into digital data within the same health professional organization. While these data are being used to create internal feedback loops on the quality of patient care, the corporate islands remain intact. To an extent, some of these corporate islands have grown to incorporate smaller neighbors and create larger fiefdoms, increasing the number of patients on whom they zealously guard information; but they've also widened the barriers between every other corporate island. In other words, the archipelago is still alive and well, and health information exchange between health professionals, much less care coordination, is barely better today than it was close to a decade ago.

While this assessment might seem bleak–and it is–it is only today's assessment and does not have to be tomorrow's. There are several innovative forces at play that will likely shape health information exchange tomorrow if policymakers, payers, and health professionals show leadership and vision. Two forces have the potential to break through the current institutional impediments preventing a fluid and meaningful exchange of useful health information data: 1) the growing movement of payment innovation; 2) and the emergence of interoperable software architectures that can make data liquid and fungible. We begin with payment reform.

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[1] de Brantes, F., Emery, D.W., Overhage, J.M., et al. 2007. "The Potential of HIEs as Infomediaries." *Journal of Healthcare Information Management*. 21(N1).

Payment Reform and Health Information Exchange

A recent report by the nonprofit Catalyst For Payment Reform[2] indicates that the volume of private sector payer transactions using methods other than basic fee-for-service (FFS) has risen considerably. The Center for Medicare and Medicaid Innovation has also been pursuing alternative payment models, adding further momentum to FFS erosion. The upshot is that payment reform is well under way and most health professional organizations understand that they will have to take increasing responsibility for the financial and clinical outcomes of the care provided to patients[3]. This is one of the reasons health systems are turning stores of digitized medical record information into internal measures of clinical performance and trying to tie them to financial performance.

The key word here is "internal." The larger vertically "integrated" health systems are rushing to warehouse clinical and financial data, but ultimately for the wrong reason. They simply want to enhance their private holdings. Very little information emanates from these private islands unless there is a mandate compelling it. Optimizing the health of patients or the efficiency of health care resource allocation becomes secondary to capturing an increasing wallet share of the total cost of care. And in the total wallet share game, controlling information matters, which is why the mode of payment matters.

Some argue that organizational structures should be the focal point of payment reform such as Patient-Centered Medical Homes (PCMH) and Accountable Care Organizations (ACOs). Others tend to place more emphasis on bending the ultimate metric, the total cost of care (TCOC), rather than stressing a preferred delivery system structure. We suggest these arguments are neither new, nor are they particularly productive; with little change, these were the classic parleys of managed care in the 1990s. Perhaps it is time to look at things differently.

Classic and behavioral economics suggest that form follows function and function follows incentives: products are produced to respond to market needs, and the incentive to meet any given market demand creates and optimizes corporate functions. The organization that ultimately is shaped around these functions is simply a by-product. There's no reason health care organizations should be different. The goal is to produce the best possible patient outcomes at the lowest possible price. Yet, there is no evidence that vertically integrated systems outperform other health professional organizational structures in accomplishing that goal. In fact, the only evidence used to support the spread of large ACOs is a small number of very long-standing integrated systems that have struggled to export their models into new market areas. That's not a very solid evidence base.

Exhibit 24 lays out a framework within which to consider the implications of payment reform on health professional integration and, hence, on the need for external data sharing. Ironically, the lowest level of cooperative data sharing can be predicted in both FFS and TCOC payment models. That's because in both systems, the incentive to guard patients' information within the organizational walls is very strong.

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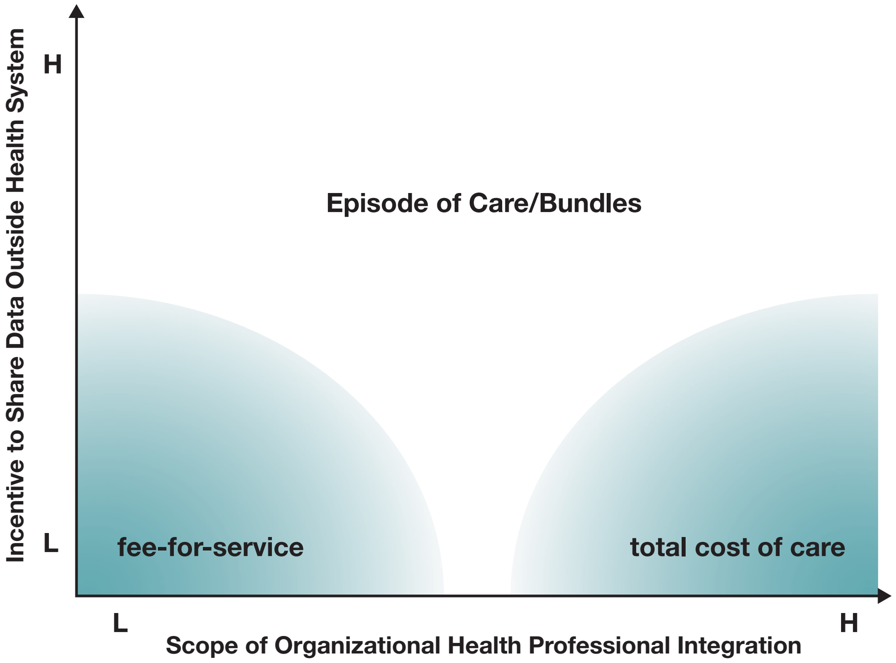
[2] See *http://catalyzepaymentreform.org/how-we-catalyze/national-scorecard*

[3] See, for example *www.availity.com/wp-content/uploads/2014/05/provider-attitudes-research-availity-may2014.pdf*

Exhibit 24: **Effect of Payment Type on Data Sharing Between Health Professionals and Integration Health Professionals**



This is an original figure designed by the authors.

The figure offers a model of how the boundaries for exchanging data in a fee-for-service (FFS) or total cost of care (TCOC) model rapidly diminish because the mode of payment between health professionals and payers is not patient-centered; rather, payment is health professional-centered. Neither speaks to the consumer's individual health concerns, which usually hinges on specific health problems and their related treatments. Disaggregated, atomic unit prices and hyper-aggregated populations convey no meaningful information that consumers can individually act upon. Therefore, both occlude the emergence of consumer markets for health care delivery, and even worse, give health professionals substantial incentives to resist transparency and external data exchange. Riskless FFS preserves the medical archipelago, and full-risk ACO arrangements turn the archipelago into quasi-monopolistic super islands using landlocked patients to achieve institutional rents. Either way, it's a numbers game: FFS ramps up the atomistic unit volume and TCOC leverages patients as massed populations. Patient sovereignty is lost in the fog of paternalism and opacity.

A patient-centered payment model, as the figure further illustrates, has at first a narrow aperture of market entrance. This is what we currently see in the movement to bundle a handful of acute, elective procedures such as total hips and knees. However, as the number and type of episodes expands, and with it, the need for coordinating factor inputs, something remarkable happens to the archipelago: it begins to create links and self-organize around distinct and specialized chains of clinical value. It doesn't matter whether the factor inputs reside in large health system islands or fragmented FFS islands. Contracting for those chains applies the right amount of risk to motivate searches for the right factor combinations to make delivering the value chain products profitable. And to be profitable, the entities that own the factors must coordinate, and to coordinate, they must *communicate*.

The most important point is that payments for episodes of care significantly increase the likelihood of data sharing *if the health professionals co-managing the patient come from different health professional organizations*. In other words, while total cost of care payments (and variations thereof) almost always call for vertical integration of health professionals; payments centered on episodes don't. That's not to say that only non-integrated organizations can deliver care around episodes. What we are asserting, based on solid field implementation results, is that health professionals who are paid for episodes of care can and do come from *either* integrated or non-integrated organizations. However, when they are from non-integrated organizations, most significantly, the demand for clinical data sharing increases.

In episode-of-care payment systems based on shared protocols, communication capacity and utilization trumps total asset ownership, or corporate scope, as Exhibit 24 reveals.

This insight cannot be overemphasized. If the payment system arcs pricing and contracting models oriented around TCOC, then ownership is everything. Which is why hospital-centered health systems struggling to become ACOs buy everything in sight, long before they get their internal houses in order. Vertical bulk is the only rational response if your business is pricing a massed population. And to the extent health information exchange is considered, it's purely a feudal, bureaucratic affair. Channeling Orwell, when ACO health systems and their IT vendors claim HIE, what they really mean is enterprise-wide HIE, not community HIE, much less a national information highway.

This, in the final analysis, means no HIE, and rests on the original managed care vision of Paul Ellwood and Alain Enthoven, where all consumers belong to one of several competing Kaiser-like vertical ACOs. Some may recall that the health plan component of these behemoths was referred to in the 1990s as Accountable Health Plans. At the time, we were as critical of these models as we currently are of their rebranded cousins. Then, and once again, form preceded function, not the other way around.

If the payment system arcs pricing and contracting models around clinically discrete value chains, i.e., episodes of care, then ownership of the *product*, not real estate, becomes paramount. The search for optimal factor inputs, which economists call the marginal rate of technical substitution, becomes "promiscuous." Medical delivery firms contracting for episodes will be completely agnostic as to ownership of downstream factors, only that the factors can be obtained at the lowest price with the highest quality, from whomever, wherever. Product competition thrives in transparent environments because the continuous search for optimal rates of technical substitution drives innovation, what Joseph Shumpeter called "creative destruction." It is this singular lack of market dynamic that explains why American health care is the only industry where new technologies make the whole complex more and more expensive with inexcusable cost and outcomes variation. In every other product-competitive industry, the dynamic is exactly the opposite. Said simply, the right payment incentives will drive the right functions and from those will stem more optimal delivery system forms, optimized around the patient's needs.

Returning to Figure 1, as the initial entry aperture expands for episode contracting, so, too, the space for innovation expands. The drive to innovate will create an overwhelming demand from delivery system firms to communicate with each other *and their patients,* or they will never be able to effectively coordinate their supply chains and manage patient care consistent with care quality benchmarks, much less achieve consumer satisfaction. Because highly finessed and efficient coordination is the road to profits, rather than big box bricks and mortar (with its lunging overhead), data sharing as a means of establishing sophisticated feedback loops will be foremost; lightness and nimbleness will be the way to succeed. Flexible data exchange that connects the archipelagic islands is what we mean by

"Bridges to Excellence,"[4] which we envision to mean a patient-centered system of virtual linkages, revealing episode price and care quality to consumers, where patients are sovereign, have privacy, and rights of access to their own medical data.

Health Information Exchange and Semantic Interoperability

At least since the 1990s, there has been much fanfare about the potential of health information exchange, with CHINs, HIEs, EMRs, HITECH and meaningful use leading the parade. And yet, after all this time, effort and expense, the needle indicating genuine exchange *across* health system entities, as opposed to *within*, has barely advanced. In the first section of this chapter, we gave an economic analysis for the glacial rate of change: the emphasis on form preceding function gets the incentives all wrong. But even if the economic incentives for sharing data changed overnight, the challenge of linking legacy systems–literally thousands of EMRs and other health-related systems that can't talk to each other–remains.

It is therefore important to understand how health information technology and design practices *per se* have succeeded or failed to overcome the challenges of linking legacy systems. We must also explore the potential for new technologies and practices to overcome these challenges.

The primary reason it is difficult for legacy health information systems to talk to each other is that they were not initially designed to do so. They were designed as applications to support specific areas of clinical practice within a clinical organization without much thought, if any, given to their suitability for information exchange with other external systems. For this reason, their models of information structures and clinical domain knowledge differ significantly from each other, even when they were designed to support the same areas of clinical practice. These application-centric models of information structure and domain knowledge, expressed via differing forms of metadata, are the root cause for the evolution of the data islands that mirror and support the archipelago of medical organizations described above.

While enabling useful information exchange among the current data islands is conceptually and technically difficult, the challenge is not insurmountable. It is encouraging that other industries have made much more progress. Vast electronic data interchange networks linking manufacturing supply and distribution chain partners have evolved to enable trillions of dollars of workflows and transactions. Similarly vast and real-time electronic data networks have evolved to enable complex derivative securities to be priced, traded, and settled among multiple, different financial intermediaries.

Consistent with our economic argument above, one of the reasons these improvements have been achieved is that these industries operate in highly price-competitive markets where the incentives are aligned with data exchange innovation. And one area where they have made great strides, in contrast to health care, is semantic interoperability. Semantic interoperability is "the ability of computer systems to exchange data with unambiguous, shared meaning."[5] Semantic interoperability is to be distinguished from syntactic interoperability. Syntactic interoperability enables a base level of communications and information exchange via shared rules for parsing and mapping data formats. For example, XML (extensible markup language) or CSV (comma-separated values) formats can be parsed and mapped in this way. However, data tagging and parsing do not

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[4] See *www.hci3.org/what_is_bte/premise*

[5] *http://en.wikipedia.org/wiki/Semantic_interoperability*

by themselves enable computable shared understanding of the meaning of the data. Syntactic interoperability (or information exchange) is the necessary but not sufficient condition for semantic interoperability.

To date, the efforts of the medical informatics community to develop and deploy standards to achieve information sharing across organizational boundaries have fallen short of semantic interoperability. HL7 has been the *de facto* standard body and framework for clinical information exchange, while X.12, HIPAA, CPT and ICD govern electronic medical claims information. Other independent standards groups have developed terminology and vocabulary models for clinical knowledge domains. The most important of these independently developed standards include LOINC, RXNorm, and SNOMED.

The initial efforts of HL7, begun decades ago, were focused on creating application layer protocols for syntactic messaging interoperability between systems. Indeed, the very name HL7 alludes to the application layer of the standard OSI messaging stack. These efforts have been perceived as somewhat successful not least because they have helped the larger vertically integrated delivery organizations to exchange information from within to specific points outside, such as labs and pharmacies. Indeed, this decades-old messaging model now known as HL7v2 has enabled millions of lab order transactions to be processed with reasonable reliability. Improving the effectiveness and efficiency of such messaging has been appealing to patients and thus has helped larger clinical organizations to achieve the wallet share growth referenced earlier.

However, the HL7v2 messaging model is not successful as a standard. How can a standard be considered successful, or even a standard, if every implementation connecting two systems is different? HL7v2 allows so much implementation variation that every implementation connecting a laboratory and a hospital is unique. The interface definitions of HL7v2 are not fungible and the definitions increase proportionately to the square of the number of organizations being connected. Furthermore, every interface has to be painstakingly programmed by hand and agreed to by the parties wishing to exchange. This is an expensive, time-consuming, and error-prone process which is not scalable to the whole of clinical information. Again, these characteristics of HL7v2 are not entirely accidental. HL7v2 is an artifact of the economic incentives of the organizations that wanted and created it, and of the technologies available at the time it was developed.

The HL7 standards body tried to address these shortcomings with the development of the HL7v3 reference information model or RIM. Unfortunately, almost two decades later, the tiny adoption rate of the HL7v3 RIM indicates that it has failed. In retrospect, it's hard to imagine that any solution harmonizing medical domain knowledge and electronic information structures in order to achieve semantic interoperability would have emerged organically and succeeded. In fact, the macroeconomic incentives context stacks the odds against such a solution emerging organically. Incumbent delivery networks raking in hundreds of billions of dollars a year–with apparently no end in sight–have no incentives to change their business models. Asking them to do so via semantic interoperability, without simultaneously changing the incentives, is a fool's errand.

The dismal adoption rate of the HL7v3 RIM has served as an important and productive learning opportunity for the medical informatics community. The reasons for the failure of HL7v3 have been intensely discussed and analyzed. There appears to be a consensus about the reasons for its failure. This consensus has, in turn, led to a new set of principles to guide the path to semantic interoperability, along with a new set of informatics and software development initiatives to push the needle forward. These principles and initiatives are very promising and could set the stage for the emergence and co-evolution of increasing semantic interoperability, enabling flexible episode of care pricing, centered on patient conditions, and tightly coordinated among multiple organizations.

To understand why this is becoming a new reality, we address the three core design elements that doomed the HL7 RIM, and discuss the potential solutions: Resource Description Framework (RDF), Fast Healthcare Interoperability Resources (FHIR), and Suitable Medical Apps and Reusable Technology (SMART).

The RIM "Trilemma" and Ontology Problems: RDF as Solution

The RIM failed to serve as a comprehensive, rigorous, and timely model for all health information that can be exchanged. That's because *all* information standards are subject to a "trilemma."[6] While it is possible to optimize two of the three in any information standard, it is not possible to optimize all three in the same standard. If the model is comprehensive and rigorous, it will not be timely. If it is timely and rigorous, it will not be comprehensive. If it is timely and comprehensive, it will not be rigorous.

Given the vastness of medical data, the rate of change of medical knowledge, and the ambiguity of medical knowledge, the RIM could not succeed on its own terms–the attempt to be comprehensive is, for all intents and purposes, doomed to fail. The success of true health information exchange must therefore abandon comprehensive coverage in favor of rigorous smaller standard models of medical knowledge that can be developed in a timely fashion, and can be interconnected semantically via translation and linking. The best available information medium for this approach is a resource description framework, or RDF. RDF makes it possible to build models called "ontologies" that are more rigorous because they support automated reasoning.

Ontologies deal with the knowledge representation of real-world things. An ontology describes, in a way that is computable, what is true about these relationships among real-world things. Ontologies are better at dealing with changing and ambiguous medical knowledge than the RIM because they conform to "open-world" assumptions rather than the closed-world assumptions of databases and object-oriented programming languages.

Episode-of-care definitions are also designed to represent, in a computable way, knowledge of clinical practice, and the way clinical treatments structurally relate to each other and the medical conditions they treat.

While the RIM can model "information structures, such as documents, messages, records, clinical and observations,"[7] it confuses the distinction between information recording structures and acts, and the medical conditions recorded and addressed by them.

This failure creates significant semantic confusion, leading to unintelligible models, and, as a consequence, leads to great semantic confusion when trying to use RIM concepts to describe such basic things as a disease or condition. Strictly speaking, the RIM only allows the capture of observations made about a disease or condition, but not statements referencing the current medical knowledge of the disease or condition itself. The information structure that captures a clinician's observation should reference an ontology of the real-world condition or disease observed rather than another observation. RDF and ontologies will significantly

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[6] David Booth. *The Yosemite Project: A Roadmap for Healthcare Information Interoperability*

[7] *HL7 RIM: An Incoherent Standard*, Barry Smith and Werner Ceusters

reduce semantic confusion and improve both human and machine readability. Finally, RDF also makes translations between models and linking models together much simpler. The Yosemite Project has laid out a very achievable roadmap for using RDF as the information medium to achieve semantic interoperability of heterogeneous clinical and administrative systems.

The RIM and App Developments: FHIR as a Solution

The RIM uses "design-by-constraint" as the approach to apply specific use cases. This makes application development and software engineering based on the RIM difficult and error prone. The design-by-constraint approach requires that an application developer have a very thorough understanding of the entire reference information model before he or she can build applications that use only part of the RIM. That's because applications are forced to use constrained instances of data derived from the core classes of the entire RIM. While this approach does make data much more consistent than the data found in HL7v2 messages, the resulting HL7v3 XML is virtually unreadable to the majority of programmers, and hence impractical.

The new HL7 FHIR (Fast Healthcare Interoperability Resources) initiative explicitly recognizes these difficulties for developers by creating very simple and readable information structures that are not derived from an abstract information model. FHIR's simplification will no doubt lead to a much larger developer base and much more productive partitioning of work between programmers and clinical informaticists.

A group of HIT vendors calling themselves the Argonauts has already committed to recreating the components of the Consolidated Clinical Document Architecture (CCDA) in FHIR by April 2015. This means that document sections from the CCDA, such as Immunizations, Allergies, Medications, and Vital Signs will be individually addressable over the Web as information resources via the FHIR API. No longer will a requestor have to receive an entire CCDA document when only the medication list is required. In addition, and this is where the archipelago can become linked, it will be possible to retrieve the medication list directly over the Web from an EHR that has exposed the FHIR interface. A central community, statewide or even national node for information exchange, while potentially useful for data aggregation, would no longer be needed for point-to-point communication.

HL7v3 and the Web: SMART as Solution

HL7v3 does not natively support all the ubiquitous tools and architecture of the World Wide Web, and has not historically employed widely used and well-understood technologies and tooling to implement its standards. Both FHIR and SMART dramatically change this. FHIR and SMART adopt the "RESTful" architecture of the Web. REST stands for representational state transfer and "is a software architecture style consisting of guidelines and best practices for creating scalable Web services."[8]

This approach brings with it a huge base of developers who know how to program in this style because it brings with it many key architectural components and tools that are ubiquitous in the software engineering world. These components and tools include, but are not limited to: the HTTP stateless protocol, standard

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[8] See *http://en.wikipedia.org/wiki/Software_architecture_styles_and_patterns* and *http://en.wikipedia.org/wiki/Representational_state_transfer*

methods for identifying, referencing, and de-referencing information resources; standard methods for aggregating resources such as paragraphs into documents; standard implementations of namespaces; standard Web programming languages like JavaScript; and standard data and serialized data structures via JSON.

All of these components and tools in the past tended to be quirky HL7-developed software. But now, because they are intrinsic to the Web, they can be learned, adopted, and improved by a much broader community of developers and users. SMART also provides a way to create an information "container" for existing applications such as EHRs so that once the container is created, applications can be created in SMART using the data from the source EHR via SMART's container APIs. This capability means that a whole new generation of semantically interoperable mobile and Web applications can be built to supplement or replace existing EHRs or other health care applications without having to employ programmers trained on the vendor's EHR software. Imagine the disruptive power that this solution brings to re-organizing the delivery system around poles of excellence.

Concluding Thoughts

With the advent of true semantic interoperability, leveraging the ubiquitous information technology tools that have revolutionized every other sector, and the vast stores of clinical and claims data available, a real revolution in medical informatics is finally at hand.

Close to a decade ago we posited that health information exchanges could be the lever that finally links the archipelago of cloistered health professional institutions and creates the network of data and feedback loops that are essential to an efficient and effective health care system. That vision never came to be, partially because payment reform lagged the push to get health professionals to adopt health information technology, and partially because the models used to link data, the HL7v3 RIM, were deeply flawed. Those two failures have now been partially overcome and the promise of true health information exchange–linking data across health professional organizations–is finally set to dawn.

Chapter 6: Roadmaps for the Future of National Health Information Technology Infrastructure

Sunny Lin, MS; David McCallie Jr., MD; and Julia Adler-Milstein, PhD

Context

Beginning over a decade ago, Presidents Bush and Obama, along with influential groups such as the Institute of Medicine, called for national investment that would result in widespread use of interoperable electronic health record (EHR) systems. The motivation for such investment was to facilitate improvements in the quality and efficiency of care, as well as patient engagement, clinical research, and public health. A series of key reports has examined the state of national HIT infrastructure[6] as it developed, and identified challenges to achieving interoperable EHRs and associated benefits. The reports also make specific recommendations for actions to overcome these challenges.

In this chapter, we profile and compare three of the most influential reports that speak to the development of our country's HIT infrastructure, and shaped current efforts, led by the Office of the National Coordinator for Health Information Technology (ONC), to bolster this infrastructure by specifically focusing on a key challenge: the lack of robust interoperability. The first report, *The Report to the President Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: the Path Forward* was written by the Presidential Council of Advisors on Science and Technology (PCAST) HIT Working Group and was published in December 2010. The second report, *A Robust Health Data Infrastructure*, was published three years later (November 2013) and describes the findings from JASON, an independent group of scientists that advises the Federal government on matters of science and technology. The third report, published in October 2014 by the ONC-convened Jason Task Force (JTF), reflects a response to the JASON report and presents a different set of recommendations for promoting nationwide interoperability.

The three reports are motivated by the need to address a specific set of challenges perceived to inhibit the ability of HIT to improve health and health care.

The first challenge is lack of ready access and ability to transport and use patient health data that is stored within electronic health record systems. This gap inhibits the flow of data to where it is needed to support clinical care, as well as stifles the emergence of innovative technologies that could use the data to support patient self-management, research, and other valuable use cases. This challenge is attributed to an EHR landscape that is dominated by proprietary technologies. Third-party developers do not typically have access to the application programming interfaces (APIs) that would enable them to pull data from (or write data into) existing EHRs. Without an environment that enables widespread development of third-party solutions, health professional organizations often engage in local customization of EHRs, which in turn hinders interoperability efforts, even within organizations that use the same vendor system. Exacerbating this problem is health professional reports of high vendor fees for interoperability, particularly if they want to share data with organizations that use EHRs from other vendors. These dynamics contribute to perceived "vendor lock-in" where health professionals stay with a vendor because it is too costly to switch, which weakens the incentives for EHR vendors to improve their systems and make them interoperable. A vendor's reluctance to interoperate with competitors can also lead to detrimental local monopoly effects, as smaller entities have incentives to select the same vendor as the more dominant local health professionals.

A second challenge stems from a perceived need for health care delivery organizations to control patient data–to manage liability risks and for competitiveness concerns. HIPAA regulations have led to an industry view of health data as largely owned and controlled by health professional organizations and other nonpatient stakeholders. Health professional organizations are therefore responsible for custodianship and protection from improper access, which makes them cautious about sharing data. This problem is exacerbated by variation in patient privacy legislation across states, resulting in health professional organizations that are hesitant to engage in electronic exchange out of fear of violating patient data laws.[1] Beyond liability concerns, patient data is perceived to confer a competitive advantage because it ties patients to particular health professional organizations. In combination, these factors create incentives for health professional organizations to engage in "data hoarding," an emerging term that is being used to describe the activity of amassing and controlling patient data, coupled with a reluctance to share it, to the detriment of patients and their care.[2,3]

A third and final challenge is that current health information exchange (HIE) efforts, which seek to facilitate electronic sharing of patient data across unaffiliated health professional organizations, have struggled to enable robust exchange. HIE efforts have had to navigate the same set of challenges described above, leading to limited scalability (due to wide variation in both business and technical practices), low health professional participation, technical challenges and difficulty identifying sustainable business models. As a result, there is concern about whether HIE efforts, as they exist today, offer a robust foundation on which to build nationwide interoperable infrastructure.

Each of the reports we profile articulates a vision for how to overcome these persistent challenges and achieve broad-based interoperability in an ecosystem that supports new, innovative solutions for the various stakeholders seeking to use electronic clinical data. In the next section, we summarize the key recommendations of each report. We then describe the commonalities and differences across the reports. We conclude by describing the ONC's recently released *Shared Nationwide Interoperability Roadmap*, and the key ideas from the three reports that are included in it.

Summary of Reports

PCAST 2010

The Report to the President Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: the Path Forward was written by the Presidential Council of Advisors on Science and Technology (PCAST) HIT Working Group, consisting of experts in IT, health care, public health, and economics from IT, hospital systems, and university settings. The group was tasked with examining how a national HIT infrastructure could improve the quality and reduce the cost of health care, and whether federal efforts were optimized to meet those goals.

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[1] *http://e-caremanagement.com/stage-2-mu-rules-shifting-competition-from-hoarding-to-sharing/*

[2] *www.emrandhipaa.com/emr-and-hipaa/2014/10/16/are-you-a-healthcare-data-hoarder/*

[3] *http://e-caremanagement.com/stage-2-mu-rules-shifting-competition-from-hoarding-to-sharing/*

Particular emphasis was placed on aligning current and future federal efforts to enable a coordinated, innovative, and clinically effective HIT ecosystem.

What should a national HIT infrastructure look like?

PCAST envisions a single, national HIT architecture and infrastructure "in which every consumer, doctor, researcher, and institutions has appropriate access to the information they need, and in which these groups are served by a vibrant market of innovators."

Structure

This vision is operationalized through the creation of a federated architecture in which data is held locally within health professional EHRs (and other repositories of clinical data) and is located and then accessed by leveraging a crawling, indexing, searching, and security service. Similar to an Internet search engine, this service would allow authorized users to find and then access patient information across all sources, essentially enabling the ability to create a patient-centric medical record by pulling together information held by different health professional organizations.

Recommended Approach

PCAST suggested enabling data access by creating a set of Data Element Access Services (DEAS), which unify the nation's approach to security, indexing, and searching. These DEAS would essentially "crawl" local databases for information about a given patient or group of patients.

The PCAST report claimed that patient data could be reliably identified without the need for a national patient identifier. Patient data would be linked to patient identities using probabilistic matching of intrinsic patient information such as name, birthdate, or even email address. The DEAS approach proposed to use a "universal exchange language" (UEL) with metadata-tagged elements (information attached to clinical data that describe the data itself, such as patient-identifying information, privacy protections and permissions, and provenance information, such as who created and/or edited it, when it was created, and where). Metadata-tagged elements would enable more fine-grained permission setting and better control over data access, while the universal exchange language would enable third-party developers to create technologies that access relevant subsets of data to support various patient and health professional use cases.

While the recommendation of a UEL was central to the PCAST report, there was little specificity that would enable the language to be developed and adopted by industry. PCAST did, however, recommend that ONC incorporate the universal exchange language requirement into meaningful use (by 2013); develop a roadmap for standards adoption and DEAS development; support EHR system certification based on interoperability; promote research into metadata-enabled security; and facilitate a competitive environment for the development of third party and cloud-based technologies that would use DEAS.

PCAST suggested that the majority of initial costs be borne by the government (e.g., creating the UEL), and health professionals and vendors (e.g., modifying existing systems to use the UEL). After initial development and rollout, PCAST predicted that costs would gradually be offset by increased competition between new and existing EHR vendors as well as new firms that provide middleware technologies enabled by the universal exchange language. Finally, to promote adoption of the universal exchange language, PCAST recommended that the Centers for Medicare & Medicaid Services update its IT systems to be able to receive and aggregate clinical data using the language, as well as receive reports in the UEL.

The PCAST report advocates the view that patients should control their electronic health data and be empowered to use it to become more involved in their own health and care through technologies such as third-party personal health records. With assistance from clinicians, they should set explicit permissions for their health data at an element level, and this would enable robust privacy and security features represented in the metadata. However, the report does not describe this process in detail nor did it address the security measures needed to adequately prevent DEAS use by unauthorized parties. Since DEAS servers would essentially contain comprehensive indexing information describing all available data on all patients in the United States, any successful attempt to breach DEAS security would have enormous negative consequences.

JASON 2013

A Robust Health Data Infrastructure was prepared for the Agency for Healthcare Research and Quality (AHRQ) to address the challenge of developing a national approach to interoperability that would support clinical care and research. The report was written by JASON, an independent group of expert, anonymous scientists that is called on to advise the government (primarily on military and defense issues). The report focused on technical and policy barriers to achieving nationwide interoperability, arguing that the HITECH policies have failed to overcome two key barriers to meaningful exchange of patient data. First, the current approach to exchange is document-centric (and therefore akin to an electronic fax) as opposed to data-centric in which discrete data elements can be more readily used for a variety of purposes. Second, even where electronic exchange of clinical data is occurring, it is primarily limited to *intra*-organizational exchange, which does not address the many instances when *inter*-organizational exchange is needed.

JASON observes that there has been no major movement toward building a national interoperable data infrastructure, even after the PCAST report that called for action. While ONC-led efforts to define standards, integrate interoperability into EHR certification, and promote adoption of a "common mark-up language" (a similar but less granular version of what the PCAST report referred to as a "universal exchange language"[4]) have been helpful, JASON argues that more is needed to achieve broad interoperability and foster innovation from third-party developers. In addition to speeding the creation of a common mark-up language by relying more heavily on a top-down, federally led approach, JASON also calls for the standardization of Application Program Interfaces (APIs) to EHR systems. Such standardization would enable access to, and exchange of, discreet data elements as opposed to just clinical documents. Unlike the PCAST report (that focused on DEAS to enable widespread search of the patient's federated record via the DEAS indexes of all patient data), JASON did not focus heavily on data indexing or search services. Instead, JASON focused on providing programmatic access to existing data via the proposed "standard API." While both a standard API and DEAS-like services are key facilitators of discrete patient data sharing, the key difference between the JASON and PCAST approach was on the emphasis placed on each. PCAST emphasized the importance of DEAS in connecting multiple

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[4] The PCAST UEL was envisioned to contain more detailed metadata than JASON's "common markup language." The common mark-up language is akin to the clinical document architecture (CDA) which "marks up" at a fairly course-grained level (i.e., section headers, but not necessarily detailed content).

databases through a unifying search tool. JASON emphasized the use of standard APIs (with the assumption that DEAS, or another approach to indexing and search, would be developed subsequently).

What should a national HIT infrastructure look like?

JASON described an ideal national infrastructure based on a “vibrant software ecosystem that fosters innovation and entrepreneurship and offers a diversity of products and apps that support aggregation of rich clinical data collected in real-world environments.” JASON criticized ONC’s existing “document-centric” approach to data access and proposed instead that discrete data elements should be made accessible for both clinical care and biomedical research.

Structure

The JASON report, like PCAST, operationalizes their vision through a federated architecture that enables access to data within local databases through common technological standards. Data exchange would occur through an environment that encourages third-party solutions (i.e., middleware) that would pull data to meet the varied needs of patients, health professionals, and researchers. To do this, vendors would use a common mark-up language (similar to the PCAST recommendation) and be required to expose access to their products’ data and services via standard APIs (the new recommendation of JASON). The API defines how components of a software system interact with each other, including the technical standards that enable one software system to locate and pull data from another software system. If the common mark-up language defines how clinical data is translated from one system to another, the API is the protocol that allows one system or service to access the data in another system. Standardizing the API and making access public would allow third-party developers to develop applications that can locate and access the needed and appropriate (in terms of privacy and permission) data elements for a wide variety of functions. Like PCAST, the hope is that a competitive market for innovative third-party applications would emerge to solve the data access and exchange needs of various stakeholders.

Recommended Approach

JASON proposes that a nationwide interoperable infrastructure can be achieved through a common mark-up language coupled with standard APIs. Like PCAST, a key component of JASON’s common mark-up language includes atomic metadata-tagged elements for permission setting and privacy. JASON additionally calls for a language with inherent flexibility to accommodate new types of data and data aggregation.

Key components of the standard API architecture include a multilayer software architecture that would allow different applications to fulfill different roles or functions without interfering with one another or accessing unnecessary information. This compartmentalized API approach would support third-party development of such applications, as well as support more advanced security features than mark-up language alone. These features can be included in the API, and are comprised of data encryption at rest and during transfer, cryptographic key management, and identity, authorization and authentication functions that are separate from patient privacy management to allow functions to be performed by different entities (such as third-party data sharing networks). In addition, the overall architecture should be location- and function-agnostic to promote innovation of alternate technologies (cloud-based, mobile, etc.).

JASON recommendations are premised on the assumption that government intervention is required to develop the common software architecture (both the mark-up language and APIs) because EHR vendors do not have sufficiently strong incentive to pursue this approach. Similar to PCAST, JASON suggests using Stage 3 meaningful use as the vehicle to achieve their recommendations. Specifically, meaningful use criteria should define successive stages of API adoption, and common security and business practices. JASON also suggests interoperability certification by the ONC supported by third-party code-a-thons and the promotion of third-party interface applications to ease the initial migration of legacy systems to standard APIs.

JASON recommends an aggressive timeline for moving toward national interoperability. Specifically, JASON suggested that ONC define overarching software architecture by 2015. The software architecture should provide logical organization of interoperability functions, patient privacy, and access, while also identifying a small set of necessary standard APIs. In the process, ONC should consider using international connectivity standards to enhance international interoperability for research purposes.

JASON recognizes that, as more third parties facilitate greater access to patient data, it will be hard to conceal patient identities. To enhance patient privacy and reduce the complexity and tediousness of setting preferences for each atomic data element, JASON recommends the use of Patient Privacy Bundles, which are pre-specified sets of default privacy settings for atomic data elements that adhere to a predefined security policy. Patient privacy bundles would be created and recommended to patients by third-party entities, such as patient advocacy groups, health professionals, and government advisory boards.

Update Since 2013

In November 2014, JASON released a second report entitled *Data for Individual Health*.

This report focuses on including alternate sources of data in the national data infrastructure, in particular, data generated by consumer-facing applications, medical devices and genomics. While JASON's overall recommendation (a common mark-up language coupled with standard APIs) does not change, the new report emphasizes incorporating health and wellness data into the health data ecosystem and generating a closed loop learning health system. To do this, JASON recommends using not-for-profit organizations to endorse consumer apps that use standard APIs, in order to increase demand for products that use standard APIs and indirectly speed use of standard APIs. Furthermore, JASON recommends that the FDA and other agencies regulate patient apps separately from clinically oriented apps in order to create a more nimble regulatory environment that promotes innovation.

JASON Task Force Response to JASON Report 2014

ONC assembled the Jason Task Force (JTF), comprised of members from ONC's advisory committees on HIT policy and HIT standards, to review the 2010 PCAST report and the 2013 JASON report. The goal of the JTF was to evaluate the implications and feasibility of the recommendations from both reports, reconcile PCAST and JASON recommendations, and develop further recommendations. However, the response ended up focusing more heavily on the JASON report.

Overall, the JTF agreed with JASON's recommendation of a common mark-up language and standard APIs as the best approach to nationwide interoperability, and further defines these concepts. JTF did not, however, agree with JASON's characterization of the utility and level of innovation in the current market to support interoperability. They argue that, since the JASON report was released, the business model for data exchange has strengthened due to changing payment models (in particular, an increase in risk-based health professional contracting) and increased demand from health professionals for interoperability. As a result, JTF felt that there are market forces driving progress toward interoperability. They believe that the critical view of interoperability described by the JASON report was because they conducted their analysis prior to Stage 2 meaningful use, which includes requirements for cross-vendor sharing of structured (marked-up) summary of care documents. Therefore, JTF believes that markets and regulations are already addressing many of the JASON concerns, and suggests a more evolutionary approach in which the market drives toward interoperability through standardization of APIs that are made public to expose access to discrete data elements as well as the summary of care documents included in Stage 2 meaningful use requirements.

While the JASON report was based in part on the notion that patients are the owners of their data, JTF felt that the JASON perspective failed to reflect the reality that "ownership" of patient data is complex and nuanced. Today, health professionals who generate data also have certain rights and responsibilities regarding patient data that is beyond the control of patients[5]. JASON did not address the comprehensive policy strategy that would be necessary to reconcile patient ownership with clinician use rights. The JTF did not tackle this issue directly either, but urged that the proposed standard API should be used to grant consumers direct access to their own records, via health professional portals and other means.

What should a national HIT infrastructure look like?

In contrast to the JASON report, which called for a "unified national architecture" to create widespread interoperability, the JTF vision limits the extent of rigid, top-down standardization required, in order to allow for better scaling, be less complex and therefore, be more universal. The JTF proposes a hybrid approach, with some standardized features and other features that are more flexible. Specifically, their proposed a model assumes the emergence of many diverse "data-sharing networks" (DSN) that would use standard, public APIs based on a "loosely coupled" design approach (i.e., that does not require substantial top-down coordination). Allowing for multiple DSNs and a loosely coupled approach to APIs would better accommodate specific market needs, and would not require a "one-size-fits-all" top-down approach to interoperability. DSNs would also help organizations in the same market address other key requirements when sharing patient health data, such as governance, finance and security, which JASON did not address.

Structure

The JTF approach to achieve a national interoperable infrastructure is comprised of three features: 1) loosely coupled API design; 2) limited set of standardized core services; and 3) market-based DSNs to address a broader set of issues related to data sharing that can emerge and vary across markets.

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[5] *www.healthit.gov/archive/archive_files/HIT%20Standards%20Committee/2014/2014-06-17/HITSC_Summary_Draft_2014-05-21.pdf*

Loose coupling (as opposed to tight coupling) is an approach to API design that enables systems (e.g., individual EHRs, HIE networks) to connect to each other with little pre-existing knowledge of each other's systems, reducing the need for many pre-negotiated terms and reducing the probability that a change in one system would inhibit the ability to share data with another system. This concept is currently used in Internet systems to facilitate efficient information exchange. For example, a tightly coupled approach might require widespread agreement on complex, health care-specific Web services. A loosely coupled approach would likely use common Internet standards (HTTP) to simplify the APIs to use only well-understand service models (e.g., GET, POST, etc.–the actions that underlie the wide scale of the Internet). Tightly coupled design is typically found in "enterprise scale" systems where a top-down directive from a CIO can ensure service compliance across the enterprise, whereas loosely-coupled design would assume that no top-down decision could be enforced, and would instead standardize around simple, well-understood transactions, such as those exposed by HTTP.

While loosely coupled systems require little to no pre-negotiation to achieve data flow, standardization of some core services is still necessary to enable loosely coupled systems to share data. In the case of Web servers on the Internet, a standard universal language, HTML, is used to complement loosely coupled APIs. For health care interchange, the JTF focused on standardizing two additional services: data resource definitions and associated data profiles. Data resources define the major chunks of clinical data that need to be exchanged (for example, resource definitions could define patient, encounter, vital signs, allergies, etc). Data profiles allow for multiple parties to agree on the syntactic and semantic content of the data resources they interchange. So, for example, a simple GET model of a patient resource would be expected to return a well-defined data structure that included all of the required and optional data parameters necessary to describe a patient. The data profile would also specify the proper "value sets" for those data elements that needed to be exchanged in coded form, such as the patient's gender. The JTF specifically calls out HL7's FHIR is an example of a well-specified exchange standard that includes many of the JTF recommended features: it is based on simple use of HTTP, defines a library of common data resources, and supports data profiles to encourage better interoperability.[6] JTF does note, however, that FHIR is not yet a mature standard.

The JTF suggested that DSNs at the market level would complement loosely coupled APIs by addressing sociopolitical issues, such as finance and data-sharing agreements. DSNs could also address variations in the standardized core services

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[6] While the JTF does not specifically endorse FHIR, they recommend standards with a description identical to FHIR. FHIR is a set of clinical data standards developed by HL7. FHIR (Fast Healthcare Interoperability Resources) (and is pronounced "fire") was designed for Web-based exchange using a common API approach called Representational State Transfer, or more simply, "REST." The use of the RESTful approaches gives FHIR usability and scalability advantages over standards that use other APIs. First, REST is not constrained to a single messaging language; message exchange can occur using one of many different common Internet data encoding languages including XML or JSON. Second, to access data, REST uses a simple URL as opposed to complex remote procedure definitions. The openness of FHIR means that data in FHIR format can be exchanged with relative ease, as well as increased speed and efficiency, without proprietary software for either the host or recipient. In addition, FHIR decomposes clinical data into more granular pieces ("resources"), which enables data users to search for, aggregate, and utilize data more efficiently and effectively. These benefits would enable third-party developers to create innovative products not just for traditional EHR systems and information exchange, but for cloud-based technologies, mobile devices, and even consumer-facing apps.

FHIR is a relatively new standard (three years old) and, while promising, has generated some concern over its potential use as a government standard because of this newness. It is currently in Draft Standard Trial Use (DSTU), which means that is has not been subject to exhaustive review and much of it is still evolving. In general, HL7 states that the FHIR infrastructure is stable, though resources (the term HL7 uses to describe exchange content within FHIR) are subject to change.

that might be needed in agreeing upon the Data Resource and Data Profile definitions that are necessary for the DSN's use cases. For example, a DSN that focused on clinical research might need different Data Resources and Data Profiles than a DSN focused only on clinical medicine. This approach would therefore build on existing HIE networks while encouraging heterogeneity in DSN governance and technology, as well as a market for third-party applications.

Recommended Approach

To enable their approach, the JTF modified the JASON recommendation of creating standard APIs. In particular, JTF suggests that only core API services should be rigidly standardized, while the rest of the standardization should emerge based on market practices ("standards-based APIs"). JTF goes further to specify what it means to make an API available in a public way. "Public" means that the standards-based API is exposed to the public for access in a fair, reasonable, and non-discriminatory way.[7] Thus, vendors who claim to use a Public API must agree to expose, or publish, their API in a way that does not discourage interoperability (e.g., by charging prohibitively high licensing fees). This approach is modeled after current standards that allow the Internet to be publicly accessible.

JTF also describes how DSNs would be operationalized. Health professional organizations may choose to participate in a DSN, or use an EHR with a standard API for exchange without participating in a DSN. Technical connections between DSNs are enabled by vendor-neutral technical standards for services such as patient-identity reconciliation, authorization, and authentication. Sociopolitical considerations would be facilitated by legal and business standards for data sharing arrangements within each DSN. DSNs ultimately create the basis for a heterogeneous set of systems that support the varied needs of national data exchange. JTF points out that despite their recommendation for a heterogeneous set of DSNs, there may be a need to develop a small set of national-level core services that could be shared by multiple DSNs, such as nationwide health professional directories and standardized public use vocabularies for such elements as medications, problems, lab test names, etc.

JTF suggests that ONC align incentive programs and processes to stimulate standard API development and adoption. Future meaningful use requirements should require and certify standard APIs, and CMS should consider delaying or staggering Stage 3 meaningful use to accommodate API requirements. JTF also recommended that ONC immediately specify the standard API architecture in collaboration with industry leaders, and develop voluntary standards for cross-DSN bridging and national level services. Since the JTF report was released, CMS did not delay the timeline. They did, however, issue a Notice of Proposed Rule Making (NPRM)[8] on Stage 3 meaningful use that would require the use of EHRs certified to include an API for access to patient data, and also for meeting the current view, download, and transmit measure. The complementary NPRM for 2015 EHR certification criteria incorporates a requirement that an API demonstrate certain capabilities,[9] including providing access to discrete patient data, as well as to summary CCDA documents.

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[7] This concept is known as FRAND in the world of Internet licensing standards. The JTF report specifically stated: "What is "public" in a "public API" is that the means for interfacing to it are uniformly available, it is based on nonproprietary standards, it is tested for conformance to such standards by trusted third parties, and there are well-defined, fairly applied, business and legal frameworks for using the API."

[8] *www.federalregister.gov/articles/2015/03/30/2015-06685/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3#h-51*

[9] *www.federalregister.gov/articles/2015/03/30/2015-06612/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base*

Commonalities and Differences in Paths to Improve National HIT Infrastructure

PCAST, JASON, and JTF reports build on each other, by adding features and more clearly defining key concepts, to help create a vision for a national interoperable HIT infrastructure. PCAST first introduces the concept of the common mark-up language. JASON adds on the standard, public API that would enable compartmentalization of functions for third-party development and innovation. JTF suggests a specific API approach based on Internet-style loose coupling and further suggests the use of heterogeneous DSNs for addressing the sociopolitical issues that arise from electronic data sharing across organizational boundaries. In this section, we summarize the key commonalities and differences between the PCAST, JASON, and JTF reports and then discuss the implications for ONC's efforts to promote greater interoperability.

The first key commonality is that nationwide data exchange does not require centralized clinical databases and should instead be based on connections of local databases enabled by common exchange language(s) (e.g., a federated architecture). This requires an approach for: (1) how one system or service accesses the data in another system; and (2) how data is translated from one system to another. Beyond agreement on what is needed, the reports diverge in terms of where they focus and what they describe as the best approach to operationalize these required components.

Related to access, a second key commonality in the JASON and JTF reports is the need for standard, public APIs to promote broad interoperability and innovation. JASON introduces the idea of a standard, public API for EHR products. Standards for the API would be developed by a centralized agency (presumably the federal government) and rolled out through meaningful use requirements, with third party apps functioning as temporary mediators for legacy systems while they migrate to standard APIs. JTF suggests that only a set of core API services need be rigidly standardized through collaboration between government and industry, while allowing API extension and evolution to meet differing needs in varied data sharing networks. JTF additionally calls for explicit use of loosely coupled services, modeled on existing Internet approaches.

A third commonality in the reports is the important role of third-party developers in advancing interoperability and innovation in how clinical data is used. Apps that utilize existing technologies such as cloud computing, personal health records, owned, controlled, and managed by patients, and mobile devices would help data move to where it is needed and be manipulated to meet varied stakeholder use cases. Further, innovation for interoperable third party apps should be encouraged through market mechanisms.

A fourth commonality is that all reports suggest that the primary mechanisms for driving interoperable HIT products are the meaningful use program and EHR certification. The reports also recognize the market power of CMS to promote adoption of new standards, and therefore recommend that CMS (and other government purchasers of health care) upgrade their systems to be able to send and receive data using the new approach.

Finally, the reports agree that patient engagement would be facilitated by patients learning to better use their own health data and to exercise greater control over how others use their data. This means that the patient's complete record should be available to the patient (and his or her health professionals) regardless of the location of care or of which vendor's products contain the data. PCAST and JASON suggest that patients should be able to set their own data access permissions, and to control the privacy and security protections that are necessary to gain public trust in the infrastructure.

The table below compares key features across the reports:

	PCAST	JASON	JTF
Philosophy	Top down	Top-down, "unifying software architecture," Move from document centric exchange to atomic data element exchange	"Coordinated architecture" that allows for heterogeneity and builds on existing infrastructure; minimal top-down standardization
Key Features of Approach: Data Access	National data indexing crawlers (DEAS—Data Element Access Services)	Standard API with middleware (government-defined)	Loosely coupled, standards-based public APIs; many data sharing networks (in which sociopolitical issues, like governance, can be addressed).
Key Features of Approach: Data Semantics	"Universal Exchange" language (government-defined)	Common mark-up language (similar to PCAST but less granular)	APIs that exchange standardized data resources and data profiles (some may need to be standard but others could be customized by DSNs)
Use Case Emphasis	Clinical	Clinical, Biomedical and Public Health Research	Clinical, consumer/patient

Moving Toward a National Interoperable HIT Infrastructure: ONC 2015

To help put the key ideas from the reports into action, and create a national interoperable HIT infrastructure, ONC released *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap* in February 2015. This document follows a report released in June 2014 called *Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure*. ONC does not propose a specific vision for interoperability; rather, it highlights broad principles and policies for promoting the development of an interoperable HIT ecosystem. ONC proposes to encourage nationwide interoperability slowly, by scaling up regulations over the next ten years. This incremental approach reflects ONC's emphasis on working with stakeholders to roll out interoperability and establish trust, and on trying to achieve the appropriate balance between top-down regulation and allowing flexibility in how interoperability is achieved in the market. The goal of both of these documents is to solicit feedback from HIT stakeholders on how best to move forward. Specifically, ONC asked stakeholders to submit use cases of interoperable systems and respond to the comprehensiveness and appropriateness of the principles laid out in the 2015 document.

A Shared Nationwide Interoperability Roadmap, a report issued by ONC in 2015, does draw on key recommendations from the PCAST, JASON, and JTF reports while focusing primarily on business and socio-technical regulations to standardize business, clinical, cultural and regulatory environments surrounding information exchange. The Roadmap follows an implementation philosophy that emphasizes the maintenance of modularity in existing HIE efforts to promote resiliency to change while developing core technical and functions together with stakeholders. The Roadmap places strong emphasis on improving existing systems and infrastructure, pursuing a modular approach that does not impose a single solution for all HIE efforts, and leveraging market forces to promote innovation in interoperable HIT.

ONC proposes to roll out interoperability through four high-level, near-term foundational actions. These foundational actions draw from recommendations included in the PCAST, JASON, and JTF reports. Specifically, the ONC is pursuing the JASON/JTF recommendation on the need to establish standard APIs, and the JTF recommendation on the need to establish API standards for core services (including definitions of Data Resources and Data Profiles for key data domains such as problems, medications, and lab results). These needs are embodied in the foundational action to "improve technical standards and implementation guidance." ONC also recognizes the importance of the market in developing innovative solutions as embodied in the foundational action to "advance incentives."

ONC shares JTF's concern over the sufficiency of data encryption methods, and the market's confusion over HIPAA regulations. Therefore, the third foundational action is to "clarify privacy and security requirements." However, the Roadmap does not suggest that the creation of DSNs is a solution to overcome sociopolitical barriers to data sharing. Instead, they pursue governance of data exchange by standardizing and clarifying regulatory policies to establish a common set of governance standards for data sharing entities and removing regulatory barriers to information flow; this foundational action is the creation of a "governance framework."

a) Technical Standards

The impact of PCAST, JASON and JTF reports is most evident in how ONC proposes to improve technical standards and implementation guidance for sharing and using a common clinical dataset. Recognizing the need for a consistent set of standards that facilitate the exchange of atomic data elements as well as clinical documents, ONC builds on the JTF recommendation by suggesting the use of common exchange languages and standards-based, public APIs. ONC proposes to do this by assessing common exchange standards (language and APIs) and publishing a list of "the best standards" annually. In addition, ONC has developed a list of standard patient identifying information (first name, last name, date of birth, etc.) to address a JTF-raised concern about the lack of patient identifiers. To support the development of a standard API in the next few years, ONC is requesting stakeholder input on common use cases for exchange, as well the use of FHIR as the basis for a standard API.

b) Incentives

ONC recognizes the importance of using policy and market levers to motivate electronic clinical data exchange, beyond what meaningful use has been able to drive. This is especially critical for ensuring that exchange can take place with long-term care and nursing home health professionals. ONC agrees with the observations made by PCAST and JASON that fragmentation in the health care market has created weak incentives for information exchange. To remedy this, the Roadmap issues a call to action for federal, state and private payers to support pay-for-value initiatives, as well as incorporate exchange technologies into Medicaid contracts, and advance HIT capabilities in government departments such as Medicare.

c) Privacy & Security

ONC acknowledges that common misconceptions about HIPAA are a key barrier to information exchange and proposes to work with government agencies and industry leaders to clarify existing HIPAA requirements as well as applicability to HIT and value-based purchasing. Drawing on both PCAST and JASON recommendations for enhanced security approaches, ONC proposes to develop standard cyber security and encryption guidelines and seek feedback from stakeholders on encryption technologies. Specifically, ONC wishes to encourage widespread encryption adoption into HIT by developing "at- rest" standards for data encryption and promote the use of risk assessment tools and educational and outreach programs.

d) Governance Framework

Finally, rather than rely on a bottom-up approach to sociopolitical aspects of electronic data sharing via market-driven emergence of DSNs, ONC is emphasizing its role in establishing a governance framework for such exchange. This foundational action addresses the previously identified issues of trust between entities exchanging information. By establishing a common set of governance standards, policies and practices, ONC hopes to standardize and clarify regulatory policies surrounding shared information in order to promote participation of exchange among more cautious stakeholders. ONC's description of this foundational action is essentially a list of principles that will be followed to promote stakeholder access to information by removing barriers to data flow. Specifically, ONC supports policies that prevent data holders from limiting availability of information, and requiring that data holders implement transparent policies that promote security and individuals' access to and control over their own information.

Conclusion

ONC's current approach to work toward nationwide interoperability has been heavily shaped by the ideas developed in the PCAST, JASON, and JTF reports. In particular, ONC favors an approach to nationwide interoperability enabled by standard approaches to data access (APIs) and data translation (common exchange languages), key features of the reports. ONC is also following JTF's recommendation to take a cautious approach to standardization by developing standards with the active input of industry leaders and other stakeholders, and proposing a common set of governance standards, policies and practices. While many of the operational details remain uncertain, five years after the PCAST report, the path to a future in which a national interoperable HIT infrastructure is a reality is beginning to come into focus.

Chapter 7: Coordinator’s Corner

Liana Rosenkrantz Woskie, MSc and Julia Adler-Milstein, PhD

This annual report coincides with a large transition in our country’s Health Information Technology (HIT) journey. Not only are we coming to the end of an intensive period of policy efforts to promote broad HIT adoption, but there is also substantial anticipation of resulting gains in health care outcomes, particularly as new HIT infrastructure is used to support evolving models of care delivery.

Since it was established in 2004, the Office of the National Coordinator (ONC) has played a pivotal role in promoting adoption of HIT and ensuring that it is enabling broader health system reform. Specifically, ONC serves to coordinate “nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.”[1] Each Coordinator has shaped the national development and implementation of the approach to HIT adoption and the past three Coordinators have focused on implementing HITECH. Therefore, the Coordinators have a unique vantage point on the successes and challenges of using policy to move the health care system toward widespread HIT adoption that delivers on the substantial possible benefit for the public.

In an effort to provide insight on how our national investment in HIT has, has not, and can catalyze broader efforts to transform health care delivery, we asked David Brailer, David Blumenthal, Farzad Mostashari, and Karen DeSalvo to reflect on their time as Coordinator. In this chapter, we synthesize their reflections.

The Initial Vision. What Were We Trying To Do With This New Office?

When asked about their overarching vision for ONC, the Coordinators described ONC as a serving to ensure that health care delivery progressed toward the goal of improved population health through HIT. Given that each Coordinator served at a different point in the evolution of HIT policymaking, each emphasized different goals for their tenure as Coordinator.

> ***Brailer:*** *“Our overall goal was to move the U.S. into the digital era of health care. We wanted to do this by showing what was possible and how that could transform the way medicine was practiced and the health status of our country. This had never been done before on such a large scale, and the President gave us only a decade to do it, so we were–and continue to be–pleasantly surprised by the rapid progress that has been made in health information technology.”*
>
> ***Blumenthal:*** *“Once staging [of meaningful use] became a framework, then the question of course came up “What should be in the first stage?”[…] The challenge was political, conceptual–it had to do with change management. We needed a theory of change. We needed an understanding of the policy process. It was both daunting but also exciting and in the end, a very gratifying intellectual and policy exercise.”*
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> ***Mostashari:*** *“When I started, it was not at all clear whether health professionals were going to take on meaningful use at all. In fact, I remember some people who got panicky about low activation numbers […] saying, ‘Oh, you made it too hard. You should have allowed for partial credit. You went overboard on meaningful use Stage 1. There is no way hospitals can do this. Only 2 percent of hospitals have ten (EHR functionalities)’.”*

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[1] *www.healthit.gov/newsroom/about-onc*

> ***DeSalvo:*** *"I set out, when I got here, to do a few big things. One was to work on the role of ONC in advancing priorities, like the Secretary's delivery-system reform effort, and more broadly as a Coordinator across the federal government, and its responsibility, as envisioned back 10 years ago and then again in the HITECH Act."*

Accomplishments and Reflections on Key Decisions

The Coordinators identified a range of distinct accomplishments during their respective tenures. These accomplishments build off one another and center on the defining piece of legislation for ONC: the HITECH Act.

Coordinator (Tenure)	Major Accomplishments Identified by Each Coordinator During Their Tenure
David Brailer 2004–2006	■ Garnering bipartisan political and public support ■ Setting foundational definitions for Health Information Technology as relevant to ONC
David Blumenthal 2009–2011	■ Defining meaningful use (MU) ■ Creating the framework for a learning health system ■ Identifying the first stage of MU
Farzad Mostashari 2011–2013	■ Rolling out MU; garnering public support and aiding implementers in the achievement of identified MU goals ■ Establishing the building blocks for interoperability ■ Advocating for and engaging patients in getting access to their own data
Karen DeSalvo 2013–present	■ Transitioning away from the grant-giving model and building relationships with other federal agencies ■ Focusing on long-term sustainability of HIT infrastructure and enabling population health

In the early days of ONC, key accomplishments were ensuring that the existence of ONC and its policy agenda garnered bipartisan support and were in a position to enable massive adoption of a new, needed technology in American health care. A key component was developing the language for HIT, determining what exactly it is and understanding the government's role in improving health.

> ***Brailer:*** *"Our top priority was to prevent health IT from becoming politicized and partisan. […] We almost lost this fight a few times, but to this day everybody views health IT as nonpartisan."*
>
> ***Brailer:*** *"We viewed ourselves as educators of the public, political leaders, clinicians and business executives about health information. When I started, the tech community spoke a language that people didn't understand and it created a lot of fear and ambivalence. Part of what we did was create a language, a framework, a sense of urgency, and a strategy that let everyone own the health information movement. That was bully pulpit education, getting certain political leaders, like the President, to declare their support for health information above all else. I visited every state to get the governors and legislatures to make their state first in leading in this new, popular and economy-stimulating field of high technology."*

As the shift from education to action began, new policies and programs were developed, and while the Coordinators took pride in these accomplishments, key decisions were also questioned. One of the earliest efforts related to establishing an EHR certification process.

> ***Brailer:*** *"We established a certification process which we felt was essential for a uniform and objective definition of technologies and features across the private companies, the public sector, and federal and state agencies. If we want to use health information to improve the health and safety of the public, the underlying technology has to be built with this in mind."*

A more controversial early decision, particularly given the current sense that EHR adoption has not translated into easy sharing of digital health information, is that more attention should have been paid to the plan for the underlying infrastructure to facilitate wide access to and sharing of data.

> ***Brailer:*** *"Putting adoption ahead of health information sharing has left us with billions of dollars invested in legacy systems that will have to be upgraded or swapped out if we want to have real and beneficial data portability."*

Other Coordinators felt differently, and argued that we needed adoption in order to create demand for the sharing of data. As Dr. Blumenthal observes, without the basic technology building blocks in place, people did not and could not really understand the challenges of making the systems interoperable.

> ***Blumenthal:*** *"There is a demand from the market from the users of the data to make it liquid. That demand was never there until about a year or two ago, but it has grown up from the roots of the health care system, which is a very, very helpful thing from the standpoint of policymaking, so that while there was some interest in Congress in interoperability, there was not a great deal of interest in the health care community for interoperability. We have a groundswell now."*

The next set of accomplishments came after the passage of HITECH and effort shifted to focus on creating a framework for meaningful use. Dr. Blumenthal described this as an intellectual challenge, and one for which it was critical to include the opportunity for continuous learning:

> ***Blumenthal:*** *"If you had done a Google search on the term "meaningful use" in March of 2009 when I arrived you would've found very little.. There would be reference to the law but certainly no academic literature, no conceptual discussion, no previous speculation or writing or anything that indicated what meaningful use of electronic health records was or should be."*

> ***Blumenthal:*** *"Everything begins with the collection of data in electronic form, so that had to be the first stage."*

> ***Blumenthal:*** *"To the extent possible you should build into any decision-making process the opportunity to learn and make corrections along the way… It enabled the federal government to introduce the electronic health record and the requirements for use in a gradual way that was more compatible with the capabilities of the profession and the hospital industry, who were most of the key targets."*

After the early efforts to define meaningful use, Mostashari led the shift to implementation of the MU programs, requiring a substantial change in focus for ONC. Key efforts centered on supporting health professional organizations in meeting Stage 1 MU requirements, with a particular focus on organizations that may have a more difficult time doing so. As such, Mostashari worked to garner support for the program and ultimately leverage existing resources for effective implementation, thus conveying a broader sense of momentum.

> ***Mostashari:*** *"When I started, it was not at all clear whether health professionals were going to take on meaningful use at all.[…] You have to give them more help, so getting more funding for the regional extension centers to create more of a resource for rural health care,*

> *but critical access hospitals, and to project the–almost a sense of inevitability. And that was really important, because health care doesn't change until it feels like it has to change."*

> ***Mostashari:*** *"Let's look at the early indicators of this. What's happening on adoption figures? What's happening in our surveys? What are our regional extension centers reporting? What's happening with registration counts?" And we felt pretty confident that if we kept the pressure on, kept the support on, that movement would occur and kind of projecting that sense of momentum."*

An additional achievement under Mostashari was a strong focus on patient access to their data. His team drove:

> ***Mostashari:*** *"… the emphasis on patients' access to their own data and really pushing on things like Blue Button and things like the view, download, transmit requirements, the certification requirements for that, arguing for the lab, you know, patient direct access as part of the HITECH mods around lab access and embracing the consumer kind of e-patient movement."*

The most recent transition, and perhaps the largest for ONC, is becoming an entity with regulatory authority in the midst of health care delivery reform. Shifting focus to the broader HIT ecosystem and working to realize HIT's promise of improved population health, neither of which are easy tasks.

Under DeSalvo's leadership, most HITECH programs were up and running (or already completed). Therefore, her key accomplishments centered on identifying a long-term role and associated strategic priorities for ONC.

> ***DeSalvo:*** *"The world has so evolved since the last (ONC strategic) plan was done right after HITECH, and that plan was focused on executing on HITECH. This new ONC strategic plan is much more about executing in the broader health IT ecosystem to a broader goal of health… a broad stage for all of the Feds to work together for some important issues like privacy, security, data portability, market transparency, interoperability, etc."*

> ***DeSalvo:*** *"Part of why I came was to work on that applied piece, particularly around delivery-system reform… (which is) changing the way doctors are paid, changing the way care is delivered, and seeing that information is available to make better decisions."*

The Coordinators expressed different opinions about the best role for ONC today and how to redefine ONC's role beyond the HITECH policies.

> ***Brailer:*** *"You're seeing ONC face a midlife crisis about the role it plays in the future and, more broadly, how the government can avoid slowing down the tech revolution that it started. The HITECH incentives, in my view, largely replaced private capital with public capital and corrupted the markets like all subsidies do. This has to be avoided if we want the benefits of digital medicine in the future."*

> ***DeSalvo:*** *"The grant model is a catalyst, and it was great. Yet, it goes away. And so, now is a time for us to figure out how we have a sustainable model that treats data more like a utility… a public good so that it's available and we can take it for granted, meaning the movement of data and the other policy framework, like our roads and our power grid."*

> ***DeSalvo:*** *"It's not just about policymaking. It's about how we work on policy with the VA and the DOD and the FTC and the FSA, and then, even within HHS. So, we have quite a bit of work to do to make sure we're touching the right places, that we're looking at all the rules, and contracting and other ways that we can advance health IT that's, frankly, more sustainable than grant programs."*

Despite broader questions on how ONC should proceed, ensuring that HIT adoption translates into better health and health care has continued bipartisan support, suggesting that ONC will continue to have an important role to play.

> ***Mostashari:*** *"Fundamentally, I think there's a lot of continuity, and that's actually something else that gives me hope […] even to this day, this remains one of the only health issues that is rather bipartisan."*

Challenges for ONC

The Coordinators identified numerous challenges for ONC–some philosophical and some practical–with which they wrestled during their tenures and which ultimately remain unresolved. The Coordinators all pointed to interoperability as a critically important part of HIT infrastructure, but an area in which progress is slow.

> ***Brailer:*** *"The process of articulating and setting the foundation for health information exchange was by far our biggest goal and I think it's the goal that's been least realized."*

> ***Mostashari:*** *"The things that people are having trouble with [in Stage 2 meaningful use] is sharing data with each other and the patient."*

Perspectives varied on the key underlying obstacle, including: prioritization of EHR adoption over interoperability and lack of market incentives for achieving interoperability across legacy systems.

> ***Brailer:*** *"I get electronic records sitting on every desk is a very visible, dispersed thing that doctors can point to and patients can talk about in every congressional district… But we blew it by putting adoption ahead of HIE and now we're stuck with systems… that cannot get to the goal of much more portable information."*

> ***Blumenthal:*** *"We want, in effect, for BMW to share its client list and their proclivities, their purchasing power, their use of services with Toyota. That's what we're asking the health care market. And we want it to be done free. Not just free, but we want Toyota and BMW to pay for the opportunity to give away some of their most precious proprietary assets."*

Suggestions included the need for more regulation and broad alignment of incentives as well as developing public infrastructure to allow the private sector to innovate toward interoperability.

> ***Blumenthal:*** *"To actually set, develop and adopt a binding group of standards that will force common definitions of critical terms that will enable interoperability. It was always a politically difficult thing to do, because behind standards there's a required agreement on the ways of recording information and the ways of translating information, and behind those agreements are individuals and groups that have stakes in the current ways of defining and transmitting information."*

However, a clear point of agreement was the need to rethink the approach to patient data sharing in a way that puts patients more at the center. The Coordinators agreed that today enterprise-based silos of information were the norm and this was problematic.

> ***Brailer:*** *"You've got to look at the market and say probably in the end, the one thing we would do differently now, given the progress in the tech world around us, is not make the unit of data sharing the enterprise. It is the consumer."*

> ***Mostashari:*** *"Really starting with the patient first on some of this [interoperability], because it cuts through all the policy and business-model B.S., right?"*

> ***DeSalvo:*** *"I'm really intrigued… about this notion that we're going to have a health IT ecosystem that's person-centered and not institution-centered, where people's data is going to be hosted by trusted third parties that will allow data feeds from a variety of sources, health care and otherwise… And I see some of the technology developing, and it's really exciting to me, because of the opportunity for there to be more engagement and control on the part of the consumers."*

Blumenthal and Mostashari were both optimistic about the pace of progress toward interoperability and better access to EHR data.

> ***Mostashari:*** *"Under HIPAA and HITECH, you have the ability to give the patient their data in electronic format and you have to give it to them. And the price has to be reasonable and cost-based. Those HIPAA protections end up cutting through so much of the usual obstacles. And I really do believe that if someone wants to, 12 to 18 months from now, that they can, they will be able to serve as their HIE of one, right, the medium for their own exchange, to get their data from wherever they get care and share it with whoever the hell they want to share it with."*

However, Blumenthal also noted the need for ensuring interoperability and access to data that is informative, while DeSalvo emphasized that the need to ensure that progress is equitable.

> ***Blumenthal:*** *"There's an assumption that more data is always better. That assumption is wrong. […] Valid, reliable, purposeful and well-targeted data is needed, and more of that is needed, but just tsunamis of data are not going to be helpful to anybody in the short term."*

> ***DeSalvo:*** *"How do we see the data move with somebody and it doesn't move just because they can pay enough money for it to move or a health professional has enough money to pay for it to move? Or how do we see that there is an equity issue attended to?"*

A second key challenge raised by the Coordinators is how best to balance government involvement in specifying meaningful use (and associated EHR and HIT capabilities) and ensuring the market is motivated and innovation driven, as reflected by Mostashari.

> ***Mostashari:*** *"It becomes about compliance and it kills what you are really trying to do, which is to enable and empower innovation and improvement. And what I think the big challenge… is to give purpose to the capabilities, to the potential that's there, and not to let this become one more CMS payment program that you comply with grudgingly and check the boxes."*

Brailer's opinion was that the regulations went too far and harmed innovation, while DeSalvo highlighted the important market-enabling role of the regulations.

> ***Brailer:*** *"Once the government pays for certain behaviors, two things happen. First, the recipients figure out how to game the requirements to get the most from the least work. Second, they wait to do new things, trying to goad the government into paying for that also. Together, these undermine the very entrepreneurship and innovation that we need to move health care to a better future."*

> ***Brailer:*** *"I visit a lot of smaller information technology companies that want to disrupt the world of health care as we know it. None of them know how strongly HITECH regulations protect legacy companies and create a disadvantage for new entrants."*

> ***DeSalvo:*** *"These are complex, consensus-building, but also they have sometimes required setting a floor using regulations and other mechanisms to really attend to a dynamic marketplace that needs freedom so that it can continue to evolve and expand, but it also*

> *needs to be shepherded so it's serving the societal good of data being available for care and scientific advancement and the public's health."*

The Coordinators suggested that a promising way out of this tension between HIT regulations and HIT innovation was to push on expanding new payment and delivery models put forth in the ACA and their potential to align incentives toward the adoption of patient-centered technologies and ultimately the shared goal of improved health.

> ***Brailer:*** *"Let's pay for value in health care and this will figure itself out."*

> ***Mostashari:*** *"[Enabling innovation] comes along with new payment models, where it actually matters to your bottom line that you are getting good outcomes. Without that, this would have no hope… More and more, payment is tilting away from pure fee-for-service with some variety of value-based purchasing, and people more and more and more are saying, "Oh, in that value-based model… capabilities and analytics are having the data and using the data and changing the workflows through technology… and exchanging information, that all is essential to the success of these new payment models."*

> ***Blumenthal:*** *"IT is a tool for doing the business of health care, and people will use the tool according to the incentives and needs that are encountered in the process of delivering health care. If we create incentives for people to be accountable, for health professionals to be accountable for the health of populations, really meaningful incentives, then the infrastructure for exchange will be created by the private sector, because organizations will need to know what's happening to their patients."*

The Legacy of HITECH

Has HITECH, ONC's signature policy implementation, been a success? A key metric of success is whether or not HITECH successfully catalyzed adoption of EHRs, and there was debate among the Coordinators about the extent to which HITECH should get the credit for the increases in EHR adoption over the past five years.

> ***Mostashari:*** *"'Oh, the marvels of technology that would have emerged had the government not stepped in. Oh, you should have just waited.' So, first of all, waited until when? We waited 20 years, right? Waited for what? Second of all, where's the counterfactual? You know what the counterfactual is? Behavioral health. You know what the counterfactual is? Long-term care. Show me the beautifully innovative technology that's now easily adopted by long-term care health professionals. It doesn't exist."*

> ***Brailer:*** *"Three thing are clear. First, there was significant uptake in adoption before HITECH because the industry knew it was time and desperately wanted improvements. They simply needed the government, as the biggest payer for health care, to lead. Second, a vast amount of expensive public capital has been spent in HITECH, largely as a substitute for private capital, and the market will be wary of new investments if there is ever the potential for new government money to pay for it. Third, HITECH left us with an unwieldy, confused regulatory scheme that will slow down or block the innovations of the future."*

However, the Coordinators agreed that the ultimate judgment rests on whether the performance of the health system improves as a result. And while this has yet to be definitively established, early signs are promising, and based on the experience in other industries, we should expect that it will take time to see the full impact. It is therefore too early for a final word on the legacy of HITECH.

Blumenthal: *"Performance of the health system is improving. Costs are going up at a slower rate than ever before in the modern era. We're extending health care to more people. There's some gratifying evidence of quality improvement, especially in things like hospital-acquired infections and diabetes management. So can I attribute that to HITECH? Not with any certainty. Do I believe that HITECH and the availability of electronic health information systems potentiates the changes that are going on and the positive changes in the delivery system? I do based on many, many personal anecdotes and reports as well as personal observation, but I can't prove it."*

Brailer: *"Financial services provide a telling benchmark: the lag between enterprise IT investment and significant changes in commercial operations averaged four to six years. Health care is barely four years into electronic records being used on a widespread basis. We have a long way to go. I think we have to have patience."*

Notes

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