

PIT CREWS WITH COMPUTERS: CAN HEALTH INFORMATION TECHNOLOGY FIX FRAGMENTED CARE?*

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[W]e have amazing clinicians and technologies but little consistent sense that they come together to provide an actual system of care, from start to finish, for people. We train, hire, and pay doctors to be cowboys. But it's pit crews people need.¹

I. INTRODUCTION

According to the Institute of Medicine (IoM), “[c]are delivery has become increasingly fragmented, leading to coordination and communication challenges for patients and clinicians.”² Katherine Baicker and Helen Levy have put it more bluntly, noting “[b]adly coordinated care, duplicated efforts, bungled handoffs, and failures to follow up result in too much care for some patients, too little care for others, and the wrong care for many.”³ John Toussaint agrees that it is patients who suffer, “waiting weeks for routine appointments, using emergency rooms for primary care, driving miles between doctors’ offices for a single condition, and having little understanding of their disease condition or their plan of care.”⁴

As we have searched for explanations of and solutions to these problems, attention has often alighted on the promise of Health Care

¹ Atul Gawande, *Cowboys and Pit Crews*, THE NEW YORKER (May 26, 2011), <http://www.newyorker.com/online/blogs/newsdesk/2011/05/atul-gawande-harvard-medical-school-commencement-address.html>.

² INST. OF MED., BEST CARE AT LOWER COST: THE PATH TO CONTINUOUSLY LEARNING HEALTH CARE IN AMERICA 11 (Mark Smith et al. eds., 2012) available at <http://www.iom.edu/Reports/2012/Best-Care-at-Lower-Cost-The-Path-to-Continuously-Learning-Health-Care-in-America.aspx>.

³ Katherine Baicker & Helen Levy, *Coordination versus Competition in Health Care Reform*, 369 NEW ENG. J. OF MED. 798 (2013).

⁴ John Toussaint, *Profile of System Fragmentation*, in INST. OF MED., THE HEALTHCARE IMPERATIVE, LOWERING COSTS AND IMPROVING OUTCOMES 1, 519 (Pierre L. Yong and LeighAnne Olsen eds., 2010).

Information Technology (HIT). More than a decade ago, the President's Information Technology Advisory Committee (PITAC) argued that IT "can help ensure that health-related information and services are available anytime and anywhere, permit health care practitioners to access patient information wherever it may be located, and help researchers better understand the human body, share information, and ultimately develop more beneficial treatments to keep Americans healthy."⁵

Because IT has had such a profound and often positive impact on so many contemporary personal, professional and industrial domains, the prevailing intuition is that it should also be a major force in the improvement of health care delivery. For example, in 2005 RAND researchers Richard Hillestad and colleagues predicted that HIT could result in health care savings of \$81 billion annually in efficiency and safety savings.⁶

Over the past two decades the HIT-panacea narrative has been persistent even though the context has shifted. At various times there have been promises that patient safety technologies would solve medical error problems, electronic transactions would simplify healthcare administration and insurance, and clinical data would become interoperable courtesy of electronic medical records (EMRs).⁷ Today the IoM believes that HIT is central to its new "continuously learning" health care model that is in large part aimed at solving our fragmentation and lack of coordination problems. According to the IoM, "[a]dvances in computing, information science, and connectivity can improve patient-clinician communication, point-of-care guidance, the capture of experience, population surveillance, planning and evaluation, and the generation of real-time

⁵ PRESIDENT'S INFORMATION TECHNOLOGY ADVISORY COMMITTEE, PANEL ON TRANSFORMING HEALTH CARE, REPORT TO THE PRESIDENT ON TRANSFORMING HEALTH CARE THROUGH INFORMATION TECHNOLOGY 1, 17 (Feb. 2001).

⁶ Richard Hillestad et al., *Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs*, 24 HEALTH AFFAIRS 1103, 1106 (2005).

⁷ In this article "EMR" and electronic health records or "EHR" are used interchangeably. Strictly the latter refers to an interoperable EMR, but the usage is not universal, plus the days of non-interoperable EMRs are limited. Cf. Peter Garrett & Joshua Seidman, *EMR vs HER – What is the Difference?*, HEALTHIT (Jan. 4, 2011, 12:07 PM), <http://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference/>.

knowledge.”⁸

While the consensus judgment that HIT can reduce fragmentation and increase coordination has intuitive force, the specifics are more complicated, and the answer may, for example, need to be calibrated to the particular type of fragmentation or provider at issue. This cautious approach is justified for the reasons discussed in this article. First, the relationship between health care and IT has been both culturally and financially complex. Second, HIT has been overhyped as a solution for all of health care’s woes; it has its own problems. Third, the HIT-fragmentation solution presents difficult timing, even a chicken-and-egg problem: Can HIT solve health care fragmentation and lack of coordination problems or must health care problems such as episodic care be solved prior to successful deployment of HIT?

The article proceeds as follows: Part II examines the fragmentation phenomenon (including its effects and likely causes) and the history of IT in healthcare. Part III examines the promise of HIT. Parts IV and V look at the same basic question of barriers to HIT, but from two different perspectives. Part IV examines the argument that health care must itself change prior to widespread, successful HIT implementation. Part V takes the reverse perspective and discusses the extent to which HIT must adapt and possibly take a leading role in molding the future of health care. Part VI takes a brief detour from industry processes and technology to ask whether legal or regulatory barriers have been responsible for HIT under-implementation. Finally, Part VII suggests some admittedly difficult paths forward with a view to breaking the chicken-and-egg deadlock.

II. FRAGMENTATION AND THE COORDINATING ROLE FOR HIT

If HIT is the potential answer to fragmentation it is important to define the problem. Kurt Stange has defined fragmentation as “focusing and acting on the parts without adequately appreciating their relation to the evolving whole.”⁹ For Stange, fragmentation plays

⁸ INST. OF MED., *supra* note 2, at 116-17, Conclusion 4-1.

⁹ Kurt C. Stange, *The Problem of Fragmentation and the Need for Integrative Solutions*, 7 ANN. FAM. MED. 100, 100 (2009).

out in several ways: inefficiency, ineffectiveness, commoditization, commercialization, deprofessionalization, depersonalization, and patient despair and discord.¹⁰ Einer Elhauge pinpoints the fragmentation discussed herein—lack of coordination in treating a patient’s “particular illnesses” or “between different providers that a patient might see for different illnesses.”¹¹ Survey results are in agreement. For example, in a 2007 study of Californian primary care physicians, 40% reported their patients had experienced coordination problems in the prior year and 20% of those surveyed reported repeating tests because of an inability to locate prior results.¹²

Whatever the definition, and regardless of whether the phenomenon is referred to as fragmentation, lack of coordination, episodic relationships or healthcare’s “patchwork” problem, it is clear that the issue plays out across multiple dimensions. That was a clear conclusion of the 2010 IoM report, *The Healthcare Imperative, Lowering Costs and Improving Outcomes* that identified “system fragmentation” as one of the key drivers of healthcare costs and underperformance.

[With f]ragmented communication between providers, duplicate testing and the absence of vital information compromise both outcomes and economic prospects—discontinuities that pose costs to both patients and society. While patients were described as having to complete paperwork requesting the same information again and again, providers were also identified as suffering from a lack of harmonization around administrative policies and reporting requirements from payers and quality monitors.¹³

As lawyers we see the fragmentation problem first hand. We deal with legislation and regulation emanating from multiple federal and state bodies supplemented with a heavy dose of private ordering. Our physician and institutional clients are reimbursed at

¹⁰ *Id.* at 101-02.

¹¹ Einer Elhauge, *Why We Should Care About Health Care Fragmentation and How to Fix It*, in *THE FRAGMENTATION OF U.S. HEALTHCARE* 1, 1 (Einer Elhauge ed., 2010).

¹² California Healthcare Foundation, *Uncoordinated Care: A Survey of Physician and Patient Experience* (2007).

¹³ INST. OF MED., *THE HEALTHCARE IMPERATIVE, LOWERING COSTS AND IMPROVING OUTCOMES*; PIERRE L. YONG AND LEIGHANNE OLSEN, *ROUNDTABLE ON EVIDENCE-BASED MEDICINE*, INSTITUTE OF MEDICINE 622-23 (2010) (references omitted).

different rates and certainly in accordance with diverse metrics by a bewildering assortment of insurers, state and federal agencies, and even the patients who are subject to our industry's opaque price discrimination model. And whatever (but sometimes because of) the source of payment those patients are bounced around between highly skilled (and well-meaning) "cowboys" and ancillary diagnostic services such as labs and scanning suites while being treated everywhere from doc-in-a-box cubicles in supermarkets, to medical buildings, ambulatory surgical centers and hospitals.

As policymakers our attempts at increasing institutional coordination themselves are fragmented between fully, partial, and (now courtesy of ACOs) virtually integrated providers. Further, it is arguable that even successful implementation of the Affordable Care Act (ACA) individual mandate will be ineffective in the face of a fragmented private insurance market.¹⁴

a. Fragmentation and Its Causes

The specifics of fragmented and uncoordinated care, and the safety, quality, and cost issues that result, are well-known: communication breakdowns as patients move among providers and settings (including an array of errors and duplicative services); failures to pass test results and histories among providers; deficient communication between primary and specialist providers and between clinicians and patients; poor patient handoff communication; and readmissions caused by communication lapses between inpatient and community resources.¹⁵

There are many theories as to why health care is so fragmented. The evolutionary path that health care followed over the last half-century or so must shoulder much of the blame. Sociologists Richard Scott and colleagues identified three eras of health care governance and cultural orientation: professional dominance (1945-65), federal involvement (1966-82), and managerial control and market mechanisms (1983-2000).¹⁶ Perhaps of greatest salience, however, is

¹⁴ Allison K. Hoffman, *Oil and Water: Mixing Individual Mandates, Fragmented Markets, and Health Reform*, 36 AM. J.L. & MED. 7, 7 (2010).

¹⁵ See generally INST. OF MED., *supra* note 2, at 95-97.

¹⁶ W. RICHARD SCOTT ET AL, INSTITUTIONAL CHANGE AND HEALTHCARE ORGANIZATIONS: FROM

that as much as health care changed during these eras it never succeeded in simplifying its structures or processes—the next era always seemed to be built on the rubble of the previous, and that rubble was never cleared.

The same is true of the modern era (or eras). The 1994 collapse of President Clinton's health care plan rendered single payer proposals politically toxic, even dooming the modest and popular "public option" proposal in 2010.¹⁷ Instead, the post-Clinton era confirmed the dominance of the private sector, the faith in market mechanisms, and most importantly, denied us any centralized organizing principle (such as a single payer). President Bush's endorsement of Consumer Directed Health Care¹⁸ was complemented by the 2003 Medicare Modernization Act's (MMA) pro-market, anti-regulatory, "noninterference" provision that prohibited the Secretary from entering the negotiations between the newly introduced prescription drug plans and manufacturers.¹⁹ Jonathan Oberlander bemoaned the MMA as "1965 all over again," noting how "the federal government has once again explicitly abdicated its authority, forsworn direct cost controls, and relied on private institutions that the affected industry prefers to the federal government."²⁰ The MMA doubled down on the "extraordinarily complex . . . array of organizational forms in medicine" that Starr had observed thirty years ago²¹ with ever increasing layers of rent-seeking stakeholders and a lack of centralized regulation. Fragmentation was king.

This post Medicare/Medicaid trend, whereby the federal

PROFESSIONAL DOMINANCE TO MANAGED CARE, 21-22 (2000).

¹⁷ See generally Ezra Klein, *Whatever happened to the public option?* WASH. POST (Mar. 22, 2013, 4:56 PM), <http://www.washingtonpost.com/blogs/wonkblog/wp/2013/03/22/whatever-happened-to-the-public-option/>.

¹⁸ George W. Bush, President, United States, State of the Union Address at the Chamber of the U.S. House of Representatives (Jan. 28, 2008), (transcript available at <http://georgewbush-whitehouse.archives.gov/news/releases/2008/01/20080128-13.html>) ("[W]e must trust patients and doctors to make medical decisions and empower them with better information and better options The best way to achieve that goal is by expanding consumer choice, not government control").

¹⁹ 18 U.S.C. §1860D-11(i) (2003).

²⁰ Jonathan Oberlander, *Through the Looking Glass: The Politics of the Medicare Prescription Drug, Improvement, and Modernization Act*, 32 J. HEALTH POL. POL'Y & L. 187, 194 (2007).

²¹ PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 439-40 (1982).

government was more involved in funding than programmatic decision-making,²² has not been fundamentally altered with the passage of the Affordable Care Act (ACA). Title I endorsed the gatekeeping function of private health insurance, albeit supplemented with what Tim Jost describes as “the most comprehensive effort to date to create a uniform national program for health insurance regulation in the United States.”²³ Only the ACA’s Title III offers a direct promise of better-coordinated care courtesy of the ACOs and Medical Homes (PCMH) using bundled payment models²⁴ discussed below.

Historical roots aside, John Toussaint suggests a cultural explanation for fragmentation, noting how “the delivery of care has been designed around doctors and institutions, not around the patient.”²⁵ This has been exacerbated by the growth of practice silos as “doctors have splintered into specialties and subspecialties” with the result that “[w]hile the level of technical skill has been rewarded, integration and team-based practice have not been valued.”²⁶ Similarly Atul Gawande made a point about this false hypothesis of specialization driving better outcomes in his well-known *Cowboys and Pit Crews* Harvard commencement address quoted at the beginning of this article.²⁷

Other critics point to our financing models. Stuart Guterman blames the prevalent fee for service (FFS) payment model that both fails “to provide incentives for efficiency, quality, or outcomes” but also “encourages the provision of unnecessary care and often discourages coordination of care and management of patients across providers and settings.”²⁸ Mark Miller, like Toussaint, also a

²² Scott, *supra* note 16, at 341-342.

²³ Timothy Stoltzfus Jost, *Loopholes in the Affordable Care Act: Regulatory Gaps and Border Crossing Techniques and How to Address Them*, 5 ST. LOUIS U.J. HEALTH L. & POL'Y 27, 27 (2011).

²⁴ Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (codified as amended in scattered sections of 25, 26, 29, 42 U.S.C.).

²⁵ Toussaint, *supra* note 4, at 519.

²⁶ *Id.*

²⁷ See *supra* text accompanying note 1.

²⁸ Stuart Guterman, *Wielding the Carrot and the Stick: How to Move the U.S. Health Care System*

contributor to *The Healthcare Imperative* like Toussaint, also allocates the blame to Medicare's FFS model for creating "payment silos" and "not encourag[ing] coordination among providers within a silo or across silos."²⁹ For solutions, Miller focuses on reducing readmissions, increasing use of bundled payments, and a mandatory ACO model featuring both bonuses and penalties.³⁰

b. IT in Health Care Space

Telemedicine is the country's oldest established HIT³¹ while transactional technologies such as those required by HIPAA's *Administrative Simplification*³² likely have the most penetration.³³ However, safety technologies were the first to gain traction with policymakers. *To Err is Human*³⁴ is best known for illuminating "an outcomes pattern that was disturbing and frightening"³⁵ and for recommending a "systems approach" to improving health care safety. The report engendered a national discussion on adverse events and patient safety, led to the Patient Safety and Quality

Away from Fee-for-Service Payment, THE COMMONWEALTH FUND BLOG (Aug. 27, 2013), <http://www.commonwealthfund.org/Blog/2013/Aug/Wielding-the-Carrot-and-the-Stick.aspx>.

²⁹ Mark E. Miller, *Payments To Promote Delivery System Integration*, in INST. OF MED., *THE HEALTHCARE IMPERATIVE, LOWERING COSTS AND IMPROVING OUTCOMES* 1, 520 (2010).

³⁰ *Id.* at 521-24.

³¹ See generally Patricia C. Kuszler, *Telemedicine and Integrated Health Care Delivery: Compounding Malpractice Liability*, 25 AM. J.L. & MED. 297, 300-02 (1999).

³² See CMS, HIPAA - General Information, <http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/HIPAAgenInfo/index.html?redirect=/hipaageninfo/> (last modified Apr. 4, 2013, 10:13 A.M.); see also *Transactions & Code Sets Standards*, CMS.GOV, <http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/TransactionCodeSetsStand/index.html?redirect=/transactioncodesetsstand/> (last modified Apr. 17, 2013, 8:18 P.M.).

³³ See generally Nicolas Terry, *To HIPAA, A Son: Assessing the Technical, Conceptual, and Legal Frameworks for Patient Safety Information*, 12 WIDENER L. REV. 134, 134 (2006).

³⁴ INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 74 (Linda T. Kohn et al. eds., 2000).

³⁵ John A. Anderson, *Evolution of the Health Care Quality Journey*, 31 J. OF LEGAL MED. 59, 68 (2010).

Improvement Act of 2005 (creating Patient Safety Organizations),³⁶ and triggered the Agency for Healthcare Research and Quality's (AHRQ) national patient safety initiative.³⁷

To Err is Human also began a tradition of borrowing solutions to health care problems from other industries.³⁸ Thus, *To Err* emphasized the importance of lessons learned in aviation and occupational health, noting there that "a growing awareness of safety concerns and the need to improve performance" led to "comprehensive strategies, which included the creation of a national focal point for leadership, development of a knowledge base, and dissemination of information. . . ."³⁹

Two years after *To Err*, the relationship between HIT and the systems approach was comprehensively addressed in *Crossing the Quality Chasm*.⁴⁰ Therein the Institute of Medicine (IoM) provided detailed mapping of IT to process reform and explained how HIT was pivotal to the success of a systems approach.⁴¹ *Crossing* hinted that IT had a role in improving health care across multiple dimensions; not only safety but also effectiveness, patient-centricity, timeliness, efficiency, and equity.⁴² However, the report primarily viewed HIT from the perspective of collecting and disseminating clinical information. In large part this was because "[m]uch of the potential of IT to improve quality is predicated on the automation of at least some types of clinical data."⁴³ The report also identified and discussed four barriers to the automation of clinical data: "privacy concerns, the need for standards, financial requirements, and human

³⁶ Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (2005).

³⁷ AHRQ's Patient Safety Initiative: Breadth and Depth for Sustainable Improvements, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, ch. 3 (Dec. 2003), available at <http://www.ahrq.gov/research/findings/final-reports/pscongrpt/psini3.html>.

³⁸ INST. OF MED., *supra* note 34, at 74.

³⁹ *Id.*

⁴⁰ INST. OF MED., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* 164-80 (Rona Briere ed., 2001).

⁴¹ *Id.*

⁴² *Id.* at 164-65.

⁴³ *Id.* at 170.

factors issues.”⁴⁴

Crossing’s analysis of HIT concluded where it had begun: with a relatively narrow conception of HIT as supportive of a process-based, error-trapping approach to health safety.

IT has barely touched patient care. . . . Many medical errors, ubiquitous throughout the health care system, could be prevented if only clinical data were accessible and readable, and prescriptions were entered into automated order entry systems with built-in logic to check for errors and oversights in drug selection and dosing. The pace of change is unacceptably slow. Much more can and should be done.⁴⁵

This “safety technologies” model of HIT dominated the decade that followed. Promising patient-safety related technologies such as EMRs⁴⁶ and computerized physician order entry⁴⁷ (CPOE) were well known but suffered from a woefully low level of implementation. In 2004, the Bush Administration began a major market-leading initiative to promote EMRs, partly driven by patient safety concerns but increasingly pressing for the transparency and interoperability of clinical data as an end in itself. However, by 2009, only derisory numbers of hospitals had EMRs or CPOE.⁴⁸ Progress was left to the market that, unfortunately, exhibited severe failures. In response, the Obama administration funded the Meaningful Use (MU) program⁴⁹ with approximately \$30 billion in funds to be dispensed by CMS as staged subsidy payments to drive the adoption of EMRs.⁵⁰

⁴⁴ *Id.* at 171.

⁴⁵ *Id.* at 176.

⁴⁶ See, e.g., Lawrence L. Weed, *Medical Records that Guide and Teach*, 278 *NEW ENG. J. MED.* 593 (1968); *INST. OF MED., THE COMPUTER-BASED PATIENT RECORD: AN ESSENTIAL TECHNOLOGY FOR HEALTH CARE* (Richard S. Dick & Elaine B. Steen eds., 1st ed., 1991).

⁴⁷ See, e.g., William M. Tierney et al., *Physician Inpatient Order Writing on Microcomputer Workstations: Effects on Resource Utilization*, 269 *JAMA* 379 (1993).

⁴⁸ Ashish K. Jha et al., *Use of Electronic Health Records in U.S. Hospitals*, *NEW ENG. J. MED.* 1628, 1631 (2009).

⁴⁹ ARRA included funding for the Health Information Technology for Economic and Clinical Health Act (HITECH). American Recovery and Reinvestment Act of 2009, H.R. 1, 111th Cong. (1st Sess. 2009).

⁵⁰ *EHR Incentive Programs*, CENTERS FOR MEDICARE AND MEDICAID SERVICES <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/EHRIncentivePrograms/> (last modified Apr. 10, 2014, 9:54 A.M.); Lipika Samal et al., *Research Letter: Meaningful*

Policymakers and analysts have continued to double-down on HIT. For example, in 2005 the Hillestad RAND HIT study attempted to answer the question: “What if health care could produce productivity gains similar to those in telecommunications, retail, or wholesale?”⁵¹ The IoM has amplified expectations for HIT beyond safety improvements or clinical data flows, viewing it as the “silver bullet” for its “learning” health care system and so the key to unlocking quality improvements and cost savings.

Advances in computing, information science, and connectivity can improve patient-clinician communication, point-of-care guidance, the capture of experience, population surveillance, planning and evaluation, and the generation of real-time knowledge—features of a continuously learning health care system.⁵²

This conception of a continuously learning health care system has several properties: it should leverage science and informatics to provide “[r]eal-time access to knowledge” and “[d]igital capture of the care experience,” engage and empower patients, feature aligned incentives, “systematically monitor[] the safety, quality, processes, prices, costs, and outcomes of care, and make[] information available for care improvement and informed choices and decision making by clinicians, patients, and their families,” and develop “system competencies” to create learning “feedback loops.”⁵³

III. THE POTENTIAL OF HIT

Ever since the IoM published its *Learning* agenda there has been a quite narrow view of HIT that consists of a cluster of underused safety technologies, administrative exchanges, and (thanks to subsidies) an expanding capability to store (if not always share) clinical information. Indeed, the federal government even uses a narrow definition of HIT; “the exchange of health information in an

Use and the Quality of Care, JAMA INTERN MED. E1 (2014), available at jamanetwork.com/data/Journals/INTEMED/0/ild140012.pdf.

⁵¹ Hillestad, *supra* note 6, at 1106.

⁵² INST. OF MED., *supra* note 2, at 16.

⁵³ *Id.* at 138 tbl.5-1.

electronic environment."⁵⁴ However, IT has a far broader footprint (or, actually, footprints) connoting "technologies . . . designed to improve the capture, organization, analysis, tracking, access, and dissemination of information."⁵⁵

Outside of the health care domain industry, incumbents have integrated technology in every step of their businesses, from internal communications to customer relations and supply chain management. In addition, disruptive businesses have attacked established businesses (incumbents) with IT-based products that provide cheaper, more convenient alternatives to existing products or services.

As to incumbents, consider some of the uses to which IT is put in large, non-health businesses: communication; inventory, logistics, and supply chain management; data management and storage; management information systems (business-wide data-sharing); customer relationship management (record keeping); automated processes, decision support; and business-to-business (B2B) purchasing and procurement. As to incumbents, consider some of the uses to which IT is put in large, non-health businesses: communication; inventory, logistics, and supply chain management; data management and storage; management information systems (e.g. business-wide data-sharing); customer relationship management (e.g. record keeping); automated processes and decision support; B2B purchasing and procurement; and business intelligence relating to customers, competitors, sub-contractors, and employees.⁵⁶ These common, almost everyday implementations of IT increase coordination and improve decision making between and within firms

⁵⁴ *Health Information Technology*, U.S. DEPT OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthit/index.html> (last visited June 9, 2014).

⁵⁵ Ben-Tzion Karsh & Richard J. Holden, *New Technology Implementation in Health Care*, in *HANDBOOK OF HUMAN FACTORS AND ERGONOMICS IN HEALTH CARE AND PATIENT SAFETY* 393 (Pascale Carayon ed., 2007).

⁵⁶ See generally Chris MacKechnie, *Information Technology & Its Role in the Modern Organization*, HOUSTON CHRONICLE, <http://smallbusiness.chron.com/information-technology-its-role-modern-organization-1800.html> (last visited June 9, 2014); Kyra Sheahan, *What Are the Advantages of Information Technology in Business?*, HOUSTON CHRONICLE, <http://smallbusiness.chron.com/advantages-information-technology-business-774.html> (last visited June 9, 2014).

by reducing friction and increasing data liquidity to further data sharing and operational transparency. Similar approaches are finding their way into relationships with customers in order to reduce the costs of servicing them and to increase the “stickiness” of the seller-consumer relationship. It is clear that firms are implementing IT to avoid fragmentation and improve coordination across multiple dimensions of their business.

In 2010, the *President’s Council of Advisors on Science and Technology* (PCAST) chimed in:

Health information technology can allow clinicians to have real-time access to complete patient data, and provide them with support to make the best possible decisions. It can help patients become more involved in their own care.... It can enable a range of population-level monitoring and real-time research such as the detection of developing epidemics, health risks in the environment, or adverse events caused by medications. It can improve clinical trials, leading to more rapid advances in personalized medicine. It can streamline processes and reduce administrative overhead, as it has in other industries. It can lead to the creation of new, high-tech markets and jobs. Finally, it can help support a range of economic reforms in the healthcare system that will be needed to address our country’s long-term fiscal challenges.⁵⁷

Clearly this larger agenda is similar to what the IoM has in mind for healthcare. The argument advanced in *Learning* was that “advances in computing and connectivity have the potential to improve health care by expanding the reach of knowledge, increasing access to clinical information when and where needed, and assisting patients and providers in managing chronic diseases.”⁵⁸

Even for the technology neophyte, it is relatively easy to see how modern communication technologies, such as text messaging and collaboration-furthering intranets might improve healthcare. Similarly, it is hard to see even the most backward facility not having at least a rudimentary information management system for data sharing or, courtesy of the Meaningful Use subsidy program, electronic clinical record-keeping while providers are increasing their

⁵⁷ PRESIDENT’S COUNCIL OF ADVISORS ON SCI. & TECH., REPORT TO THE PRESIDENT REALIZING THE FULL POTENTIAL OF HEALTH INFORMATION TECHNOLOGY TO IMPROVE HEALTHCARE FOR AMERICANS: THE PATH FORWARD 9 (2010).

⁵⁸ INST. OF MED., *supra* note 2, at 15.

use of social media to manage customer (patient) relationships.

However, the leveraging of some other IT models may not be as obvious. Healthcare institutions are not only the sources of valuable “big data” but increasingly will become major customers of resulting “business intelligence.”⁵⁹ For example, predictive analytics are being used to identify doctors who are likely to be responsible for expensive readmissions or patients who are at risk to adverse events.⁶⁰

Increasingly, there is an interest in reengineering healthcare systems to better mirror industry leaders from other domains such as Toyota which, in Steven Spear’s words, use “continuous learning, improvement, and innovation that transcend their business differences.”⁶¹ Spear argues that healthcare’s complexity “creates many opportunities for ambiguity in terms of how an individual’s work should be performed and how the work of many individuals should be successfully coordinated into an integrated whole.”⁶² Healthcare workers “tend to work around problems, meeting patients’ immediate needs but not resolving the ambiguities themselves,” so they “confront ‘the same problem, every day, for years’ . . . regularly manifested as inefficiencies and irritations—and, occasionally, as catastrophes.”⁶³

Some healthcare providers are reengineering by adopting *Lean Six Sigma* efficiency models.⁶⁴ Derived from Toyota’s “just-in-time-production” model and Motorola’s quality control system, *Lean* seeks to simplify, streamline, and optimize processes (often through counting and categorizing mistakes).⁶⁵ Terry Young and colleagues

⁵⁹ See generally Nicolas Terry, *Big Data Proxies and Health Privacy Exceptionalism*, 24 HEALTH MATRIX 65 (2014).

⁶⁰ See, e.g., Jennifer Bresnick, *VA to Use NLP, EHR Data Mining in Vista “Prediction Engine,”* EHR INTELLIGENCE (Feb. 4, 2013), <http://ehrintelligence.com/2013/02/04/va-to-use-nlp-ehr-data-mining-in-vista-prediction-engine>.”

⁶¹ Steven J. Spear, *Fixing Healthcare From the Inside, Today*, HARV. BUS. REV., Sept. 2005, at 15.

⁶² *Id.* at 3.

⁶³ *Id.*

⁶⁴ Julie Bartels et al., *Lean IT: Making Healthcare More Efficient*, THE INST. FOR HEALTH TECH. TRANSFORMATION 16 (Sept. 20, 2013), available at <http://ihealthtran.com/iHT2LeanHealthIT.pdf>.

⁶⁵ *Id.* at 5-6; See also *Just-in-time*, TOYOTA <https://www.toyota->

identified the key concepts of *Lean*: value, value stream, flow, pull, and perfection.⁶⁶ Referring to the 4-50 rule (four percent of actions cause more than 50 percent of the errors), Jay Arthur describes the value of reengineering healthcare using this model as follows: "When you find the 4 percent of the process that causes 50 percent of the delay, defects, and deviation, health care can easily boost quality, cut costs, and increase profits without breaking a sweat."⁶⁷

Regulatory agencies are also attempting to stimulate more market-like conditions by increasing the transparency of quality and pricing information. As to the former, *Nursing Home Compare*⁶⁸ and *Hospital Compare*⁶⁹ are well-established federal websites that allow consumers to compare various facilities; the ACA-encouraged *Physician Compare* has now joined them.⁷⁰ As to the latter, in 2013 the non-profit organization Catalyst for Payment Reform argued, "[c]onsumers must have access to meaningful, comprehensive information about the quality and price of services to make informed health care decisions."⁷¹ Indeed, CMS is now collecting and publishing comparative cost data for 100 inpatient services and 30 outpatient services.⁷² At the state level, a new North Carolina statute requires hospitals to submit an even broader range of pricing

forklifts.eu/En/company/Toyota-Production-System/Just-in-time/Pages/default.aspx (last visited Apr. 18, 2014).

⁶⁶ Terry Young et al., *Using Industrial Processes to Improve Patient Care*, 328 *BMJ* 162, 162 (2004).

⁶⁷ Jay Arthur, *Lean Six Sigma Can Reduce Health Care Costs*, *QUALITY DIGEST* (Oct. 8, 2009), <http://www.qualitydigest.com/inside/twitter-ed/lean-six-sigma-can-reduce-health-care-costs.html>.

⁶⁸ *Nursing Home Compare*, available at <http://www.medicare.gov/nursinghomecompare/search.html> (last visited June 9, 2014).

⁶⁹ *Hospital Compare*, MEDICARE.GOV, <http://www.medicare.gov/hospitalcompare/search.html> (last visited June 9, 2014).

⁷⁰ *Physician Compare*, available at, <http://www.medicare.gov/physiciancompare/search.html> (last visited June 9, 2014).

⁷¹ *Statement on Price Transparency*, CATALYST FOR PAYMENT REFORM, <http://www.catalyzepaymentreform.org/2013-03-03-05-08-38/2013-03-03-06-20-41/price-transparency/statement-on-price-transparency> (last visited Apr. 7, 2014).

⁷² CENTERS FOR MEDICARE & MEDICAID, *Medicare Provider Charge Data*, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html> (last visited Apr. 7, 2014).

information to the state health department for web publishing.⁷³ As the richness of such data increases, so data intermediaries (if not the government departments themselves) will increase transparency and link in other decisions and financing tools aimed at putting downward pressure on pricing.

Can IT go further and transform, or even disrupt healthcare? A 2011 *Booz Allen Hamilton* report concluded “Soon, health IT will revolutionize the entire American health care system, making it more efficient, more effective and more focused on meeting the needs of patients.”⁷⁴ Unfortunately, the HIT space either shares or reflects the market failures of healthcare, and the modest attempts to correct HIT market failure, such as EMR subsidies, continue to leave us short of the inflection point.⁷⁵ Disruptive products usually take one of two forms. First, they may be products (or services) that are strikingly new, typically do not implicate existing (incumbent) suppliers, and initially (and ironically) appear to be inferior products. The second form of disruption tends to attack established relationships or supply chains through disintermediation. Here, novel entities create new lines of communication that bisect existing complex systems. Most of today’s healthcare technologies should be classified as the “sustaining technologies” of industry incumbents (physicians, hospitals, physicians, and insurers) rather than examples of “disruptive technologies” that have upended incumbents in other domains.⁷⁶ In the absence of disruptive innovation, there will likely be continued build-out of sustaining technologies that may improve the quality of care but are unlikely to have any positive impact on the cost of or access to healthcare in the near future.⁷⁷

⁷³ Anthony Brino, *North Carolina Pushes Price Transparency*, HEALTHCARE IT NEWS (Aug. 26, 2013), <http://www.healthcareitnews.com/news/north-carolina-pushes-price-transparency>.

⁷⁴ *Booz Allen Lists Top Nine Ways Information Technology is Transforming Health Care*, BOOZ ALLEN HAMILTON (Nov. 15, 2011), <http://www.boozallen.com/media-center/press-releases/48399320/49523820>.

⁷⁵ See generally Nicolas Terry, *Information Technology’s Failure to Disrupt Healthcare*, 13 NEV. L.J. 722, 731-38 (2013).

⁷⁶ CLAYTON M. CHRISTENSEN, *THE INNOVATOR’S DILEMMA: WHEN NEW TECHNOLOGIES CAUSE GREAT FIRMS TO FAIL* XV (1997).

⁷⁷ Terry, *supra* note 75, at 30.

IV. HEALTHCARE BARRIERS TO EFFECTIVE HIT

As part of the IoM's *Healthcare Imperative* report, Andrew Wiesenath posed the \$64,000 question: "If integrated systems are such a commonly accepted movement in the right direction, then why are we not creating them everywhere?"⁷⁸ His answer was "the barriers [historical, political, and cultural] presented by our current healthcare system, which hinders integration."⁷⁹ Similarly, an AHRQ literature review identified the central "need for clinical medicine as it is now practiced in the majority of settings to undergo a major structural and ideological reorganization, so it can be integrated with and enjoy the benefits of HIT."⁸⁰

What, however, are the specifics of the perceived antecedent changes to healthcare that will open the door for HIT implementation? In 2013, when Arthur Kellermann and Spencer Jones revisited the failed 2005 prediction by Hillestad that HIT could deliver \$81 billion in annual savings, they concluded:

[W]e believe that the anticipated productivity gains of health IT are being hindered by the sluggish pace of adoption, the reluctance of many clinicians to invest the considerable time and effort required to master difficult-to-use technology, and the failure of many health care systems to implement the process changes required to fully realize health IT's potential.⁸¹

There appears, therefore, to be a consensus that some of the fault lies with HIT design (usability included) and implementation and possibly the technology's failure to cope with patient⁸² or provider

⁷⁸ Andrew M. Wiesenath, *Health Information Technology To Promote Integration*, in THE HEALTHCARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES 529, 529 (Pierre L. Yong & Leigh Anne Olsen eds., 2010).

⁷⁹ *Id.*

⁸⁰ PAUL SHEKELLE ET AL., COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY 58 (2006), available at <http://healthit.ahrq.gov/sites/default/files/docs/page/hitsys.pdf>.

⁸¹ Arthur L. Kellermann & Spencer S. Jones, *What It Will Take To Achieve The As-Yet-Unfulfilled Promises Of Health Information Technology*, 32 HEALTH AFFAIRS 63, 64 (2013).

⁸² Michael C. Christensen & Dahlia Remler, *Information and Communications Technology in U.S. Health Care: Why is Adoption so Slow and is Slower Better?*, 34 J. HEALTH POL. POL'Y & L. 1011, 1019 (2009).

heterogeneity.⁸³ These aspects of the problem are dealt with later in this article.⁸⁴

The other hindrances appear to be laid at the feet of the healthcare system itself—its history, politics, financing, culture, and processes. Therefore, this section looks at the problem from the perspective of health care structures and operations, examining barriers, and possible solutions.

a. Payment Reform and Process Change

To Err is Human staked out a strong position: “Given the experience of other industries, health care is not likely to make significant safety improvements without a more comprehensive, coordinated approach.”⁸⁵ However, once we start looking inside our healthcare institutions, we find many theories to the causes of fragmentation and at least as many suggested approaches to its cure. For example, Toussaint primarily targets waste and the removal of process steps that fail to bring value to the care.⁸⁶ Most typical, perhaps, is placing blame on our payment systems. For example, Guterman blames FFS as inherently fragmenting.⁸⁷ The Bipartisan Policy Center’s Janet M. Marchibroda has testified before Congress saying:

The most significant barrier to exchange is the lack of a business case for information sharing. Because the predominant method of payment in the U.S. health care system today provides reimbursement for volume—or the number of visits, tests or procedures performed—as opposed to rewarding outcomes or value, there are limited financial incentives for providers to access or share information across care settings to reduce duplicative tests or procedures, or otherwise

⁸³ PAUL SHEKELLE ET AL., SOUTHERN CALIFORNIA EVIDENCE-BASED PRACTICE CENTER, COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY v-vi (Sydney J. Newberry ed. 2006) (“a lack of generalizable knowledge about what types of HIT and implementation methods will improve care and manage costs for specific health organizations”).

⁸⁴ See *infra* text accompanying note 149.

⁸⁵ INST. OF MED. *supra* note 34, at 75.

⁸⁶ Toussaint, *supra* note 4, at 519-20.

⁸⁷ Guterman, *supra* note 28.

improve the quality or cost of care.⁸⁸

Our health care system infamously separates out those who pay (insurers), those who recommend treatment (providers), and those who experience treatment (patients), and this lack of integration frequently is blamed for fragmentation and lack of coordination. Clayton Christensen and colleagues target third-party reimbursement for “sap[ping] motivation for innovation—particularly disruptive innovation—out of the system.”⁸⁹

James Walker and Pascale Carayon sum up how the payment model, workflow, and HIT underperformance intersect when they identify “the current focus of health IT on improving the performance of isolated tasks rather than on supporting team-executed, value-added processes of care.”⁹⁰ They elaborate as follows:

Task-focused care is centered on the provider or facility rather than on the patient. The focus on tasks (and payment for isolated tasks) is a fundamental cause of the fragmentation, low quality, and high cost of U.S. health care. On the other hand, process-focused care is centered on the patient. It coordinates the work of many care team members (including patients, physicians, nurses, midlevel providers, lay caregivers, clinical educators, pharmacists, case managers, and call-center personnel) to provide each patient with high-quality, efficient care across time and across all venues of care.⁹¹

In short, Walker and Carayon argue that because we continue to think in terms of individual tasks (to use Gawande’s metaphor, “cowboys”) rather than team-based processes (“pit crews”), our quality improvement efforts, including the application of HIT, tend to “mirror” our fragmented systems.⁹² Meaningful adoption of HIT is a challenge to the individuals who thrive in our individualistic healthcare organizations. In contrast, as noted by Jon Katzenbach and

⁸⁸ *Health Information Technology: Using it to Improve Care: Hearing Before the S. Comm. on Finance*, 113th Cong. 7 (2013) (statement of Janet M. Marchibroda, Director, Health Innovation Initiative, Bipartisan Policy Center).

⁸⁹ CLAYTON M. CHRISTENSEN ET AL., *SEEING WHAT’S NEXT: USING THE THEORIES OF INNOVATION TO PREDICT INDUSTRY CHANGE* 197 (2004).

⁹⁰ James M. Walker & Pascale Carayon, *From Tasks to Processes: The Case for Changing Health Information Technology to Improve Health Care*, 28 *HEALTH AFFAIRS* 467, 467 (2009).

⁹¹ *Id.* at 468.

⁹² *Id.* at 469; Gawande, *supra* note 1.

Douglas Smith in *The Wisdom of Teams*, “[b]ecause of their collective commitment, teams are not as threatened by change as are individuals left to fend for themselves.”⁹³

David Baker and colleagues report, “despite the importance of teamwork in health care, most clinical units continue to function as discrete and separate collections of professionals.”⁹⁴ They ascribe this fact to the absence of joint training and the team members coming from “separate disciplines and diverse educational programs.”⁹⁵ There is a robust amount of literature on teams and teamwork that suggests routes for improved performance in healthcare institutions. Eduardo Salas and colleagues argue, “[t]eams have become the strategy of choice when organizations are confronted with complex and difficult tasks.”⁹⁶ They argue that teams should be deployed “when errors lead to severe consequences; when the task complexity exceeds the capacity of an individual; when the task environment is ill-defined, ambiguous, and stressful; [and] when multiple and quick decisions are needed.”⁹⁷ According to Eric Knox and Kathleen Rice Simpson:

[H]igh-reliability clinical environments that support teamwork and patient safety do not occur randomly or by luck. They are the result of strong interdisciplinary leaderships that instills and frequently communicates safety as its main value and operational principle. Teamwork requires more time and more professional energy than traditional models of care and traditional methods of communication and workplace behavior. It is possible, however, for an organization to learn and refocus on the principles of high reliability, teamwork, and the clinical practices that are needed to ensure patient safety.⁹⁸

The science of teams is behind much of AHRQ’s work with its

⁹³ JON R. KATZENBACH & DOUGLAS K. SMITH, *THE WISDOM OF TEAMS* 19 (1993).

⁹⁴ David P. Baker et al., *Teamwork as an Essential Component of High-Reliability Organizations*, 41 *HEALTH SERVS. RESEARCH* 1576, 1579 (2006).

⁹⁵ *Id.*

⁹⁶ Eduardo Salas et al., *On Teams, Teamwork, and Team Performance: Discoveries and Developments*, 50 *J. HUMAN FACTORS & ERGONOMICS SOC’Y* 540, 540 (2008).

⁹⁷ *Id.*

⁹⁸ G. Eric Knox & Kathleen Rice Simpson, *Teamwork: The Fundamental Building Block of High-Reliability Organizations and Patient Safety*, in *THE PATIENT SAFETY HANDBOOK* 379, 400 (Barbara J. Youngberg & Martin J. Hatlie eds., 2004).

Team STEPPS program, which is a three-step process “aimed at creating and sustaining a culture of safety,” focusing on, “pretraining assessment,” “[t]raining for onsite trainers and health care staff,” and “[i]mplementation and sustainment.”⁹⁹

Baker and colleagues recognize that “simply installing a team structure does not automatically ensure it will operate effectively. Teamwork is not an automatic consequence of co-locating people together and depends on a willingness to cooperate for a shared goal.”¹⁰⁰ Similarly, Katzenbach and Smith have noted the way in which “teams and performance are inextricably connected.”¹⁰¹ Successful teams only come together around “a common purpose” and “performance goals.”¹⁰² Of considerable importance for this article, Salas and colleagues also caution that “the mere insertion of technology into a system does not guarantee that it will augment team performance or even be used by the team,” and that the technology “must be guided by a thorough understanding of team needs and capabilities.”¹⁰³ And, as noted by Spencer Jones and colleagues, “IT-driven productivity growth” is “more likely in organizations with such characteristics as high levels of education and individual autonomy, self-directed work teams, and incentive systems that reward team performance.”¹⁰⁴

Finally, there is an important linkage between team models and the emerging integrated models, which is discussed below. In *There Is No ‘I’ in Teamwork in the Patient-Centered Medical Home*, Emily Leasure and colleagues argue that the following five teamwork competencies should be implemented for PCMH-standard primary care: “team leadership,” “mutual performance monitoring,” “backup behavior,” “adaptability,” and “team orientation.”¹⁰⁵

⁹⁹ *About Team STEPPS*, DEPARTMENT OF HEALTH & HUM. SERVICES, <http://teamstepps.ahrq.gov/>.

¹⁰⁰ Baker et al., *supra* note 94, at 1576, 1579.

¹⁰¹ Katzenbach, *supra* note 93, at 44.

¹⁰² *Id.* at 45.

¹⁰³ Salas et al., *supra* note 96, at 543-44.

¹⁰⁴ Spencer S. Jones et al., *Unraveling the IT Productivity Paradox—Lessons for Health Care*, 366 NEW ENG. J. MED. 2243, 2244 (2012).

¹⁰⁵ Emily L. Leasure et al., *There Is No “I” in Teamwork in the Patient-Centered Medical Home*:

b. Institutional Integration

In the search for a healthcare environment that will promote HIT considerable, interest is given to integrated financing models lined up to replace FFS (and some other) payment models. Harold Luft notes how integration brings “better coordination of care and more effective use of resources,” and how “[i]mproved payment incentives, coupled with accessible data and extracting information from the data can also increase efficiency and value.”¹⁰⁶ Indeed, integration has an almost mythical promise in HIT circles. The stated examples are obvious even if the assumed causality is less than evidence-based.

First, fully integrated care systems, such as the Department of Veterans Affairs (VA) and Kaiser Permanente, are frequently celebrated for their efficient operations *and* their pervasive adoption of HIT. Indeed, a 2012 survey of Californian physicians found that 99% of Kaiser physicians and 93% of VA or military physicians had access to EMRs, and that those EMRs generally exhibited more sophisticated or comprehensive capabilities.¹⁰⁷ In *The Innovator's Prescription*, Christensen and colleagues argued that tightly integrated providers furnished one of the best platforms for efficiency and some disruption¹⁰⁸ in part because “[i]ntegrated fixed-fee provider systems can, to some extent, circumvent the inertial blocking power of guild membership because reimbursement is not an issue. They can more easily make the decisions that are best for the overall system.”¹⁰⁹

Second, healthcare systems outside of the US frequently exhibit both better implementation of HIT and more integration. For all of

Defining Teamwork Competencies for Academic Practice, 88 ACADEMIC MED.585, 590 (2013).

¹⁰⁶ Harold S. Luft, *Payment Reform To Promote Integration And Value*, in THE HEALTHCARE IMPERATIVE, LOWERING COSTS AND IMPROVING OUTCOMES 529(Pierre L. Yong & LeighAnne Olsen eds., 2010).

¹⁰⁷ Janet M. Coffman et al., *On the Road to Meaningful Use of EHRs: A Survey of California Physicians*, CAL. HEALTHCARE FOUND. 14(June 2012), <http://www.chcf.org/~/.media/MEDIA%20LIBRARY%20Files/PDF/R/PDF%20RoadMeaningfulUseEHRsPhysicians.pdf>.

¹⁰⁸ See CLAYTON M. CHRISTENSEN ET AL., THE INNOVATOR'S PRESCRIPTION: A DISRUPTIVE SOLUTION FOR HEALTH CARE 184 (2008).

¹⁰⁹ *Id.* at 201.

their heterogeneous-detail nature, these health care systems tend to feature universal care and frequently single payer, government-funded models. Government funding also seems to promote higher levels of HIT adoption. The Netherlands, for example, has launched a successful HIT program and a national EMR system, attributes that are often used to explain its reputation as the world's top performing healthcare system.¹¹⁰

Of course, integration may not be a win-win. Baicker and Levy posit a coordination-competition dichotomy as follows:

Well-integrated provider networks may promote coordinated care that improves the allocation of health care resources, but they are likely to undermine competitive pressures to keep prices down while maintaining high quality. Coordinated systems may thus deliver the right care to the right patient at the right time, but at the wrong price.¹¹¹

Further, not all integrated models are created equal. Harold Luft favors integration of delivery, yet suggests well-regarded fully integrated systems have had difficulty spreading or scaling.¹¹² He therefore favors integrative models that do not require "total organizational change."¹¹³ For Luft, the key is a bundled payment system for care delivery teams that reflects the costs incurred by teams with above average outcomes and use "learning" HIT systems.¹¹⁴ These virtual integrated care models are crucial components of the cost and quality strategies adopted in the ACA. Both the Accountable Care Organization (ACO) and the more "retail" oriented patient-centered medical home (PCMH) are also important aspects of the ACA.¹¹⁵ Most attention has been paid to ACOs and the

¹¹⁰ *Netherlands' e-health systems linked to top healthcare performance*, WIKIHEALTH, <http://www.wikehealth.org/column/netherlands-e-health-systems-linked-top-healthcare-performance> (last visited June 21, 2014).

¹¹¹ Baicker, *supra* note 3, at 790.

¹¹² Luft, *supra* note 106, at 525.

¹¹³ *Id.*

¹¹⁴ *Id.* at 527.

¹¹⁵ See generally David L. Longworth, *Accountable Care Organizations, the Patient-Centered Medical Home, and Health Care Reform: What Does it All Mean?* 78 CLEV. CLINIC J. MED. 571 (2011); Frank Pasquale, *Accountable Care Organizations in the Affordable Care Act*, 42 SETON HALL L. REV. 1371 (2012); Sallie Thieme Sanford, *Designing Model Homes for the Changing Medical Neighborhood: A Multi-Payer Pilot Offers Lessons for ACO and PCMH Construction*, 42

Medicare “shared-savings” financing model established by the ACA¹¹⁶ and complex regulations made there under.¹¹⁷

HIT is viewed as having a fundamental role to play in both Accountable Care Organizations and PCMH care models.¹¹⁸ Indeed, the original, proposed ACO rule treated the ACO-HIT bond as particularly strong, stating: “An ACO . . . will draw upon the best, most advanced models of care, using modern technologies, including telehealth and electronic health records, and other tools to continually reinvent care in the modern age.”¹¹⁹ However, as criticisms mounted,¹²⁰ the final rule backtracked from the vision of the ACO as being the new poster-child for HIT implementation. Downgraded from a condition of participation, EMR use was repositioned as aspirational, although it was retained as a highly weighted quality measure.¹²¹

Notwithstanding this legal downgrade, HIT appears to retain its practical importance in making new integrated models successful. For example, CCHIT’s suggested HIT framework for ACOs has four

SETON HALL L. REV. 1519 (2012); Meredith B. Rosenthal et al., *Effect of a Multipayer Patient-Centered Medical Home on Health Care Utilization and Quality: The Rhode Island Chronic Care Sustainability Initiative Pilot Program*, 173 JAMA INTERNAL MED. 1907 (2013).

¹¹⁶ Medicare Shared Savings Program, Pub. L. No. 111-148, § 3022, 124 Stat. 395, 395 (2010).

¹¹⁷ Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425).

¹¹⁸ DAVID MEYERS ET AL., U.S. DEP’T OF HEALTH & HUMAN SERVS., 11-M005-EF, THE ROLES OF PATIENT-CENTERED MEDICAL HOMES AND ACCOUNTABLE CARE ORGANIZATIONS IN COORDINATING PATIENT CARE 7–8 (2010).

¹¹⁹ Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 19,528, 19,533 (proposed Apr. 7, 2011) (to be codified at 42 C.F.R. pt. 425); see generally Amy K. Fehn, *The Importance of Health Information Technology for Accountable Care Organizations*, A.B.A. HEALTH L. SECTION (June 2011), https://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1106_aco_fehn.html.

¹²⁰ See, e.g., Ron Klar, *Saving the Shared Savings Program (ACOs) Part Three: Quality, Payment, and Data Issues*, HEALTH AFFAIRS BLOG (June 6, 2011, 11:03 AM), <http://healthaffairs.org/blog/2011/06/06/saving-the-shared-savings-program-acos-part-three-quality-payment-and-data-issues/>; Letter from Michael Maves, Exec. Vice President, Am. Med. Ass’n, to Donald Berwick, Adm’r, Ctrs. for Medicare and Medicaid Servs. 25 (June 3, 2011), available at <http://www.ama-assn.org/resources/doc/washington/aco-shared-savings-comment-letter-3june2011.pdf>.

¹²¹ Electronic Health Records Technology, 45 C.F.R. § 425.506 (2012).

top-level requirements: (1) information sharing among clinicians, patients, and authorized entities; (2) data collection and integration from multiple clinical, financial, operational, and patient-derived sources; (3) HIT functions supporting patient safety; and (4) strong privacy and security protections.¹²²

The CCHIT framework describes the second of these as “challenging when the data are extracted from disparate clinical systems.”¹²³ The required care coordination is described as being of two types. The first “provides information to the clinician who must be able to access from and provide relevant clinical data to multiple sources in order to determine and provide for appropriate next steps in diagnosis or treatment.”¹²⁴ The second “is to assure that patients are in the appropriate setting as they transition among multiple levels of care.”¹²⁵ The framework then identifies the care coordination functions that need support from IT systems: (1) access real time health insurance coverage information, (2) establish payer relationships, (3) establish provider relationships, (4) share data during transitions of care, (5) identify best setting for care, (6) identify community and social supports, (7) manage referrals, (8) patient centric medication management and reconciliation, and (9) clinical information reconciliation.¹²⁶

In a 2012 Commonwealth Fund report, Eugene Kroch and colleagues surveyed ACO-supportive providers in an attempt to gauge the capabilities that showed readiness to succeed with a shared savings model. With regard to the role of HIT the report noted, “[o]rganizational leaders need to appreciate that the required technology involves more than electronic health records and health information exchanges, although these are also important[,]” and the fact that ACOs required “an information technology infrastructure

¹²² CERTIFICATION COMMISSION FOR HEALTH INFORMATION TECHNOLOGY, A HEALTH IT FRAMEWORK FOR ACCOUNTABLE CARE 5 (June 6, 2013), available at https://www.cchit.org/c/document_library/get_file?uuid=47dd2a86-2872-41c7-8fbd-dbc260eddf5d&groupId=18.

¹²³ *Id.*

¹²⁴ *Id.* at 12.

¹²⁵ *Id.*

¹²⁶ *Id.* at 13-15.

that can support data mining is key, as monitoring a patient population's health care quality, spending, and utilization is fundamental to operating an ACO effectively."¹²⁷

There is optimism that HIT and ACOs will be mutually successful, despite the fact that both represent big bets in the high stakes game of health reform. However, there are certainly doubts about whether ACOs will succeed. For example, Christensen and colleagues have claimed "[t]he ACO concept is based on assumptions about personal and economic behavior—by doctors, patients and others—that aren't realistic."¹²⁸ It has also been argued that as physicians are driven into ACOs their productivity falls and continuity of care suffers.¹²⁹ Even if ACOs are successful, an overabundance of enthusiasm is likely unwise. As Wiesenthal cautions, "unlike the assumption that integration builds and supports better systems and outcomes . . . the development of integrated systems is not a natural by-product of introducing HIT. Again, the change process is much more complex."¹³⁰

c. "Waiting Out" Market Failure and Underperforming Products

The question of whether institutional integration has created a situation more amenable to successful HIT implementation is not limited to a "yes" or "no" answer. An entirely rational answer is "not yet." After all, as noted by the IoM, "[IT] capacities are still relatively early in their development in the health care arena, and there is substantial room for progress and improvements as technologies are implemented in the field."¹³¹ As discussed herein, there are major market failures associated with how HIT is financed (e.g. its

¹²⁷ Eugene Kroch et al., *Measuring Progress Toward Accountable Care*, THE COMMONWEALTH FUND 22 (December 2012) <http://www.commonwealthfund.org/Publications/Fund-Reports/2012/Dec/Measuring-Accountable-Care.aspx#citation>.

¹²⁸ Clayton Christensen et al., *Christensen, Flier and Vijayaraghavan: The Coming Failure of 'Accountable Care'*, WALL ST. J. (Feb. 18, 2013), <http://online.wsj.com/news/articles/SB10001424127887324880504578296902005944398>.

¹²⁹ Scott Gottlieb, *The Doctor Won't See You Now. He's Clocked Out*, WALL ST J. (Mar. 14, 2013), <http://online.wsj.com/news/articles/SB10001424127887323628804578346614033833092>.

¹³⁰ Wiesenthal, *supra* note 78, at 530.

¹³¹ INST. OF MED., *supra* note 2, at 113.

disconnection from reimbursement) and with the quality of the HIT that currently is available.

Health care institutions have some excellent reasons to be cautious about IT investments. First, there is the exhaustion factor, as previously noted, which calls for more and better HIT followed by HIPAA's unfunded e-transactions mandate, escalating privacy and security costs, MMA's e-prescribing requirement, the tapering of the HITECH subsidy program, and the adoption of ICD-10.¹³²

Second, it is primarily hospital budgets that will be squeezed for the savings necessary to make health care reform work. This will certainly be the case for hospitals in states that took advantage of the Supreme Court's ruling on the ACA¹³³ to reject the funds that would have accompanied Medicaid expansion.¹³⁴ Margins also are likely to shrink as hospitals pay penalties for readmissions¹³⁵ and see reimbursement for HACs refused.¹³⁶ Value-based purchasing,¹³⁷ new rules reducing price discrimination among patients,¹³⁸ and limits on debt collection will all have an impact on hospital budgets, as will shifts in reimbursement models away from hospitalization to primary and preventative care. Stacked against these other demands are the "cripplingly" high costs associated with HIT.¹³⁹ Even the largesse of the Meaningful Use subsidy program will soon end, exposing some hospitals to the sticks that have always been promised

¹³² Terry, text accompanying note 75, at 118-19.

¹³³ Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012).

¹³⁴ Jeffrey Young, *North Carolina Hospital Closes, Citing No Medicaid Expansion*, HUFFINGTON POST (Sept. 6, 2013, 7:49 PM), http://www.huffingtonpost.com/2013/09/06/north-carolina-medicaid-expansion_n_3882976.html?ir=Business.

¹³⁵ Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. § 3025 (2nd Sess. 2010).

¹³⁶ Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. § 2702 (2nd Sess. 2010).

¹³⁷ *Hospital Value-Based Purchasing*, CTFS.FOR MEDICARE & MEDICAID SERVS. (Mar. 31, 2013, 7:35 PM), <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/>.

¹³⁸ See, e.g., Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. § 1557 (2nd Sess. 2010).

¹³⁹ See generally Jennifer Bresnick, *Why Have EHR Adoption, EMRAM Scores Stalled for Hospitals?*, EHR INTELLIGENCE (Oct. 16, 2013), <http://ehrintelligence.com/2013/10/16/why-have-ehr-adoption-emram-scores-stalled-for-hospitals/>.

to follow the subsidy carrots.¹⁴⁰

Third, some cultural and professional issues seem to be spiked by HIT. For example, a recent union contract negotiated with a Missouri hospital included a provision that the hospital would not implement IT “that undermines RN professional judgment,”¹⁴¹ while in California and Ohio alleged safety problems with hospital EMR systems have become embroiled in labor negotiations.¹⁴²

Fourth, relatively few health care institutions have clear HIT strategies. The Meaningful Use subsidy program was about buying a certified EMR that qualified for subsidy, not necessarily the product that best suited the institution. As Michael Christensen and Dahlia Remler have cautioned: “[T]here are real advantages to approaching ICT [information and communication technology] adoption carefully and waiting for the right technology to come along before system-level adoption takes place.”¹⁴³ This waiting strategy has particular applicability to HIT “because the costs of adopting the wrong type of ICT are so much higher: the risks and irreversible consequences of technical errors and the consequences of lock-in into a suboptimal technology.”¹⁴⁴

Rationally, therefore, the argument that successful HIT implementation is dependent on antecedent change by health care cultures, processes, precepts, and stakeholders has merit. Unfortunately, HIT has been “waiting” since 2001 when the IoM urged information technologies to join the healthcare improvement

¹⁴⁰ See generally Catherine M. DesRoches et al., *Some Hospitals Are Falling Behind In Meeting ‘Meaningful Use’ Criteria And Could Be Vulnerable To Penalties in 2015*, 32 HEALTH AFFAIRS 1355, 1355-56 (2013).

¹⁴¹ Press Release, Nat’l Nurses United, St. Louis University Hospital RNs Win First Contract (June 17, 2013), <http://www.nationalnursesunited.org/press/entry/st-louis-university-hospital-rns-win-first-contract>.

¹⁴² Press Release, Nat’l Nurses United, Affinity RNs Call For Halt To Flawed Electronic Medical Records System Schedule To Go Live Friday (June 18, 2013), <http://www.nationalnursesunited.org/press/entry/rns-say-sutters-new-electronic-system-causing-serious-disruptions-to-safe-p/>; Press Release, Nat’l Nurses United, RNs Say Sutter’s New Electronic System Causing Serious Disruptions To Safe Patient Care At East Bay Hospitals (July 11, 2013), <http://www.nationalnursesunited.org/press/entry/affinity-rns-call-for-halt-to-flawed-electronic-medical-records-system-sche/>.

¹⁴³ Christensen & Remler, *supra* note 82, at 1024.

¹⁴⁴ *Id.* at 1030.

movement.¹⁴⁵ Asa Beckett character might say, “[n]othing happens, nobody comes, nobody goes, it’s awful!”¹⁴⁶ Unless we are convinced that there is a fundamental mismatch between IT and healthcare, “waiting” is beginning to look like a flimsy excuse.

V. IMPROVING AND RETHINKING HIT

There is no reason to suppose that healthcare can avoid the apparently endemic problems faced by organizations adopting IT. These include training costs, switching costs, getting interlinked or dependent technologies to work together,¹⁴⁷ and a shortage of trained employees.¹⁴⁸ Given the complexity of major IT deployments, the occasional monumental crash is perhaps to be expected.¹⁴⁹ However, beyond such generic problems there is evidence of a fundamental mapping or matching problem between the current iterations of HIT and healthcare. Some technologies such as MIS and email¹⁵⁰ operate quite well in healthcare environments (or at least no worse than in other domains). But anytime the technology seeks to interface with beyond such generic problems, there is evidence of a fundamental mapping or matching problem between the current iterations of HIT and healthcare. Some technologies such as MIS and email¹⁵¹ operate quite well in healthcare environments (or at least no worse than in other domains). But anytime the technology seeks to interface with

¹⁴⁵ INST. OF MED., *supra* note 41, at 165.

¹⁴⁶ SAMUEL BECKETT, *WAITING FOR GODOT* (1953).

¹⁴⁷ Christensen & Remler, *supra* note 82, at 1015.

¹⁴⁸ See generally HIMSS WORKFORCE SURVEY JULY 2013, HEALTHCARE INFO. & MGMT. SYS. SOCIETY 15, available at <http://www.himssanalytics.org/research/AssetDetail.aspx?pubid=82097&tid=127>.

¹⁴⁹ See e.g., Erin McCann, *What To Do (And What Not To Do) When Your \$1B System-Wide EHR Fails*, HEALTHCARE IT NEWS (Sept. 10, 2013), <http://www.healthcareitnews.com/news/what-to-do-when-your-%241B-EHR-system-fails-lessons-learned-sutter-ehr-software?page=0> (describing software glitch that brought down a hospital system’s \$1 billion EMR system).

¹⁵⁰ Albeit, not email between patients and providers. See Tara F. Bishop et al., *Electronic Communication Improves Access, But Barriers To Its Widespread Adoption Remain*, 32 HEALTH AFFAIRS 1361, 1361 (2013).

¹⁵¹ Albeit, not email between patients and providers. See Bishop *supra* note 150, at 1364.

healthcare workflows (whether financial or clinical), there seems to be resistance or friction.

An *Accenture* study found that of the eight developed countries surveyed, the US had significantly lower percentages of doctors who believed HIT improves diagnoses, health outcomes, or quality of treatment decisions.¹⁵² Indeed, the US healthcare establishment appears uncomfortable with innovation. The overcautious advice it gives to practitioners suggests it views technologically mediated care as analogous to or as an organ of the industrialization of medicine.¹⁵³ Of course, there are plenty of physicians in the vanguard of HIT adoption. As one physician commented in support of widespread EMR adoption, “It is time for us to give up medicine by the seat of our pants and work with information technology to provide safe and consistently effective care.”¹⁵⁴

Attitudes aside, however, a history of market failure and market underperformance suggests that HIT is being pushed into a misshapen box. This is certainly the case with the fragmentation problem—early adopters of *Lean* found that new coordinated care (patient-centric) models were simply inconsistent with provider-centric software design, while implemented technology solutions tended not to export well to other health care entities because of the institutions’ heterogeneous nature.¹⁵⁵

If there is a mismatch, is the problem the healthcare box or the technology being pushed into it? There seem to be good reasons to blame the technology. For example, Christopher Nemeth and Richard Cook argue “[t]he technical work that clinicians perform is *hiding in*

¹⁵² Press Release, Accenture, Doctors Agree on Top Healthcare IT Benefits, But Generational Divide Exists, According to Accenture Eight-Country Survey (Jan. 10, 2012), http://newsroom.accenture.com/article_display.cfm?article_id=5370.

¹⁵³ See e.g., *Opinion 5.027 - Use of Health-Related Online Sites*, AM. MED. ASS’N., <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion5027.page> (last visited April 1, 2014 at 8:30 PM); see also, *Policy On Medical Information Technology*, DOCS4PATIENTCARE.ORG, <http://docs4patientcare.org/> (last visited April 1, 2014 at 8:35 PM).

¹⁵⁴ Joseph E. Scherger, *Meaningful Use Means Safer and Higher-Quality Care. Who Can Argue Against That?*, LOCUM LIFE (May 2010), <http://digital.healthcaregroup.advanstar.com/nxtbooks/advanstar/locumlife0510/index.php?startid=8#>.

¹⁵⁵ See generally Bartels, *supra* note 64, at 15.

plain sight. Those who know how to do research in this domain can see through the smooth surface and understand its complex and challenging reality. Occasional visitors cannot fathom this demanding work, much less create IT systems to support it.”¹⁵⁶ Working from that proposition, this section looks at the reverse answer to the chicken-and-egg problem discussed above, considering the extent that the technology is to blame.

a. Market Failure

At least one of the roles envisioned for HIT (certainly in any sentence that also includes “transformative” or “disruptive”) is to reduce or eliminate one or another of the causes of healthcare’s market failures (e.g., by increasing consumer or payer transparency). Yet, HIT either shares or reflects the well-known market failures exhibited by health care and then throws in a few of its own. These barriers may be serious enough that modest attempts to correct HIT market failure, such as EMR subsidies, will leave us wanting.¹⁵⁷

The most often cited HIT market failure is a healthcare classic: misaligned incentives. The commonsense assumption that EMRs would be purchased by physicians is frustrated by the fact that the physicians would capture little or no benefit from the investment. Instead, benefits would accrue to EMR non-purchasers such as insurers, patients, or hospitals to which patients were referred. Absent the alignment of incentives such that those purchasing the equipment would capture benefit, EMRs remained unsold.¹⁵⁸ The misaligned incentives problem with HIT clearly has been a source of frustration among the intellectual leaders of medicine. For example, David Blumenthal (President Obama’s first ONC coordinator) noted, “We have years of professional agreement and bipartisan consensus regarding the potential value of EHRs. Yet we have not moved

¹⁵⁶ Christopher Nemeth & Richard Cook, *Hiding in Plain Sight: What Koppel Et Al. Tell Us About Healthcare IT*, 38 J. BIOMEDICAL INFORMATICS 262, 262 (2005).

¹⁵⁷ See text accompanying note 75 at 102.

¹⁵⁸ Hall and Schulman also posit slightly different incentive problem—market failure based on some physicians predominantly being “senders” and others “receivers,” with only the latter capturing benefit. See Mark A. Hall & Schulman, *Property, Privacy, and the Pursuit of Integrated Electronic Medical Records*, in *THE FRAGMENTATION OF U.S. HEALTHCARE* 165, 171 (Einer Elhauge ed., 2010).

significantly to extend the availability of EHRs from a few large institutions to the smaller clinics and practices where most Americans receive their health care.”¹⁵⁹

Many of those large institutions were fully integrated HMOs that combine insurance, hospitals, clinics, physicians, labs, and pharmacies. The coincidence of sophisticated HIT implementation and better care coordination these institutions display frequently is given as the best evidence of the potential of HIT.¹⁶⁰

It is often forgotten that government has also led by example with the work of the Department of Veterans Affairs (VA).¹⁶¹ Writing in 2010, Colene Byrne and colleagues at the VA’s Center for IT Leadership noted “the VA is one of the few national, health IT-enabled, integrated delivery systems in the United States,” concluding that investment in HIT was “associated with significant value through reductions in unnecessary and redundant care, process efficiencies, and improvements in care quality.”¹⁶²

¹⁵⁹ David Blumenthal & Marilyn Tavenner, *The “Meaningful Use” Regulation for Electronic Health Records*, 363 NEW ENG. J. MED. 501 (2010).

¹⁶⁰ See, e.g., Reed Abelson, *The Face of Future Health Care*, N.Y. TIMES (March 20, 2013), http://www.nytimes.com/2013/03/21/business/kaiser-permanente-is-seen-as-face-of-future-health-care.html?_r=0.

¹⁶¹ See generally Kyle Buckley, *VA Electronic Health Records: What Federally Mandated Health Integration Really Looks Like*, NAT’L CTR. FOR POLICY ANALYSIS, (May 8, 2013), <http://www.ncpa.org/pub/ib120>.

¹⁶² Colene M. Byrne et al., *The Value from Investments in Health Information Technology at the U.S. Department of Veterans Affairs*, 29 HEALTH AFFAIRS 629, 629, 634 (2010). This should not be taken as a blanket endorsement of VA or even government IT; witness the sad history of attempts to integrate the VA and DoD records frameworks. See, e.g., Phil Stewart, *U.S. Scales Back Goal on Veteran’s Health Records with an Eye on Cost*, REUTERS (Feb. 5, 2013, 10:38 P.M.), <http://www.reuters.com/article/2013/02/06/us-usa-veterans-idUSBRE91500Q20130206>; Bob Brewin, *Congress to Defense and VA: Give us a Plan for Integrating Health Records by February*, NEXTGOV (Dec. 12, 2013), <http://www.nextgov.com/defense/2013/12/congress-defense-and-va-give-us-plan-integrating-health-records-february/75441/?oref=ng-dropdown>; Jennifer Bresnick, *Bulk of EHR Money Went to Support Contracts*, HER INTELLIGENCE, (Dec. 25, 2013), <http://ehrintelligence.com/2013/11/25/bulk-of-wasted-dod-va-iehr-money-went-to-support-contracts/>. More recently, of course, the CMS-run federal insurance exchange had its well-publicized meltdown. See, e.g., Amy Goldstein & Juliet Eilperin, *HEALTHCARE.GOV Contractor Had High Confidence But Low Success*, WASH. POST (Nov. 23, 2013), http://www.washingtonpost.com/national/health-science/healthcaregov-contractor-had-high-confidence-but-low-success/2013/11/23/1ab2c2b2-5407-11e3-9fe0-fd2ca728e67c_story.html; Richard Pollock, *Troubled Obamacare Website Wasn’t Tested Until a Week Before Launch*, WASH. EXAMINER (Oct.

The Bush Administration explicitly decided against any unfunded government mandate modeled on HIPAA's *Administrative Simplification* that had annoyed and befuddled so many in health care. David Brailer, President Bush's first coordinator, was clear that "I don't want to see a Son of HIPAA put into law."¹⁶³ Further, his boss, Secretary Leavitt, coined the Bush administration's public, non-regulatory mantra—that the movement to an interoperable EMR should be "a smooth market-led way."¹⁶⁴ Some progress on the technical standards aside, the initiative was a well-intentioned failure.¹⁶⁵ By 2009, only hospital implementation of even the most basic EMRs remained in single digits with CPOEs penetration only slightly better.¹⁶⁶

Subsidy was a lever that had not yet been pulled. This changed when Congress passed the American Recovery and Reinvestment Act of 2009 in an attempt to slow the recession. The legislation included approximately \$30 billion in funds to subsidize EMR purchases by doctors and hospitals through the Meaningful Use (MU) program.¹⁶⁷ These subsidies are to be replaced by penalties at the end of the

17, 2013, 12:00 A.M.), <http://washingtonexaminer.com/troubled-obamacare-website-wasnt-tested-until-a-week-before-launch/article/2537381>. See generally, David Blumenthal, *Reflecting on Health Reform: A Tale of Two Procurements*, THE COMMON WEALTH FUND BLOG, <http://www.commonwealthfund.org/Blog/2013/Nov/A-Tale-of-Two-Procurements.aspx?omnicid=20>

¹⁶³ Chris Murphy, *Industry Must Improve Its Technology*, INFO. WEEK, (Jun. 21, 2004, 2:49 PM), <http://informationweek.com/software/information-management/industry-must-improve-its-technology-use/d/d-id/1025782?>

¹⁶⁴ See News Release, Health and Human Servs., Secretary Leavitt Takes News Steps to Advance Health IT (June 6, 2005), <http://archive.hhs.gov/news/press/2005pres/20050606.html>.

¹⁶⁵ *Health Information Technology, HHS is Continuing Efforts to Define a National Strategy*, GAO Testimony Before the Subcomm. on Federal Workforce and Agency Organization, Committee on Government Reform, House of Representatives, GAO-06-346T, (2006); Zach Brennan, *Funding Issues Add To Doubts About Future of Health IT Office*, iHEALTHBEAT (Sept. 20, 2007), <http://www.ihealthbeat.org/Features/2007/Funding-Issues-Add-To-Doubts-About-Future-of-Health-IT-Office.aspx>.

¹⁶⁶ Jha, et al, *supra* note 48, at 1632.

¹⁶⁷ Phyllis Patrick, *The Meaningful Use Program: Auditing Challenges and Opportunities*, ASS'N HEALTHCARE INTERNAL AUDITORS: NEW PERSPECTIVES (2013), http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Meaningful_Use.html.

staged adoption program.¹⁶⁸

The MU regulatory model was conceptualized around a staged rollout of escalating requirements. Befitting the “insider” genesis of the enabling legislation (that was the product of cooperation from provider and vendor interests), MU has resembled more of a bazaar as CMS-ONC where providers and vendors haggle over metrics and timelines. MU standards are almost invariably downgraded after initial publication while more recently wholesale extensions to or delays in the MU stages have become the norm.¹⁶⁹ In December 2013, for example, CMS, apparently bowing to pressure from industry and increasingly vocal critics on the Hill,¹⁷⁰ announced that Stage 2 would be extended for another year and the start of Stage 3 pushed back to 2017.¹⁷¹ Whether by then the technology will be ready for the criteria is an open question. Some on the industry side have expressed doubts.¹⁷²

The fundamental problem was that MU created a synthetic market whereby health care providers concluded they were compelled to accept the subsidy money even though that meant purchasing products that underperformed or failed to integrate into their workflows. If providers ended up as “losers” (albeit subsidized ones) the “winners” (other than the EMR vendors) were the highly sophisticated minority of providers who had already embarked on an HIT upgrade path but who would now receive government largesse. At its midpoint, it appears that the MU subsidy model “may end up not so much fixing health care, but confirming one of its fundamental

¹⁶⁸ *Are there penalties for providers who don't switch to electronic health records (EHR)?* HEALTHIT.GOV, <http://www.healthit.gov/providers-professionals/faqs/are-there-penalties-providers-who-don%E2%80%99t-switch-electronic-health-record> (last updated June 4, 2014, 8:46 A.M.).

¹⁶⁹ Nicolas P. Terry, *Meaningful Adoption: What We Know or Think We Know about the Financing, Effectiveness, Quality, and Safety of Electronic Medical Records*, 34 J. LEGAL MED. 7, 19-20 (2013).

¹⁷⁰ See e.g., Press Release, U.S. Senate Committee on Finance, Health Information Technology: Improves Care, (July 24, 2013); Press Release, U.S. Senate Committee on Finance, Health Care Providers Improving Care with Information Technology, (July, 17, 2013).

¹⁷¹ *Progress on Adoption of Electronic Health Records*, CMS.GOV (last modified Dec. 13, 2013, 12:41 PM), http://www.cms.gov/eHealth/ListServ_Stage3Implementation.html

¹⁷² See, e.g., Press Release, CHIME, Meaningful Use Timeline Shift Does Not Afford Flexibility in 2014 (Dec. 6, 2013), available at http://www.cio-chime.org/chime/PressReleases/pr12_6_2013_6_28_53.asp.

problems[:]" the "growing discrepancy between high performing, well-funded vertically integrated models or teaching hospitals and the lower quality providers responsible for the care of millions of other Americans."¹⁷³ Many hospitals are simply "stalling" on the progression to sophisticated HIT implementation.¹⁷⁴

In contrast to selective deployment by well-financed, technically adept providers, this synthetic market has had several negative effects, primarily pushing the purchase of technology before it was ripe for mass deployment. Jonathan Bush, CEO of Athena health, famously described the MU subsidy program as "health care information technology's version of cash-for-clunkers," and argued that "[t]raditional health software now is on Medicare, being kept alive like grandma."¹⁷⁵ Similarly, it has been argued that relatively unusable products were rushed to market to take advantage of the subsidies and that EMR research and development was "hijacked" by MU priorities, diverting vendors away from making usability improvements to satisfying frequently arcane MU criteria.¹⁷⁶

When the history of health care at the beginning of the twenty-first century is written, HIT likely will feature prominently. However, it is unclear whether that history will record the MU subsidy program as a successful intervention to cure market failure or a classic tale of government failure.

b. The Interoperability Fail

Many of the technical problems with today's generation of HIT are described below. However, one of those issues critically implicates another aspect of HIT market failure. Network effects issues have been more closely scrutinized as critical attention has turned from the adoption of *any* EMR to one that is fully

¹⁷³ Terry, *supra* note 169, at 42.

¹⁷⁴ See generally Bresnick, *supra* note 139.

¹⁷⁵ Steve Lohr, *The Agenda Behind Electronic Health Records*, N.Y. TIMES (May 9, 2010, 6:29 P.M.), http://bits.blogs.nytimes.com/2010/05/09/the-agenda-behind-electronic-health-records/?src=me&ref=technology&_r=1.

¹⁷⁶ David F. Carr, *Why Doctors Hate EHR Software*, INFO. WEEK (Oct. 18, 2013, 5:24 P.M.), http://www.informationweek.com/healthcare/electronic-health-records/why-doctors-hate-ehr-software/d/d-id/1112001?itc=edit_in_body_cross&page_number=1.

interoperable. As Hall and Schulman described the pre-interoperable (networked) records space—no one who is in a position to build the network can capture anywhere near its full social benefits.¹⁷⁷ Indeed, Kellermann and Jones have pointed out that our HIT systems are neither interconnected nor interoperable, the rate of adoption still lags behind Western Europe, and those in place are not used effectively.¹⁷⁸

There are, as ever, indirect explanations. Marchibroda identified various technical barriers, such as lack of standards, interoperable systems, and inadequate infrastructure.¹⁷⁹ Although HHS broadly celebrates the progress made since the subsidy program was introduced, Sandra Decker and colleagues argue, “[t]hese patterns continue to show the ability of large practices and those owned by health maintenance organizations and other health care organizations to adopt EHR systems,” but, “physicians in these practices make up only a small portion of all practicing office-based physicians.”¹⁸⁰ Similarly, large (top third in beds), urban, or teaching hospitals seem to account disproportionately for implementation.¹⁸¹ Often forgotten is a compounding problem, that of individual, professional “interoperability.” After all, many doctors practice in several different facilities and have to learn and stay current on multiple EMR platforms.¹⁸²

The MU subsidy program has escalating requirements for interoperability and other data sharing. However, many providers

¹⁷⁷ Hall & Schulman, *supra* note 158 at 165, 170.

¹⁷⁸ Kellermann, *supra* note 81, at 64-65

¹⁷⁹ *Statement of Janet M. Marchibroda, supra* note 88.

¹⁸⁰ Sandra L. Decker et al., *Physicians in Nonprimary Care and Small Practices and Those Age 55 and Older Lag in Adopting Electronic Health Record Systems*, 31 HEALTH AFFAIRS 1108, 1111 (2012).

¹⁸¹ Catherine M. DesRoches et al., *Small, Nonteaching, and Rural Hospitals Continue to Be Slow in Adopting Electronic Health Record Systems*, 31 HEALTH AFFAIRS 1, 6 (2012); U.S. Gov't Accountability Office, *Electronic Health Records: Number and Characteristics of Providers Awarded Medicare Incentive Payments for 2011*, GAO-12-778R at 5 (Jul. 26, 2012), available at <http://www.gao.gov/assets/600/593078.pdf>.

¹⁸² Dan Morhaim, *An Electronic Medical Records Mess*, WASH. POST (Sept. 27, 2013), http://www.washingtonpost.com/opinions/americas-electronic-medical-records-mess/2013/09/27/651a81f0-2716-11e3-b75d-5b7f66349852_story.html.

avoided some of the more difficult MU criteria according to an April 2012 report from the General Accounting Office (GAO).¹⁸³ Interoperability may be the hardest to implement. It also appears to be beyond the capabilities of many of the EMRs that have been installed both before and after the subsidy program. To meet the goals set for HIT EMRs must be able to exchange data with each other, whether or not they are in the same office, hospital, or HMO/ACO. They must also be capable of sharing data with patients and external stakeholders, such as public health authorities.¹⁸⁴ Michael Furukawa and colleagues studied information exchange between hospitals from 2008-12, concluding, "despite substantial progress since the enactment of HITECH, a majority of hospitals still do not electronically exchange clinical care summaries and medication lists."¹⁸⁵

While sharing is on the increase,¹⁸⁶ non-communicative "basic" EMRs still seem to outnumber interoperable or "comprehensive" machines. HIMSS has created an *EMR Adoption Model* that ranks hospitals by reference to their stage of HIT adoption (including the sophistication of the adopted technology). The highest level, Stage 7 includes the metric, "The hospital no longer uses paper charts to deliver and manage patient care and has a mixture of discrete data, document images, and medical images within its EMR environment."¹⁸⁷ The cumulative total of US hospitals that satisfied all of the Stage 7 criteria in the second quarter of 2013 was just 2.1%.¹⁸⁸

Even when the EMRs are interconnected, the quality of the data

¹⁸³ U.S. Gov't Accountability Office, *First Year of CMS's Incentive Programs Shows Opportunities to Improve Processes to Verify Providers Met Requirements*, GAO-12-481, Apr 30, 2012, available at <http://gao.gov/assets/600/590538.pdf>.

¹⁸⁴ See generally PRASHILA DULLABH ET AL., *WHITE PAPER: MEASUREMENT OF THE UTILIZATION OF AN INSTALLED EHR*, U.S. DEP'T HEALTH & HUMAN SERVS. 3 (2009).

¹⁸⁵ Michael F. Furukawa et al., *Hospital Electronic Health Information Exchange Grew Substantially In 2008-12*, 32 HEALTH AFFAIRS 1346, 1353 (2013).

¹⁸⁶ *Id.*

¹⁸⁷ HIMSS ANALYTICS, U.S. EMR ADOPTION MODEL TRENDS, available at http://www.himssanalytics.org/docs/HA_EMRAM_Overview_ENG.pdf (last visited June 16, 2014).

¹⁸⁸ HIMSS ANALYTICS, U.S. EMR ADOPTION MODEL, available at <http://www.himssanalytics.org/stagesGraph.asp> (last visited June 16, 2014).

interchanged can be limited. According to the 2013 HIMSS Analytics Report seventy-three per cent of hospitals belong to some health information exchange.¹⁸⁹ Yet those participants believe, “data sharing within HIOs is not robust, which reduces the value of the information that is available to healthcare providers,” that “the impact on patient care from participation in information exchanges was limited,” while, “only 20 percent reported that this improved access led to improved patient safety.”¹⁹⁰

An even more fundamental problem may be that existing EMR systems fail to use a common data standard. HIT requires data transparency and full interoperability to leverage the network effects of these interlinked clinical systems. This was the plea from PCAST in 2010 when it urged ONC to refocus on “the capability for universal data exchange, able to unleash the power of the competitive market, to produce increasingly better and less expensive systems, and to create the ‘network effect’ that spurs further adoption.”¹⁹¹ Of course, vendors have little incentive to adopt common standards. As Alan Portela, CEO of a mobile health company, stated in his 2013 Congressional testimony, “The industry has largely over-promised and under-delivered when it comes to vendors ‘playing nice in the sandbox,’ integrating systems, medical device interoperability and making data across the continuum available in a simple and cost-effective way.”¹⁹²

In June 2013 the Electronic Health Record Association (EHRA), representing most large EMR vendors, issued a voluntary EHR Developer Code of Conduct.¹⁹³ In a section headed, “Interoperability

¹⁸⁹ HIMSS ANALYTICS, 2013 HIMSS ANALYTICS REPORT: BARRIERS, CHALLENGES, AND OPPORTUNITIES WITH INFORMATION SHARING IN HIEs: OUTPUT/PRINT ENVIRONMENTS 5 (May 2013), *available at* <http://www.himssanalytics.org/research/AssetDetail.aspx?pubid=82090&tid=127>.

¹⁹⁰ *Id.* at 15.

¹⁹¹ PRESIDENT’S COUNSEL ADVISORS SCI. & TECH., REPORT TO THE PRESIDENT REALIZING THE FULL POTENTIAL OF HEALTH INFORMATION TECHNOLOGY TO IMPROVE HEALTHCARE FOR AMERICANS: THE PATH FORWARD 3 (2010).

¹⁹² Alan Portela, *Mobile Medical App Entrepreneurs: Changing the Face of Health Care: Hearing Before the Subcomm. on Health And Technology of the Comm. On Small Business*, 113rd Cong. 7 (2013).

¹⁹³ EHRA Association, *EHR Developer Code of Conduct*, EHRA (June 11, 2013),

and Data Portability,” the code recognized, “data should follow the patient” and pledged to “enable our customers to exchange clinical information with other parties, including those using other EHR systems, through standards-based technology, to the greatest extent possible.”¹⁹⁴ However, the persistent seriousness of the problem was illustrated later that month when the AMA House of Delegates voted to direct the association to seek legislation that would force EMR vendors to standardize their software to facilitate interoperability.¹⁹⁵

For HIT to combat fragmentation it must excel at sharing data within and across providers. Baicker and Levy do see HIT as a potential win-win “if it is implemented well.” But, as they note, “health IT without interoperability may simply lock patients in to their current providers or provider networks by making it difficult or costly to move their records, reducing competition.”¹⁹⁶ John Halamka completed the circle back to the network effects market failure problem when he noted,

In the long term, the total cost of implementing and maintaining standards is reduced when all participants in data exchange use the same content standards. With more data flowing, care will be better coordinated, and data can be used for multiple purposes such as population health, personal health records and clinical research.¹⁹⁷

The apparent problem is that most fragmented providers are not doing HIT well, and frequently that is because EHR vendors are not doing interoperability well. This will only turn around when accurate and secure health information can be easily exchanged across interoperable EHR systems.

c. Underperformance

One of the major reasons that providers have had problems

<http://www.himssehra.org/docs/EHR%20Developer%20Code%20of%20Conduct%20Final.pdf>.

¹⁹⁴ *Id.* at 3.

¹⁹⁵ Sue Ter Maat, *AMA Meeting Guidance Offered on Effective EHR Use*, AMERICAN MEDICAL NEWS (July 1, 2013), <http://www.amednews.com/article/20130701/house/130709957/7/>.

¹⁹⁶ Baicker & Levy, *supra* note 3, at 790

¹⁹⁷ John D. Halamka, *Making the Most of Federal Health Information Technology Regulations*, 29 HEALTH AFFAIRS 596, 597-598 (2010).

meeting MU targets is that their suppliers have not been able to deliver the appropriate, certified technology.¹⁹⁸ In late 2013 the CEO of one of the leading certification bodies described EHR vendors as “struggling a little bit” to move their products towards Stage 2 certification, particularly with regard to clinical quality measures, interoperability, and automated reporting of MU compliance.¹⁹⁹

In an August 2013 letter to Secretary Sebelius the Medical Group Management Association (that represents group practices) noted “2,200 products and almost 1,400 ‘complete EHRs’ certified under the 2011 criteria for ambulatory eligible providers. As of this writing, there are only 75 products and 21 complete EHRs certified for the Stage 2 (2014) criteria. This lack of vendor readiness has significant implications for EPs. Without the appropriate software upgrades and timely vendor support, EPs will be unable to meet the Stage 2 requirements and thus will be unfairly penalized starting in 2015.”²⁰⁰

EMR problems relating to usability and safety are quite serious. The EMR market is relatively dysfunctional with almost 450 vendors.²⁰¹ Dissatisfaction levels with existing EMR products led the “Black Book” market survey company to label 2013 as “the Year of the Great EHR Vendor Switch.”²⁰² Stories of provider unhappiness are legion. For example, one dermatologist testified before Congress about the difficulties she faced when a company that did not support her network acquired her EMR vendor.²⁰³ In Florida a class action has

¹⁹⁸ *EHR Incentives & Certification: Certification Process for EHR Technologies*, HEALTHIT.GOV, <http://www.healthit.gov/providers-professionals/certification-process-ehr-technologies> (last visited 06/19/2014).

¹⁹⁹ Anthony Brino & Diana Manos, *EHR Makers Surprised by Stage 2 Complexity*, GOV'T HEALTH IT (Oct. 22, 2013), <http://www.govhealthit.com/news/vendors-struggle-mu-stage-2-EHR-ONC>.

²⁰⁰ Letter from Susan Turner, President and CEO, MGMA, to the Honorable Kathleen Sebelius, Department of Health and Human Services (Aug. 21, 2013).

²⁰¹ Jon Conn, *5 EHR vendors lead pack in ambulatory-care niche*, MODERN HEALTHCARE (Sept. 24, 2013), 1:45 P.M., <http://www.modernhealthcare.com/article/20130924/NEWS/309249937/5-ehr-vendors-lead-pack-in-ambulatory-care-niche>.

²⁰² *Electronic Health Record sellers face make-or-break year of client ultimatums and revolts, reveals 2013 Black Book survey*, PRWEB.COM (Feb. 18, 2013), <http://www.prweb.com/releases/2013/2/prweb10416655.htm>.

²⁰³ *Not What the Doctor Ordered: Barriers to Health IT for Small Medical Practices: Hearing Before the*

been filed on behalf of 5000 small group physicians after their EMR vendor stopped production of an allegedly substandard EMR and attempted to transition the physicians to a different product.²⁰⁴ There have also been reports of providers being unable to access their records during a fee dispute with an EMR vendor.²⁰⁵

“Black Book” polling data also suggested that providers looking to switch vendors were considering a relatively short list of preferred vendors. This should mean that the long expected consolidation in the EMR market would soon arrive.²⁰⁶ However, in practice changing technology platforms is expensive, not only in technology terms but also in staff retraining costs. Some of these problems are being exacerbated and perpetuated by vendor lock-in practices. Technological lock-in leverages proprietary data formats and lack of interoperability to make it hard for customers to move to competing products.²⁰⁷

HIT’s greatest market problem, however, is that the technology on offer is not very good and may even be worse than contemplated by *Sturgeon’s Law*.²⁰⁸ Misaligned incentives and network effects may explain some of the slow adoption HIT has experienced over the last two decades, yet the technical problems with our current generation of HIT, particularly EMRs, suggest that providers had some very good reasons for not purchasing them. For example, Kellermann and

Subcomm. on Health Care and Technology, 112nd Cong. 18–20 (2011), <http://www.gpo.gov/fdsys/pkg/CHRG112hhrg68062/html/CHRG112hhrg68062.htm> (statement of Sasha Kramer, M.D.).

²⁰⁴ Brian Bandell, *Class Action Lawsuit in Miami-Dade Targets Allscripts*, S. FLA. BUS. J. (Jan 3, 2013, 12:16 P.M.), <http://www.bizjournals.com/southflorida/news/2013/01/03/class-action-lawsuit-in-miami-dade.html?page=all>.

²⁰⁵ See, e.g., Murtha Law, *The Stuff of Nightmares: EMR Vendor Cuts Off Access to Medical Records, Leaves Health Center in Very Bad Place*, MURTHALAW.COM (August 1, 2013), http://www.murthalaw.com/news_alerts/1283-the-stuff-nightmares-emr-vendor-cuts-off-access-medical-records-leaves-health.

²⁰⁶ Tom Sullivan, *The Great EHR Market Shakeout*, GOV’T HEALTH IT (Sept. 03, 2013), <http://www.govhealthit.com/news/great-ehr-market-shakeout-HIE-meaningful-use>.

²⁰⁷ Sarita Harbour, *What is a Vendor Lock-In?*, HOUSTON CHRONICLE (2014), <http://smallbusiness.chron.com/vendor-lockin-33663.html>; John Lynn, *Meaningful Use Provides Hospital EHR Vendor Lock In*, HOSPITAL EMR & EHR (Apr. 10, 2012), <http://www.hospitalemranderhr.com/2012/04/10/meaningful-use-provides-hospital-ehr-vendor-lock-in/> (last visited June 19, 2014).

²⁰⁸ *Sturgeon’s Law*, WIKIPEDIA.COM, http://en.wikipedia.org/wiki/Sturgeon's_Law.

Jones describe our EMRs as functioning “less as ‘ATM cards,’” allowing a patient or provider to access needed health information anywhere at any time, than as ‘frequent flier cards’ intended to enforce brand loyalty to a particular health care system.”²⁰⁹

Still there are more issues. HIT persists in underperforming and particularly seems to have quality and safety issues. First, and of considerable concern, there is evidence that current EMR and CPOE products do not significantly improve health care across quality, safety or efficiency dimensions, particularly when they are used in isolation.²¹⁰

Second, some HIT products introduce additional adverse events into the health care system.²¹¹ As noted above, the FDA has been tracking HIT adverse events since 2009, but HHS seems to have favored only light regulation during what it seemed to consider the fragile period of MU adoption.²¹² Indeed, the certification process for EMRs that qualify for MU currently does not include safety criteria, although a safety surveillance plan was announced by ONC in July 2013.²¹³ There are now many studies detailing safety problems with HIT²¹⁴ and the phenomenon was extensively explored by the IoM in

²⁰⁹ Kellermann, *supra* note 81 at 64.

²¹⁰ See Karen C. Nanji et al., *Errors Associated with Outpatient Computerized Prescribing Systems*, 18 J. AM. MED. INFORM. ASS’N 767, 767 (2011); Jesse C. Crosson et al., *Typical Electronic Health Record Use in Primary Care Practices and the Quality of Diabetes Care*, 10 ANNALS FAM. MED. 221, 221 (2012); Daria O’Reilly et al., *Cost-Effectiveness of a Shared Computerized Decision Support System for Diabetes Linked to Electronic Medical Records*, 19 J. AM. MED. INFORM. ASS’N 341, 341 (2012); Ajit Appari et al., *Meaningful Use of Electronic Health Record Systems and Process Quality of Care: Evidence from a Panel Data Analysis of U.S. Acute-Care Hospitals*, 48 HEALTH SERVS. RESEARCH 354, 371 (2012); Danny McCormick et al., *Giving Office-Based Physicians Electronic Access to Patients’ Prior Imaging And Lab Results Did Not Deter Ordering Of Tests*, 31 HEALTH AFFAIRS 488, 493 (2012); cf. Mary Reed et al., *Implementation of an Outpatient Electronic Health Record and Emergency Department Visits, Hospitalizations, and Office Visits Among Patients With Diabetes*, 310 JAMA 1060, 1060(2013).

²¹¹ See generally Sue Bowman, *Impact of Electronic Health Record Systems on Information Integrity: Quality and Safety Implications*, PERSPECTIVES IN HEALTH INFORMATION MANAGEMENT (Fall 2013), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3797550/>.

²¹² See generally text accompanying note 269.

²¹³ THE OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, HEALTH INFORMATION TECHNOLOGY PATIENT SAFETY ACTION & SURVEILLANCE PLAN (July 2, 2013), available at http://www.healthit.gov/sites/default/files/safety_plan_master.pdf.

²¹⁴ See, e.g., Heather L. Farley, *Quality and Safety Implications of Emergency Department*

their 2011 report "Health IT and Patient Safety: Building Safer Systems for Better Care."²¹⁵

Recently the Pennsylvania Safety Authority has issued a patient safety advisory warning of errors that occur when clinicians fail to change default values such as data or dosage in EMRs.²¹⁶ And the UnitedHealth Group recalled, through its manufacturer, emergency department electronic health record software because of errors associated with missing physician notes.²¹⁷ Quantifying the risks involved likely has been hampered by vendors' use of "gag" clauses, clauses that limit disclosure of product errors or inadequate performance, in EMR supply contracts with health care providers.²¹⁸ However, in June 2013, in its newly issued code of conduct, the EHRA brought an end to these clauses, at least for those vendors who signed on to the code.²¹⁹ Currently, the FDASIA Workgroup is undertaking the most active analysis of HIT safety issues. The Workgroup is named after the Food and Drug Administration Safety Innovation Act of 2012 that mandated its work,²²⁰ and it is charged with developing "an appropriate, risk-based regulatory framework pertaining to health information technology."²²¹

Information Systems, 62 ANNALS OF EMERGENCY MED. 399, 399 (2013); Joan S. Ashet et al., *Some Unintended Consequences of Information Technology in Health Care: The Nature of Patient Care Information System-Related Errors*, 11 J. AM .MED. INFORM. ASSOC. 104, 104 (2004); Farah Magrabi et al., *Patient Safety Problems Associated with Healthcare Information Technology: an Analysis of Adverse Events Reported to the US Food and Drug Administration*, 2011 ANN. SYMP. PROC. 853, 853 (2011).

²¹⁵ INSTITUTE OF MEDICINE, HEALTH IT AND SAFETY: BUILDING SAFER SYSTEMS FOR BETTER CARE 59-76 (2011), available at [http://www.iom.edu/~media/Files/Report Files/2011/Health-IT/HealthITandPatientSafetyreportbreiffinal_new.pdf](http://www.iom.edu/~media/Files/Report%20Files/2011/Health-IT/HealthITandPatientSafetyreportbreiffinal_new.pdf).

²¹⁶ Erin Sparnon, *Spotlight on Electronic Health Record Errors: Errors Related to the Use of Default Values*, 10PA PATIENT SAFETYADVIS. 92 (2013), available at [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2013/sep;10\(3\)/Pages/92.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2013/sep;10(3)/Pages/92.aspx).

²¹⁷ Class 2 Recall ED PulseCheck, FDA (July 29, 2013), <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=119832>.

²¹⁸ Bonnie Darves, *EHR Vendor Contract Controversy Persists*, IHEALTHBEAT (May 07, 2012), <http://www.ihealthbeat.org/insight/2012/ehr-vendor-contract-controversy-persists>.

²¹⁹ *EHR Developer Code of Conduct*, *supra* note 193.

²²⁰ Food and Drug Administration Safety Innovation Act, Pub. L. No. 112-144, § 618, 126 Stat. 993, 1063 (2012) (codified at 21 U.S.C. § 618 (2012)).

²²¹ *Id.* at §618(a); Preliminary workgroup recommendations have been presented to the ONC's

Third (and undoubtedly explaining some of the other flaws just discussed), the current generation of HIT seems to suffer from major usability problems.²²² As noted by one physician, “many electronic health record systems have pull-down screens listing each of the 68,000 possible diagnosis codes . . . and 87,000 possible procedure codes.”²²³ Worse, clinical decision support (CDS) products seem to generate “alert fatigue” in physicians²²⁴ and CPOEs have been found to have “inadequate alert interface design.”²²⁵ Christine Sinsky and John Beasley, having observed physicians unsuccessfully multitask patient interactions with data entry, concluded: “Reducing texting while doctoring will decrease the hazards of distracted physicians making perceptual and cognitive errors during the medical encounter.”²²⁶

A 2013 RAND study summarized the adverse impact of the current generation of EMRs on physician professional satisfaction as follows: “Poor EHR usability, time-consuming data entry, interference with face-to-face patient care, inefficient and less fulfilling work content, inability to exchange health information between EHR products, and degradation of clinical documentation were prominent sources of professional dissatisfaction.”²²⁷

HIT Policy Committee. See *HIT Policy Committee Approves FDASIA Workgroup Recommendations*, HIMSS (Sept 6, 2013), <http://www.himss.org/News/NewsDetail.aspx?ItemNumber=22239>.

²²² See generally HIT STANDARDS COMMITTEE & HIT POLICY COMMITTEE IMPLEMENTATION AND USABILITY HEARING (July 23, 2013), available at http://www.healthit.gov/sites/default/files/archive/FACA%20Hearings/2013-07-23%20Policy%3A%20Implementation%20%26%20Usability%20Hearing/2013-07-23_standards_si_hearing_transcript_final.pdf.

²²³ Morhaim, *supra* note 182.

²²⁴ M. Susan Ridgely & Michael D. Greenberg, *Too Many Alerts, Too Much Liability: Sorting Through the Malpractice Implications of Drug-Drug Interaction Clinical Decision Support*, 5 ST. LOUIS U.J. HEALTH L. & POL’Y 257, 259 (2011–2012).

²²⁵ Alissa L. Russ et al., *Prescribers’ Interactions with Medication Alerts at the Point of Prescribing: A Multi-Method, in Situ Investigation of the Human–Computer Interaction*, 81 INT’L J. MED. INFORMATICS 232, 240 (2012).

²²⁶ Christine A. Sinsky & John W. Beasley, *Texting While Doctoring: A Patient Safety Hazard*, 159 ANN. INTERN. MED. 782, 783 (2013).

²²⁷ MARK W. FRIEDBERG ET AL., FACTORS AFFECTING PHYSICIAN PROFESSIONAL SATISFACTION AND THEIR IMPLICATIONS FOR PATIENT CARE, HEALTH SYSTEMS, AND HEALTH POLICY, RAND CORP. xv, xvi (2013).

Abraham Verghese coined the label *iPatient* to describe the interaction of the provider with the electronic facsimile of the patient created by HIT.²²⁸ He argues that the “iPatient threatens to become the real focus of our attention, while the real patient in the bed often feels neglected, a mere placeholder for the virtual record.”²²⁹ Some doctors report reverting to pen and paper so that they are not distracted from dialog with the patient, but then have to type the electronic note after the patient leaves.²³⁰ Research from a community emergency department seems to substantiate these problems with Robert Hill and colleagues finding physicians spent 44% of their time on data entry, 12% reviewing test results and records, and only 28% in direct patient care.²³¹ Faced with such issues, hospitals are frequently turning to professional “scribes” to relieve their doctors of the burdens associated with operating hard-to-use EMRs.²³²

Not surprisingly, usability may be the greatest current technological barrier to effective HIT implementation. Spencer Jones and colleagues argue for “[u]ser-centered design calls for end users to be involved in every stage of product development. . . . Maximizing the productivity of health IT will require that commercial IT vendors also adopt user-centered design principles, but such practices aren’t yet sufficiently widespread.”²³³ In the words of Paul Tang, “[t]he ultimate goal of meaningful use of an EHR is effective use and exchange of electronic health information to improve health care and

http://www.rand.org/pubs/research_reports/RR400/RR439/RAND_RR439.pdf.

²²⁸ Abraham Verghese, *Treat the Patient, Not the CT Scan*, N.Y. TIMES (Feb. 26, 2011), http://www.nytimes.com/2011/02/27/opinion/27verghese.html?_r=2&ref=homepage&src=me&pagewanted=all.

²²⁹ *Id.*

²³⁰ Morhaim, *supra* note 182.

²³¹ Robert G. Hill Jr. et. al., *4000 Clicks: A Productivity Analysis of Electronic Medical Records in a Community Hospital ED*, 31 AM. J. EMERGENCY MED. 1591, 1591 (2013).

²³² Harris Meyer, *Scribes are Doctors’ Tech Support*, L.A. TIMES (Sept. 6, 2010), <http://articles.latimes.com/2010/sep/06/health/la-he-medical-scribes-20100906>; see also Sinsky & Beasley, *supra* note 226, at 782 (“Emerging innovative models hold promise. We have observed in other practices and developed our own collaborative care model in which nurses, medical assistants, or health coaches manage electronic information, thus allowing the physician to provide undivided attention to the patient.”).

²³³ Jones et. al., *supra* note 104, at 2244-45.

manage chronic disease while decreasing costs and inefficiencies.”²³⁴ This requires time, education, workflow redesign and improvement of the overall health care delivery system.²³⁵ Overall it is hard to disagree with the conclusion of Kellermann and Jones:

If market forces were allowed to work, doctors might drive vendors to produce more usable products. But it is currently difficult, if not impossible, for providers to get comparative data on the usability of competing health IT systems. Instead of demanding product transparency or insisting that health IT vendors create more user-friendly technology, many large health care systems have rushed to adopt existing systems to qualify for time-limited incentives. As a result, their clinicians must read thick user manuals, attend tedious classes, and accept periodic tutoring from ‘change champions’ to master the various steps required to enter and retrieve data.²³⁶

At the very least, if it is to achieve its goals, including assisting in the fight against fragmented care, our underperforming HIT must get a lot better.

d. Matching Processes and HIT

Here it is necessary to address two mirrored problems. The first was discussed above noting how HIT has, to an extent, “parachuted” into an unchanged (and only slowly changing) health care environment. Second, it is necessary to examine the “forcing” that takes place when IT workflows are imposed on health care workflows without adjustment. The dangers here are as well known as they are varied. First, extant health care workflows are frequently expected to adjust to the new HIT tools visited upon them. Second, many providers, at least those who are not transforming their care models, may simply slide siloed EMRs or other poorly thought out HIT into their existing dysfunctional workflows, destined to find themselves added to the victims of the IT productivity paradox.²³⁷

²³⁴ Letter from Paul Tang, Vice Chair, Health IT Comm., to David Blumenthal, Nat’l Coordinator for Health Info. Tech., Office of the Nat’l Coordinator (Aug. 10, 2009) [hereinafter Tang Letter]; see also David Blumenthal, *Launching HITECH*, 362 NEW ENG. J. MED. 382, 382 (2010).

²³⁵ Tang Letter, *supra* note 234.

²³⁶ Kellermann & Jones, *supra* note 81 at 65.

²³⁷ See generally Jones et al., *supra* note 104, at 2243.

Ben-Tzion Karsh and Richard Holden have argued “Successful HIT outcomes depend on the fit between elements within the work system where the HIT is implemented.” In particular correctly mapping technology to healthcare workflows seems particularly challenging.²³⁸ The IoM seems to be on the same page:

[I]nitiatives that focus merely on incremental improvements and add to a clinician’s daily workload are unlikely to succeed. Just as the quantity of clinical information now available exceeds the capacity of any individual to absorb and apply it, the number of tasks needed for regular care outstrips the capabilities of any individual. Significant change can occur only if the environment, context, and systems in which these professionals practice are reconfigured so that the entire health care infrastructure and culture support learning and improvement.²³⁹

Earlier, this article discussed Walker and Carayon’s observation that HIT focuses on “improving the performance of isolated tasks rather than on supporting team-executed, value-added processes of care.”²⁴⁰ One of their examples is the CPOE, which they note “is frequently described as the ‘Holy Grail’ of health IT.”²⁴¹ They also note that while order entry is “a one-person task” order management is a “complex process” involving many persons playing “distinct but flexible and overlapping roles to plan, order, review, adjust, dispense, administer, and monitor the effects of medications and other orders throughout an episode of care.”²⁴² Yet, “health IT researchers and developers have focused almost exclusively on the task of CPOE” rather than “analyzing the process of order management and designing health IT to support it.”²⁴³ Walker and Carayon also make the crucial observation, “[p]rocesses that are computerized without careful analysis and redesign can lead to inefficiencies and workarounds, with potential loss of patient

²³⁸ Richard J. Holden & Ben-Tzion Karsha, *A theoretical model of health information technology usage behaviour with implications for patient safety*, 29 BEHAVIOUR & INFO. TECH. 21, 30 (2009).

²³⁹ INST. OF MED., *supra* note 2, at S-12.

²⁴⁰ Walker, *supra* note 90, at 467.

²⁴¹ *Id.* at 468.

²⁴² *Id.*

²⁴³ *Id.*

safety.”²⁴⁴ Not surprisingly they recommend team-based approaches, the identification of value-added processes, and the design of HIT to support these processes.

Clearly therefore the HIT choices and matching of HIT to improved team-based processes are paramount. According to Jones and colleagues:

Health care professionals are tempted to simply digitize paper-based workflows, but swapping out the medical record cabinet and prescription pad for a computer is proving insufficient to realize the benefits of health IT. Instead, newly IT-enabled processes that support teamwork, care coordination, and innovative approaches such as interactive patient portals have the potential to yield greater convenience, access, and quality for patients and physicians at a lower cost — the definition of greater productivity.²⁴⁵

VI. LEGAL AND REGULATORY BARRIERS

This article generally has focused on the hypothesis that flaws in health care or HIT markets explain the sluggish or ineffective implementation of IT in the health care space. In contrast, this section questions whether a somewhat exogenous explanation is credible—that legal or regulatory incentives or disincentives are in some way responsible.

It is certainly arguable that the legal system has been an uninformed and frequently negative force in the development of health care. Its indolence was captured perfectly by an Australian judge who pithily described the law’s inability to comprehend the realities of medical care as “[l]aw, marching with medicine but in the rear and limping a little.”²⁴⁶ Equally exasperated the Supreme Court of New Jersey later complained: “Our medical-legal jurisprudence is based on images of health care that no longer exist.”²⁴⁷ Reinforcing the outdated conception that medical rights and duties stem from the bilateral model of the physician-patient relationship and perpetuating

²⁴⁴ *Id.* at 470.

²⁴⁵ Jones et al., *supra* note 104, at 2244.

²⁴⁶ *Mount Isa Mines v. Pusey* (1970) 125 C.L.R. 383, 395.

²⁴⁷ *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245, 1246 (N.J. 1999).

the professional hegemony that met its end several decades ago, is at the root of the problem.²⁴⁸

Worse, the law (except when it really mattered, when exceptionalism was argued before the Supreme Court²⁴⁹) has promulgated various types of health care exceptionalism that have had the effect of distancing health care enterprises from the realities and incentives faced by other enterprises. There are plenty of examples. Thus, the standard of care in most adverse event cases has retained the pro-enterprise custom-based negligence standard²⁵⁰ that was jettisoned for other businesses almost a century ago²⁵¹ while courts have been sluggish in applying evidence-based principles in health care litigation.²⁵² Similarly and exceptionally the courts have refused to extend products liability to hospitals when they were involved in the chain of distribution of defective drugs or devices.²⁵³

Or take institutional liability. Over fifty years ago the New York Court of Appeals recognized that "The conception that the hospital does not undertake to treat the patient, does not undertake to act through its doctors and nurses, but undertakes instead simply to procure them to act upon their own responsibility, no longer reflects the fact."²⁵⁴ But then in a classic instance of pulling defeat from the jaws of victory the court applied a badly wounded version of vicarious liability rather than the direct or corporate liability model it had justified. This not only had the effect of delaying the adoption of corporate negligence²⁵⁵ but also allowed the courts to become invested in inefficient line-drawing exercises as to the reach of

²⁴⁸ See, e.g., Starr, *supra* note 21.

²⁴⁹ See, e.g., Abigail R. Moncrieff, *Understanding the Failure of Health-Care Exceptionalism in the Supreme Court's Obamacare Decision*, CHEST, July 16, 2012, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2109396 (noting the Supreme Court's refusal to recognize special constitutional treatment for healthcare legislation).

²⁵⁰ See, e.g., Hall v. Hilburn, 466 So. 2d 856 (Miss. 1985).

²⁵¹ The T.J. Hooper, 60 F.2d 737 (2d Cir. 1932).

²⁵² See, e.g., Hinlicky v. Dreyfuss, 6 N.Y.3d 636 (2006) (clinical practice guidelines); see generally David M. Eddy, *Evidence-Based Medicine: A Unified Approach*, 24 HEALTH AFFAIRS 9 (2005).

²⁵³ See, e.g., Royer v. Catholic Medical Center, 741 A.2d 74 (N.H. 1999).

²⁵⁴ Bing v. Thunig, 2 N.Y.2d 656, 666 (1957)

²⁵⁵ See generally Darling v. Charleston Community Memorial Hospital, 33 Ill. 2d 326 (1965); Thompson v. Nason Hosp., 527 Pa. 330, 591 A.2d 703, 707 (Pa. 1991)

various doctrines such as apparent agency.²⁵⁶ Once delayed, corporate negligence arrived in less than pristine condition.²⁵⁷ And, its growth has been hindered by still more judicial fantasies about health care practices such as the extraordinary conclusion that a “hospital does not know the patient’s medical history, nor the details of the particular surgery to be performed” that was used to justify not extending corporate liability to informed consent cases.²⁵⁸

Beyond the ill-informed or maybe sluggish work of the common law courts, critical fire is often aimed at the regulatory systems applied to health care and its stakeholders. There are two common complaints. First, over-regulation is targeted as stifling innovation. Second, legal indeterminacy is held out as causing market hesitancy.

Over-regulation seems a justified criticism of how state medical boards have reacted to telemedicine. The hoops that state boards make out-of-state licensed physicians jump through before being permitted any virtual presence bespeak either protectionism or technophobia.²⁵⁹ While telemedicine would appear to be an attractive model at a time when *increased* access to health care is urgently required and rural areas are particularly hard hit, a large number of U.S. states have re-written their licensure rules to make them less amenable to treating underserved populations. The modern excuse, of course, is the ‘war on drugs.’ State legislatures or medical boards increasingly require what they describe as a “traditional” or “proper” relationship between the prescribing physician and the patient. This approach is designed to guarantee in-person contact or a “good faith prior examination,” thus outlawing so-called “questionnaire

²⁵⁶ See, e.g., *Roessler v. Novak*, 858 So.2d 1158, 1163-65 (Fla. App. 2nd Dist. 2003), Chief Judge Altenbernd concurring (“[O]ur twenty-year experiment with the use of apparent agency as a doctrine to determine a hospital’s vicarious liability for the acts of various independent contractors has been a failure.”); see also *Jackson v. Power*, 743 P.2d 1376, 1385 (Alaska 1987).

²⁵⁷ See, e.g., *Gafner v. Down E. Community Hosp.*, 735 A.2d 969 (Me. 1999)

²⁵⁸ *Krane v. Saint Anthony Hosp. Systems*, 738 P.2d 75 (Colo. App. 1987); see also *Ward v. Lutheran Hospitals & Homes Society Of America, Inc.*, 963 P.2d 1031 (Alaska 1998)

²⁵⁹ See generally Nicolas P. Terry, *Prescriptions sans Frontières (or How I Stopped Worrying about Viagra on the Web but Grew Concerned about the Future of Healthcare Delivery)*, 4 YALE J. OF HEALTH POL’Y. L. ETHICS 183 (2004).

prescribing."²⁶⁰

Another argument is that existing regulatory models hamper a necessary shift from an era of professional hegemony to integrated care systems. For example, Elisabeth Belmont and colleagues arguing that licensing laws, eligibility criteria, and accreditation standards "reflect the historical focus on the competence or professionalism of each provider as an individual, rather than as part of a system of care." Jim Blumstein has made a similar point, suggesting legal doctrines continue to elevate physician interests over those of the institutions in which they practice.²⁶¹ According to Belmont and her colleagues:

One of the biggest impediments to a fully integrated systems-based approach to quality oversight is the historic division of management and medical oversight functions in the hospital setting, a separation now embodied in many state licensure laws, Medicare requirements, and accreditation standards. . . . This can have the practical effect of segregating the hospital's medical leadership from the institution's management structure, thus making bold action toward systems-base care less likely.²⁶²

Structural issues aside, do our legislative, regulatory or judicial bodies have any comprehension of the HIT-health care interface? A *Ponemon Institute* study made headlines in 2013²⁶³ with an estimate that "outdated communication technologies" caused an annual \$8.3 billion cost in "decreased clinician productivity and lengthier patient discharge times." The implication was that "more modern and efficient technologies" did not satisfy security and privacy policies and regulation.²⁶⁴ More recently the OCR, HHS's HIPAA enforcement

²⁶⁰ The California statute provides that, "[p]rescribing, dispensing, or furnishing dangerous drugs . . . without a good faith prior examination and medical indication therefor, constitutes unprofessional conduct." CAL. BUS. & PROF. CODE § 2242(a); *see also* ARIZ. STAT. § 32-1854(51).

²⁶¹ James F. Blumstein, *Setting the Analytical Framework for Managing and Regulating the Relationship*, in *THE FRAGMENTATION OF U.S. HEALTHCARE*, 135 (Einer Elhauge ed., 2010).

²⁶² Elisabeth Belmont et al., *A New Quality Compass: Hospital Boards' Increased Role Under the Affordable Care Act*, 30 *HEALTH AFFAIRS* 1828 (2011).

²⁶³ Byron Acohido, *Hospitals lose \$8.3 billion using old technology*, USA TODAY (May 8, 2013, 11:01 A.M.) <http://www.usatoday.com/story/cybertruth/2013/05/07/healthcare-technology-cybersecurity-privacy-patient-care/2142739/>.

²⁶⁴ PONEMON INSTITUTE, *THE ECONOMIC AND PRODUCTIVITY IMPACT OF IT SECURITY ON*

arm, published the extraordinary estimate that stakeholders would take 32.8 million hours to comply with the Omnibus Rule's HIPAA and GINA requirements.²⁶⁵

The argument that over-regulation is chilling the adoption of health care technologies is not a new one. For example, the Bush administration's HIT narrative included the characterization of divergent state laws ("variations in privacy and security policies that can hinder interoperability") as impeding the nationwide plan to implement EMRs and their national interoperability.²⁶⁶ The Bush Administration wanted to replace the HIPAA Code "floor," whereby more stringent state privacy protections are not preempted, with existing or reduced HIPAA protections as the new "ceiling."²⁶⁷ The issue was even raised in some tense exchanges between the Government Accountability Office (GAO) and the Office of the National Coordinator for Health Information Technology.²⁶⁸

A different type of potentially damaging regulation was identified by the Obama administration as impacting the subsidized EMR program. The FDA has been monitoring iatrogenic HIT events

HEALTHCARE (May 2013), available at <http://www.imprivata.com/Ponemon-economic-impact-study>. The survey found that "HIPAA reduces time available for patient care (according to 85 percent of respondents), makes access to electronic patient information difficult (79 percent)" and "restricts the use of electronic communications (56 percent)." *Id.* at 11.

²⁶⁵ Department Of Health And Human Services, Office of the Secretary Agency Information Collection Activities; Submission to OMB for Review and Approval, 78 FR 54667, Sept. 4, 2013, available at <http://www.gpo.gov/fdsys/pkg/FR-2013-09-04/pdf/2013-21398.pdf>

²⁶⁶ *Activities of the Office of the National Coordinator for Health Information Technology: Testimony before the S. Comm. on Commerce, Science, and Transportation Subcomm. on Technology, Innovation, and Competitiveness*, 109th Cong. (2005) (statement of David J. Brailer, M.D., Ph.D., National Coordinator for Health Information Technology, U.S. Department of Health and Human Services) <http://www.hhs.gov/asl/testify/t050630a.html>.

²⁶⁷ Nicolas P. Terry & Leslie P. Francis, *Ensuring The Privacy and Confidentiality of Electronic Health Records*, 2007 U. ILL. L. REV. 681, 681-735 (2007).

²⁶⁸ *Health Information Technology: Efforts Continue but Comprehensive Privacy Approach Needed for National Strategy: Testimony Before the Subcomm. on Information Policy, Census, and National Archives Comm. on Oversight and Government Reform*, GAO-07-988T (2007) (statement of Linda D. Koontz, Director, Information Management Issues); *Health Information Technology: HHS is Pursuing Efforts to Advance Nationwide Implementation, but Has Not Yet Completed a National Strategy: Testimony Before the Senate Comm. on the Budget*, GAO-07-988T (2008) (statement of Valerie C. Melvin, Director, Human Capital Management Information Systems Issues).

and has characterized its own regulatory inaction as an exercise of discretion as it evaluates the field.²⁶⁹ Even in the absence of a formal reporting system, the FDA disclosed in 2010 that it had recorded 260 HIT-related “malfunctions” in the preceding two years.²⁷⁰ Potential regulatory responses range from post-market surveillance to full FDA device premarket approval.²⁷¹ In contrast, both the HIT industry and ONC believed that safety regulation would slow innovation and implementation.²⁷² The IoM was asked to weigh in on the issue and recommended that a new entity, the Health IT Safety Council, should be established within HHS to collect and provide information and set safety standards.²⁷³ In 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) required the HHS Secretary to create “a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.”²⁷⁴ In 2014 the targeted agencies responded with a regulation-light, risk-based strategy.²⁷⁵ EMRs and other devices

²⁶⁹ *Examining Federal Regulation of Mobile Medical Apps and Other Health Software: Hearing Before the Subcomm. on Health Committee on Energy and Commerce, FDA Dept. of Health and Human Servs.* (2013) (statement of Jeffrey Shuren, Director, Center for Devices and Radiological Health).

²⁷⁰ Fred Schulte & Emma Schwartz, *FDA Considers Regulating Safety of Electronic Health Systems*, HUFFINGTON POST (Apr. 25, 2010, 6:12 AM), http://www.huffingtonpost.com/2010/02/23/fda-considers-regulation_n_474137.html; Fred Schulte & Emma Schwartz, *Electronic Medical Record Shift: Signs of Harm Emerge As Doctors Move From Paper*, HUFFINGTON POST (June 20, 2010, 6:12 AM), http://www.huffingtonpost.com/2010/04/20/electronic-medical-record_n_545441.html.

²⁷¹ See generally *Overview of Device Regulation*, FDA (March 5, 2013), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm>.

²⁷² Schulte, *supra* note 270; Neil Versel, *FDA, ONC Clash Over EMR Safety Issues*, FIERCE EMR (August 5, 2010), <http://www.fierceemr.com/story/fda-onc-clash-over-emr-safety-issues/2010-08-05>; Milt Freudenheim, *Panel Set to Study Safety of Electronic Patient Data*, N.Y. TIMES (Dec. 13, 2010), <http://www.nytimes.com/2010/12/14/business/14records.html>.

²⁷³ INST. OF MED., *supra* note 215, at 7.

²⁷⁴ Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-114, § 618, 126 Stat. 993, 1063 (2012).

²⁷⁵ FDA, FCC, ONCE, FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework, April 2014,

managing “health management health IT functions generally will not be regulated by the FDA.”²⁷⁶ However, the report did endorse the creation of a public-private Health IT Safety Center to collect data on and promote HIT safety.²⁷⁷ In straining to avoid untimely over-regulation, the FDA may have under-regulated. If the agency had asserted its jurisdiction over EMRs rather than backing down to ONC and CMS during MU, maybe better, safer products would have been brought to market (admittedly later).

Why does the legal system perpetuate indeterminacy and so create disincentives to market solutions (markets preferring certainty)? Mark Hall and Kevin Schulman wrote the most cogent critique, albeit prior to the MU subsidy program and HITECH’s tightening of the privacy rule. They contemplated “the dystopia of health care information automation” and questioned whether legal rules created the unfriendly economics of HIT and hence the “balkanization of medical information.”²⁷⁸ Their “unfriendly economics” hypothesis was laid at the feet of legal indeterminacy surrounding the property interests in what they assumed to be exploitable, but yet unexploited, medical information. Specifically, they argued, “[a]ll parties are looking to the law to define the ownership, control, and commercialization potential of medical information.”²⁷⁹ In fact, these legal positions are reasonably clear. Physicians and hospitals have (as a matter of state law²⁸⁰) ownership rights in their records, although HIPAA grants patients not inconsistent quasi-property rights of access²⁸¹ and amendment.²⁸² More recently, HITECH’s Omnibus privacy rule added a gloss of partial inalienability, “a covered entity or business associate may not

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf>.

²⁷⁶ *Id.* at 12.

²⁷⁷ *Id.* at 14-15.

²⁷⁸ Hall & Schulman, *supra* note 158, at 165-66, 169.

²⁷⁹ *Id.* at 177.

²⁸⁰ *See, e.g.*, CAL. CODE REGS. tit. 22, § 70751(b) (2014); LA. REV. STAT. ANN. § 40:1299.96(A)(2) (2013).

²⁸¹ Access of Individuals to Protected Health Information, 45 C.F.R. § 164.524 (2014).

²⁸² Amendment of Protected Health Information, 45 C.F.R. § 164.526 (2014).

sell protected health information,"²⁸³ subject to some exceptions.²⁸⁴

Legal indeterminacy is often the slogan chosen by those who believe less that the current state is indeterminate and more that the current determined state is frustrating their particular goal. This was the case with the Bush administration's critique of HIPAA's preservation of some state privacy regimes.²⁸⁵ So, is the fact that the current health privacy model stops providers from externalizing privacy risks to patients the real target for Hall and Schulman? That does not seem the case. Although in favor of loosening the trade in medical information, they are clear that "special protections and institutions are needed to prevent marketplace abuses"²⁸⁶ including "giving patients a nonwaivable right to terminate permission to access and use their information, and making their rights to inspect, copy, and correct medical information inalienable."²⁸⁷ This was not the language of those who wish to remove privacy protections. Indeed it was quite prescient, foretelling the proposed EU approach to increasing data protection that adds a quasi-property 'right to erase' to run with the subject's data.²⁸⁸ What, however, of the broader point made by Hall and Schulman in favor of transfer payments between custodians of patient data? This position is grounded in their statement that, "[i]ncreasingly, participants in and observers of the HIT sector recognize that monetizing access to medical information is necessary in order to align interests and overcome the economic barriers to forming [interactive] EMRs."²⁸⁹ The proposition seems to be that providers will demand far better (i.e. truly interoperable) EMRs from vendors so they can engage in a (privacy

²⁸³ Uses and disclosures of protected health information: General rules, 45 C.F.R. § 164.502(a)(5)(ii)(A) (2014).

²⁸⁴ Uses and disclosures of protected health information: General rules, 45 C.F.R. § 164.502(a)(5)(ii)(B) (2014).

²⁸⁵ See *supra* text accompanying note 268.

²⁸⁶ Hall & Schulman, *supra* note 278, at 199.

²⁸⁷ *Id.*

²⁸⁸ *Proposal for a Regulation of the European Parliament and of the Council on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data (General Data Protection Regulation)*, COM (2012) 11 final (Jan. 25, 2012).

²⁸⁹ Hall, *supra* note 278, at 176.

law-restricted) patient data market. Given that there is no real legal indeterminacy, why is this not happening today?²⁹⁰ Either the benefit of freely moving patient data is being outbid by the providers' real or assumed proprietary value of their data or once again we must confront an underperforming EMR industry that cannot respond to providers' data market aspirations.

VII. MOVING BEYOND THE CHICKEN-AND-EGG BOTTLENECK

Hall and Schulman, like so many others who have studied fragmentation, came to the conclusion that "health care finance and delivery cannot be defragmented just by pressing a button"²⁹¹ forcing a "search for effective ways to manage and mitigate its information management symptoms, along with all its other ills."²⁹² There are two strategies that are likely to break the bottleneck and bring true IT benefits to health care. The first is as fundamental and obvious as it is politically toxic—pressure on prices.

Insurance regulations aside, the ACA's modest approaches to bend the cost curve primarily punish very expensive practices (e.g. readmissions) or promote provider integration. However, the initial ACOs have seemed more adept at increasing quality than reducing prices,²⁹³ while even fully integrated care models (with superior HIT) such as Kaiser have found it difficult to make major cost reductions.²⁹⁴ Further pressure on prices is inevitable and needs to be introduced sooner rather than later. While providers continue to extract profit from FFS, they will pick only the low-hanging fruit of reform. In contrast, major reimbursement reform will force them to engage in the radical re-engineering that *Lean* and similar models require, and

²⁹⁰ To be clear, there is a thriving market in patient information operating outside of HIPAA-protected space. However, it doesn't seem to be connected, negatively or positively, to EMR deployment; See Nicolas Terry, *supra* note 59.

²⁹¹ Hall, *supra* note 278, at 173.

²⁹² *Id.*

²⁹³ See Melinda Beck, *Mixed Results in Health Pilot Plan*, WALL ST J. (Jul. 16, 2013, 12:01 AM), <http://online.wsj.com/news/articles/SB10001424127887323664204578608252999249808> (discussing Pioneer ACO performance).

²⁹⁴ See, e.g., Abelson, *supra* note 160.

that will make them more amenable to additional cost savings provided by IT. The Advisory Board has noted that although some health care providers have favored *Lean*-like models since the 1980s, “[c]omplex and variable hospital processes have been difficult to break down and standardize, and real-time performance measures, common in Lean Manufacturing, are few and far between in hospitals.”²⁹⁵

Lean and its fellow travelers must be elevated from management sloganeering to operational imperatives, and that has to be done by price pressure, particularly with regard to improving patient flow management.²⁹⁶ The shift from FFS to bundled or capitated payment systems has to be accelerated.²⁹⁷

The second strategy is no more industry friendly. Providers disliked the unfunded mandate to upgrade technology inherent in HIPAA’s Administrative Simplification. Since then, regulators have avoided such mandates, hoping instead to rely on markets or jump-start failing ones. There are only a few exceptions. For example, a decade ago a California statute required larger hospitals to design medical error-reducing strategies that included HIT implementation.²⁹⁸ More recently, the Excellence in Diagnostic Imaging Utilization Act of 2013 that broadly requires evidence-based criteria as preconditions for the ordering of diagnostic imaging essentially requires the use of CDS tools.²⁹⁹ The potential for direct regulatory intervention is important as MU shows signs of stagnation. It is likely that the MU program will sputter on through

²⁹⁵ DOUGLAS THOMSON & ANTHONY PERRY, IMPLEMENTING LEAN IN HOSPITAL IT DEPARTMENTS: INCREASING CAPACITY WITHOUT PAYING FOR IT, THE ADVISORY BOARD COMPANY (July 25, 2012).

²⁹⁶ See generally Martha Hostetter & Sarah Klein, *In and Out of Hospitals and Beyond*, COMMONWEALTH FUND (Oct-Nov 2013), <http://www.commonwealthfund.org/Newsletters/Quality-Matters/2013/October-November/In-Focus-Improving-Patient-Flow.aspx?omnicid=13>.

²⁹⁷ See generally Guterman, *supra* note 28.

²⁹⁸ CAL. HEALTH & SAFETY CODE § 1339.63 (West 2004).

²⁹⁹ H.R. 3705, 113th Cong. (1st Sess. 2013); see generally Press Release, Congressman Erik Paulsen, Paulsen Introduces Legislation to Streamline and Enhance U.S. Healthcare Delivery (Dec. 11, 2013), available at <http://paulsen.house.gov/press-releases/paulsen-introduces-legislation-to-streamline-and-enhance-us-healthcare-delivery/>.

various extensions and softening of requirements until the subsidy money is spent, at which point providers will attempt to persuade ONC-CMS to drop the regulatory “sticks” that are scheduled to follow. Here, the regulators need to stand their ground. MU (its sticks, not its carrots) needs to be extended, mandating a common data standard and the integration of other HIT components such as CDS. The current checklist-approach of MU must be abandoned and replaced with broader performance-based criteria, including procedure costs, usability, and safety.

There is a third way forward, but one that operates outside of the current health care system: disruption by IT-enabled outside attackers.³⁰⁰ The potential for HIT transformation of health care is twofold. First, major industrial players with tremendous IT skills and resources may build out into the health care space and transform some or all of it. Second, we are already seeing the emergence of disruptive technologies such as personal health technologies for patient curation of health records or the legion of smartphone wellness apps. True to the disruption model, currently these technologies appear inferior to traditional sustaining products offered by incumbents. How can a smartphone app even approach the diagnostic accuracy of an expert physician? However, and with little warning, such devices may achieve low cost/high convenience scale and task complexity to annex parts of the health care space from today’s health care incumbents.

VIII. CONCLUSION

This article has concerned itself with a general question: the potential for HIT to be the panacea for fragmentation and lack of coordination in contemporary health care delivery. Much of the discussion above has revolved less about HIT but focused more on the core competencies and processes that successful IT implementation seems dependent upon. However, it has also emphasized how HIT suffers from chronic (and classic) market failures and underperforming products that can result in quality, safety, and matching problems. Consistent with the “pit crews”

³⁰⁰ See generally Terry, *supra* note 75.

theme, something of a race has begun between incumbent reformers who would change the way health care is financed and organized, so as to better absorb IT, and attackers from outside who are moving disruptive health applications to personal devices such as smartphones.

The central question posed in this article, whether HIT can fix fragmentation, remains hard to answer. Given the problems and issues discussed herein, we still know too little about the potential impact of HIT on health care generally and on fragmentation issues specifically. It is still unclear whether IT adoption is capable of the same kind of transformative impact on health care as on other industries. The infamous 2005 RAND report noted that “when thought leaders discuss transforming health care with HIT, they are talking about the kinds of benefits seen in the telecom and securities industries: gains of 8 percent or more per year, year after year.”³⁰¹ However, the report was unclear whether such benefits could be replicated in the health care space: “the ingredients needed to achieve this growth (strong competition on quality and cost, substantial investments in EMR systems, an enhanced infrastructure that can accommodate increased future demand or reduce costs without increasing labor, a strong champion firm or institution that drives change, and integrated systems) are mostly absent in today’s health care industry.”³⁰²

Where does that leave government? About the only lever that has not been pulled (after market-leading, example, and subsidy) is an unfunded mandate. While politically unlikely, it is possible; for example, outcomes research being performed under ACA by AHRQ or PCORI could come up with a clear finding that could render such a mandate politically acceptable. For example, research (or ACO and PCMH experience) could conclude that either new HIT paradigms or HIT-friendly integrated team models need to be dramatically accelerated to “save” health care. Equally, it is possible that a new political consensus could emerge after the ACA’s reforms become embedded and relied upon; that consensus could form around the need to dramatically control costs forcing the industry into major re-

³⁰¹ Hillestad et al., *supra* note 6, at 1107.

³⁰² *Id.*

engineering.

Absent such dramatic twists, the chicken-and-egg narrative seen in this article will continue—which needs to be re-designed, health care or HIT? This article generally takes the position that it is the former, agreeing with Andrew Wiesenthal’s sentiment, “[a]t Kaiser Permanente, we did not introduce HIT in order to integrate; we introduced HIT to take advantage of our integrated systems.”³⁰³ Or to channel the words of the baseball catcher Bob Uecker, “[t]he way to catch a knuckleball is to wait until it stops rolling and pick it up.”³⁰⁴ When health care stops rolling, maybe a new generation of improved HIT will be ready. Unless, by then health care will have been fundamentally disrupted. In which case, we may all be staying healthy by using our own “Star Trek” tricorders.³⁰⁵

³⁰³ Wiesenthal, *supra* note 78, at 530.

³⁰⁴ Quoted in Benjamin Hoffman, *Not So Easy on the Eyes*, NY TIMES (Jun. 23, 2012), http://www.nytimes.com/2012/06/24/sports/baseball/knuckleball-is-tough-for-umpires-to-follow.html?pagewanted=all&_r=0.

³⁰⁵ See generally *Introducing the Qualcomm Tricorder XPRIZE*, QUALCOM TRICORDER, <http://www.qualcommtricorderxprize.org/>. See also Vivek Wadhwa, *Is iPhone 5S a version 1 of the Star Trek tricorder?*, WASH. POST, (Sept. 11, 2013, 11:42 AM), <http://www.washingtonpost.com/blogs/innovations/wp/2013/09/11/is-iphone-5s-a-version-1-of-the-star-trek-tricorder/>.