Information technologies in health care delivery and policy: giant steps and missteps

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Abstract
The influences of information technology have touched almost all aspects of our lives, and health care delivery has been no exception. Law, policy, and regulation have driven the adoption of electronic medical records, particularly over the past decade, driving fundamental changes to the practice of medicine in general and dermatology in particular. This article reviews the history of these changes, the regulations that drove these changes, the intended and unintended consequences of these initiatives, and our insights into the appropriate roles for policy and regulation to drive positive change.

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Health care has undergone, and continues to undergo, dramatic changes in how information is handled, influencing how medicine is practiced. There is a role for policies, policymakers, and regulations in this ongoing transition. However, as the saying goes, the devil is in the details, and the best intentions do not always translate into the best results, especially early in the process.

Within the physician community, there is a general consensus that how health information technology (HIT) has been deployed has created a host of unintended and undesirable consequences,1 including increased physician burnout, administrative burden, and a focus on insurance billing.2 Furthermore, the deployments have not been uniformly effective at improving patient care across a broad swath of health care delivery. The reasons for these suboptimal outcomes are complex and will not be amenable to simple solutions. In part, the issue is traceable to the processes of electronic medical record (EMR) software development involved, which have major barriers to correcting perceived flaws. In light of this, we must recognize that only some, but clearly not all, problems identified are amenable to policy and regulatory solutions.

In order to approach the issues around HIT and how regulatory and policy tools can drive new information that actually improves patient care, we need to better understand the issues we face and the future state we desire. At its core, HIT is valuable because it can improve our ability to use data to drive optimal practice. Various aspirational documents use this premise to propose frameworks for how this might come about.3-5 A unifying theme from all of these documents are basic principles focusing on the optimal use of information to facilitate health care delivery. A representative example is President George W. Bush’s Executive Order 13335 issued in August 2004, which created the Office of the National Coordinator for Health Information Technology (ONC) with the vision of developing a nationwide, interoperable HIT infrastructure (Table 1).6-8

These aspirations are all highly desirable. Similarly, the high-level goals of various pieces of legislation, including the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, and Medicare Access and Children’s Health Insurance Program Reauthorization Act (MACRA) of 2015, are also desirable. However, the questions that arise revolve around how to translate these aspirations into everyday reality. What tradeoffs are involved, and what is the appropriate role of policy and regulation to facilitate these goals? Therefore, the focus of this paper will be to look at the current policy and regulatory landscape governing HIT, including intended and unintended effects, examine some of the factors that have hindered the development of truly useful and widely adopted HIT, and touch upon new and current trends in regard to the future regulatory, policy, and payment landscape.

It makes intuitive sense that complex and unpredictable HIT systems may require careful planning approaches. However, perhaps what is needed as we enter the future is a view borrowed from design thinking for more prototyping and testing to imbue agility, flexibility, and innovation into our existing systems. Design thinking is not a new concept but a way of approaching problems that has gained widespread popularity, especially among Silicon Valley startups. From one definition, the process of design thinking includes 5 steps: (1) empathize with those who experience a problem, (2) define what the problem is, (3) ideate potential solutions, (4) prototype those solutions and iterate quickly, and finally, (5) test assumptions and potential solutions with rapid iteration. Swift iterations to improve the design of HIT is challenging, as the concepts of design thinking become more difficult to apply effectively to large institutions. Despite this, perhaps there is a way that regulation and policy can foster iterative cycles of build-measure-learn, as described in Lean Startups by Eric Reis, in order to implement improved HIT development strategies in our large enterprises, such that the process of improving HIT is a more routine and rapidly occurring process.7 The concept of design thinking has already been recognized to improve upon traditional interventions of chronic diseases by the Centers for Disease Control and Prevention.8 Outside of health care, a well-known example of this is found in the history of the iPhone, with the first iterations being the epitome of the minimal viable product. Dropped calls were frequent, and security was rudimentary at best. Apple went after
The evolution of medical documentation and billing

The earliest forms of physician documentation in the United States are traced back to New York Hospital in the early 19th century. Documentation was free-form and of the physician’s individual style.11 The purpose of this documentation was for reflection and to accumulate cases from which medical students could learn from their mentors. At its core, medical documentation was educational and for exclusive use by physicians. By the end of the century, around when dermatology started being recognized as an independent entity,12 physicians began appreciating the importance of the physician’s note beyond education—mainly for research and the sharing of best practices. Standardization, therefore, was needed for documents to be intelligible by a larger audience and was guided by standardized classifications of diseases emerging at the time.

The free exchange of mutually understandable information formed the backbone of our modern institutions of medicine.11,13 The idea of standardizing the medical documentation with an optimally functional format was transformed with the introduction of the problem-oriented medical record by Dr Larry Weed. His “subjective, objective, assessment, and plan” (SOAP) format transformed the patient’s problem list into the focal point of the medical encounter, moving personal notes about patients by their physicians into a more efficient tool for interprovider communication.14 The SOAP note documentation format continues to form the backbone of our encounter documentation to this very day. This transition happened because it served the needs of patients and the physicians who cared for them, not because it was mandated by regulation.

The rise of structured data collection in health care in the late 20th century—and more recently, the automation of data collection via EMRs—have led to the creation of massive data sets by which payers (insurance companies, Medicare, Medicaid) have turned micromanaging reimbursements into a science.15 These initiatives shifted the focus of data gathering in medicine from direct patient care to billing. Getting paid in a reasonable amount of time has become an intricate cat and mouse game in health care, such that now, EMR vendors market their software’s ability to efficiently capture reimbursements.

This is a huge motivator for physicians and health care organizations. After all, individual practices and systems cannot continue to function if they are not paid. However, the core functionality of EMRs has become the conversion of patient encounters into bill-
ing codes. An aspirational goal list of any new policy will not talk about ensuring cash flows, but the practical reality is that just about every provider and organization is fully, and often times painfully, aware of this. The current end of the feedback loop is reimbursement. We must recognize that if we are to change behavior, we must be sure we end up paying for what we desire. The challenge is whether policy and technology can work together to accomplish this goal.

Changes in technology and changes in society
The creation of EMRs and their widespread adoption, made possible by technological advances in software development and accelerated by legislation, is the single greatest driver of change to medical documentation.16 The early 1990s saw a push by the Institute of Medicine to create a more integrated medical record system superior to paper charts—more amenable to oversight and quality metrics—and reduce decentralization and fragmentation of care. At the time, a focus of concern was that up to 98,000 people died in hospitals per year due to medical errors in the United States, with an associated $17 billion to $29 billion in annual losses. With a significant proportion of US workers receiving their health care through their employers, there was a strong push from both the private and public sectors to reduce the costs of health care. Given the giant strides made in information technology that drove improvements in cost and quality in other sectors of the economy, it was time to apply this technology to health care delivery.

In 1991, the Institute of Medicine began unfolding their agenda to replace paper charts with what would become the modern-day EMR, setting forth 8 core functions: health information and data, results management, orders management, decision support, electronic communication and connectivity, patient support, administrative processing and reporting, and population health reporting.17 The first wave of legislation to regulate HIT was HIPAA, passed in 1996 to encourage the development of an HIT system with standards and requirements for the electronic transmission of certain administrative data sets created by these initiatives, became critical for ensuring the portability of information critical to actual patient care. In addition, it can be argued that the privacy and security concerns that evolved from this legislation have become more cumbersome, contributing to rising physician administrative burden. The use of EMR outside of directly driving patient care has added to unprecedented reporting and data entry burden, contributing to “e-iatrogenesis” secondary to increasingly complex data systems, poorly designed user interfaces, chaos in communication, and an overreliance on automation.

Adoption of EMRs showed slow growth into the 2000s but experienced a significant push in 2009 through the HITECH Act, within the American Recovery and Reinvestment Act. This law aimed to create a nationwide network of EMRs that “promised” improvements in patient care, a reduction of health care expenditures, and the fostering of new industry (eg, HIT vendors, data analytics, etc.) to stimulate the then-struggling economy.18

HITECH worked in conjunction with the 2010 release of final Meaningful Use criteria, a roughly $36 billion federal incentive program to drive adoption of EMRs that accomplished specific tasks particularly in the realms of preventative medicine and screening. Practices received $44,000 to $63,000 for integrating EMRs that could achieve Meaningful Use criteria. Not adopting an EMR led to financial penalties to the practice for noncompliance. Importantly, the foundation of these initial EMRs was designed in the context of a fee-for-service reimbursement model to automate the process of converting patient encounters and interventions into billing codes. Improvements in integrated clinical support tools, interprovider communication, and patient experience were lower priorities for incentives than was billing efficiency. However, the administrative data sets created by these initiatives have become very valuable for a host of reasons, including health services research and quality improvement.

Now nearly a decade out from the passing of the HITECH Act, the cracks of our immature HIT infrastructure are widening. Its original designs and codes structured to support billing purposes are quickly being stressed by additional and important functions physicians and health care systems require from EMRs.19 Just because EMRs were adopted that could be used in theoretically meaningful ways does not mean that they were designed to improve the many domains critical to successful delivery of care to the patient. EMR software needs to achieve multiple discrete objectives. It is up to policymakers to set objectives for EMR vendors that improve quality, cost, and accessibility to health care and to create regulations that facilitate their implementation.20 Furthermore, the environments into which these tools are deployed must allow enough agility to respond within a meaningful period to fix flaws in deployment. We will never get it right the first time, no matter how detailed the planning. Regulations can never be that prescriptive, and those writing the rules will never have complete information required to know what real needs will be.

A focus on the patient has forgotten the needs of the provider
Over time, the requirements to meet Meaningful Use through EMR have become more cumbersome, contributing to rising physician administrative burden. The use of EMR outside of directly driving patient care has added to unprecedented reporting and data entry burden, contributing to “e-iatrogenesis” secondary to increasingly complex data systems, poorly designed user interfaces, chaos in communication, and an overreliance on automation.21 Somewhere in the journey to create more patient- and consumer-centric care through a focus on safety and reporting patient outcomes, the provider began to suffer. The burden of EMR deployment placed on those providing care was not fully anticipated. Technological advancements have made it possible to measure and gather more data points and have facilitated coordination of care and shared decision-making. Yet it has also meant that providers became responsible to innumerable stakeholders under the pressure of significant oversight to maintain certification and quality for institution financial incentives (eg, ONC HIT Certification Program and MACRA). Newer technologies and regulations meant more mandates on quality and cost of care. Moreover, despite their good intentions, the demonstration of value did not always measure what they intended. Most measures certified by the nonprofit National Quality Forum are process measures that are surrogates for quality.22 Focusing on fulfilling these may serve as a distraction
There are numerous benefits for having free exchange of HIT through a form of open market such that, many assume, the quality of health care delivery, eg, through the reduction of administrative burdens related to EMR, removing barriers to interoperability, improving price transparency, and leveraging EMR to improve patient care.

**Addressing data silos**

Future developments of EMR need to allow for more agility and flexibility for change in order to reduce waste and support the patient–provider relationship. Again, there is something to be learned from the build-measure-learn model: to engineer into institutional–vendor relationships avenues for rapid prototyping, testing, and improving for a desired outcome prior to—and even after—widespread implementation. Certainly, for a smaller specialty like dermatology, such avenues are needed to meet the unique needs of a specialty often overlooked when designing EMRs for health care systems. Institutional policy and regulatory tools can be fashioned to facilitate this, eg, protecting the ownership rights of third-party applications that interoperate with EMRs. What does not appear to be in doubt is that the current regulatory environment has done little to foster agility and iterative development.
ility, safety, and cost of patient care can be improved.21 Government regulations have already begun addressing the barriers to health information exchange through the passage of the HITECH Act, by incentivizing a move away from paper records to electronic records. Yet still, the majority of Americans’ HIT is still stored in paper form or is in a non-user-friendly format scanned into an EMR. Still the physical exchange of HIT is laughably archaic at many medical centers: facsimile.

The requirements of the HITECH Act shrank the competitive market of large system-based EMR vendors from thousands to dozens, and the fiercely competitive EMR market has reduced the pool of viable players even further through several mergers and acquisitions. The EMR market is expected to continue to grow, increasing the size of the market from $70 billion in 2016 to $120 billion by the end of 2023, driven by a rise in the volume of health information and new technologies such as blockchain to boost health information security, cloud-based solutions, and artificial intelligence to accelerate the pace of processing large quantities of data.24

In the absence of direct government intervention, however, the EMR companies that remain in the consolidated market have few financial incentives to promote true interoperability between systems. Furthermore, there are no great incentives to meet the individual needs of a particular specialty like dermatology.19 Data are siloed within different EMR vendor systems and institutions, limiting the potential benefits of care delivery improvements that may be enjoyed by larger managed care consortia, such as Kaiser Permanente.25 Organizations like Health Level 7 and their Fast Healthcare Interoperability Resources, as well as the Food and Drug Administration Safety and Innovation Act of 2012,26 seek to promote the exchange, integration, and sharing of health information to promote health data interoperability. The 21st Century Cures Act of 2016, Section IV, in particular, amended the HITECH Act to require the Department of Health and Human Services through the ONC to promote the reduction of administrative burdens related to EMR—eg, require HIT developments, not engage in information blocking; promote interoperability; and enhance usability, accessibility, and security.27 However, these goals remain largely aspirational, and there are technical, legal, and financial barriers to attaining them in meaningful ways.

Conclusion
In many respects, what has been accomplished represents the low-hanging fruit. The financial and administrative parts of health care delivery, which already had one foot within the digital realm, are all-in. The insurance industry has already adopted standard diagnosis and billing codes, and the workflows to move to electronic entry and capture did not result in a massive positive disruption. Improved abilities to bill and track collections served to justify use cases for financial returns on investments.

The actual practice of medicine is quite distinctly different. Enhancements in disease management tools will require financial investments and likely substantial ones. They may result in improved disease outcomes, but even the least cynical among us recognizes that the current payment structure does not readily allow any physician or system to monetize this. This is unfortunate. What role policy, regulation, and law can and should play in fostering the transition envisioned in George W. Bush’s Executive Order in 2004 is what we all are grappling with. Obviously, an approach could be to pay for better outcomes, but we need the capacity to measure real outcomes meaningful to patients. We are not there yet, and accomplishing this will take time. Furthermore, the regulatory approach to fostering this will need to be nuanced—strong enough to push people and institutions into acting, but not so prescriptive so as to preclude agility in creating solutions in an iterative fashion.

It is essential to meet this challenge because measuring outcomes is essential for physicians and health systems. The iterative build-measure-learn cycle requires that people and health systems know what works and what does not. Access to information that informs us as to how we are doing in real or near real time can inform decision-making that affects individual patients or populations. Like the iPhone, the first prototypes and releases do not need to be perfect, only good enough to allow us to have confidence that we are moving in the right direction, flexible enough to accommodate changes, and embedded in systems capable of providing feedback to its stakeholders.

References