EHR Evolution: Policy and Legislation Forces Changing the EHR

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By Micky Tripathi

Electronic health records (EHRs), like all computerized technologies, have undergone rapid transformation over the past 50 years. The pace of change has greatly accelerated since the January 2009 passage of the Health Information Technology for Economic and Clinical Health Act (HITECH)-a $30 billion effort to transform healthcare delivery through widespread use of EHR technology. Also, "meaningful use" EHR Incentive Program requirements have helped to create greater commonality in basic EHR functions across systems at a much faster pace than would have otherwise occurred.

But the path of EHR innovation is not solely determined by technological progress. Other factors such as legal requirements, business drivers, and accountable care organizations and programs can affect the rate and type of change as well. While meaningful use has fundamentally altered the EHR industry and system design as a whole, these other factors stand to become the main drivers of change in the future.

EHRs Taking Shape

John Glaser, the CEO of Siemens Healthcare, describes four large technology changes that have inspired corresponding changes in EHR technology. First, the advent of mainframe computers brought the promise of digitization of medical record information, but it was only available to organizations that could manage complex IT infrastructures. Next, mini-computers and personal computers allowed the development of smaller footprint EHR software that could be accessible and affordable to even the smallest ambulatory practices. The third change was the launch of the Internet, which has enabled not only secure communication and data sharing with patients and other entities, but even more "lightweight" EHR systems delivered through digital offsite storage "clouds" as well.

The last change, just beginning to take shape in the current healthcare environment, is the proliferation of microprocessors into all manner of devices-not just computers and mobile phones. As medical and consumer devices are increasingly imbued with processing and networking capability, EHRs will increasingly incorporate this information for a variety of care and efficiency purposes.

The shape of EHR technology won't just be determined by technical factors. As with every other industry, legal, business, and cultural factors also play large roles in which technologies get the most market traction.

The Tinkering Period

The history of EHRs in the US goes back to the late 1960s when multiple parallel efforts sprang up around the country. From the moment technological advances moved data entry from punch cards to keyboards, and data display from printed results to video display terminals, innovative physician tinkerers around the country have seized on the opportunity to improve healthcare delivery. Some of the more well-known efforts include:

- Lockheed Corporation, in 1971, created the system that eventually became Eclipsys (now part of Allscripts) for El Camino Hospital, featuring computerized physician order entry (CPOE) and allowing multiple, simultaneous users.
- In the early 1970s, the University of Utah, 3M, and Latter Day Saints Hospital deployed the Health Evaluation through Logical Processing system.
- Researchers at Massachusetts General Hospital launched the Computer Stored Ambulatory Record project in 1968, which had modular design and accommodated flexible clinical vocabularies through vocabulary mapping.
- The Regenstrief Institute in Indianapolis created the Regenstrief Medical Record System in 1972, incorporating then nascent object-oriented programming principles to automate integration of structured, electronic clinical data from their

sources, such as laboratories and pharmacies.
- The Veterans Administration (now known as the Department of Veterans' Affairs) began work on the Decentralized Hospital Computer Program, the progenitor of the Veterans Health Information Systems and Technology Architecture, which innovated an enterprise-wide EHR system spanning hundreds of clinical settings across the country.

Though each of the designers of these systems had different ways of describing their motivations, the irrepressible Dr. Clem McDonald from the Regenstrief Institute captured it best with his rare gift for combining insight, vision, and straight-talk:

> "Our goal was to solve three problems: (1) to eliminate the logistical problems of the paper records by making clinical data immediately available to authorized users wherever they are – no more unavailable or undecipherable clinical records; (2) to reduce the work of clinical book keeping required to manage patients – no more missed diagnoses when laboratory evidence shouts its existence, no more forgetting about required preventive care; (3) to make the informational 'gold' in the medical record accessible to clinical, epidemiological, outcomes and management research."[1]

Though the 2010 and 2014 Edition Federal EHR Certification Rules together comprise over 700 pages, the goals for EHR systems are the same today as Dr. McDonald expressed in the above paragraph over a quarter of a century ago.

Commercialization of EHRs

As homegrown systems in academic medical centers matured, the technologies began to commercialize, some as outgrowths of these homegrown provider-designed systems and others that were designed commercial from the start. As the IT industry delivered larger and larger amounts of computing power in smaller and smaller boxes, the customer base for EHRs began to expand.

Arguably the biggest challenge to EHR system design in the 1990s was growing user heterogeneity, in particular the opening of the ambulatory market forged by the widespread availability of personal computers and the Internet. As noted by the authors of a 1997 Institute of Medicine (IOM) published book, *The Computer-Based Patient Record: An Essential Technology for Health Care, Revised Edition* the introduction of EHR technology to the new ambulatory market presented special challenges to the existing EHR companies whose roots and orientation were in the acute care setting:

> "There are differences in the temporal nature of information, the responsibilities of each member of the healthcare team, the need for a communications infrastructure to facilitate coordination of care, and other logistical concerns which impact the detailed design of information systems. Consequently, vendors of information system products for hospitals find that there is a steep learning curve to understanding the information needs of physicians in the ambulatory care setting."

The opening of the ambulatory market tested the limits of the existing commercial vendors who, accustomed to the unique demands of the inpatient market, could not quickly or easily adapt to the opportunity. This opening brought in a raft of new, more nimble vendors, who focused more closely on the unique needs of ambulatory providers. Among those needs were:

- **Physician-specific workflows**-Hospital systems had traditionally been designed to integrate information from disparate clinical source systems (such as lab, radiology, etc.), and store dictated notes from physicians. Manual data documentation was performed mainly by finance personnel entering billing codes and unit clerks entering orders dictated by physicians orally or on paper. Physicians were thus shielded from direct interaction with the hospital EHR, using it primarily for viewing information entered by others. Computerized physician order entry (CPOE) systems, which do require active physician interaction with EHRs, were not introduced into hospital EHR systems until the early 2000s.
- **Manageable footprint**-Ambulatory EHR vendors embraced systems that could be managed by smaller, less sophisticated IT staffs, and deployed on new consumer-oriented Windows operating systems.
- **Integrated billing**-As systems moved from inpatient to outpatient settings, the need to have billing functions simple enough for clinicians and their staff to use became critical to keeping revenue cycle functions intact and justifying return on investment for the EHR.
- **Interoperability**-The ability to connect with in-office diagnostic equipment, as well as receive lab results and other basic functions from other entities, became more pronounced in the ambulatory settings.

The trajectory of the EHR market at this time followed patterns very similar to other industries. Studies of innovation cycles in other industries have noted that product markets typically have long periods of continuity marked by continuous but incremental innovation. But those relative periods of calm are periodically punctuated by episodes of major product change and upheaval, which often usher in new businesses and may at the same time foment the dissolution of old ones.[2,3]

The opening provided by the inpatient EHR vendors' hesitation in meeting the growing needs of the ambulatory market provided an opening for new ambulatory EHR vendors to enter and dominate the market. Indeed, some of the upstart ambulatory vendors have even in recent years been able to encroach on the inpatient markets of the established players-as witnessed by Epic's successful entry into the inpatient market and Allscripts' recent acquisition of the venerable Eclipsys inpatient system.

Technology Advances, but Results Stall

While systems matured and continued to exploit advances in hardware and software technology, proliferation of EHR adoption among providers did not keep pace with technical advances. Soon it became clear that widespread adoption of medical records was perhaps more challenging than logic seemed to suggest. Fragmentation of the healthcare delivery industry allowed each hospital and physician to practice medicine in their own way, which encouraged customization of EHR systems according to individual physician and hospital needs and generated little market demand for enterprise- or population-level features such as common technical standards, decision support for adherence to guidelines, measurement capability for population health, or plug-and-play interoperability for coordination across care settings.

In short, EHR systems were not getting standardized because their users-physicians and hospitals-were not standardized. As the healthcare industry continued to practice medicine like guilds of independent craftsmen and artisans, they insisted that their tools be custom-crafted as well, which made it impossible for the industry to reap the benefits of economies of scale and scope that have driven high penetration of information technology in other parts of the economy.

In IOM's *The Computer-Based Patient Record*, the authors noted barriers related to EHR systems themselves, as well as other non-technical obstacles to adoption. The technical barriers were grouped into three categories: disparate definitions of an EHR, poor system usability, and lack of standards. EHRs at the time were basically electronic versions of paper records-electronic filing cabinets-which mimicked the diverse and idiosyncratic record-keeping approaches that were a hallmark of narrative- and dictation-focused paper-based systems. These early EHR systems didn't unlock the unique capabilities for data management, presentation, and analysis that computerization offered.

System designers seemed to have spent precious little effort on identifying workflows appropriate to an electronic medium, and instead tried to force-fit paper-oriented workflows into a computer-based system-with very little success. Lack of common standards for types of content, format, and nomenclature prevented data sharing across care settings, leading to a warning from IOM: "Until standards exist for uniquely identifying individuals and coding and exchanging health data, the value from capturing and aggregating data will go unrealized and each organization will be its own pioneer."[4]

The result was a classic "chicken-and-egg" conundrum. EHR systems wouldn't become more usable, standardized, interoperable, or affordable until more customers demanded such features. In a world of custom-crafted medical care, few customers had the incentive to make purchasing decisions that allowed vendors to affordably offer such features. Indeed, a common refrain heard from clinicians, and verified by a number of studies, was that while the additional costs of fully functional EHRs were borne largely by clinicians, the incremental benefits flowed largely to others, such as public and private health insurers, employers, and ultimately, patients. The result was a systematic under-investment in information technology by an industry that constitutes 15 percent of the US economy and an even larger share of citizens' well-being.

The Meaningful Use Disruption

HITECH introduced a large disruptive market force-namely Medicare and Medicaid-into the equation. Recognizing that the gap in EHR capabilities reflected a problem of insufficient and unsophisticated demand, the Centers for Medicare and Medicaid Services (CMS) offered to incentivize physician investment in the systems. The incentives were designed to lead physicians to use EHRs in ways that not only optimized provider performance, but promoted improvements in health system performance as well-basically, to make physicians and hospitals "smarter buyers" of EHR systems. This meant promoting the

use of technology in ways known to improve individual care as well as population health. In effect, since healthcare providers were not demanding better EHR systems on their own, Medicare and Medicaid would induce them to do so.

While this effort by Medicare and Medicaid is unprecedented in US healthcare, this type of "supply chain investment" is a very common feature of supply-chain management in private industry. For example, Wal-Mart has been engaged in a decade-long effort to get its suppliers to invest in RFID tagging technology, which would allow Wal-Mart to save costs and more efficiently manage inventory. They began by mandating that their suppliers invest in the technology by a deadline or face ongoing penalties. When their suppliers balked-arguing that Wal-Mart would reap all of the benefits while they would bear all of the costs-the giant retailer relented and adopted a more collaborative cost-sharing approach in order to induce RFID tag adoption.[5]

By providing large incentives to individual providers for using EHR systems in specific ways, CMS has motivated a fragmented customer base to act more like a single customer with coherent demand. In effect, CMS, as the behind-the-scenes customer, is driving standardization and the resulting economies of scale and scope in the EHR industry in the same way that large industry players have been able to standardize and draw value from IT use in banking, retail merchandising, airlines, food services, and other sectors of the economy.

The main EHR features required to fulfill HITECH meaningful use requirements are:

- A core of consistent, structured, clinical content that would be uniform across vendor systems and care settings
- Automated alerts and reminders
- Consistent, robust measurement capabilities
- Data mining capabilities
- Public health reporting
- Interoperability with other systems

Recognizing that markets are often slow to respond to customer demand, and that EHR purchasers have limited ability to evaluate the quality of EHR vendor products prior to purchase, HITECH also created federal certification of EHR products. This gives a degree of assurance to providers-and CMS-about the quality of EHR products being purchased.

The orchestration of demand, creating a legion of "smart" buyers, and a product supply that better enables vendors to meet the demands of buyers, has reshaped the EHR industry in fundamental ways.

At a macro-level, while concerns abound regarding the potential risk that federal requirements will squelch innovation in the industry-in particular that a certification requirement would be a barrier to the entry of small firms into the marketplace-the exact opposite seems to have happened. The federal Certified HIT Product List (CHPL) currently contains 1,256 certified complete EHR products that meet all of the EHR certification requirements. Companies that are focused on more niche functions can be certified as EHR components, and there are an additional 1,265 of these certified components. On the inpatient side, there are 240 certified inpatient EHRs and an additional 616 certified components. Clearly, there are many more vendor products in the market today than existed prior to HITECH, and they are taking all shapes and forms.

At a micro-level, meaningful use requirements and corresponding EHR certification programs have driven beneficial consistency in EHR systems in a variety of areas. It's important to recognize the value of coupling demand-side incentives (which motivates providers to undertake presumably value-creating activities) with supply-side requirements (which motivates vendors to develop the tools to allow providers to undertake those value-creating activities). Prior to the passage of HITECH, the federal government did establish voluntary federal certification of EHR systems through the Certification Commission on Health IT (CCHIT). With no corresponding incentive on the part of physicians to purchase certified systems, however, the program met with real but limited success.

Stage 1 of the meaningful use program focused primarily on promoting consistency of documentation in terms of what data should be captured (content) and how it should be presented (structure). It did not extend very far in terms of how data should be recorded (vocabulary).

Stage 1 also linked documentation requirements with measurement and decision support requirements, which ensures that the data being captured are more than just a description of observations, diagnoses, and treatments for future reference; clinicians

would now have the systems and the motivation to document in ways that would allow EHR systems to be tools for enhanced decision-making.

In terms of interoperability of systems, stage 1 focused on promoting inter-organization electronic transactions that were already gaining adoption in the market, such as e-prescribing, lab results delivery, and public health reporting. It also laid the foundation for new types of transactions-specifically EHR-to-EHR transactions-by requiring that systems be able to generate electronic record extracts that could be read by other systems. The ability to electronically send, receive, and incorporate such extracts from other EHR systems was left for more advanced stages.

On August 23, 2012, CMS and ONC released the stage 2 meaningful use objectives and corresponding 2014 EHR certification requirements, thereby generating the next wave of meaningful use disruption in the industry.

Stage 2 further refines the notion of system-neutral records by taking EHR-to-EHR interoperability even further and requiring not just common structures (consolidated CDA) and common content (problems, labs, medications, etc.), but use of specific vocabularies as well, such as SNOMED CT, LOINC, and RxNORM, to enable cross-system understanding of clinical information from one organization to another. And while stage 1 simply required that systems be able to generate standardized clinical documents, stage 2 requires that they be able to transport clinical information from one system to another according to a specific federally-specified secure email standard called the Direct Project protocol.

Stage 2 also expands the scope of EHR functionality by requiring the ability for patients to communicate with physicians via secure messaging, and access their information through viewing, downloading, or transmitting their information according to their preference.

Early indications are that stage 3 of the meaningful use program will move systems even more toward having the ability to generate a patient-centric, common record in the form of a structured coordination-of-care document that would be populated by members of “care teams” spanning legal and organizational boundaries. And, as predicted by John Glaser’s four steps described earlier, stage 3 will likely require EHR systems to interoperate with consumer-controlled devices, such as electronic scales and blood sugar monitors.

While each stage of meaningful use has sent ripples of change across the EHR landscape in terms of functions and capabilities, each stage has also engendered evolution in the very definition of what an EHR is. Prior to HITECH, CCHIT would certify only complete, very robust EHR systems that comprised “all the bells and whistles,” which led to criticism that the certification process was forcing the industry toward large, cumbersome systems that were expensive, difficult to implement and maintain, and laden with required cross-specialty functionality that any particular physician wouldn’t need.

Stage 1 of meaningful use (and the corresponding 2011 Edition Certification requirements) introduced the notion of “certified EHR technology (CEHRT),” “complete EHRs,” and “EHR components.” Gone was the requirement that a system had to perform every function in order to be certified. However, in order to qualify for meaningful use, providers were still required to purchase a CEHRT, which could be either a certified complete system or a collection of certified components that met a common required set of 33 certification criteria.

Stage 2 of meaningful use (and the corresponding 2014 Edition Certification requirements) has further unbundled the concept of the EHR by unveiling the “base EHR,” which is a single system or collection of components certified to meet 20 required criteria and which all providers would have to purchase. The definition of CEHRT is flexible beyond the base EHR, however, so providers only have to purchase those certified components that correspond with the core and menu meaningful use objectives that they are attesting to for incentive payments.

While directionally this would appear to point to more unbundling of EHR systems, we have yet to see full unbundling by established EHR systems. Taking the Android store as an example, one could start with a NextGen platform and add an Allscripts e-prescribing module and an Epic medication administration module and an athenahealth allergy documentation module and an eClinicalWorks practice management module. Competitive pressures, the need for smooth and seamless workflow, and a low appetite for experimentation are likely to place a limit on how much modularization the market will support.

While meaningful use is not yet complete, it’s not too early to assess how it has already shaped the industry. By setting some common functional requirements for EHRs, and incentives for users to take advantage of those functions, the meaningful use

program has imposed a degree of coordination on healthcare that the fragmentation of the industry had prevented up until now. Meaningful use can only go so far, however, as it isn't strong enough to supersede larger and deeper trends in the industry that are driving business arrangements and revenue models.

Meaningful use has certainly been successful in creating a common floor of capability across vendor systems, which has inalterably shaped the EHR industry. Vendors have yet to reach plug-and-play capability with EHR systems, however, and it is highly unlikely that meaningful use will have enough influence or enough time to instill such capability in the market.

Accountable care organizations, where disparate healthcare organizations band together to share data and lower costs, would require robust health information integration. Many systems will accomplish this with consolidation on a single-vendor platform rather than integrating disparate systems. The market has many ways of solving interoperability, and requiring disparate systems to connect deeply and seamlessly with each other may very well prove to be the path of most resistance for most provider organizations in this fast changing business climate.

How much of this EHR evolution would have happened without the intervention of HITECH is hard to tell. But without it, the changes certainly wouldn't have happened with the speed and focus that the industry has witnessed to date.

Notes

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