Finding the Meaning in Meaningful Use

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Health care has long lagged behind all other major industries in the adoption of information technology, but it is beginning to catch up. Because of the belief that electronic health records (EHRs) will be a key foundational tool for improving safety and quality of care and for reducing costs, the federal government has implemented substantial incentives for providers to adopt EHRs through the Health Information Technology for Economic and Clinical Health (HITECH) Act.[1] Some recent surveys suggest that physicians are now using EHRs in nearly half of outpatient practices[2] and in 44% of U.S. hospitals.[3] The challenge will be to ensure that adoption of these systems will actually result in the desired improvements. Data from several studies have suggested that simple adoption of EHRs does not necessarily improve the quality of care[4] and that quality does not appear to improve even over a number of years among EHR users.[5]

This challenge was recognized in the HITECH Act, which included the new concept of "meaningful use" of EHRs. The intent of meaningful use was to provide incentives to providers not only to adopt EHRs but also to use them in ways that would improve quality, safety, and efficiency.[6] However, even though the concept of meaningful use is extremely attractive, it remains to be shown that the standards that are being established will result in improvement in care. Some recent studies have suggested that achieving these goals through meaningful use of EHRs may be much harder than originally anticipated.[7,8] It is important to note that the adoption of the HITECH Act and meaningful use is intended to be only a starting point. These programs will be interacting with the delivery-system reforms encouraged under the Affordable Care Act,[9] including the Accountable Care Organization program, bundled payments, and the National Quality Strategy.

WHAT IT TAKES TO ACHIEVE BENEFITS WITH EHRs

Success in improving care with EHRs may be related to the types of EHRs that are used, their settings of use, and the incentives in place. Most studies of the successful effect of EHRs on quality and safety of care have come from four organizations that use internally developed EHRs that have been in place for more than 25 years: Brigham and Women's Hospital in Boston, LDS Hospital in Salt Lake City, Vanderbilt University Medical Center in Nashville, and the Regenstrief Institute in Indianapolis.[10] All four institutions have spent decades expanding, iterating on, and improving their EHRs and have shown improvements in safety, quality, and efficiency.[11-14] Because these systems are under local control, the EHRs have been highly customized with the use of relatively rapid improvement cycles. They also have built informatics cultures of continuous quality improvement that allow for ongoing evaluation and iterative improvement. However, such cultures have not been widely replicated in other organizations, and vendor applications do not facilitate customization to nearly the same extent.

All these organizations, however, have struggled to maintain these systems, since doing so requires substantial development, and certification has further raised the bar. Several organizations with homegrown systems have discontinued them and purchased commercial systems,[15] and nearly all future EHR implementations will probably involve vendor applications. However, the commercial EHR systems currently marketed are much younger than their homegrown counterparts and thus have been through far fewer improvement cycles. The vendors typically update only once or twice annually, and any customizations that are made may be lost with the next upgrade. Studies regarding whether commercial

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systems improve quality or safety are far less extensive than those regarding homegrown systems, but many studies have not shown any benefits for commercial systems.[16,17]

Nonetheless, large networks such as Kaiser and Geisinger, which have wholeheartedly adopted commercial EHRs and are using them heavily, have realized substantial improvements in care.[18,19] Thus, at least within large health care system networks that have aligned incentives, large changes are possible with vendor systems, though it is important to underscore that both Kaiser and Geisinger made substantial investments and changes in the design of their care delivery that went far beyond the use of health information technology. Furthermore, a recent study by Buntin et al. showed that 92% of articles on health information technology were positive and that benefits were beginning to be defined in smaller practices and organizations.[20]

MEANINGFUL USE AND COMMERCIAL EHRs

The HITECH Act and meaningful-use requirements for EHRs have been well described elsewhere.[1] To maximize the likelihood that improvement will occur, detailed criteria have been developed to certify EHRs, and certification is required under the HITECH Act.[21] The presumption is that this process will help ensure that EHR vendor products will include key functionality to enable hospitals and providers to improve their safety and quality and eventually patient outcomes. These regulations have clearly affected both vendors and health care organizations as they scramble to meet tight timelines and to ensure that their EHRs have long lists of capabilities. Vendors are adding new features and functionality, and health care organizations are changing their implementations to focus on achieving meaningful use. Nearly half of all institutions (49%) ranked meaningful use as their leading information-technology priority for 2011.[22,23] Ironically, the usual vendor-improvement cycles have been interrupted by the rush to achieve meaningful use as vendors focus the majority of their efforts on it. This explosion of organizations' interest in speeding up their implementations of EHRs to achieve meaningful-use incentives has further increased the vendor workload, which may have unintended consequences, such as unplanned system shutdowns or system-induced errors in patient care.[24] Substantial discontent with vendor EHRs among providers has emerged at some sites, often over usability problems.

GETTING TO "MEANINGFUL" MEANINGFUL USE

The stage 1 criteria for meaningful use include an array of requirements, ranging from systems for computerized physician order entry (CPOE) to decision support. A major concern is whether the criteria will be sufficient to result in the adoption of EHRs that have what it takes to enable substantial improvement. One study of commercial EHRs involved going beyond the current criteria and determining whether in safety simulations the systems identified serious medication problems in CPOE systems that had already been implemented in hospitals and pharmacies.[25,26] Only 53% of fatal medication orders were picked up by implemented commercial CPOE systems in hospitals, and only 28% of commercial information systems in ambulatory pharmacies picked up critical problems with drug–drug interactions. The study in hospitals evaluated EHR systems that had been approved by the Certification Commission for Health Information Technology in a fashion that is more rigorous than current meaningful-use certification, suggesting that certification alone does not determine performance after implementation. Other studies have catalogued new safety issues introduced with EHRs[27] and have underscored the need to address human-factor issues relating to them.[28]

The meaningful-use criteria require the collection of specific quality measures: in particular, 15 inpatient and 6 outpatient quality measures that will have to be collected and reported to meet these criteria. The stage 2 criteria for quality measures will raise the bar further, although they are still in a draft stage. Broadly, the hope is that stage 2 will encourage providers to begin improving process, whereas stage 3 will result in improved outcomes. However, vendors and hospitals have already identified major challenges in collecting, calculating, and reporting even the first 15 measures of inpatient quality.[22] Overall, it will be a challenge for organizations both to

tick all the boxes they need to cover and to make sure that they put in place the change management, processes, and clinical-decision support that will improve care.

NEED FOR EVALUATION TOOLS AFTER IMPLEMENTATION

The above-mentioned studies are consistent with several reports that commercial EHR products have not had a measurable effect on the very goals to which meaningful use aspires.[4,7,17] This finding is perhaps not surprising, given the limitations of many current EHR products in showing such effects on quality and safety, their relative immaturity, the length of vendor-improvement cycles, and the challenges in local customization of commercial vendor products. We cannot assume that increased rates of CPOE implementation for certified vendor products will result in improved patient safety — especially medication safety — in the near term. It will be necessary to go further in evaluating these systems after implementation to show their beneficial effect. Many studies have suggested that implementation of these systems is highly variable, which may be the central factor in whether patient safety and quality goals are achieved.[29] In other industries, complex information technology systems are extensively tested in an ongoing fashion after implementation to ensure proper performance. Although airplane flight-management systems are continuously retested during routine operation, EHRs in intensive care units are rarely retested, even after they crash or shut down. Indeed, the ability to send fatal medication orders through these systems after major updates that have unknowingly disabled critical safety checks is a particularly serious concern.[30]

Our health care system needs tools for evaluating these systems when they are operational, not just before implementation. Such tools will be needed to ensure meaningful benefit from EHRs, and they should be used to retest high-risk applications after unexpected EHR shutdowns or even regularly scheduled updates to EHR programs. They also should be used to assist hospitals and clinics in ongoing self-assessment and improvement of their systems. This self-assessment guide for users should include, at a minimum, questions about the top 25 most common actions that a user should be capable of performing (e.g., look up a patient according to name or medical-record number or review the three most recent laboratory test results), the organization's downtime and reactivation procedures, and any patient safety events or potential hazards that have had a direct effect on EHR users or patients. Such self-assessment tools could be developed and implemented with the use of simulation approaches similar to the way the Leapfrog Group's assessment tool for EHRs and clinical-decision support has been used.[24] In addition, each organization should carry out an extensive review of its clinical information systems on a yearly basis. This review could address each of the eight facets of the EHR safe-use model, which include hardware and software, clinical content, user interfaces, user training and authorization procedures, clinical workflow and communication, organizational policies and procedures, compliance with state and federal rules and regulations, and periodic measurements of system activity.[24] To help vendors understand how to improve the design of their products, postmarketing surveillance could be used as it currently is with respect to drugs.[31]

CONCLUSIONS

As the broad adoption of EHRs accelerates, the challenge of ensuring that meaningful use actually leads to meaningful benefits, such as improvements in safety and quality of care, remains a serious concern. Another major issue is who will produce the needed innovation for these new tools, since the vendors are far too busy meeting deadlines to innovate, and even the organizations that have historically filled this role are considering switching to vendor applications. Providers that qualify for the meaningful-use incentives will not necessarily achieve meaningful benefits, so that the links with other parts of health care reform, which will directly provide incentive for those benefits, are critical.

Getting the full benefits of EHRs will be especially hard for organizations that do not have the experiences of the pioneers, and this will be a particular challenge in primary care settings and smaller hospitals, which do not yet have cultures focused on health information technology and improvement and are using less-devel-

oped vendor systems. We have three recommendations: First, providers must go beyond making sure they qualify for the incentives and track whether they have the key tools for improving efficiency, quality, and safety. Second, testing after implementation will be essential to ensure the safety and effectiveness of clinical information systems in actual use. This will be permitted in the next phase of certification. Finally, federal research support is critically needed to ensure that continued innovation, improvement, and safe implementation of these complex EHR systems actually happen and do so in a way that promotes safety and quality of care.

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