

Health Policy Review



A Case for Restraint of Explosive Growth of Health Information Technology: First, Do No Harm

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Despite the mounting evidence of challenges with health information technology (IT) as well as patient safety concerns, the health IT industry for decades has been the beneficiary of continuing regulatory accommodation (1-8). The Economic Cycle Research Institute's (ECRI) top 10 patient safety concerns for 2014 is topped by data integrity failures with health IT systems (9). In fact, the health IT safety concerns have been extensively reported (10-20). Even then, health IT is largely unregulated, with increased funding and profits compared to other health care sectors as well as other safety sensitive industries such as aviation, automotive, or energy, with little accountability, even though it continues to be experimental with no proof of necessity or effectiveness (3). The regulatory accommodations of IT fail to follow the medical dictum *Primum non nocere*, "first, do no harm." Health IT someday may achieve many of the promises made about it, but only if done well (3,19,21). Thus far, health IT has not earned the trust of providers which is demonstrated by the continued dissatisfaction and perceived declining quality of care (19-32). When imposing regulations on society with computerization of health care, a reflective, inquisitive, logical thinking is essential on deciding the evidence or lack thereof of functionality, reliability, and cost effectiveness (3,19-21,32). In any industry before a product is sold, evidence must be established and trust must be earned; however, in the health care IT industry, no such requirement is essential as Congress and the Administration have bypassed the evidence and trust by regulation (33,34).

Health IT has been sold by promising a revolution in medicine. Regulators, and consequently the public, have been told that health care IT will transform medicine with drastic reductions in errors and costs and increased efficiency and productivity (3,19,20,32,34). Further, health care IT has promised that it will help clinicians in the delivery of health care and patients in shared decision making and self-advocacy (35). If appropriately performed with slow and careful development, being treated as an experimental device as any other device by the Food and Drug Administration (FDA), health care IT will facilitate delivery of health care, potentially improving care and access. Conversely, it is unlikely an experimental product will continue to expand for the good of the society just based on the belief of regulators, without trust from the providers and evidence of efficacy and reliability.

The concerns related to health care IT are not new, surprisingly get very little press, and continue to mount (2,4,35,36). U.S. National Academies, National Research Council has concluded that current efforts aimed at nationwide deployment of health care IT will not be sufficient to achieve medical leaders' vision of health care in the twenty-first century and may even set back the cause (36). In January 2009, after visits to 8 U.S. medical centers, National Academies, with leadership in the field of

health care IT, concluded that greater emphasis should be placed on IT that provides health care workers and patients with cognitive support, such as assistance in decision making and problem solving (2). Even though multiple institutions showed a strong commitment to deliver quality health care, the health IT systems fell short of what was needed to realize the Institute of Medicine (IOM) vision. The report described difficulties with data sharing and integration, deployment of new IT capabilities, and large-scale data management. Further, they showed that current health care IT systems offered very little cognitive support to clinicians where they continue to spend a great deal of time sifting through large amounts of raw data and integrating it with their medical knowledge to form a picture of patients' health. As expected, many providers have been using IT systems mainly to comply with regulations or to defend against lawsuits, rather than to improve quality of care or access. Thus, IOM (2) concluded as early as January 2009, and again in 2012 (4), that valuable time and energy was spent managing data as opposed to understanding the patient. The report identified multiple principles for improving the implementation of IT in health care with recommendations to embrace measurable improvements in quality of care as the driving rationale for adopting health care IT and avoiding programs that focus on adoption of specific clinical applications. Further, they concluded that the success will only depend upon accelerating interdisciplinary research in biomedical environments, computer science, social science, and health care engineering. While none of these have been considered, health care IT took off with the American Recovery and Reinvestment Act of 2009 (AARA) (33) with allocation of \$30 billion for mandatory electronic health records (EHRs). However, with the AARA came numerous regulations, including meaningful use, which have turned into 3 phases measuring thousands of pages and generally have become meaningless with ever-changing regulations and difficulty applying them with clinical relevance. In addition, the Physician Quality Reporting System (PQRS) and value-based payments also have been integrated into practices, along with the soon-to-be-integrated ICD-10, increasing the regulatory atmosphere and reducing patient care (2,21,31-40).

In contrast to the belief in the United States that health IT is greatly successful and reliable across the world, National Health Services (NHS) announced that a \$12.7 national program for IT was ending after years of delays, technical difficulties, contractual disputes,

and rising costs (22). This failure is despite NHS being a single payer system with very few regulations on providers. However, now it appears that the United States as well as the UK have worked for over 6 years and recognized the failures with UK embarking on investment of \$18 billion in health IT in 2005 (22), and the United States with \$30 billion investment in 2008, ultimately resulting in a memorandum of understanding between both countries (22-24,33).

Patient Safety Concerns

As described earlier, the ECRI showed data integrity failures with health IT systems as the number one patient safety concern for 2014 (9). The data also showed other deficiencies which may have some relationship to data integrity failures of health care IT. This report is the second annual patient safety list compiled by ECRI. It is based on patient safety reports that health care organizations voluntarily send to the institute over the past year. Since 2009, ECRI has collected over 500,000 adverse event reports from more than 1,000 hospitals. The top 5 health IT issues included Health Insurance Portability and Accountability Act (HIPAA) compliance, patient engagement, long-term and post-acute care, medical home models, and International Classification of Disease-10 (ICD-10) compliance (10,11). HIPAA compliance is extremely onerous with mandatory fines for instances of willful negligence at a minimum of \$10,000, which may climb as high as \$50,000, for a total of \$1.5 million per year. Another major issue is the ICD-10 compliance with its major disadvantages (21). However, among the top 10 health IT issues in 2013, meaningful use was the number one issue with HIPAA compliance as number four and ICD-10 as number 12 (12). In 2014, analysis of malpractice claims confirmed the risks in EHR (12). In the analysis of 147 cases in which EHRs were a contributing factor, computer systems that don't talk to each other, test results that aren't routed properly, and mistakes caused by faulty data entry or copying and pasting were among the EHR-related problems found in the claims, which represented \$61 million in direct payments and legal expenses. Unfortunately, half of the 147 cases that resulted in severe injury and patients' deaths were a likely result of IT. In earlier reports, ECRI Deep Dive Study of health IT events (13) published in 2013 that said there were 171 health IT malfunctions and disconnects that caused or could have caused patient harm. The 36 hospitals that participated in the ECRI IT project were among the hospitals around the country for which ECRI served as a patient safety orga-

nization. Among the 171 events, 53% involved a medication management system, whereas 8% were caused by radiology or diagnostic imaging systems including picture archiving and communication system. Table 1 shows the illustration of the documented events.

Further, they have described it as only the tip of the iceberg which underscores the risks associated with information technology and patient safety (13). As early as 2008, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has provided sentinel event alerts in reference to the safety of implementing health information and converging technologies. To combat these issues, JCAHO has provided 13 recommendations (15). A 2014 report provided a sobering assessment for medical economics about EHRs (16). Extensive dissatisfaction of EHRs are shown in Figure 1 (32,41):

- 73% of the largest practices would not purchase their current EHR system.
 - 66% of internal medicine specialists would not purchase their current system.
 - 60% of family medicine physicians would also make another EHR choice.
- 67% of physicians dislike the functionality of the EHR systems.
- 50% of physicians say the cost of these systems is too high.
- 40% state that patient care is worse since implementing an EHR.
 - Nearly 23% of internists say patient care is significantly worse.
- 65% of respondents say their EHR systems result in financial losses for the practice.
 - 43% of internists and other specialists and subspecialists outside primary care characterized the losses as significant.
- 69% said that coordination of care with hospitals has not improved.
- 38% continue to doubt their system will be viable in 5 years.
- 74% believe their vendors will be in business over the next 5 years.

Regulators dismiss such dissatisfaction as well as reports of harms as anecdotes, and continue to believe the statements from IT executives who continue to benefit.

More recently, the federal government has been criticized for lax oversight of health IT safety (8). An example was that in 2013, a 2-year old child's weight which was written as 35 translated into 77 lbs., requir-

Table 1. *Illustration of the documented events.*

- 171 Total events documented
 - 53% medication management system
 - 25% involved computerized order entry system
 - 15% involved electronic medication administration record
 - 11% involved pharmacy systems
 - 2% involved automated dispensing systems
 - 17% were caused by clinical documentation systems
 - 13% were caused by lab information systems
 - 9% were caused by computers not functioning
 - 8% were caused by radiology or diagnostic imaging systems, including PACS
 - 1% were caused by clinical decision support systems

Source: Peering underneath the iceberg's water level: AMNews on the new ECRI "deep dive" study of health IT "events." Health Care Renewal, February 28, 2013 (13). <http://hcrenewal.blogspot.com/2013/02/peering-underneath-icebergs-water-level.html>

ing hospitalization. Following this report, the Office of National Coordinator (ONC) has revised their IT regulations (8,14-16). Scot Silverstein, adjunct professor, Institute for Healthcare Informatics, College of Information Science and Technology, Drexel University, Philadelphia, Pennsylvania, has provided extensive information on critical thinking on building trusted, transformative medical information systems to improve health IT as the first step. IOM of the National Academies in November 2011 published another report on health IT and patient safety (42). In this report IOM was aware of severe health IT risks and safety issues and recognized that health IT is unregulated, but admits it does not know the magnitude of the risks and safety issues. U.S. National Institute of Standards and Technology from the Department of Commerce, in a September 2011 report entitled Technical Evaluation Period Testing and Validation of the Usability of Electronic Health Records, concluded that commercial health IT is not very usable, creating lost efficiency and risk, and much remedial work is needed (36). Further, Linder et al (25), in their manuscript in 2007, concluded that as implemented, EHRs were not associated with better quality ambulatory care. Romano and Stafford (26) showed that their findings indicated no consistent association between EHRs and clinical decision support (CDS) and better quality, raising multiple concerns about the ability of health IT to fundamentally alter outpatient care quality.

Clinical Decision Support (CDS)

A systematic review of the impact of e-health on

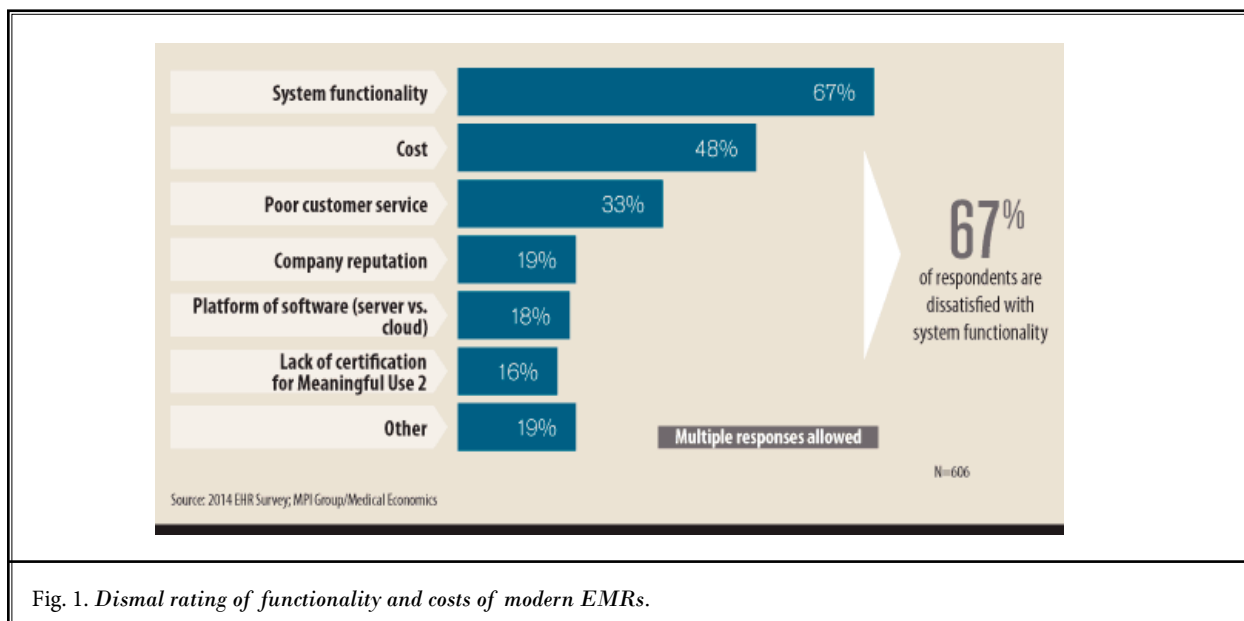


Fig. 1. Dismal rating of functionality and costs of modern EMRs.

the quality and safety of health care by Black et al (27) provided conclusions that there was a large gap between the postulated and empirically demonstrated benefits of e-health technologies. Further, they also concluded that there was a lack of robust research on the risks of implementing the IT. What is worse is that there was no evidence of cost effectiveness. DesRoches et al (28) showed more modest results with examination of EHR adoption in U.S. hospitals, comparing the relationship to quality and efficiency. They concluded that the relationships were modest at best and generally lacked statistical or clinical significance. Multiple other manuscripts have provided insight into the lack of efficacy, lack of cost effectiveness, and associated risks (5,9,27-40).

SGR Repeal and IT Relationship

The recent legislation, Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which led to the repeal of Medicare's sustainable growth rate formula (SGR) for physician payments (43-49), has provided significant incentives for IT, despite the challenges described above. One of the aspects of MACRA is the merit-based payer system combining multiple quality measures into one program which include the EHR incentive program, the physician quality reporting sys-

tem, and the value-based payment modifier established under the Affordable Care Act. This has provided a substantial boost for the IT industry. In fact, public trust in physicians has been declining in recent years (48,50) with the United States ranking number 3 in satisfaction with the treatment they receive when a patient visited a doctor the last time. In answer to the question, "All things considered, doctors in your country can be trusted," Switzerland ranked number one in both categories, however, under a different health care system and less regulatory atmosphere.

SUMMARY

Information technology has brought significant advances to modern life. We, like many others, believe that IT properly utilized in the delivery of health care ultimately bodes well for the care of our patients. The challenge is that the current technology does not live up to that promised state of multiple elements of improved care through IT. Despite that, legislative mandates have required large-scale adoption of present day health care IT solutions. These regulations have been particularly challenging for independent practitioners. Our efforts at making these points are now supported by a growing body of research including a very important analysis by the ECRI.

REFERENCES

1. Manchikanti L, Benyamin RM, Falco FJE, Hirsch JA. Metamorphosis of medicine in the United States: Is information technology a white knight or killer whale? *Pain Physician* 2014; 17:E663-E670.
2. Current approaches to U.S. health care information technology are insufficient. National Research Council, January 9, 2009. www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12572
3. Silverstein S. Critical thinking on building trusted, transformative medical information: Improving health IT as the first step. http://cci.drexel.edu/faculty/ssilverstein/HISA2012_Final.ppt
4. IOM (Institute of Medicine). 2012. *Health IT and Patient Safety: Building Safer Systems for Better Care*. Washington, DC: The National Academies Press.
5. Goodman KW, Berner ES, Dente MA, Kaplan B, Koppel R, Rucker D, Sands DZ, Winkelstein P; AMIA Board of Directors. Challenges in ethics, safety, best practices, and oversight regarding HIT vendors, their customers, and patients: A report of an AMIA special task force. *J Am Med Inform Assoc* 2011; 18:77-81.
6. Silverstein S. Contemporary Issues in Medical Informatics: Good Health IT, Bad Health IT, and Common Examples of Healthcare IT Difficulties. Drexel University. <http://cci.drexel.edu/faculty/ssilverstein/cases/?loc=home>
7. Computational Technology for Effective Health Care: Immediate Steps and Strategic Directions. National Research Council of the U.S. National Academics January 2009.
8. Tahir D. Feds criticized for lax oversight of health IT safety. *Modern Healthcare*, April 4, 2015.
9. Top 10 health technology hazards for 2015. A report from Health Devices, ECRI Institute, November 2014. www.ecri.org/Resources/Whitepapers_and_reports/Top_Ten_Technology_Hazards_2015.pdf
10. Wortman D. Top five health IT issues for 2015 – Part I. *Diagnoses*, January 26, 2015. www.diagnoses.com/top-five-health-it-issues-for-2015-part-i/
11. Wortman D. Top five health IT issues for 2015 – Part II. *Diagnoses*, January 28, 2015.
12. www.diagnoses.com/top-five-health-it-issues-for-2015-part-ii/
13. Ruder DB. Malpractice claims analysis confirms risks in EHRs. *Patient Safety Qual Healthcare* 2014; 20-23.
14. Peering underneath the iceberg's water level: AMNews on the new ECRI "deep dive" study of health IT "events". *Health Care Renewal*, February 28, 2013. <http://hcrenewal.blogspot.com/2013/02/peering-underneath-icebergs-water-level.html>
15. Another 'survey' on EHRs – Affinity Medical Center (Ohio) nurses warns that serious patient complications "only a matter of time" in open letter. *Health Care Renewal*, November 17, 2013. <http://hcrenewal.blogspot.com/2013/11/another-survey-on-ehrs-affinity-medical.html>
16. Safely implementing health information and converging technologies. The Joint Commission, December 11, 2008. www.jointcommission.org/assets/1/18/SEA_42.PDF
17. "EHRs: The real story" – Sobering assessment from medical economics. *Medical Economics*, February 28, 2014. <http://hcrenewal.blogspot.com/2014/02/ehrs-real-story-sobering-assessment.html>
18. Urbina Z. Top 12 health information technology issues. *Healthcare IT Connect*, May 15, 2013. www.healthcareitconnect.com/list-top-12-health-information-technology-issues/
19. Conn J. The good, the bad. *Modern Healthcare*, January 26, 2013. www.modernhealthcare.com/article/20130126/MAGAZINE/301269952
20. Carr D. Electronic health records: First, do no harm? EHRs are commonly promoted as boosting patient safety, but are we all being fooled? *InformationWeek Radio* investigates. www.informationweek.com/healthcare/electronic-health-records/electronic-health-records-first-do-no-harm/a/did/1278834
21. Hancock J. Health Technology's 'Essential Critic' Warns of Medical Mistakes. *Kasier Health News*, February 18, 2013 <http://kaiserhealthnews.org/news/scot-silverstein-health-information-technology/>
22. Manchikanti L, Falco FJE, Helm II S, Hirsch JA. First, do no harm by adopting evidence-based policy initiatives: The overselling of ICD-10 by Congress with high expectations. *Pain Physician* 2015; 18:E107-E113.
23. UK Press: The £12.7bn National Programme for IT is being ended after years of delays, technical difficulties, contractual disputes, and rising costs.
24. Sheikh A, Jha A, Cresswell K, Greaves F, Bates DW. Adoption of electronic health records in UK hospitals: lessons from the USA. *Lancet* 2014; 384:8-9.
25. Soumerai S, Avery T. Don't repeat the UK's electronic health records failure. *The Huffington Post*, December 1, 2010. www.huffingtonpost.com/stephen-soumerai/dont-repeat-the-uks-elect_b_790470.html
26. Linder JA, Ma J, Bates DW, Middleton B, Stafford RS. Electronic health record use and the quality of ambulatory care in the United States. *Arch Intern Med* 2007; 167:1400-1405.
27. Romano MJ, Stafford RS. Electronic health records and clinical decision support systems: Impact on national ambulatory care quality. *Arch Intern Med* 2011; 171:897-903.
28. Black AD, Car J, Pagliari C, Anandan C, Cresswell K, Bokun T, McKinstry B, Procter R, Majeed A, Sheikh A. The impact of eHealth on the quality and safety of health care: A systematic overview. *PLoS Med* 2011; 8:e1000387.
29. DesRoches CM, Campbell EG, Vogeli C, Zheng J, Rao SR, Shields AE, Donelan K, Rosenbaum S, Bristol SJ, Jha AK. Electronic health records' limited successes suggest more targeted uses. *Health Aff (Millwood)* 2010; 29:639-646.
30. Karsh BT, Weinger MB, Abbott PA, Wears RL. Health information technology: Fallacies and sober realities. *J Am Med Inform Assoc*. 2010; 17:617-623.
31. Mathison Dj, Chamberlain J. Evaluating the impact of the electronic health record on patient flow in a pediatric emergency department. *Appl Clin Inform* 2011; 2:39-49.
32. Yackel TR, Embi PJ. Unintended errors with EHR-based result management: A case series. *J Am Med Inform Assoc* 2010; 17:104-107.
33. Manchikanti L, Benyamin RM, Falco FJE, Hirsch JA. Metamorphosis of medicine in the United States: A car-

- rot and stick policy of electronic medical records. *Pain Physician* 2014; 17:E671-E680.
33. American Recovery and Reinvestment Act of 2009 (AARA), P.L. 111-5, February 17, 2009.
 34. Standards and Certification Regulations. www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations
 35. Information Technology: Not a cure for the high cost of health care. Knowledge@Wahrton, June 10, 2009.
 36. Lowry SZ, Quinn MT, Ramaiah M, Schumacher RM, Patterson ES, North R, Zhang J, Gibbons MC, Abott P. Publication Citation: (NISTIR 7804) Technical evaluation, testing and validation of the usability of electronic health records. National Institute of Standards and Technology, February 21, 2012. www.nist.gov/manuscript-publication-search.cfm?pub_id=909701
 37. Patrick J. A critical essay on the deployment of an ED clinical information system – Systemic failure or bad luck? Opinion Editorial – Draft V6.o <http://sydney.edu.au/engineering/it/~hitru/essays/Pt%201%20-%20The%20Story%20of%20the%20Deployment%20of%20an%20ED%20Clinical%20Information%20System6.o.pdf>
 38. Hoffman S, Podgurski A. E-health hazards: Provider liability and electronic health record systems. *Berkeley Technology Law Journal*, 2010. http://works.bepress.com/sharona_hoffman/7
 39. Hoffman S, Podgurski A. Meaningful use and certification of health information technology: What about safety? (October 25, 2010). *Journal of Law, Medicine and Ethics Supplement*, Vol. 77, Spring 2011; Case Legal Studies Research Paper No. 2010-34. <http://ssrn.com/abstract=1697587>
 40. Brouillard CP. Emerging trends in electronic health record liability. For the Defense, July 2010. www.bgladd.com/EHR_liability_issues.pdf
 41. Verdon D. Physician outcry on EHR functionality, cost will shake the health information technology sector. *Medical Economics*, February 10, 2014. <http://medicaleconomics.modernmedicine.com/medical-economics/content/tags/ehr/physician-outcry-ehr-functionality-cost-will-shake-health-information?page=full>
 42. Institute of Medicine. Health IT and Patient Safety. National Academy Press, Washington, DC. November, 8, 2011.
 43. Zaremba S. The forecast for health reform post-SGR repeal: Sunny or stormy? *Athenahealth*, April 17, 2015. www.athenahealth.com/blog/2015/04/17/the-forecast-for-health-reform-post-sgr-repeal-sunny-or-stormy
 44. Steinbrook R. The repeal of Medicare's Sustainable Growth Rate for physician payment. *JAMA* 2015 [Epub ahead of print].
 45. H.R.4015. SGR Repeal and Medicare Provider Payment Modernization Act of 2014. March 14, 2014.
 46. Tahir D. What the SGR bill's merit-based pay means for health IT incentives. *Modern Healthcare*, March 27, 2015. www.modernhealthcare.com/article/20150327/NEWS/150329937
 47. Perna G, Leventhal R. Blair Childs: SGR repeal is a “game-changer” for health IT. *Healthcare Informatics*, April 15, 2015. www.healthcare-informatics.com/article/sgr-repeal-game-changer-health-it
 48. Tahir D, Conn J. Health IT leaders brace for change under ‘doc fix’ bill. *Modern Healthcare*, April 15, 2015. www.modernhealthcare.com/article/20150415/NEWS/150419930
 49. Manchikanti L, Staats PS, Boswell MV, Hirsch JA. The analysis of the carrot and stick policy of repeal of infamous sustainable growth rate formula: The good, the bad, and the ugly. *Pain Physician* 2015; in press.
 50. Blendon RJ, Benson JM, Hero JO. Public trust in physicians – U.S. medicine in international perspective. *N Engl J Med* 2014; 371:1570-1572.