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The Politics of the EHR: Why we're not where we want to be and what we need to do to get there

By Bruce Wilder | October 1, 2013

By now, it seems abundantly clear that the vast potential offered by universal adoption of electronic health records (EHR) has not been achieved. Indeed, the fulfillment of that potential seems a long way off. Unsolved problems with interoperability, usability, safety, and security, to name a few, remain, and continue to pose barriers to universal adoption.

There is ample evidence in the medical literature, of the unsolved problems of the EHR. Indeed, two recent reports that offer (probably inadequate) solutions highlight the difficulties that exist with the EHR. The proliferation of these problems has only increased with the increase in adoption of the EHR by physicians and institutions. The Texas Medical Association has asked the (at the time) ONC, Farhad Mostashari, MD, to establish a health IT patient safety czar.[1]

Dr. Mostashari has called upon vendors to improve their products,[2] a solution unlikely to be effective. Hardly a day goes by when there is not some letter to the editor by a physician or nurse complaining about the burdens imposed by top-down EHR systems, not to mention comments made in the health care setting, usually the result of the may frustrations encountered by every-day users of the EHR.

In 2004, the Administration announced its intent to establish universal implementation of electronic health records in the United States by 2014.[3] Yet, a recent report has indicated that "the disappointing performance of health IT to date can be largely attributed to several factors: sluggish adoption of health IT systems, coupled with the choice of systems that are neither interoperable nor easy to use; and the failure of health care providers and institutions to reengineer care processes to reap the full benefits of health IT.[4] "[E]lectronic health record systems (EHRs) remain proprietary and risk-laden."[5] "The potential of health information technology to both improve patient care and reduce spending are unlikely to be realized until health care providers reengineer their processes to focus on the benefits that can be achieved."[6] I suggest that it is not only wrong, but counterproductive, to lay the blame for the failure to achieve the potential of HIT at the feet of "providers" (read physicians).

It is contended here, that the prevailing intellectual property regime of virtually all EHRs in use is not conducive to the level of innovation needed for optimizing and fully exploiting the value of the EHR. We should be thinking about ways that physicians, other users of the EHR, and even patients, can more effectively participate in its design and development. In other words, there needs to be an environment for innovation that is more directly driven by provider-users of the EHR. Some still view the model of multiple proprietary vendors competing to provide the best EHR as an ideal.

A properly-designed intellectual property regime that emphasizes collaboration among user-providers toward the common goal of improved safety, cost-savings, interoperability (including clinical-to-public health entities), protection of privacy, and up-to-date decision support makes more sense, and requires that user-providers be permitted to modify the code. Such a model requires that the source code be open and that any modifications made be shared with a central authority and, where appropriate, included in subsequent distributions of the EHR.

I suggest that such a solution has been in plain sight for years. On September 15, 2008, Congressman Pete Stark (D-CA) introduced H.R. 6898 in the 110th Congress, and called for the establishment of a federal open source Health IT system. Sec 3001(c)(4) of that proposed Act reads as follows:

> (4) FEDERAL OPEN SOURCE HEALTH IT SYSTEM-
>
> (A) IN GENERAL- The National Coordinator shall provide for coordinating the development, routine updating, and provision of an open source health information technology system that is either new or based on an open source health information technology system,

such as VistA, that is in existence as of the date of the enactment of this title and that is in compliance with all applicable standards (for each category described in paragraph (2)(A)) that are adopted under this subtitle. The National Coordinator shall make such system publicly available for use, after appropriate pilot testing, as soon as practicable but not later than 9 months after the date of the adoption by the Secretary of the initial set of standards and guidance under section 3003(c).

(B) CONSORTIUM- In order to carry out subparagraph (A), the National Coordinator shall establish, not later than 6 months after the date of the enactment of this section, a consortium comprised of individuals with technical, clinical, and legal expertise [in] open source health information technology. The Secretary, through agencies with the Department, shall provide assistance to the consortium in conducting its activities under this paragraph.

(C) AUTHORIZATION TO CHARGE NOMINAL FEE- The National Coordinator may impose a nominal fee for the adoption by a health care provider of the health information technology system developed or approved under subparagraph (A). Such fee shall take into account the circumstances of smaller providers and providers located in rural or other medically underserved areas.

(D) OPEN SOURCE DEFINED- In this paragraph, the term `open source' has the meaning given such term by the Open Source Initiative.[www.opensource.org][7]

This bill was quickly killed, largely due to efforts of the Health Information Management Systems Society (HIMSS), that objected to the passages quoted above, ostensibly because the government should not be involved. Instead, also due to lobbying by HIMSS, we got HITECH, which provided for $19 B in subsidies that ultimately benefitted the HIT industry,[8] as well as payment disincentives for physicians who might choose to not adopt EHRs. Moreover, we now have a whole new bureaucracy of "meaningful use."[9] That's a lot of government involvement, and we don't hear much complaining by HIMSS.

I have previously written about the need for open source code as a *sine qua non* in order to create an environment that is optimal for innovation.[10] But opening up the code is not enough. There needs to be a licensing regime that permits modification by users, contingent upon the obligation of such users to share those modifications with a central authority ("consortium") as envisioned in H.R. 6898 (and perhaps with all other users).

Ideally, the central authority would coordinate (i.e. "govern") the distribution and updating of the EHR versions, including the modifications that seem of widespread utility. Clearly, such an EHR distribution, should not be "one size fits all," but have several versions, each most useful to individual physicians, group practices, hospitals, nursing homes, mental health clinics, and even public health agencies.

Although accomplishing these goals would not be without significant expense and commitment of technological expertise, one need only take a sober look at the cost of what is in the HITECH Act ($19 B in grants, plus all the additional expenses, that have been estimated to be tens of billions more, in addition to the permanent slice taken out of the health care dollar for EHR maintenance).

Enactment of the provisions of H.R. 6898 cited above would also eliminate the seemingly endless haggling over "meaningful use." The idea is that if a low-cost, usable, efficient, interoperable system were available to all with workable innovation strategies for users, and integral to the provision of health care, there would be no need to require meaningful use: it would just happen. "If you build it [right], they will come." Such a licensing regime would, in effect, create an environment of potentially thousands upon thousands of developers to improve and update the EHR. That is, we can have more current and more productive innovation with the collaborative approach of Wikipedia, as opposed to the top-down model of Encarta.

Consider how the medical record has evolved to where it is today, and where it is going, or ought to go, in the future. Most agree that, in its evolution from paper chart to electronic health record, the medical record has become more than simply a memorandum of clinical findings and treatment of the patient. Perhaps the most influential factor has been the interest of payers. In fact, this quiet evolution actually began during the era of paper charts, and has at once both driven, and been accelerated by, a disturbing trend in just what the medical record is turning out to be in the age of the EHR.

If there is to be full realization of the potential offered by universal adoption of the EHR, it should evolve from an adjunct to patient care to a tool that is integral to the delivery of health care. For instance, decision support and artificial intelligence can and should be open, transparent, and current, in a state-of-the-art that is available to all users.

If the EHR is to be effective as an integral component of the delivery of medical care, limits must be

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placed on the demands of third parties for the entry of structured data not relevant to patient care (or, in the case of public health, not relevant to the administration of public health).

The prevailing intellectual property regime of virtually all EHRs in use today is far less conducive to the level of innovation needed for optimizing and fully exploiting the value of the EHR as an integral component of health care delivery.

The legal community, in facing the challenges of discovery of electronically stored information (ESI), is exploring sophisticated methods of extracting relevant information from huge amount of unstructured data.[11] A common complaint among users of the EHR is that considerable time is required to enter data that is collected for the purpose of payment, quality and safety metrics, among other things. This kind of data is of course important, but if not directly related to the care of the patient, users of the EHR should not be required to devote additional time to highly structured data entry, just to relieve those entities seeking the non-essential (for real time patient care) data from finding other ways to extract the necessary information.

In other words, the requirement of structured data entry should not place an undue burden on the individuals who need to devote maximal time and concentration to patient care in the patient care setting. Moreover, the requirement of highly structured data entry runs the risk of filling up the EHR with inaccurate or incomplete information, or even creating a chart note that gives the appearance that certain clinical observations were made, when in fact they were not.[12],[13] The ideal EHR should provide a way for the user-provider to say what she means in an optimal combination of free text and carefully limited form-filling and checklists.

Admittedly, there are situations where it is debatable whether the clinician or other user should be required to enter structured data that may not be necessary or relevant at the point of care. It is in those instances where the consortium envisioned in H.R. 6898 would have a role in resolving the conflicts presented.

To achieve the goal of making the EHR an integral component of health care delivery requires that devices that acquire data in electronic form be able to share that data with the EHR directly. Thus, the groundwork for the rapid development of artificial intelligence in the EHR would be laid.

For example, the huge amounts of data acquired in the ICU setting could be analyzed automatically to provide suggestions for diagnosis, prognosis, and treatment decisions, to a degree far beyond what we have achieved to date. Such an end will only be achieved when the source code is modifiable by user-providers (it is anticipated, of course, that the user-providers do not have the technical expertise, but will collaborate with IT experts in the setting of the institution to make such modifications).

Most experts would agree that cornerstones of safety in any industry, and as pointed out in the IOM report, To Err is Human: Building a Safer Health System, and many others, are simplicity, uniformity, and ease of use. Today's EHRs (of which there a hundreds of products on the market) as a whole are anything but simple, uniform and easy to use.

Most physicians, and other users such as nurses, pharmacists, etc., change practice settings frequently over the course of their careers. Why should there be need to adapt to a different EHR with each move? "Requiring physicians to spend large amounts of time to operate EHR systems that are poorly designed, is a poor substitute for creating well-designed, safe, an easy-to-use EHR systems."[14] It is stunning to me, that in a 40-minute talk on patient safety at one of the national organizations of neurosurgeons, Dr. Donald Berwick hardly mentioned HIT or the EHR.

A basic principle in the design of safe systems is that they be designed from the "ground up," instead of from the "top down." The design of EHR systems today is "top down," and it is astonishing that most experts, if not all, in EHR design and most experts, if not all, in patient safety have not acknowledged or recognized this issue, let alone provided a path toward its resolution.

It is remarkable that the American Medical Association, the American Bar Association, and the American Public Health Association have avoided serious discussion of the intellectual property issues raised here, particularly in view of ongoing concerns about physician autonomy, privacy, patient safety, and long term cost considerations relating to HIT.

We will never have an effective EHR system that fulfills the potential of HIT to transform medical care as an integral part of health care delivery unless we can move to an intellectual property regime as described above, that fosters maximal innovation in an environment of open source. Only then will the elusive goals of usability, privacy protection, interoperability, patient safety, and efficiency be achieved.

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Footnotes

1- Joseph Conn, Texas docs push for health IT safety czar, Modern Healthcare.com, 2/11/13 http://ehrintelligence.com/2013/02/11/texas-physicians-push-for-ehr-health-it-patient-safety-czar/ (access 2/24/13), also http://www.modernhealthcare.com/article/20130208/NEWS/302089975/texas-docs-push-for-health-it-safety-czar (access 2/24/13).

2- Mostashari calls on vendors to play fair: Some of their actions are "beyond the pale," and that if need be ONC will issue more regulations, Healthcare IT News, 2/6/13, http://www.healthcareitnews.com/news/mostashari-calls-vendors-play-fair?topic=,08,18 (access 2/11/13).

3-Executive Order 13335, April 27, 2004.

4-Kellerman AL and Jones SS, What It Will Take To Achieve The As-Yet-Unfulfilled Promises of Health Information Technology, Health Aff 2013;32:163-68, http://content.healthaffairs.org/content/32/1/63 (access 2/24/13, subscription required).

5-Managing ESI within Health Information Systems Riddled with Landmines, E-Discovery and Information Governance National Institute, American Bar Association, 1/23/13-1/25/13, Tampa, www.ambar.org/2013eig (access 2/24/13).

6- Note 4, supra

7- See http://thomas.loc.gov (access 2/24/13).

8- Julie Creswell, A Digital Shift on Health Data Swells Profits in and Industry, NY Times, Front Page, 2/20/13 http://www.nytimes.com/2013/02/20/business/a-digital-shift-on-health-data-swells-profits.html?src=me&ref=general (access 2/24/13)

9- Wright A, et al, Early Results of the Meaningful Use Program for Electronic Health Records, N Eng J Med 2013; 368:779-780, http://www.nejm.org/doi/full/10.1056/NE1213481?query=TOC (access 2/24/13). See also, Editorial, Fast could lead to furious over EHR meaningful use, amedews.com, 2/18/13, http://www.ama-assn.org/amednews/2013/02/18/edsa0218.htm?utm_source=nwltr&utm_medium=heds-txt&utm_campaign=20130218 (access 2/24/13)

10-Letter to the Editor, Open-source code is best path to creating physician-friendly EMRs, amednews.com Dec. 24/31/2007. http://www.ama-assn.org/amednews/2007/12/24/edlt1224.htm (access 2/24/13)

11- Note 5, supra

12- Abelson R, et al, Medical Bills Rise as Records Turn Electronic, New York Times, 9/21/12 http://www.nytimes.com/2012/09/22/business/medicare-billing-rises-at-hospitals-with-electronic-records.html?pagewanted=all&_r=0 (access 2/24/13).

13- Hirschtick RE, Electronic Records and Hospital Progress Notes, JAMA 2012;308:2337.

14- Note 13, supra

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