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Abstract:

This paper examines changes in the healthcare industry since a contrarian proposal was submitted to CMS in January 2005 for CMS to exercise its commercial power as the market master in the purchase of healthcare in the U.S. to catalyze the emergence of a commercial health record banking industry as an alternative to building a National Health Information Network (NHIN).

The original proposal, entitled the “Mt. Washington Vision”, was for CMS to provide financial incentives to, and eventually require, healthcare service providers seeking reimbursement from Medicare and Medicaid to create and deposit standard electronic documents, compliant with HL7 Clinical Document Architecture (CDA), into a patient-designated health record bank.

This paper analyzes important trends and changes in the last four years including:

- **The limited success of the RHIO and HIE models**
- **The ascendancy of the CDA standard**
- **The growing awareness of the health banking model**
- **The launch of patient-controlled PHRs by Google and Microsoft**

... And describes how these developments enhance the prospects for success of the original recommendation. The paper concludes with modifications to the original proposal and suggestions for next steps.

Mt. Washington Revisited

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Introduction

Almost four years ago the Office of the National Coordinator for Healthcare Information Technology (ONCHIT) released a Request for Information concerning the development of a National Health Information Network (NHIN). In January of 2005, a group of eight volunteers led by the authors of this paper met for three days within the shadow of Mt. Washington to craft a response. InterSystems Corporation provided financial support for the meeting which was graciously hosted by Dartmouth-Hitchcock Medical Center.

The following summarizes the essential insights and proposals of the group’s contrarian submission to the ONCHIT, entitled the “Mt. Washington Vision”. The full text is available at http://www.intersystems.com/mt_washington_vision.pdf This paper takes a look back at the positions taken in the RFI response from the vantage point of 2008.

The Original Vision is More Pertinent than Ever

The Brailer RFI was itself visionary in its effort to kick-start the widespread exchange of electronic health records with judicious government precipitants and eager participation from the commercial sector. It asked, essentially, for guidance on how to create an environment in which commercial partners could carry the burden with the trust of both clinicians and consumers of healthcare.

While much has changed since the issuance of the RFI, these core problems remain unaddressed. The lack of success of mainstream models of Regional Health Information Organizations (RHIOs) and Healthcare Information Exchanges (HIEs) in establishing an economically sustainable framework for the interoperability or portability of electronic medical records argues strongly for the consideration/reconsideration of patient-controlled, market-driven, incremental approaches to the interoperability and portability of electronic healthcare information, such as those proposed in the “Mt. Washington Vision”.

Several important changes in the healthcare industry in the last four years point to the prescience of that vision. In the remainder of this document we examine these changes and describe how they enhance the prospects for success or complement the recommendations of the initial vision. In the final sections of this paper, we indicate what modifications we would like to make to our original proposal and what next steps should be taken to implement the enhanced proposal.

Excerpts from the “Mt Washington Vision” – 18 January 2005

Do not create a central NHIN:

A single, centrally-architected NHIN for the U.S. is not required to proliferate appropriate exchanges of interoperable personal medical records information among providers, patients and other healthcare industry stakeholders.

We believe that a centrally-planned solution, even when such a solution eschews a national patient identifier, remains unfeasible in the U.S. Huge obstacles to the success of a centrally-architected solution are presented by the fragmented nature of the U.S. healthcare system and the extremely low level of adoption of electronic medical records systems outside of hospitals and large clinics. ...

Prime the Pump with Massive Amounts of Information:

We believe that ... The creation of a critical mass of standard, persistent, application-independent, electronic documents based on Health Level Seven's (HL7's) Clinical Document Architecture (CDA) will catalyze the emergence of an array of interoperability mechanisms from which all the benefits that the RFI ascribes to a NHIN will be realized.

Create Incentives for Information with Higher Reuse Value:

*The essence of our proposal is to use the position of the Center for Medicare and Medicaid Services (CMS) as the market master in the purchase of healthcare services in the U.S. to drive the creation of a critical mass of electronic documents produced by Medicare and Medicaid participating providers. **We propose that CMS provide incentives, and eventually require, healthcare providers and key ancillary service providers, such as clinical laboratories and pharmacies to create and make available standard electronic documents.***

The purpose of these electronic healthcare documents is to describe or summarize the care provided, the diagnostic test results generated, the medications dispensed, or the overall healthcare status of the patient, as appropriate to the role played by the provider of the services for which Medicare or Medicaid reimbursement is sought. ... Production of HL7 CDA-compliant electronic documents summarizing the healthcare service should be differentially rewarded according to the level of machine-processible encoding.

The Organizing Principle is that the Patient is in Control:

The author of a HL7 CDA-compliant document (i.e. a healthcare or ancillary service provider) must not only create and retain the original CDA document, but, if the patient designates a personal health record repository, must also deposit a copy into that bank. A personal health records bank is a new type of regulated, non-governmental organization created specifically to receive CDA documents from providers as the agent of the patient and store them in an Internet connected repository. Use of such repositories is discretionary and we anticipate a wide variety of such service provider to compete for this business, providers such as the RHIOs (as currently underway), commercial providers (Yahoo, Google), health plans (MyLifePath by Blue Shield of California) or PCPs and IDNs.

What Has Changed

The Ascendance of CDA

In the US: Adoption of HL7 Version 3 messaging has been slow to take hold, due principally to the high barrier of full semantic interoperability, a strategy that requires fully standardized electronic medical records on both sides of the transaction. Most immediate exchange requirements include at most one partner with an EMR and that one is unlikely to be fully standards-compliant. The spread of CDA (also an HL7 Version 3 standard) has been rapid, on the other hand, because it sets no such pre-condition. Without sacrificing the potential for full semantic interoperability, sending and receiving organizations can communicate via CDA in the familiar format of a document, while progressing toward semantic interoperability at their own vastly different speeds.

Evidence of this utility is found in the position of CDA in the Federal Health Architecture (FHA) and literally all of the efforts under the Office of the National Coordinator.

All this activity would mean little if CDA were not in production use. The number of providers producing CDA has expanded along with the recognition of the standard. In addition to Mayo Clinic, Military Health System and the Veterans Administration, there is substantial CDA implementation at New York Presbyterian, University of Pittsburgh Medical Center, Beth Israel Deaconess, Duke University Medical Center, Kaiser Permanente and others. Under the covers, millions of CDA documents are produced each year through dictation/transcription because using the CDA structures actually simplifies and expedites production.

Continuity of Care Document (CCD): The CCD is an excellent example of the ability of the CDA standard to enhance the value of other healthcare interoperability initiatives. The CCD standard was jointly developed by ASTM and HL7. The CCD standard capitalizes on the energy and domain knowledge driving ASTM's initiative to develop a XML-based summary of information critical to a safe handoff between care providers. The CCD also leverages CDA's strong technical foundation and potential for semantic interoperability. CCD documents would add great value to any Personal Health Record (PHR). The uptake of CCD, however, should not obscure the need for additional types of documents -- not everything needed for care delivery is a summary.

Beyond CCD: A Catalog of CDA Standards: The CDA for Common Document Types (CDA4CDT) project develops standards for the content of clinical documents within the HL7 CDA framework. The History & Physical and Consult Note have already been successfully adopted by HL7 as a Draft Standard for Trial Use (DSTU) and Operative Note and Diagnostic Imaging are currently being balloted. CDA4CDT has been enthusiastically championed by large and small providers of transcription services and by other vendors working with electronic documents in natural language processing and document management, an indication that EMRs are not the only applications that need a baseline standard for interoperability, in fact, the electronic document vendors need a standard to interoperate with the EMRs.

Outside the US: The adoption of CDA outside the US continues to accelerate with major projects now underway in France, Italy and Japan, joining the established regional and national exchanges in Finland, Germany and Greece. Experimental and pilot work is ubiquitous and CDA is now an International Organization for Standards (ISO) specification. Of all the activity outside the US, the most pertinent to the key points in the Mt. Washington Vision is the decision within the National Health Service to move to CDA. An early (2002) pilot of CDA in South Staffordshire had been ignored in favor of fully-encoded Version 3 messages. The reversal of

that position to the point where CDA is now the core exchange format speaks to the need to walk before you can run -- without compromising your ability to pick up speed at a later time.

Awareness of Health Record Banking is Increasing

William A. Yasnoff, MD, PhD, has adopted the concept of a health record bank as his own, establishing a non-profit agency to promote the concept and lobby for its adoption. The Health Record Banking Alliance (HRBA, <http://www.healthbanking.org/index.html>) has done much to spread the concept that management of health records should be a profitable, commercial enterprise operating independently, but with the cooperation, of current players. The HRBA has put the concept on the map.

The Principles (see draft, published May 9, 2007, <http://www.healthbanking.org/docs/HRBAPrinciplesMay07.pdf>) state unequivocally that consumers own and control their own records.

The organization, while an effective forum for discussion and lobby, has not been accompanied by a successful start-up effort. The view of HRBA from Mt. Washington highlights the failure by HRBA to see the potential to prime the pump with large amounts of unstructured or loosely structured data -- it retains the precious and data-centric view of exchange in today's NHIN projects. Another aspect of the HRBA that may be at least partially responsible is the somewhat strange notion introduced that patents have a role to play in regulating the use of standards for information exchange.

Google and Microsoft have Launched Patient-controlled PHRs

The idea that the patient and only the patient should control the contents of his or her life-time health record is foundational to both the Google and Microsoft approaches to a PHR. This has earned these PHR initiatives good marks from privacy advocates and watchdog organizations.

Unfortunately, to-date, Microsoft and Google have followed the mainstream approach to PHR architecture, in that they have emphasized the management of structured, encoded, semantically interoperable patient data despite the fact that there are almost none available for import. Based on their rich Internet history and mastery of search technology, we believe that these companies could be among the first to capitalize on a critical mass of CDA documents that implementing the recommendations of the Mt. Washington vision would make available to patients for inclusion in their PHRs or health records bank account.

What Has Not Changed

If the argument for patient-controlled, document-centric commercial records management was so compelling, then why has it not taken off and what must still occur for it to do so?

Reviewing the RFI response in light of the past three years, our emphasis on the role of CMS as the market master seems out of synch with the agency's view of its role in the industry and underplays the potential role of private insurers. While it would be convenient for CMS to do so, it seems as likely, from this vantage point, that a private carrier will adopt patient control as the organizing principle for shared patient records.

An additional boost that would be welcome would be an analysis by the Office of the National Coordinator and the American Health Information Community of who owns and controls patient records that could be embraced by the privacy lobby.

The original argument would have been stronger had it made a compelling critique of the mindset that insists that a patient record must be coded before it is complete. This mindset which

dominates thinking in exchange priorities in academia and certainly the first National Coordinator's Office is based on assumptions of what can be and what is desirable that come out of a very narrow slice of medical practice -- large, tertiary and often academic medical centers. The assumptions of what can be done and what is most urgently needed are vastly different outside those walls.

When the context of care is unknown, there are no assumptions on what kind of peer is accessing the data or for what purpose, the contextual requirements of information exchange take precedent over the granularity of the computer coding. In other words, where you do not know who will be reading the information, what other information they have access to, what the purpose of care is, even if the patient is present and conscious, it's really important to get the full story.

The whole sorry story of health IT in the hurricanes of 2005 and their aftermath more than illustrates this concept -- the all-out effort to supply medication history to the people scattered in the aftermath of the hurricanes, the KatrinaHealth project, concluded, in part, that EHR design should: "Create health information systems that are simple, interoperable, and resilient—and that accommodate the reality that data may be in different formats."¹ A strategy that values coding granularity to the exclusion of completeness and ease of implementation will never meet this need.

At the same time, minimal standards are needed so that information can flow freely and be accessed by arbitrary down-stream applications. Any data this is coded according to consensus standards should be represented as such so the value is not lost. Sending common file formats alone does not provide this minimum threshold for downstream use. The minimal CDA with seven required metadata fields can be output by just about any application and would be readily available as the common format for the 600,000,000 dictated notes produced annually in the US. Industry leaders representing the companies that produce approximately half this annual total have already signed on to support this strategy and to make their information available, under the appropriate controls, to networks and patient-centric content aggregators. As yet, the opportunity has gone wanting while industry waits on EMR adoption, enshrined still, as the pre-condition for interoperability.

Conclusions

The importance of patient control of the PHR goes beyond privacy and could be the foundation of a change in national healthcare IT policy and of an associated, sustainable business model capable of driving the exchange of healthcare information toward its true goal of higher quality care and better outcomes.

The patient is the principal beneficiary of quality care and of the best possible outcome from medical treatment. No one has ever disputed the importance of information to achieving these goals. By placing the patient at the hub of the exchange of personal health information, the patient becomes the "buyer" for healthcare information about themselves which they can use to manage personal health decisions and which they can provide to future healthcare providers to improve the quality of care they receive and the outcomes they experience. We believe that such a buyer/patient would "pay" for the automatic aggregation of the medical information in readily-available, human-readable documents in an easy to manage personal health record or health record bank account under their exclusive control. The monies involved would actually flow in

¹ P. 29 <http://katrinahealth.org/katrinahealth.final.pdf> *Lessons From KatrinaHealth*, Markle Foundation, American Medical Association, Gold Standard, RxHub, SureScripts.

the form of differential reimbursement by healthcare insurers to providers for information deposited in the patient-controlled personal health record or patient-controlled bank account. This creates a natural market for the patient-oriented information that healthcare providers could be exchanging. The illusive ROI for provider investments in healthcare information exchange is thereby produced.

While many of the individual pieces deemed crucial to success have been put into place over the past three years, no single project combines them all. Closest, perhaps, are the non-healthcare-specific, commercial efforts by Google and Microsoft which recognize that none of the established entities has a right to primary control of a patient-centric record. Even here, however, the mindset remains at a level of complexity several notches above that needed to solve many immediate needs and, critically, to prime the pump and put massive amounts of data onto the networks.

With fewer than 20% of healthcare facilities capable of creating a coded record for internal consumption, predicating exchange on the existence of coded data is tantamount to issuing a 10 year delaying order. The recent article in Health Affairs by Carol Diamond and Clay Shirky got at least one point very right: standards themselves will not drive exchange where basic adoption has not occurred. It is past time to recognize that we cannot exchange that which does not exist at the source. Insisting that data exchange originate from a fully-coded EMR simply retards the effort to put mission-critical information in front of clinicians and patients.

We believe the core insights of the Mt. Washington Vision are more pertinent today than ever.

The key barriers to free-flowing information remain:

- An attachment to centralization and complexity
- Lack of patient control of their healthcare information

We agree with Diamond and Shirky that standards are neither the barrier to nor the magic enabler of achieving the real national goals of quality healthcare and improved outcomes. We further agree that the cloudy national landscape for healthcare information policy is a major impediment to achieving these goals. We propose that patient control of their life-time personal health records be the centerpiece of national healthcare information policy and that priming the healthcare delivery system with large numbers of simple, CDA-compliant documents will foster the adoption of practical standards which support near-term national policy goals and facilitate the gradual evolution of the healthcare system to higher levels of semantic interoperability among electronic medical record systems.