

[Healthcare - EMR] Standardization and Certification: The truth just sounds different.

By Nainil Chheda [M.S in MIS] nainil.c@eliteral.com

Abstract

Over the past couple of years, many standards have evolved to improve the design and functionality of Electronic Medical Records [EMR]. Various factors involving the timing, the right players, market history, utility, governance play a key role in the overall enrichment of the standard and certification development. There are often benefits to market players and end users from standardization of a product or a service.

Standardization of healthcare components does not necessarily imply standardization of healthcare knowledge in general. It has been argued by the author that these standards and certifications even though seem to bring uniformity in the development of healthcare, do not guarantee their acceptability and sustainability in the long run.

The author discusses the extent to which the issue can be overcome by efficient analysis of the standardization and certification process and by enforcing cumulative awareness of the standards harmonization process.

Keywords

Standardization, Certification, Healthcare Governance, Electronic Medical Record, Harmonization, Interoperability.

About the Author

Nainil Chheda, 24, holds honorary Masters Degree in Management in Information Systems (MIS) from Temple University, Philadelphia PA. Nainil also holds a Masters of Commerce (1) (specialization in Management) degree from University of Mumbai, India. Nainil works as a knowledge research specialist in eClinicalWorks LLC. For many years, Nainil has served as a consultant and advisor on search engine optimization, website development for many reputed organizations.

Nainil has research interest in the Governing Dynamics of the Internet and in finding the Nash equilibrium for various scenarios in the EMR industry.

Website: <http://www.nainil.com/>

Introduction

Corporate decision makers seem hardly aware of the strategic advantages or disadvantages of standardization and certification. This lack of knowledge on the part of decision-makers means that the strategic potential of standardization and certifications is not fully appreciated.

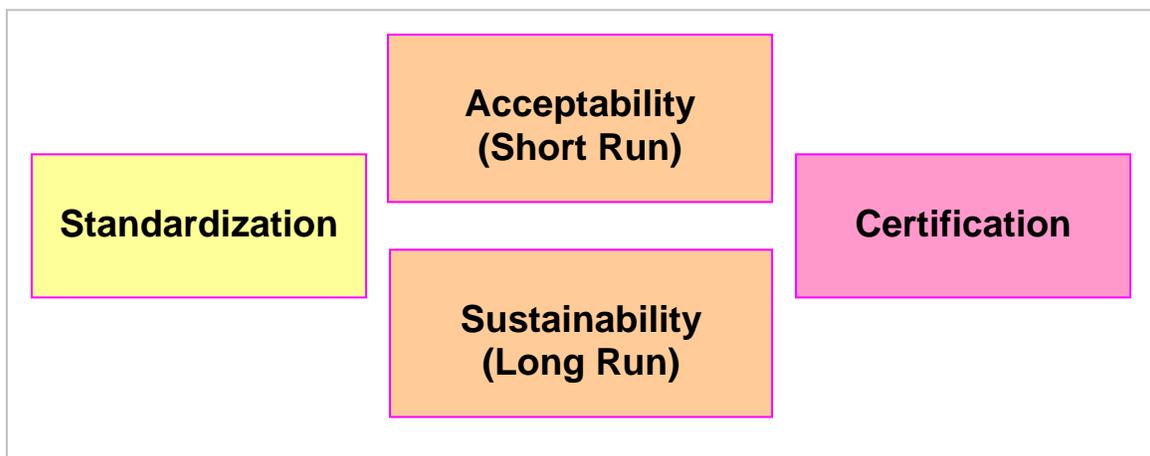
Companies are motivated to participate in standardization and certification because they gain an edge over non-participating companies in terms of knowledge.

There is a lot of pride in innovation, and when it is first pushed out the door, there is a hard fight. For individuals and companies, impulse control is important because what works in the certification and standardization phase doesn't always work in the real world scenarios.

So the question is: Are we getting there? Are we moving in the right direction, away from it, or are we stuck dead in the water? What is a feasible solution to find the governing dynamics of the EMR industry?

The standards that exist enable innovation, whereas the standards often applied to learning objects, restrict innovation. Where does our current standards development group stand?

This paper discusses the effects standardization and certification would have on the healthcare industry. It also discusses the various approaches that can lead to a better healthcare solution.



Authors view towards Standardization and Certification.

Background

In the diversity of Health Information Society, standardization and certification take on a particularly important role. Using information technology to make healthcare safe and available to all is vital in today's environment.

Many in the healthcare industry believe that electronic health records (EHRs) are the foundation of widespread adoption of IT throughout healthcare. Using IT, the healthcare industry has developed many standards and specifications to support information exchange.

The biggest problem in health care is the challenge of data availability. There are over 700 standards in health care. These standards intend to bring the health care entities in synchronization with the rest of the world. However, it has been debated that standards which are available today will be obsolete almost 5 years from now because technology is changing constantly.

In standardization, the real question that needs answer is "How can you develop evolving set of standards which can be considered extendible to the technological changes that come in the future?"

Many a times, the government intervenes in the development and operation of a standard or a certification process for a variety of different reasons. The main objectives of government intervention are to respond to policy failures, to limit abuses of market power, and to improve quality of health care.

In this document the author assumes that above all the various actors involved the government plays a very important role in standards and certifications development.

Actors involved and their roles

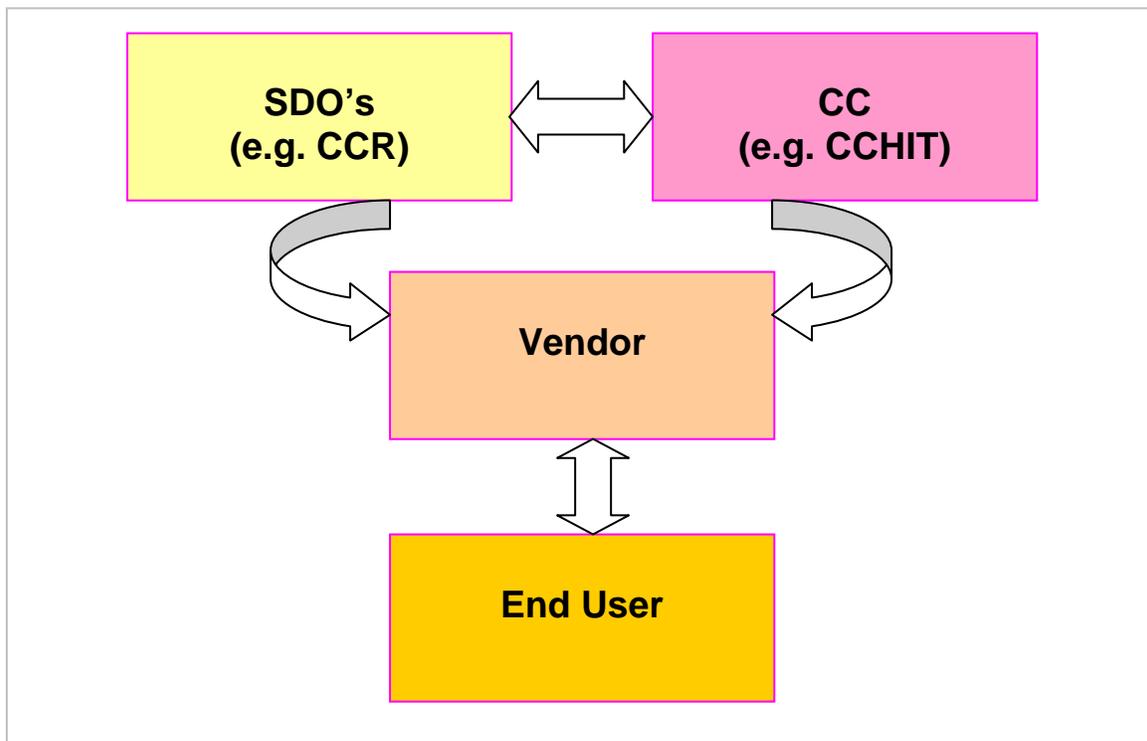
The author identifies the main actors involved and the roles they play in the standards and certification process. The actors include the following mentioned below and are not limited to:

* SDO (Standards Development Organization): SDOs are organizations that develop and maintain the models, data dictionaries, structure, syntax, and implementation materials for standards. All designated SDOs maintain policies that meet the requirements that provide an open forum for participants to identify, plan and agree on standards and assurance of due process.

* CC (Certificate Commission): CC is an organization which develops, promotes, and administers examinations and certifications for health care services.

* Vendors: An individual, partnership, corporation, or other activity that provides service (with or without the use of technology) to the end user for a fee.

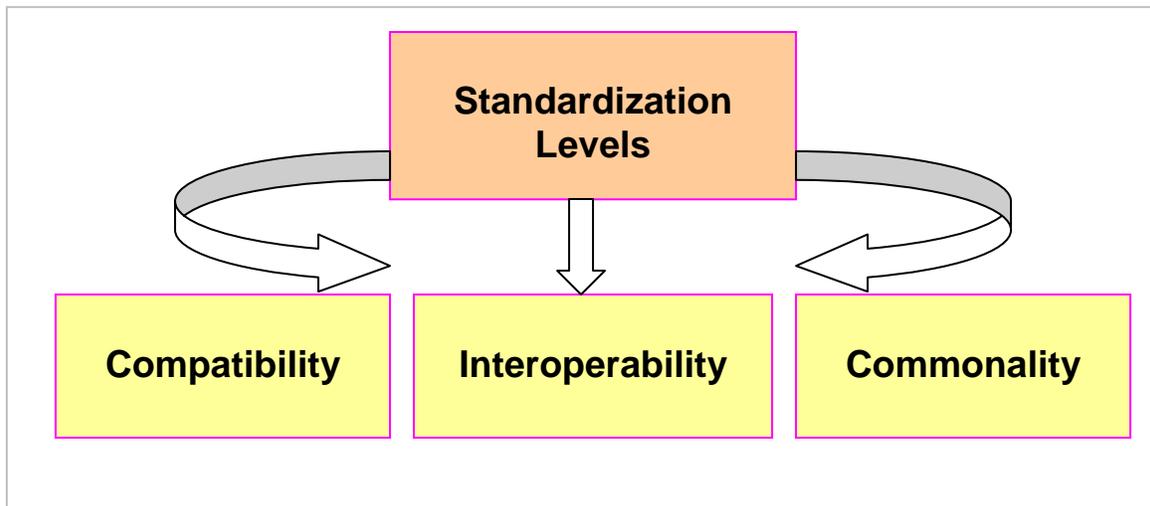
* End Users: Health care providers, health care consumers / patients and families, public health agencies, RHIO's and other network service providers, health care payers / purchasers, quality improvement and research organizations.



Authors view towards the actors involved in the development of standards and certifications.

Standardization Levels

There are different levels of standardization. These levels define the basis of the developed standard. Compatibility, Interoperability and Commonality help in maintaining proper operational, procedural and technical applicability for the standard.



Authors view towards the levels of Standardization.^[6]

The various stages involved in the development of a standard are:

- * Standards Proposal Stage
- * Building Committee Draft
- * Building Technical Committee
- * Building FD (Final Draft)
- * FD Approval Stage
- * Building the Standard Stage (by the technical committee)
- * Final Standard Approval Stage
- * Publication Stage
- * Review Stage (Periodic Review of the standard)

Standards Dilemma

In healthcare, standardization is a reasonably balanced collaborative process which intends to maintain proper quality measures and level of detail in the product or service that is provided on an ongoing basis.

Standardization is mainly for providing us with a common vocabulary for comprehending what has been done with less ambiguity. The main reason why humans can communicate with each other is that we have common concepts in terms of which we can express our ideas.

Currently, any standard that is being formed, if supported by a strong set of stakeholders gets more value than the other. This brings in the topic of “Acceptability” and “Sustainability”.

For every ultimately successful standardization effort, there are many failures. The existence of a real or proposed standard, or even the announcement of a plan to create one, can throw an entire industry into fear, uncertainty, and doubt. Standardization pays. However, does it pay in the short term or the long term of implementation is still a question that needs an answer.

Like any other industry the healthcare industry too faces the “Multiple Standards Dilemma”.

Multiple Standards Dilemma is defined as “Standards (for the same purpose) offering two or more solutions, neither of which is completely acceptable”. The case of “CCR” and “CDA” is a classic example of the Multiple Standards Dilemma.

Neither of the standards is complete. Neither of the standards has been tested successfully. Neither of the standards can meet the complete requirements of an interoperable health care data.

Because of the conflict and / or overlapping nature of both these standards a new harmonization specification known as the CCD (Continuity of Care Document) is being developed between ASTM and HL7.

However, to argue one might mention a very valid point that multiple standards are also important as this leads to a healthy competition amongst the standards and thus leads to improvement in the quality of data that is available for use.

Certification Issues

The problem that arises due to certification is the lack of knowledge for certification measures, the inaccuracy of the certificate criteria's and the extensive investment of dedicated resources for learning the certification measures. Certifications may be perpetual, may need to be renewed periodically, or may be valid for a specific period of time.

Many of the certification organizations charge a very high amount as the fees for certification. Due to competition the various health care vendors participate in the certification process and even the small vendors have to burden themselves with the certification overheads.

Certification not only involves through preparation, but it also (sometimes) involves team work, time devoted to the certification, bending the software functionality to meet the certification.

The CCHIT (Certificate Commission for Health Information Technology) is one of the leading Certification Agencies for the Electronic Health Records.

Many certificate commissions being newly formed possess functional difficulties that include:

- * Incomplete information on the test criteria's.
- * Not enough time available for allowing public comments to the test criteria's.
- * Ambiguity in test criteria's causing last minute trouble to the EHR Vendors.
- * The certificate commission is learning how to run the organization while testing various EHR Vendors for certification which costs thousands of dollars.

The health care industry brings forth a very important concept called the "Certification Dilemma". A "Certification Dilemma" in health care is explained using an example: Consider two EMR vendors both participating in the certification process. One of the EMR vendors sells his software for a very high cost while the other EMR vendor sells it for a lower price. What would happen when both of the EMR vendors get certified together? It is more likely that the EMR vendor that sells his software for a lower price wins as the customer would argue that if both the EMR products are certified, and they offer me almost the same functionality, why would I pay a higher price for the same service I am getting at a lower cost.

Conclusion

As the information technology era evolves, the health care sector continuously gains advantage by the various standardization and certification processes that have been initiated. With the help of standardization and certification, both the government and the private sector are taking bold initiatives to help raise the quality of care and reduce its cost.

Even though the acceptability and sustainability of standardization and certification in the long run is a question, the availability of patient data and its ownership (due to standardization and certification) are no longer an issue. The privacy and security areas are being accounted for by the production of reliable comparative data.

The recent focus of standardization and certification on health care has steadily broadened the focus from limited access to a broad public purpose access of data.

Accessibility of data and its protected exchange can be managed by effective standardization and certification processes. The distinctive character of modern information technology, is that it can be used to automate intelligent decision making information. The common data dictionaries, standards and certified products together aid in the fast progress of the health information networks.

Glossary of Terms Used

Standardization - The process of establishing standards that are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines, or definitions of characteristics.

Certification - A certificate is an official document affirming some fact. Certification is the process of obtaining a certificate through a certifying authority.

CCR - Continuity of Care Record, is a standard specification being developed to foster and improve continuity of patient care, to reduce medical errors, and to assure at least a minimum standard of health information transportability when a patient is referred or transferred to, or is otherwise seen by, another provider.^[1]

CCHIT Certification - CCHIT was awarded a contract by the U.S. Department of Health and Human Services (HHS) to develop, create prototypes for, and evaluate the certification criteria and inspection process for electronic health records (EHRs).^[2]

CDA - HL7 Clinical Document Architecture, Release 2 (CDA): The CDA is a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange.^[3]

Acceptability - Satisfactoriness by virtue of conforming to approved standards.

Sustainability - Meeting the needs of the present without compromising the ability of future generations to meet their own needs.

Standards Development Organization (SDO) – SDOs are organizations that develop and maintain the models, data dictionaries, structure, syntax, and implementation materials for electronic transaction standards between and within providers. All designated SDOs maintain policies that meet the requirements of the American National Standards Institute (ANSI), which accredits standards committees and provides an open forum for participants to identify, plan and agree on standards and assurance of due process.^[4]

Regional Health Information Organization (RHIO) – RHIOs are multistakeholder organizations expected to be responsible for motivating and causing integration and information exchange in the nation's revamped healthcare system.^[5]

Reference & Readings:

1. CCR Definition - Retrieved from
<http://www.medrecinst.com/pages/about.asp?id=54> and
<http://www.emrworld.net/emr-research/ccr.php>
2. CCHIT Definition - Retrieved from
<http://www.cchit.org/about/faq/general+information+faq.htm>
3. CDA Definition - Retrieved from
<http://www.hl7.org/Library/committees/structure/CCD.13Feb2006.DRAFT.doc>
4. SDO Definition - Retrieved from
www.phdatastandards.info/knowresources/tutorials/glossary.htm
5. RHIO Definition - Retrieved from
http://en.wikipedia.org/wiki/Regional_Health_Information_Organization
6. Standardization Levels - Retrieved from
<http://en.wikipedia.org/wiki/Standardization>
7. [Health Affairs] Smart Technology, Stunted Policy: Developing Health Information Networks Computer health information networks can help lower the “cost of quality.” Yet debates rage over the privacy, proprietary control, and power of such data. By Paul Starr.
8. NHIN [Health & Human Services]
http://www.hhs.gov/healthit/NHIN_Forum1.html

This whitepaper is provided "AS IS" with no warranties, and confers no rights. Any opinions expressed in this whitepaper are solely those of the author and not official positions of any organizations mentioned herewith.