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Standardization Needs for Effective Interoperability

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Abstract: The Electronic Health Record (EHR) has brought unique challenges in the effort to share information. How data is captured varies from institution to institution. In order for data to be well understood, data should have a definition that is consistent and comprehensively understood by all users of the data. Standardization of how data is captured is critical to allow the production and export of data needed to support quality assessment, decision support, exchange of data for patients with multiple health care providers and public health surveillance. Patient safety and quality improvement are dependent upon embedded clinical guidelines that promote standardized, evidence-based practices. Unless we can achieve standardization with terminology, technologies, apps and devices, the goals of EHR implementation won't be realized.

Keywords: Standardization, Interoperability, Electronic Health Record, Meaningful Use

INTRODUCTION

Good data in represents good information out. Better data is critical for better health. Organizational data should be accurate, timely, well-understood, accessible, and efficiently gathered. In order for data to be well understood, data should have a definition that is consistent and comprehensively understood by all users of the data. (Glazer, 2001) Modern medicine is very complex and information about a single patient can be reported in different ways by different doctors who are treating different conditions for the same patient. Utilizing a common terminology that translates complex medical concepts into language that is both clinician and patient friendly improves the quality of care for patients and enhances efficiency.

Department of Health and Human Services ("DHHS") Secretary Kathleen Sebelius notes that "One of the key challenges to achieving a coherent health record for every U.S. consumer is the need for consistent data across all systems and institutions". (HHS, 2010) Lack of standardized data often creates reluctance for clinicians to use other clinician's data. It appears to be oxymoronic that having too many standards creates a lack of standardization. The purpose of this article is to create awareness of problems lack of standardization creates and the progress to date on standardization of electronic health information data.

DOCUMENTATION FOR QUALITY AND REIMBURSEMENT

Standardization is critical to allow the production and export of data needed to support quality assessment, decision support, exchange of data for patients with multiple health care providers and public health surveillance. Private and public payers, public health departments, and independent accreditation organizations asked health care providers to report on quality measures, especially in light of the Affordable Care Act. Quality measures are now being publically reported, and in some cases tied to financial reimbursement. . Developing a way to standardize and harmonize data, e.g. using a minimal data set for the universe of measures, would be helpful, especially when working toward data interoperability among many different systems. (Ahmad, 2012)

Although providing accurate documentation that an organization complied with core measure for stroke or acute myocardial infarction is required for optimal reimbursement, allowing each institution to define parameters

and develop flow sheets to capture the information could hinder a standardized method or vocabulary for capturing data. Medical professionals are mobile and practice in more than one organization at any specific period of time. Reporting standardization among Electronic Health Record (“EHR”) vendors is critical, as missing documentation may adversely affect reimbursement.

VOCABULARY STANDARDS

Vocabulary standards for electronic clinical quality measures (“eQMs”) are being developed by the Office of the National Coordinator for Health IT (“ONC”), along with the National Quality Forum (“NQF”) to develop vocabulary standards. One of their goals is to create a standardized model, i.e. the Quality Data Model, turning measure specifications into computable value sets, which can then be used for quality measurement. (Ahmad, 2012)

STANDARDIZATION AND CONSISTENCY OF DATA ELEMENTS COLLECTED

There is lack of standardization and consistency in what data elements are collected, their form and where they are placed in the computer document. Text names of data elements are often defined by the institution and differ from department to department as well as from one organization to another. (Hammond, 2005) An assessment, diagnosis, or medical problem may be documented differently in different medical records. One EHR vendor may use the term Medication Administration Record (“MAR”) where another vendor may refer to the same documentation record as an electronic Medication Administration Record (“eMAR”). One vendor may allow height in inches, others feet and inches or even in centimeters. Weight can be in pounds and ounces or just pounds or kilograms and still others will convert from one to the other automatically, or display both.

Coded Data vs. Free Text

Standardization of data is necessary to create appropriate coded data. Healthcare systems use codes in place of text in many database fields. Procedure codes, diagnosis codes, lab test codes, etc. save computer space and ensure uniform standard codes for accurate interpretation of the data by another user. Codified data allows the data to be shared easily among other users that also have access to the data fields. Text data refers to data that is not codified, and consists of words, sentences and paragraphs. Data interoperability is hindered when clinicians utilize free text documentation. Although text data can be searched with a specific word or word phases, it does not allow for optimal data sharing. When an organization transfers data to another organization, standardized codified data allows for better data interpretation.

Definition of Terms

Developing, writing and standardizing definition of terms is not an easy task. Developing standardized language is highly complex. For example, nurses, physicians and other medical professionals may have slightly different interpretations of the same word, condition or diagnosis. As a result, each may be hesitant to adopt a defined standard not their own. In short, definitions should be as brief as possible, yet as complex as necessary. Non-standardization when defining code status can be problematic with various definitions and usage of such terms as “Do Not Resuscitate,” and / or “No Code”.

Units of Measure

Standardization of data not only refers to a definition of a diagnosis, but also to the unit of measure. When capturing the unit of measure, appropriate standardization should define whether milligrams will be MG, Mg, or mg. Standards, not individual vendors should establish gas or liquids flow (volumetric or mass flow) and how they should be measured.

Data Mining, Business Intelligence and the Need for Standardized Data

Standardized codified data is essential to performing data mining and business intelligence activities. Data mining is used to assist healthcare insurers detect fraud and abuse, help healthcare organizations make customer relationship management decisions and assist physicians in identifying effective treatments and best practices. Data mining can be defined as the process of finding previously unknown patterns and trends in databases and using that information to build predictive models. With the ability of computers, data mining can be used to determine which courses of treatment are effective as well as identify and track chronic diseases states and high risk patients. (Koh, 2005) However, data mining applications can only be implemented with reliability when accurate data is used. Missing, corrupted, inconsistent, or non-standardized data, such as pieces of information recorded in different formats in different data sources is a problem. "In particular, the lack of a standard clinical vocabulary is a serious hindrance to data mining". (Koh, p.70, 2005)

Business Intelligence ("BI") is commonly considered to be the "knowledge gained about a business through the use of various hardware/software technologies which enable organizations to turn data into information". (Kurdyka, 2013) BI allows an organization to access and analyze data about their operations and activities. BI software allows the data to be queried, runs reports and performs *what if* scenarios. However, information obtained through efforts expended via BI is dependent on clean, standardized data and data formatting in databases, hence again, the need for standardization in obtaining and storing data.

Non-standardization of Laboratory Values

Lack of standardization affects more than simply data terminology and nomenclature. Even when standardized vocabulary is used, the purpose of the data may be different and may not meet the intended purpose of the additional user. One example is how various healthcare organizations define laboratory results, e.g. Within Normal Limits ("WNL") or Within Defined Limits ("WDL"). If one organization indicates a Troponin level is WNL if the value is <0.01 to 0.5, yet when accepting a transfer patient from another facility, the same test result could have been considered a "Critical" or "Abnormal" lab value, that difference may affect patient care. Another example is the administration of insulin in managing hyperglycemia. Variations in dosing with an insulin sliding scale may exist and be especially problematic with brittle diabetics.

Abbreviations and Acronyms

The healthcare field uses many abbreviations and acronyms. Lack of standardization and misuse of abbreviations and acronyms can create problems with appropriate patient care, especially with medication errors. (The Joint Commission, 2013) The Joint Commission provides a list of approved abbreviations and acronyms as well as a "Do NOT Use" abbreviations list to standardize interpretation. Currently, The Joint Commission allows organizations to develop their own standardized abbreviation lists if using a published reference source. (The Joint Commission 2, 2013) In 2010, the Joint Commission's "do not use" list of abbreviations was integrated into the patient safety goal requirements, but not applied to preprogrammed health information technology systems (for example, electronic medical records or CPOE systems). However, the requirement remains under consideration for the future. (The Joint Commission 3, 2013)

“Meaningful Use” and its focus on standardization

The Health Information Technology for Economic and Clinical Health (“HITECH”) Act allows doctors, health care professionals and hospitals to qualify for Medicare and Medicaid incentive payments when they adopt and meaningfully use certified EHR technology. (The US Department of HHS, 2012) Meaningful use criteria and objectives evolve in three stages over five years with Stage 1 focusing on data capture and sharing, Stage 2 advancing clinical processes and Stage 3 focusing on improved outcomes. As many health care organizations have attested to Stage 1, Stage 2 focuses on more rigorous health information exchange (“HIE”), with increased electronic transmission of patient care summaries across multiple settings. That goal will be difficult to achieve without standardization of data and data capture within standardized formats. (Health IT, 2013)

Throughout many of the Meaningful Use Stage 1 and Stage 2 measures, the thread of requiring the data captured as structured data is prevalent. For Stage 1 and Stage 2 attestation, data such as patient name, race, smoking status, medications, medication allergies and laboratory tests are all required to be captured according to published standards. Smoking status must be coded directly to a standardized SNOMED CT code. (Health IT 2, 2013)

The U.S. Office of the National Coordinator for Health Information Technology (“ONCHIT”) in its Stage 2 Meaningful Use criteria address standardization among data formats in an effort to foster intersystem compatibility, allowing the facilitation and ease of sharing information across multiple disparate systems. (Zaleski, 2012)

INTERNATIONAL PROGRESS TO STANDARDIZE MEDICAL VOCABULARIES AND NOMENCLATURE

SNOMED-CT is an acronym for Systemized Nomenclature of Medicine (CT is an acronym for clinical terms). According to the International Health Terminology Standards Development Organization’s (“IHTSDO”) website, SNOMED CT is the most comprehensive, multilingual clinical terminology in the world and is a vital component for safe and effective communication and reuse of meaningful health information. (IHTSDO, 2013) SNOMED CT is a standard clinical terminology with specific support for multi-lingual translation and is in use in more than 50 countries. SNOMED CT has been recommended to become the core terminology for codified EHR’s in the United States. The IHTSDO is the not-for-profit association that owns and maintains SNOMED-CT. As of June 2013, SNOMED CT has distributed its first release of the SNOMED CT International Edition.

The World Health Organization (“WHO”) utilizes the International Classification of Diseases (“ICD”) as their standard diagnostic tool for epidemiology, health management and clinical purposes. The ICD is utilized to assess and analyze the general health situation of population groups and monitors the incidence and prevalence of diseases and other health problems. This classification system is used for reimbursement of medical services in the United States. (World Health Organization, 2013) In 1990, the 10th edition (ICD-10) was endorsed by the World Health Assembly, but is still not used in the United States. As of July 2013, the United States has until October 1, 2014 to begin using ICD-10-CM for diagnosis coding for inpatient hospital reimbursement. Once adoption of ICD-10 is accomplished, the United States will be a step closer to achieving international medical terminology and definition standards. Additionally, IHTSDO has a formal working arrangement with the WHO to develop and assure maps and linkages between SNOMED CT and WHO Classifications. Many SNOMED CT codes have been mapped to ICD-10.

The DHHS published the 2014 EHR certification criteria designating Logical Observation Identifiers Names and Codes (“LOINC”) as the vocabulary for reporting lab test results. LOINC can simplify integrating lab test results into an EHR system as structured data. RxNorm has been designated as the vocabulary for medications and is a standardized nomenclature for clinical drugs and drug delivery devices. RxNorm provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software. The Value Set Authority Center (“VSAC”) has been designated as the repository for Value Sets that support 2014 Meaningful Use Clinical Quality Measures (“CQMs”). Routes of

Administration and Patient Assessment Instruments value sets will be added to the VSAC soon. (US National Library of Medicine, 2013)

The Unified Medical Language System (“UMLS”) is a set of files and software that brings together many health and biomedical vocabularies and standards to enable interoperability between computer systems. The open source software can be utilized when designing and developing electronic health records to assist in standardizing the processing, grouping, categorizing and release of data in a common format. Three tools used by the UMLS are referred to as their knowledge sources and include the Metathesaurus. The Metathesaurus contains terms and codes from many vocabularies including CPT, ICD-10-CM, LOINC, MeSh, RxNorm, and SNOMED CT. (US National Library of Medicine, 2013)

Medical Devices; Need for Standardization

The mobile health (“mHealth”) market continues to grow and expected to grow in the foreseeable future. Mobile devices, applications and other social media technology provide a real opportunity to help healthcare providers deliver better, more consistent and more efficient healthcare where it is needed, which is often in remote or underserved communities. Evidence from studies indicates remote monitoring and other areas of connected health may contribute to improved clinical outcomes. (Hay, 2012)

Eventually, most mHealth technology, apps and devices will need to be integrated into the EMR. Although many vendors of mHealth technology have developed interfaces allowing integration to a specific EMR vendor, at this time there does not appear to be a mHealth technology national standard for all EMR applications. When each device manufacturer develops their own interface, it stifles the creation of an interoperable device system to provide the needed standardization for use in many EMR applications. Since it is anticipated that payment for mHealth technology will eventually be paid for by insurers and / or through providers via Accountable Care Organizations, perhaps mHealth companies would be in the best position to develop standards to integrate their technology into many EMR systems. (Arnold, 2013)

A medical device regulatory position statement for mHealth,(GSMA, 2012) discusses key policy principles that provide the appropriate balance between ensuring patient safety, while providing an environment for innovation and growth. The regulatory position provides that although differences in medical device regulations vary from country to country, the use of standards has been a key element in establishing medical device regulations and includes a wide range of specifications for products, processes and services.

Organizations such as the U.S. Federal Drug Administration (“FDA”) and the WHO Global Harmonization Task Force have been working to enable interoperability for a variety of products and devices. However, first it has to be determined whether the device is a medical device or a wellness device. The FDA provided the following definition to assist manufacturers and regulatory agencies in a guidance document “Understanding Medical Device Regulation for mHealth-A Guide for Mobile Operators”. (FDA, 2013) Mobile wellness apps may include dietary tracking logs, appointment reminders, calorie counters, and posture and exercise. Whereby mobile medical apps are those intended for “curing, treating, seeking treatment for, mitigating, or diagnosing a specific disease, disorder, patient state, or any specific, identifiable health condition”. ABA would require a footnote/citation here for the specific quote. Manufacturers of medical apps should clarify to end users whether the app is medical or wellness as specific regulations apply to medical apps. Although many standards already exist for medical devices, additional standards are needed for current medical devices, software, network service, and mobile platforms (IT system connected to the mobile network) when developing mobile medical products. (GSMA 2, 2012)

Lack of standards is prevalent even when medical devices are supported on an open standards-based data communication like Health Level Seven (HL7). Terminology and units of measurement may not be consistent across medical devices. As discussed, medical ventilators developed by different manufacturers may have parameters that differ in definition from one to the other. Critical values and alarm settings might not have similar parameters from one vendor to another or from one organization to another. Units of measure might not be captured

in a standardized method. If medical device data is going to be relied upon by various medical providers, then standardization of the terminology, measurements and data is essential for proper patient care management. (Zaleski, 2012)

State and National Health Information Exchange (HIE)

A health information exchange (“HIE”) is the sharing of EMR data between institutions and clinicians involved in providing a patient’s care. Health care organizations have different EHR systems and the goal of a HIE is to allow this information to be accessed, integrated, and applied to the patient’s current needs. Ideally, all information captured in an EHR will be accessible not only nationally but around the world.

Standards are key to achieving interoperability and meeting the goals of a national HIE. In collaboration between the Office of the National Coordinator for Health Information Technology (“ONC”) and the Office of Science & Technology (“OST”), initiatives have been developed to establish the building blocks of interoperability by standardizing:

- Meaning through the use of standardized healthcare vocabularies
- Structure by leveraging standards in Health Level Seven (HL7)
- Transport using secure email protocols
- Security through National Institute of Standards and Technology (NIST)-adopted encryption standards, and
- Services through open, and accessible application programming interfaces (APIs) (Health IT, 2013)

The ONC is leading the process to establish what is needed for a national strategy on health information exchange. Each state has been provided financial incentives (total from Congress is \$548 million) under the State HIE Cooperative Agreement Program to modernize how patient health information is stored and shared. (Health IT, 2013)

The vision for most state HIEs is to allow affiliated healthcare providers to exchange health information across the state. Exchanged health information includes clinical documents, laboratory results, imaging reports and demographic information. The broader vision is that the Nationwide Health Information Network would connect all of the state-based information networks. (University of Michigan, 2013)

Recent legislative developments of Accountable Care Organizations (“ACO’s”), bundled payment options and patient-centered medical homes (“PCMHs”) are motivating providers to participate in health information exchange (HIE) to better share medical information for more effective and efficient health care. (Health IT, 2013)

CONCLUSION

The benefits of the electronic health record can only be achieved when multiple users can look at the record and have a common understanding of what is captured in the record. Patient safety and quality improvement are dependent upon embedded clinical guidelines that promote standardized, evidence-based practices. Unless we can achieve standardization with terminology, technologies, apps and devices, the goals of EHR implementation won’t be realized.

However, such standardization is not an easy task. Capturing data in a standardized nomenclature, format and language has proven difficult for those who are developing and implementing the EHR. Modern medicine is very complex and information about a single patient can be reported in different ways by different practitioners who are treating different conditions for the same patient. Sharing of standardized data is still a goal and not a reality. Progress toward standardization is being made, but we are not there yet.

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