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Health IT and Patient Safety: Finding Relations Between EMRAM and SAFER Guides

Tecnologia da Informação em Saúde e a Segurança do Paciente: Encontrando Relações entre EMRAM e SAFER Guides

Tecnología de la información sanitaria y seguridad del paciente: encontrar relaciones entre EMRAM y SAFER Guides

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Keywords: Electronic Health Record; Electronic Medical Record Adoption Model; SAFER Guides

ABSTRACT

Objectives: The goal of this work was to identify relations between SAFER Guides and EMRAM requirements. **Method:** We conducted EMRAM requirements extraction based on materials provided by HIMSS Analytics Latin America. The process of SAFER Guides requirements extraction was performed based on the guidelines available on the ONC website. The authors identified three types of relations: direct; indirect; and partial. **Results:** We found 38 EMRAM requirements with some relation to SAFER Guides requirements. Out of 696 SAFER Guides requirements, we identified 108 relations to EMRAM requirements (15,5%) which indicates that EMRAM does not include most of SAFER Guides requirements. **Conclusion:** Despite EMRAM is more focused on Health IT maturity in organizations, it includes important requirements strictly related to patient safety not required by SAFER Guides. On the other side, most of SAFER Guides requirements are not addressed by EMRAM.

Descritores: Prontuário Eletrônico do Paciente; Electronic Medical Record Adoption Model; SAFER Guides

RESUMO

Objetivos: O objetivo deste trabalho foi identificar as relações entre os requisitos do SAFER Guides e EMRAM. **Métodos:** Conduzimos a extração de requisitos EMRAM com base em materiais fornecidos pela HIMSS Analytics Latin America. O processo de extração de requisitos do SAFER Guides foi realizado com base nas diretrizes disponíveis no site do ONC. Os autores identificaram três tipos de relações: diretas, indiretas e parciais. **Resultados:** Encontramos 38 requisitos EMRAM com alguma relação aos requisitos SAFER Guides. Dos 696 requisitos do SAFER Guides, identificamos 108 relações com os requisitos do EMRAM (15,5%), o que indica que o EMRAM não inclui a maioria dos requisitos do SAFER Guides. **Conclusão:** Apesar do EMRAM estar mais focado na maturidade de TI em organizações de saúde, ele inclui requisitos importantes estritamente relacionados à segurança do paciente e que não são exigidos pelo SAFER Guides. Por outro lado, a maioria dos requisitos do SAFER Guides não são exigidos pelo EMRAM.

Descriptores: Registro Electrónico de Paciente; Electronic Medical Record Adoption Model; SAFER Guides

RESUMEN

Objetivos: El objetivo de este trabajo fue identificar la relación entre los requisitos de SAFER Guides y EMRAM. **Métodos:** Realizamos la extracción de requisitos EMRAM basados en materiales proporcionados por HIMSS Analytics Latin America. El proceso de extracción de requisitos de SAFER Guides se llevó a cabo con base en las pautas disponibles en el sitio web de la ONC. Los autores identificaron tres tipos de relaciones: directa, indirecta y parcial. **Resultados:** Encontramos 38 requisitos de EMRAM con alguna relación con los requisitos de SAFER Guides. De los 696 requisitos de las Guías SAFER, identificamos 108 relaciones con los requisitos de EMRAM (15,5%), lo que indica que EMRAM no incluye la mayoría de los requisitos de SAFER Guides. **Conclusión:** Aunque EMRAM se centra más en la madurez de TI en las organizaciones sanitarias, incluye requisitos importantes estrictamente relacionados con la seguridad del paciente que no son exigidos por SAFER Guides. Por otro lado, EMRAM no exige la mayoría de los requisitos de SAFER Guides.

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INTRODUCTION

Despite benefits offered by Electronic Health Records (EHR) in healthcare, studies have shown that such technologies may lead to unintended consequences when improperly developed, used or implemented[1-4]. Analysis of incident reports showed that EHR was associated with prescribing errors, wrong medication administration, tests assigned to wrong patients, and missing tests results in EHR[5]. Many errors are detected before harming a patient (near miss), but undetected errors may still harm patients[6]. In this context, several approaches have been emerged with the goal of supporting healthcare organizations in implementing and using EHR[7].

The Healthcare Information and Management Systems Society (HIMSS) Analytics developed the Electronic Medical Record Adoption Model (EMRAM) composed by eight stages (from zero to seven). The goal of EMRAM is to measure the adoption and utilization of EHR functions in hospitals, focusing specially on patient safety and operational efficiency. A survey from HIMSS Analytics in partnership with The Advisory Board Company shows that the achievement of stages 6 and 7 of EMRAM has brought several benefits to the hospitals validated[8]. However, studies show that maturity models regarding EHR in healthcare settings are not comprehensive and still lack further details. In this sense, it is important for EMRAM to learn from other sources of EHR evaluation in healthcare organizations.

Another approach related to Health Information Technology (IT) is the SAFER Guides, which is a set of guides with recommended practices related to the safety and safe use of EHRs[9]. It was designed to be a self-assessment to healthcare organizations. The recommended practices are organized in three domains: Safe Health IT, Using Health IT Safely, and Monitoring Safety. Safe Health IT presents recommendations related more specifically to the design of health IT, whereas Using Health IT Safely presents recommendations related to safe use of heath IT. Monitoring Safety is composed by recommendations focused on monitoring the processes of design and use of health IT in order to optimize safety.

A study has been conducted to evaluate SAFER Guides recommended practices across eight organizations[10]. The 8 sites fully implemented only 18% SAFER Guides recommendations, which means that most organizations are not adherent to important practices to improve patient safety in relation to Health IT. Once Safer Guides is a self-assessment tool, it depends on the organization to demonstrate interest in implementing it. On the other side, evaluations like EMRAM stimulate adoption by organizations, once it results in a certificate. Therefore, it is relevant to certification and accreditation bodies to include Health IT patient safety requirements to their scope.

In this article, we conduct a study to identify relations between SAFER Guides and EMRAM requirements. Our solution provides a mapping between their requirements, which can help to identify opportunities to improve both EMRAM and SAFER Guides. Obtained findings might be useful for creating a new model consisting on the merging of these evaluations. To the best of our knowledge, such mapping has not been conducted by any study in literature.

This work is an extension of our previous work performed to identify relations between EMRAM and Joint Commission International (JCI) requirements[11]. In that study, we found important Information Technology requirements from JCI that could be include in EMRAM validation, such as organizational policies for copy and paste functionalities which is also addressed by SAFER Guides.

We organize this paper as follows: section 2 presents the conducted methodology, including the process for requirements extraction and relations identification. Section 3 reports on the results and discusses the findings. Section 4 concludes the work by presenting the main contributions and opportunity for future work.

METHODS

This investigation was conducted through two main activities: the extraction of EMRAM and SAFER Guides requirements and the identification of relations between them.

Extraction of Requirements

The process of EMRAM requirements extraction was performed by the authors based on our previous work[11]. This work conducted EMRAM requirements extraction based on materials provided by HIMSS Analytics Latin America, represented by the Brazilian company FOLKS, in partnership with this work. Such material corresponds to a sheet of EMRAM requirements based on the current version of EMRAM and it is more detailed than the original material provided by HIMSS Analytics on their website. Once the EMRAM stages are cumulative (each stage includes the criteria of all previous stages), we only considered stage 7 requirements.

All EMRAM requirements presented in the available material was atomic, which was one of the criteria for this work. We consider a requirement as atomic when it cannot be divided into two or more other requirements. For example, the requirement "the hospital shall use clinical decision support alerts on Computerized Provider Order Entry (CPOE) for allergy and drugs interactions" is not atomic because it could be divided into two requirements (one for allergy and another for drugs interaction).

Each EMRAM requirement has the following attributes: identification number, category, and requirement text. The identification number uniquely identifies each requirement. The category is the domain area of the requirement, such as "information security" and "clinical documentation". The requirement text describes the criteria demanded by the requirement.

The process of SAFER Guides requirements extraction was performed based on the guidelines available on the The Office of the National Coordinator for Health Information Technology (ONC) website. SAFER Guides are organized in three categories: Clinical Process Guides,

Foundational Guides, and Infrastructure Guides. Clinical Process Guides is composed of four guides: Computerized Provider Order Entry (CPOE) with Decision Support, Patient Identification, Test Results Reporting and Follow-Up, and Clinician Communication. Foundational Guides is composed of the guides High Priority Practices and Organizational Responsibilities. Infrastructure Guides is composed of Contingency Planning, System Configuration, and System Interfaces.

Each guide consists of a set of good practices organized in three phases: Safe Health IT, Using Health IT Safely, and Monitoring Safety. The first phase addresses safety concerns unique to technology (for example, providing specific EHR functionalities), whereas the second phase is related to the safe use of Health IT. The third phase addresses capabilities to monitor and improve patient safety.

Each guide contains a set of recommended practices in three domains. Each recommended practice is complemented by "examples of potentially useful practices/scenarios", which goal is to give a rationale and examples of how to implement each recommended practice. In this study, we considered the recommended practices as a general requirement and the examples as specific requirements.

Each SAFER Guides requirement has the following attributes: identification number, guide category, domain, phase, indication for generic or specific, and requirement text. In this work, we did not consider the requirements of High Priority Practices Guide because it is composed of a set of the main recommended practices, which means that its requirements are already included in the other guides.

Types of Relations Investigated

During the process of relation establishment between EMRAM and SAFER Guides requirements, the authors identified three types of relations: (1) direct; (2) indirect; and (3) partial. Therefore, the relations identified in this work were manually classified by the authors using these three types of relations. The direct relation indicates a perfect match, that is, both requirements are equivalents. The indirect relation indicates that one of the requirements indirectly requires the same criteria as the other. For example, SAFER Guides requires that allergy shall be coded. Despite EMRAM does not have this requirement, it requires drug-allergy alerts which indirectly implicates that the allergy should be coded. The partial relation indicates that one requirement partially requires the same criteria as the other.

For each SAFER Guides requirement, we identified one of these three relations to EMRAM requirements. We included a rational when the relation was "indirect" or "partial".

RESULTS

We extracted 775 SAFER Guides requirements which 696 was considered after the removal of the duplicate requirements from High Priority Practices guide. The list of Stage 7 EMRAM requirements provided by HIMSS Analytics Latin America is composed of 116 requirements organized in 15 categories.

We identified 108 SAFER Guides requirements with some relation to EMRAM requirements. On the other hand, we found 38 EMRAM requirements with some relation to SAFER Guides requirements, which means that the relations were not one-to-one. For example, the SAFER Guides requirement "Orders for diagnostic tests are placed using CPOE and electronically transmitted to the diagnostic service provider (e.g., laboratory, radiology)" is related directly to two EMRAM requirements: "Lab orders shall be sent electronically from the CPOE to the Laboratory Information System (LIS)" and "Radiology orders shall be sent electronically from

Table 1 - Number of relations with EMRAM identified for each SAFER Guides guide

Guide Category	Domain Guide	No. SAFER Guides Requirements	No. Direct Relations	No. Indirect Relations	No. Partial Relations	No. SAFER Guides Requirements with some relation to EMRAM
Clinical Process	Computerized Provider Order Entry (CPOE) with Decision Support	130	9	21	5	35
Clinical Process	Patient Identification	60	0	0	1	1
Clinical Process	Test Results Reporting and Follow-Up	90	5	1	3	9
Clinical Process	Clinician Communication	66	0	0	0	0
Foundational Guides	Organizational Responsibilities	123	1	13	1	15
Infrastructure	Contingency Planning	73	11	13	5	29
Infrastructure	System Configuration	80	6	10	0	16
Infrastructure	System Interfaces	81	0	2	1	3

the CPOE to the Radiology Information System (RIS)". The many-to-many relations are inherent to the SAFER Guides structure and EMRAM requirements extraction.

Out of 696 SAFER Guides requirements, we identified 108 relations to EMRAM requirements (15,5%) which indicates that EMRAM does not include a most of SAFER Guides requirements. Most of these relations is associated to Contingency Planning (39,7%) and Computerized Provider Order Entry (CPOE) with Decision Support (26,9%).

In this paper, we present the results focusing on the relations from SAFER Guides to EMRAM requirements. Table 1 presents the number of relations with EMRAM identified for each SAFER Guides requirement.

Direct Relations

We identified 32 SAFER Guides requirements with a direct relation to EMRAM requirements, which 14 are from Clinical Process Guides (9 from CPOE with Decision Support Guide and 5 from Test Results Reporting and Follow-Up Guide), 17 from Infrastructure Guides (11 from Contingency Planning and 6 from System Configuration), and one from Foundational Guides (all of them from Organization Responsibilities Guide). Table 3 presents some examples of direct relations between SAFER Guides and EMRAM requirements.

Most of the direct relations identified is related to contingency planning, which goal is to prevent and mitigate EHR downtime. Nine requirements from CPOE with Decision Support Guide are directly related to EMRAM, specially because of the requirement of alerts in CPOE. It is important to note that there are other types of CPOE alerts required by SAFER Guides, but not required by EMRAM, such as drug-patient age alerts. Besides, SAFER Guides require other kinds of functionalities related to clinical decision support on CPOE that are not required by EMRAM, such as the external knowledge bases access. To that purpose, the EHR can be integrated to the Health Level 7 (HL7) Context Aware Knowledge Retrieval Application ("Infobutton"), which provides the communication between the EHR and knowledge resources*.

Indirect Relations

We identified 60 indirect relations between SAFER Guides and EMRAM requirements, which 22 are from Clinical Process Guide (21 from CPOE with Decision Support Guide and 1 from Test Results Reporting and Follow-Up Guide), 25 from Infrastructure Guides (13 from Contingency Planning, 2 from System Interfaces, and 10 from System Configuration), and 13 from Foundational Guides (all of them from Organization Responsibilities Guide). Table 4 presents some examples of indirect relations between SAFER Guides and EMRAM requirements.

Most of indirect relations is due to EMRAM requirements that are not so specific as SAFER Guides. For example, EMRAM requires the hospital to have one or more committees to discuss Clinical Decision Support (CDS) governance and functionalities, but it does not specify what exactly should be discussed, while SAFER

Table 2 – Examples of direct relations between SAFER Guides and EMRAM requirements

SAFER Guides Requirement	EMRAM Requirement Related
Drug-allergy interaction checking occurs during the entry of new medication orders.	CPOE shall provide drug-allergy alerts.
Drug-drug interaction checking occurs before medication orders are submitted for dispensing.	CPOE shall provide drug-drug interaction alerts.
Dose range checking for single dose occurs before medication orders are submitted for dispensing.	CPOE shall provide dose range alerts.
Results outside normal reference ranges, or otherwise determined to be abnormal, are flagged (i.e., presented in a visually distinct way).	Laboratory testes results outside normal reference ranges shall be flagged (i.e., presented in a visually distinct way).
Hardware that runs applications critical to the organization's operation is duplicated.	The hospital shall have an IT redundancy plan (data redundancy, support hardware, and network).
Users are trained on how to proceed during system unavailability (i.e., downtimes).	The care team of the hospital shall be aware of the IT resources available during systems unavailability.

Table 3 - Examples of indirect relations between SAFER Guides and EMRAM requirements

SAFER Guides Requirement	EMRAM Requirement Related	Relation Rationale
Coded allergen and reaction information (or "no known allergies" [NKA]) are entered and updated in the EHR prior to any order entry.	CPOE shall provide drug-allergy alerts.	EMRAM requires drug-allergy alerts, which requires coded entry of allergies in the EHR.
Backup media are rendered unreadable (i.e., use software to scramble media contents or physically destroy/shred media) before disposal.	The hospital shall have data destruction policy (devices, backup media, paper documents, servers, computers, etc.).	EMRAM requires that the hospital has data destruction policies, which includes access to backup media destruction.
The server hosting the interface hardware and software is maintained in a physically secure (i.e., locked room) location.	The hospital shall have physical access policy to IT system / datacenters.	EMRAM requires physical access policy, which includes interface hardware.
The EHR is hosted safely in a physically and electronically secure manner.	The hospital shall have physical access policy to IT system / datacenters.	EMRAM requires physical access policies, which includes the EHR.

* http://www.openinfobutton.org/hl7-infobutton-standard

Guides requires specific aspects that should be addressed, such as order-sets updating and alert fatigue.

Partial Relations

We identified 16 partial relations between SAFER Guides and EMRAM requirements, which 9 are from Clinical Process Guide (5 from CPOE with Decision Support Guide, 3 from Test Results Reporting and Follow-Up Guide, and 1 from Patient Identification Guide), 6 from Infrastructure Guides (5 from Contingency Planning and 1 from System Interfaces), and 1 from Foundational Guides (from Organization Responsibilities Guide). Table 5 presents some examples of partial relations between SAFER Guides and EMRAM requirements.

The main reason for partial relations is because of SAFER Guides structure that usually requires more than one criteria in the same requirement, while EMRAM requirement extraction considered only atomic requirements. For example, SAFER Guides require the hospital to use and maintain updated operating systems, virus and malware protection software, application software, and interface protocols. On the other hand, EMRAM only addresses the use and maintenance of anti-virus and anti-malware.

Another important partial relation is due to an important requirement from EMRAM that is not required in SAFER Guides, the Technology-Enabled Bedside Product Administration. That process specifies that the hospital must use some technology (barcode, QR code, etc.) to identify patients and products to be administrated at the bedside (at least medication, human milk, and blood products). Through scanning of patient wristband and product, the Electronic Medical Record (EMR) shall verify whether the patient and product identification are correct. If some mistake is detected (for example, professional scanned a drug not prescribed to the patient), the EMR shall alert the professional, preventing a potential product administration mistake. For medication, EMRAM also requires the EMR to alert about correct time, dose, and administration route.

Despite SAFER Guides does not require Technology-Enabled Bedside Product Administration, it demands a comprehensive set of practices related to safe patient identification. Most of them are not addressed to EMRAM because only one relation in Patient Identification Guide was identified.

Limitations and Future Work

The results of this work can be used to identify improvement opportunities to EMRAM validation, especially considering patient safety. Therefore, as a future work, it is important to evaluate the relations between EMRAM, SAFER Guides and JCI requirements together, which can enable the creation of a more comprehensive model to evaluate patient safety in healthcare organizations in the perspective of information technology.

It is worth mentioning that the identification of relations of EMRAM and SAFER Guides requirements performed in this study was not submitted to a validation process by other specialists, which is a limitation of the study. Such validation was not possible because of the limited number of specialists in EMRAM in Brazil. In addition, EMRAM requirements were extracted based

Table 4 - Examples of partial relations between SAFER Guides and EMRAM requirements

SAFER Guides Requirement	EMRAM Requirement Related	Relation Rationale
Order entry information is electronically communicated (e.g., through the computer or mobile messaging) to the people responsible for carrying out the order.	All medications and other materials must be automatically sent from the CPOE to the pharmacy worklist (PHIS).	SAFER Guides requirement is more comprehensive.
The EHR facilitates the tracking of "send-out" tests at the point of ordering and provides a mechanism to allow clinicians or organizations to incorporate these results into the EHR and assign them to the correct patient.	Results of laboratory tests are electronically sent in a structured form and stored on the EHR, so that the data can be used for analysis and for clinical decision support mechanisms.	EMRAM requires that tests result to be incorporated into the EHR automatically.
Patient identity is verified at key points or transitions in the care process (e.g., prior to procedures and surgeries, rooming patient, vital sign recording, order entry, medication administration, check out).	The patient shall be identified using a technology that allows unique identification, such as a bar code on a wristband.	EMRAM requires Technology-Enabled Bedside Product Administration
Organizational policy facilitates reporting of EHR-related hazards and errors and ensures that reports are promptly investigated and addressed.	The hospital shall report "overrides" and "near miss" in order to track potential mistakes during bedside product administration. For example, scanning an incorrect drug.	EMRAM requires EHR-related hazards reporting only for bedside product administration.
The EHR downtime policy describes when the warm-site backup process should be activated (ideally, before the system has been down for 2 hours).	The hospital shall have a formal procedure for EHR reactivation after downtime describing all steps to activate the redundant datacenter and subsequent return to the main datacenter.	EMRAM requirement has less specifications.
Established and up-to-date versions of operating systems, virus and malware protection software, application software, and interface protocols are used.	Hospital shall use and maintain anti-virus and anti-malware tools on their devices.	This EMRAM requirement requires only virus and malware protection.

on a material provided by a company that represents HIMSS Analytics in Latin America, which is a copyright of the company. Therefore, we did not use a material provided officially by HIMSS Analytics once they do not provide a publicly detailed source with EMRAM requirements.

CONCLUSION

EHR evaluation can benefit from the mapping between distinct models and recommendations. However, literature lacks studies for discovering to which extent existing models overlap and how they are correlated. This investigation identified relations between EMRAM and SAFER Guides requirements. Despite EMRAM is more focused on Health IT maturity in organizations, it includes important requirements strictly related to patient safety, such as the technology-enabled bedside administration which is not covered by SAFER Guides. On the other side, most of SAFER Guides requirements are not addressed by EMRAM. Our results are useful as a source for the improvement of both methods. Healthcare organizations can use our achieved results to identify technologies and implement them to ensure compliance with both validations.

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