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Functionalities of free and open electronic health record systems

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Abstract

Objectives: The aim of this study was to examine open-source electronic health record (EHR) software to determine their level of functionalities according to the International Organization for Standardization (ISO) standards. Methods: ISO standards were used as a guideline to determine and describe the reference architecture and functionalities of a standard electronic health record system as well the environmental context for which the software has been built. Twelve open-source EHR systems were selected and evaluated according to two-dimensional criteria based on ISO/TS 18308:2004 functional requirements and ISO/TR 20514:2005 context of the EHR system. Results: Open EHR software programs mostly fulfill structural, procedural, evolutional, and medicolegal requirements at the minimal and full functionality levels. Communication, privacy, and security requirements are accomplished in less than 23 percent of the cases, mainly at minimal functional level. Ethical, cultural, and consumer requirements still need to be fulfilled by free and open-source EHR applications. Conclusions: Most analyzed systems had several functional limitations. Nevertheless, especially for clinicians and decision makers in developing countries, open-source EHR systems are an option. The limited functionalities are likely to become requirements for further releases of open-source EHR systems.

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Results: Open EHR software programs mostly fulfill structural, procedural, evolutional, and medicolegal requirements at the minimal and full functionality levels. Communication, privacy, and security requirements are accomplished in less than 23 percent of the cases, mainly at minimal functional level. Ethical, cultural, and consumer requirements still need to be fulfilled by free and open-source EHR applications.
Conclusions: Most analyzed systems had several functional limitations. Nevertheless, especially for clinicians and decision makers in developing countries, open-source EHR systems are an option. The limited functionalities are likely to become requirements for further releases of open-source EHR systems.

Keywords: Open source, Electronic health record system, Standard requirements, Evaluation

Electronic health records (EHRs) have long been considered as an important element for improving the delivery of healthcare services. EHRs have been defined as information repositories for the health status of a subject of care; they usually reside on a database or other digital media (8). EHRs contain retrospective, concurrent, and prospective information concerning physical and mental health, descriptions of the medical condition, and treatments administered to a subject of care (1;5;9;11). According to the U.S. Institute of Medicine, EHR systems (i) improve accessibility to health records, (ii) facilitate communication between staff, (iii) are repositories for information collected during the treatment of the patient, (iv) support continuing treatment of the patient, (v) are a repository of information for further treatment of the same patient, and also a knowledge base for advanced research and medical education (4;13). Structured, secured, and reliable EHR systems must adhere to standards that allow them to interact independently of the platform or technology used for their implementation (3).

In recent years, open-source and free license information systems have emerged as viable models for electronic health record systems (12). Open-source EHR systems are developed under the modality of free and open-source software (FOSS) and can be used freely and modified according to specific requirements without infringement of their licenses (10;12). The FOSS EHR applications that have been included

in this study are distributed under three modalities of open-source licensing: the GNU General Public License (GPL), GNU Lesser General Public License (LPGL), and Eclipse Public License (EPL). The GPU GPL stipulates free use, modification, and redistribution of the software without restrictions as long the source code is released under the terms of GPL. The GNU LGPL extends GPL by allowing linkage to proprietary software without the latter becoming a derivative work (10;12). The FOSS EHR systems licensed under EPL are applications developed under Eclipse extensible frameworks.

To the best of the authors' knowledge, no previous study has been conducted to analyze and compare functionalities of FOSS healthcare software. A list of software requirements was selected from ISO/TC 18308 and ISO/TR 20514. Both standards have been developed by the technical committee 215 of the International Organization for Standardization (ISO). The ISO technical document 18308:2004 is a compendium of clinical and technical requirements for a standardized Electronic Health Record Architecture (EHRA) that supports the storing, use, sharing, and exchange of EHR across different models of health care (7).

It is important to note that the ISO/TS 18308 provides a set of requirements for an EHRA but does not establish the architecture itself (7). The ISO technical report 20514 defines the scope, context, and categories for electronic health records and provides a set of basic characteristics, classifications, and functional descriptions for electronic health record systems (8).

METHODS

The goal of the study is to examine open-source EHR systems to determine how their functionalities and architectures comply with international standards. To reach this goal, we evaluated the level of reaching a set of standard requirements. ISO, CEN, open EHR, and U.S. Institute of Medicine core EHR were initially considered as sources for establishing the requirements and their contextual implementation. The ISO standards (ISO/TR 20514 and ISO/TS 18308) were selected due to their international acceptance and comprehensive description; they also provide a clear and hierarchically structured set of requirements to be compared and analyzed at different aggregation levels (7).

The sourceforge.net portal was used to identify the most relevant FOSS EHR software projects. This site provides information of open-source projects developed all over the world. At the time of the search, twenty-nine open EHR applications were identified as active projects. Nineteen of them provided an implemented source code and documentation. Finally, a total of twelve active FOSS electronic health record projects (alternatives) were selected for this study: CHITS, Cottage Med, Elexi, FreeMED, GNUmed, MedClipse, MirrorMed, OpenEMR, OpenMRS, OSCAR, PatientOS, and Tolven. The selection criteria were that the project provides software and source code under an open-source license, has been developed to manage information about the health status of a subject of care, and has demonstrated the capability of managing clinical data in an application that has been implemented. The data were collected between December 2007 and March 2008.

The collection and analysis of the data consisted of the following stages: (i) Literature Review: Review of standards for EHR systems, OpenEHR architectures, open-source and free software, (ii) Classification of EHRA requirements according to contextual environments described by ISO/TR 18308 standards, (iii) Subscription to test Web sites and software deployment, (iv) Data collection by testing current functionalities of the selected software, and (v) Analysis of results.

Although both standards define requirements for EHR architecture, the classification of each of the 124 requirements of the ISO/TS 18308 into the three contextual levels of EHRA described in ISO/TR 20515 is not straightforward. To determine a reliable contextual classification of requirements, we consulted five experts (health informatics, software engineering, computer science, system security, and a medical doctor). First, the experts independently received the complete list of requirements and their definitions according to the ISO/TS 18308 standards and a description of each of the contextual levels of a health information system environment according to ISO/TR 20515 report. From this list, 102 of the requirements were classified in similar manner by the experts, whereas the remaining 22 requirements were classified to different contextual levels. At the second stage, the participants were invited to discuss the classification of the remaining twenty-two requirements; after several rounds of discussion each requirement was classified under one contextual level only.

Scope

The ISO/TS 18308 defines altogether 124 requirements which are categorized in a hierarchical classification into 52 sub-sections. Each subsection is associated to one of the twenty-four sections and each of the twenty-four sections is grouped into one of the eight main classes (7). The classification of requirements is shown in Table 1.

A Boolean scale (0,1) was used to evaluate 120 of the 124 requirements; zero (0) suggested that such requirement was not included at any level within the architecture of the analyzed software. If the requirement was included, the score given for the software was one (1). Four of the requirements were analyzed considering a scale including values between zero and one (both inclusive). A value between zero and one suggested some level of implementation, a value of one suggested that all of the requirement subdivisions were

Table 1. Families of Requirement According to Environmental Context (MF = Minimally Functional, FF = Fully Functional and PE = Provider Enterprise)

Main	Sections	MF	FF	PE
Structure ($n = 50$)	Record organization	3		2
	Data organization	10	6	
	Type and form of data	22	1	
	Supporting health concept representation	6		
Process ($n = 24$)	Clinical processes	3	12	2
	Record processes	6	1	
Communication ($n = 7$)	Messaging			1
	Record exchange			6
Privacy and security ($n = 15$)	Privacy and confidentiality		3	
	Consent		4	
	Access control		4	
	Data integrity		1	
	Auditability of access		3	
Medico-legal ($n = 20$)	Support for legal requirements	2		
	Actors	9	1	
	Clinical competence/governance		1	
	Faithfulness	2		
	Preservation of context	2		
	Permanence	1		
	Version control		2	
Ethical ($n = 1$)	Support for ethical justification			1
Consume/cultural ($n = 4$)	Consumer issues			3
	Cultural issues			1
Evolution ($n = 3$)	EHR architecture and EHR system evolution		3	

implemented. It is important to note that the latter scale does not represent weight in terms of relevance.

A second classification of requirements was based on the environmental context of the software detailed in the ISO/TR 20515 report and by Beale in his Health Information Standards Manifesto (2). EHR software can be contextually classified within three levels, from a minimal set of requirements to a fully functional, interconnected electronic health information environment. Software classified at the "minimally functional" level are those that maintain an EHR repository with the core patient health information, medical terminology, reference data, patient identification and archetypes. This level refers to the core of an Electronic Health Record System. Applications classified at "fully functional" context level are expected to include functionalities such as decision support systems, guidelines, health protocols, mobile computing, events management, workflow management, multimedia information, and genetic information. At this level applications are also expected to include security requirements such as access control systems, user-roles management and access consent management. Health information systems that reach the "provider enterprise" level are expected to accomplish a set of further services typical to the provider organization, such as administration, billing and resource location. At this level, software may also allow institutions to participate as cooperative entities in a larger network of public or private health information facilities (2;8).

Data Collection

The authors gathered data from the projects' Web pages, existing product reviews and software documentation, accessing the source code, and exploring the software functionalities by accessing installed practice sites and/or by installing the software in test computers. All EHR software were tested using a predefined set of data, which was adjusted to be imported to the native database of each analyzed system. In the case of testing sites, the data sets were imputed manually or imported depending of the functionalities available at the moment of the testing.

RESULTS

The results were analyzed first considering both dimensions separately, then using a cross analysis which included both dimensions. Initial analysis provided a comparative view of the environmental context of each application as well as the families of requirement in which each FOSS project has concentrated their development efforts. The cross analysis combined both dimensions to provide a comprehensive view of the level of accomplishment for each alternative within each environmental context.

Table 2. List of Analyzed FOSS Alternatives: Level of Accomplishment According to the Contextual Environments

Software	License	Platform	Minimally Functional (MF) ($n = 64$)	Fully Functional (FF) ($n = 44$)	Provider Enterprise ($n = 16$)	Total ($n = 124$)
A01	GPL	Cross-platform	30.9	10	1	41.9
A02	GPL	Windows OS	49.8	18	8.5	76.3
A03	GPL	Windows OS	37.5	14	3	54.5
A04	GPL	Cross-platform	43.2	14	1	58.2
A05	GPL	Cross-platform	48.8	20	3.5	72.3
A06	GPL	Cross-platform	32.8	15	2	49.8
A07	LGPL	Windows OS	39.3	17	2	58.3
A08	EPL	Cross-platform	30.3	11	2	43.3
A09	GPL	Cross-platform	43.3	17	1	61.3
A10	GPL	Cross-platform	52.3	24	11.5	87.8
A11	EPL	Cross-platform	44.3	14	0	58.3
A12	GPL	Linux	53.3	21	5	79.3
Average			42	16	4	61.6

Software		Type of license	Platform	Number of requirements accomplished			
Number	Name			Minimally Functional (MF) ($n = 64$)	Fully Functional (FF) ($n = 44$)	Provider Enterprise ($n = 16$)	Total ($n = 124$)
A01	MirrorMed	GPL	Cross-platform	30.9	10	1	41.9
A02	PatientOS	GPL	Windows OS	49.8	18	8.5	76.3
A03	Cottege Med	GPL	Windows OS	37.5	14	3	54.5
A04	OpenEMR	GPL	Cross-platform	43.2	14	1	58.2
A05	OpenMRS	GPL	Cross-platform	48.8	20	3.5	72.3
A06	FreeMED	GPL	Cross-platform	32.8	15	2	49.8
A07	Tolven	LGPL	Windows OS	39.3	17	2	58.3
A08	MedClipse	EPL	Cross-platform	30.3	11	2	43.3
A09	GNUmed	GPL	Cross-platform	43.3	17	1	61.3
A10	OSCAR	GPL	Cross-platform	52.3	24	11.5	87.8
A11	Elexis	EPL	Cross-platform	44.3	14	0	58.3
A12	CHITS	GPL	Linux	53.3	21	5	79.3
Mean number of requirements accomplished				42	16	4	61.6

Initial Analyses

Contextual Classification of the Data. As a starting point the data obtained were organized to explore the environmental context of each analyzed alternative. The first step was the elaboration of a classification table associating each of the 124 requirements contained in the ISO/TS 18308 within one of the three contexts as shown in Table 1.

Contextual Analysis. Table 2 presents the assessment of the twelve alternatives based on the environmental classification of requirements. On average, forty-two of the sixty-four minimally functional (MF) requirements were present. For fully functional (FF) and provider enterprise (PE) requirements, sixteen and four, respectively, had been incorporated on average. This result suggests that in general the analyzed FOSS EHR projects have concentrated their development efforts in the core functional features of EHR systems. Exceptions to these results are the alternatives A02 and A10 that not only emphasized the development on MF requirements, but also presented a relevant incorporation of fully functional and provider enterprise functionalities in comparison to other analyzed software. The alternative A12 had 52.3 MF requirements implemented, the highest value obtained in this context. It also had accomplished twenty-four requirements at the FF context, which was the second highest value. At the PE context, it only accomplished five of the seventeen requirements, however.

In general, the applications had at least one requirement implemented at any contextual level with the exception of alternative A11. Alternatives A02 and A10 were the only ones reaching more than five requirements at the PE level.

Functional Analysis. The next step of the analysis focused on the level of accomplishment of the systems according to requirements defined by ISO/TS 18308. The data were organized according to the families of requirements and analyzed alternatives. Data were aggregated to provide

Table 3. List of Analyzed FOSS Alternatives: Level of Accomplishing Functional Requirements

	A01	A02	A03	A04	A05	A06	A07	A08	A09	A10	A11	A12	AVG
Structure ($n = 50$)	23.6	35.8	31.5	32.2	34.8	19.8	26.3	23.3	26.3	37.3	30.3	33.3	29.5
Process ($n = 24$)	4.3	17	15	10	15	14	16	14	15	19	15	18	14.4
Communication ($n = 7$)	1	4.5	1	0	2.5	0	0	0	0	5.5	0	4	1.5
Privacy and security ($n = 15$)	2	4	0	4	5	2	4	0	4	8	3	7	3.4
Medicolegal ($n = 20$)	9	12	5	10	13	12	12	6	13	15	10	17	11.2
Ethical ($n = 1$)	0	0	0	0	0	0	0	0	0	0	0	0	0.0
Consumer/cultural ($n = 4$)	0	2	0	0	0	0	0	0	0	3	0	0	0.4
Evolution ($n = 3$)	2	1	2	2	2	2	0	0	3	0	0	0	1.2
Total	41.9	76.3	54.5	58.2	72.3	49.8	58.3	43.3	61.3	87.8	58.3	79.3	61.6

Table 4. Level of Accomplishment by Family of Requirements and Contextual Environments

Alternative			A01	A02	A03	A04	A05	A06	A07	A08	A09	A10	A11	A12	MEAN
Structure ($n = 50$)	Record organization	MF ($n = 3$)	3	2	3	3	3	3	2	2	3	3	2	3	2.7
		PE ($n = 2$)	0	1	1	1	1	2	2	1	1	2	0	1	1.1
	Data organization	MF ($n = 10$)	8.3	9.8	9.8	7.7	9.8	7.8	6.8	6.8	7.8	9.8	9.8	8.8	8.6
		FF ($n = 6$)	4	4	3	5	3	5	3	4	2	5	4	3	3.8
	Type and form of data	MF ($n = 22$)	7.3	17	11.7	14.5	15	1	10.5	8.5	11.5	14.5	11.5	13.5	11.4
		FF ($n = 1$)	0	1	0	0	0	0	1	0	0	1	1	1	0.4
	Health concept representation	MF ($n = 6$)	1	1	3	1	3	1	1	1	1	2	2	3	1.7
Process ($n = 24$)	Clinical processes	MF ($n = 3$)	0.3	3	3	2	2	3	3	3	2	3	3	3	2.5
		FF ($n = 12$)	1	7	8	2	9	5	8	7	7	9	6	8	6.4
		PE ($n = 2$)	0	1	1	0	0	0	0	1	0	1	0	0	0.3
	Record processes	MF ($n = 6$)	3	6	2	6	4	5	5	3	6	6	6	6	4.8
		FF ($n = 1$)	0	0	1	0	0	1	0	0	0	0	0	1	0.3
Communication ($n = 7$)	Messaging	PE ($n = 1$)	0	0.5	0	0	0.5	0	0	0	0	0.5	0	0	0.1
	Record exchange	PE ($n = 6$)	1	4	1	0	2	0	0	0	0	5	0	4	1.4
Privacy and security ($n = 15$)	Privacy and confidentiality	FF ($n = 3$)	0	1	0	0	1	0	0	0	0	0	0	0	0.2
	Consent (n = 4)	FF ($n = 4$)	0	0	0	0	0	0	0	0	0	0	0	0	0
	Access control	FF ($n = 4$)	2	3	0	2	2	2	3	0	1	4	2	4	2.1
	Data integrity	FF ($n = 1$)	0	0	0	0	0	0	1	0	0	1	1	0	0.3
	Auditability of access	FF ($n = 3$)	0	0	0	2	2	0	0	0	3	3	0	3	1.1
Medicolegal ($n = 20$)	Support for legal requirements	MF ($n = 2$)	2	2	2	1	2	2	2	2	2	2	2	2	1.9
	Actors	MF ($n = 9$)	6	7	2	7	7	9	8	4	9	8	4	9	6.7
		FF ($n = 1$)	1	1	0	1	1	0	1	0	1	1	0	1	0.7
	Clinical competence & governance	FF ($n = 1$)	0	0	0	0	0	0	0	0	0	0	0	0	0
	Faithfulness	MF ($n = 2$)	0	1	0	1	2	0	0	0	0	2	1	2	0.8
	Preservation of context	MF ($n = 2$)	0	0	0	0	0	0	0	0	0	1	2	2	0.4
	Permanence	MF ($n = 1$)	0	1	1	0	1	1	1	0	1	1	1	1	0.8
	Version control	FF ($n = 2$)	0	0	0	0	0	0	0	0	0	0	0	0	0

an overview of the development level reached by each alternative, considering each family of requirements.

The central focus of open-source EHR projects has been the implementation of structural (29.5 of 50), procedural (14.4 of 24), and medicolegal (11.2 of 20) requirements. Meanwhile communication, evolution, consumer/cultural issues and privacy and security presented limited or no coverage, and ethical issues had not been considered at all. Again, alternatives A02, A10, and A12 showed a harmonically distributed development for each group or requirements.

The alternatives A02, A05, A10, and A12 present the highest level of accomplishment of the twelve analyzed software. However, all EHRs had a limited level of development in two key families of requirements: communication and privacy/security. In fact, communication (messaging and records exchange) on average covered 1.5 of seven issues.

FOSS presented a relatively limited level of development regarding security and privacy.

Cross Analysis

In the cross analysis, only five of the eight families of requirements were considered. Ethical, consumer/cultural, and evolution issues were not included because of the low number of requirements presented in each family and the observed low level of accomplishment. To conduct this analysis the data were disaggregated within one level, and organized according to the family of requirement and the corresponding environmental context.

Structure

Most applications had incorporated the three minimally functional requirements associated to organizing records (EHR format, sections, and archiving). However, only one of the two provider's enterprise requirements (portability) was incorporated in most of the analyzed FOSS. Organization of the data for secondary use was presented in the alternatives A06, A07, A10, and A12.

Concerning data organization, most applications had a high level of accomplishment of MF requirements, and the FF set of data reaches 63 percent. This is explained by the fact that most software presented little or no support to recording the legal status for guardianship or informed consent, or to data aggregation supporting population level initiatives, surveillance and reporting.

The level of implementation for the type and form of information under MF requirements was only 11.4 of 22, which is explained by low level of development for requirements related to reference data, support for different type of data, link to external data, and semantic representation of information. Requirements associated to data types had an average of 5.7 of 11, explained by scant implementation of requirements concerning representation of percentages, partial and fuzzy representation of data, logical structure of data, and recording of time zone or time. Contextual data linked to recorded events such as reason for recording the information, data, time, and personal responsibilities was incorporated in almost all assessed FOSS except alternative A6. However, contextual data regarding health facility, location, and protocols was presented in less than half of the cases.

Processes

On average, nine of seventeen clinical process requirements were implemented. Most of the analyzed FOSS projects have focused their development efforts on operational and care support related processes rather than processes associated with knowledge management and decision support. In fact, requirements on providing support for clinical processes, problems/issues and health status, order and service processes, and care planning were incorporated in most cases (83 percent). On the contrary, requirements on clinical reasoning, decision support, guidelines, protocols for integrated care, and quality assurance had limited or no implementation in most applications.

Record processes such as data entry, verification, validation, data translation, data retention and review of recorded data along with scalability and retrieval of information were implemented in most alternatives. Nevertheless, representation of data according to devices (desktop, laptop, PDA, etc.) where the information will be presented was implemented in alternatives A3, A6 and A12 only.

Communication

Our analysis of the FOSS EHR systems revealed a low level of development for records and messaging exchange requirements, especially under record exchange support. In general, the alternatives did not provide support for exchanging EHR data with compatible applications, serialization of data (XML, SOAP, CORBA), semantic interpretation of the data exchanged, audit trail of exchanged data, rules for data interpretation, or semantic interoperability. Positive exceptions were alternatives A2, A10, and A12. In most cases, support for exportation/importation of database in standard protocols (HL7, UNI/EDIFACT, and DICOM) was limited or nonexistent. Alternatives A02, A05, and A10 incorporated HL7 message compatibility that allows both the generation and the interpretation of received messages. However, no software provided support for other message standards such as UNI/EDIFACT or DICOM.

Privacy and Security

Even though privacy and security is considered a critical component of a modern HER, the analyzed open-source EHR systems presented little development of these specifications. In cases where security has been implemented, it was based on user/password access control with some level of user role management. However, advanced features such as access consent, consent of information use, privacy and confidentiality rules, user control and purposes of information use, data integrity, and auditability were rarely seen. Exceptions were alternatives A10 and A12 that incorporated all requirements related to access control, data integrity and auditability of use, but none of privacy, confidentiality, and consent.

Medicolegal

Even though medicolegal requirements are defined as a separate set of features that may not have been considered by the analyzed FOSS projects, most medicolegal requirements were already covered. In fact, chronological storage of information was incorporated in all applications included in this study. Recovery and viewing of historical data were also supported by all applications as well.

All applications associated the information to the patient/subject. Although most applications also associated

users and clinicians to recorded data, not all of them ensure that all clinicians have to a unique identifier. In fact, in most FOSS EHR systems the application identifier attributes are auto-incremental numbers instead of unique identifiers such as driver's license number, security numbers, or national identifiers. This allows information related to one clinician to be stored more than once and therefore be linked with more than one identifier. Furthermore, in some of the analyzed EHRs that supported role-based access control capabilities, a user could have more than one identifier associated to different roles which also can be considered as a potential breach of security.

The protection of stored data against unintentional or unauthorized modification or deletion was secured by most applications except A1, A4, and A8. Preservation of context, especially the maintenance of translated or mapped documents and linking clinical context information to relevant data element had been considered only by alternatives A10, A11, and A12.

CONCLUSIONS

This study examined how open-source electronic health record software accomplished functionalities included in ISO standards. The results show that FOSS EHR projects have focused their development efforts in the core requirements of an EHR system: EHR repository, demographics, clinical reference data, medical terminology, identifier services, etc. The study also revealed limitations within different environmental contexts of FOSS EHR. At the MF level, FOSS EHRs provide limited support for identification services and representation of health concepts. At the FF level, the limitations are related to privacy and confidentiality of EHR, access consent management, integrity of EHRs, auditability of access to EHRs, knowledge management, and decision support. At the provider enterprise level, FOSS software presents little support for communication services.

The main issue at MF level is related to the different methods of implementing identifier services. FOSS software provided a variety of representations and data definitions for key attributes such as patients, physicians, nurses, and other user identifiers. Software developed for the U.S. market use the social security number or driver's license number to identify patients and users, while most open-source software developed for international context use an auto-incremental number or an arbitrary number assigned while registering patients or users; this may present problems in portability of the data, reliability of information, and security. In fact, restrictions of data types do not allow direct transference of data from an alphanumeric value (generally used for social security or driver's license numbers) to a numeric value (auto-incremental number or an arbitrary number); in those cases the information must be standardized before transferring it into a restricted data type.

Additionally, the use of auto-incremental or arbitrary numbers does not secure unique identification of a person. Even when systems do not allow more than one user sharing the same identifier, they do not prevent one user from having more than one identifier. This situation also affects the registry of users and roles. This may also lead to security breaches especially when an individual has been assigned multiple roles for accessing the stored information. A solution to this problem is the parameterization of identifier attributes. Parameterization allows the use of a valid identifier that already exists in the country or region in which the software is used. The use of local identifiers reduces the risk of assigning more than one identification attribute to the same user and facilitates the generation of identifiers which are independent from the data type definition, reducing the need to modify data types during the exchange of information. Finally, the use of parameters also allows the introduction of validation mechanisms and rules, without the necessity of modifying the source-code, to make possible the validation of the information recorded in the system.

A recurrent limitation in the analyzed software systems was partial or no support for privacy and security services. In most cases security is reduced to a user/password mechanism; sometimes user roles have been incorporated only to restrict access to specific content or sections of the system, but not for protecting information based on consent or privacy policies. No EHRs had implemented confidentiality mechanisms that allow protection against unauthorized access or release of health records (or definition of guidelines). In most cases, a user without enough credentials could also add new data or alter existing health records in the system. The research also revealed that some of the FOSS software, especially those based on OpenEHR information architecture, already incorporate some of the data architecture required to provide access control and security protection or to link data to specific users or roles, but such functionalities were not implemented at the application level.

At the fully functional level FOSS software also presented reduced functionalities for decision support and knowledge management. Clinical reasoning, decision support, guidelines and protocols, quality assurance, and integrated care were rather limited or nonexistent in most applications.

A current limitation for FOSS EHR at the provider enterprise level was the lack of support for exchanging medical records. Achieving a basic level of communication is not straightforward and requires the consideration of several elements. The exchange of health records based on serialized records (XML, SOAP, CORBA,.Net, etc.) can be done between systems that share the same data structures (6).

The analyzed FOSS EHR presented low use of standard codes for medical terminology. This may reduce semantic interoperability among different software systems. Although most applications have the data structure required for codification of data they do not provide guidelines or

recommendations in this matter. In fact, different implementations of the same software could use different approaches for codifying and defining medical data. The incorporation of clinical vocabulary, document contents, and messaging standards may facilitate communication and interoperability. The issue of secure exchange of EHRs had not been covered by any software analyzed here.

In summary, the study revealed that most analyzed FOSS EHRs currently have several functional limitations including general but not universal lack of support for identification services; representation for health concepts; privacy and confidentiality of EHR; access consent management; integrity of EHRs; auditability of access to EHRs; knowledge management; decision support capabilities; and support for communication services. Nevertheless, for clinicians and decision makers in developing countries especially, open-source EHR systems become an option due to their flexibility and low cost. Moreover, due to the nature of FOSS EHR development methods, most limited functionalities are expected to become requirements for further releases of most of the twelve analyzed open-source EHR systems.

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CONFLICT OF INTEREST

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