# An Analysis Framework for Electronic Health Record Systems

## Interoperation and Collaboration in Shared Healthcare

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### Keywords

Electronic health records, analysis, comparison, framework, two-level modeling, archetypes, integration, interoperability, semantic interoperability

### Summary

**Background:** The timely provision of complete and up-to-date patient data to clinicians has for decades been one of the most pressing objectives to be fulfilled by information technology in the healthcare domain. The so-called e*lectronic health record* (EHR), which provides a unified view of all relevant clinical data, has received much attention in this context from both research and industry. This situation has given rise to a large number of research projects and commercial products that aim to address this challenge. Different projects and initiatives have attempted to address this challenge from various points of view, which are not easily comparable.

**Objectives:** This paper aims to clarify the challenges, concepts, and approaches involved, which is essential in order to consistently compare existing solutions and objectively assess progress in the field.

**Methods:** This is achieved by two different means. Firstly, the paper will identify the most significant issues that differentiate the points of view and intended scope of existing approaches. As a result, a framework for analysis of EHR systems will be produced. Secondly, the most representative EHR-related projects and initiatives will be described and compared within the context of this framework.

**Results:** The main result of the present paper is an analysis framework for EHR systems. This is intended as an initial step towards an attempt to structure research on this field, clearly lacking sound principles to evaluate and compare results, and ultimately focusing its efforts and being able to objectively evaluate scientific progress.

**Conclusions:** Evaluation and comparison of results in medical informatics, and specifically EHR systems, must address technical and non-technical aspects. It is challenging to condensate in a single framework all potential views of such a field, and any chosen approach is bound to have its limitations. That being said, any well structured comparison approach, such as the framework presented here, is better than no comparison framework at all, as has been the current situation to date. This paper has presented the first attempt known to the authors to define such a framework.

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## 1. Introduction

Healthcare generates large volumes of data at disparate clinical environments (e.g. hospitals, clinics), at distributed locations, and by a wide variety of users (e.g. GP, nurses, social workers). Caregivers often make their decisions based on this multi-sourced information, and may require access to heterogeneous and autonomous legacy systems [8] storing patient data. This real-life scenario identifies what can be referred to as shared multidisciplinary healthcare, which characterizes the health care provided in most industrialized societies. That is, patient care is shared among several independent caregivers, and a health condition commonly requires collaboration between several clinicians.

The realization of this shared healthcare scenario clearly requires integrating all the relevant information to provide appropriate patient care, which poses organizational, technical and even political challenges. The so-called *electronic healthcare record* (EHR) is central to the solution of this challenge [15].

### 1.1 Current Situation in Healthcare

In recent years, there has been a trend in industrialized countries towards new more efficient models of healthcare delivery, while governments have been spending a significant percentage of GDP on complex large health information systems [3]. One prominent side effect of this process has been the steady decrease in the number of hospital beds across Europe [41]. The trend has been towards smarter use of resources with larger better equipped 'centers of excellence' in health, towards larger general practices and shared care teams. It is widely accepted that the competence, responsiveness and productivity of the health workforce is positively affected by improved information technology (IT) and by team-based approaches to healthcare among other factors [3, 50].

An Institute of Medicine's 2001 report [29] identified four stages of health organization evolution in the progression from autonomous modes of working to fully coordinated shared care with a high degree of specialization and expertise as follows:

- Stage 1: highly fragmented practice with individuals functioning autonomously and little specialization.
- Stage 2: referral networks of loosely structured multidisciplinary teams.
- Stage 3: more patient-centered team-based care but focusing primarily on needs and intentions of health care professionals with some decision support but little integration of health information.
- Stage 4: shared multidisciplinary care, evidence-based and patient-centric practice with strong service coordination between practices and with good quality practices and performance measures.

It is clear then that some fulfilment of the EHR advocate's promise of seamlessly integrated clinical information is desirable in this context. It should also be considered a fundamental requirement for effective implementation of the final shared care stage in the above evolution. As a result, most existing healthcare systems are currently between stages 1 and 3 in this progression. Stage 4 requires more intensive use of IT; while other data-intensive industries, like telecoms and banking, invest over 10% of their budget in IT, health care puts only 2–3% [49].

Numerous approaches have been proposed as to how an EHR must be built, varying widely in their scope, objectives and applicability. The most naive and common approach considers an EHR simply as a clinical data repository, that is, as a collection of information captured electronically and available in a user-accessible form, sometimes referred to as the *default EHR* [13]. Despite its appealing simplicity, this approach does not come close to addressing the challenges posed by the shared healthcare scenario. The default EHR suffers from lack of data quality, completeness, and structure, among other deficiencies. This is not surprising when one considers that except in the exceptional case of a 'green field site', the production of an EHR involves considerable legacy system integration challenges [8]. Therefore, a more general and structured approach must be followed.

Most healthcare institutions have already come to terms with the need for some kind of IT support, and even of data integration, in order to improve efficiency, reduce human errors, audit clinical practice, etc., and ultimately provide better care [50]. Many of them would claim to have some form of EHR in place, which explains the overwhelming number of different approaches to building an EHR. The major differences between these approaches can be partially explained by a lack of clear agreement [32] on the relevant challenges and concepts associated with building an EHR.

### 1.2 Consequences of Lack of Data Integration

It was estimated in 1999 that at least 44,000 Americans died as a result of medical errors [35]. This same study also calculated that the annual cost of preventable adverse drug events alone in the USA cost $2 billion while the total health costs of medical errors was estimated to be at least $8.5 billion. Data integration of the type offered by an EHR system is an essential and central part of any technological approach to reducing both mortality and costs [3, 33] by for example providing a solid framework in which computerized order entry (CPOE) can be performed.

It is worth noting that while CPOE systems have been in place for a number of years and so have been shown to provide clear benefits [17], widespread and strong evidence for the cost-effectiveness of EHR systems has yet to be gathered [3, 14, 44, 47]. At the same time, according to [46], potential end users of the EHR expected certain benefits to follow EHR introduction, including increased availability of health information, less administrative work, better support for analysis of business processes and for clinical research, more uniform working practice and increased reliability of health information. The respondents expressed concern about the potential for increased demands on their time, impact on their contacts with the patient, and on quality of care as well as collaboration with colleagues.

Taking another perspective, a recent study of patient satisfaction found that there was a positive correlation between developed clinical information technology and patient satisfaction [50].

## 2. Related Work

In Section 1.2, it was shown that an EHR has many different uses and must fulfil many disparate requirements [20]. This partially explains the significant number of approaches taken to build an EHR system, and the variety of alternative terms used to describe this and related concepts. An International Standards Organization technical report [31] provided a useful categorization of EHR systems. It had a different purpose than the framework presented here, however. The ISO report sought mainly to unify terminology, rather than provide a framework for comparison. This paper, wherever possible, follows the terminology already defined by that ISO Report.

A previous review of EHR contributions [16] had a narrower scope than what is presented here, including only relevant standards, and did not provide any comparison criteria. Finally, the literature review of EHR approaches reported in [23] can be seen as complementary to the present paper. The focus of that paper is not on providing a comparison framework, but on structuring the existing contribution according some coherent criteria. As such, there is some overlap with the framework presented here. Also, that literature review is made up to 2004, therefore the present paper includes more up-to-date contributions.

## 3. Framework for Comparison of EHR Approaches

### 3.1 Framework Design

In order to describe the framework presented here, it is important to differentiate between an electronic health record, which is a structured collection of health information about a subject of care, and an EHR system (EHR-S), which is an information system which provides access to an EHR [31]. A framework for comparison of existing EHR system approaches needs to be abstract enough to include all existing views of EHR systems, without trying to describe all fine details of each system, as this would render the framework unusable and comparisons impossible. Therefore, the framework presented here is described through a set of axes, or dimensions, each of which describes these alternative views of the problem, as illustrated in ▶Table 1.

Each of these views has had a strong influence on some of the existing approaches. The possible values of each axis represent the choices that have been made when building systems based on these approaches. It should be noted that a given EHR system could cover more than one choice for a given axis (for example, the 'Temporal' axis, as an EHR system can include retrospective, concurrent and prospective information). In some other dimensions, in contrast, a given EHR system will occupy exactly one of the values of that dimension. Multiple choice dimensions are marked (*) in Table 1.

Due to the complexity of the information and concepts summarized in ▶Table 1, the reader is advised to read this table horizontally, and not vertically. The motivation for each axis will become clearer as the reader understands its possible options as explained below.

EHR system approaches which focus only on the values of mainly one axis make assumptions about the others, even for example as to what functionality can be provided, the actual uses the resulting EHR can be put to, and which objectives it can fulfil.

The number of views being considered was also limited to the most significant ones. Including too large a number would not have been practical when comparing EHR approaches. A basic principle that was applied was that each axis represents a clearly defined view of an EHR system, and its meaning should be easily differentiated from the other axes.

The main objective in describing the framework this way was to explicitly identify which are the alternative views that have driven the construction of EHR systems. It is expected that the framework presented here will raise awareness of the decisions that, possibly implicitly, are being made regarding the possibilities of the EHR system resulting from or being used in a given project.

## 3.2 Framework Description

▶Table 1 presents a summary of the framework presented in this paper. This framework defines the solution space that over 40 years [15, 20] of research on EHR systems have produced. It synthesizes the points of view and decisions that, explicitly or implicitly, researchers in this field have been making as systems were being created. Although the main objective of this framework is to be used for comparison purposes, another interesting application would be to identify which region of the solution hyperspace defined by its dimensions is occupied by each existing EHR system. As a consequence, it will also facilitate a gap analysis, identifying which regions are not currently covered by existing solutions and why.

What follows is a description of each of the axes (views and choices) that make up this framework.

### 3.2.1 Model Type

EHR systems developed using traditional software engineering principles capture all required information used by the clinical applications in one, possibly very large, data model. This approach is referred to in ▶Table 1 as *single model*. When clinical knowledge evolves, the data model must be revised. This is, indeed, the case for any other information system project, in any domain, leading to well known maintenance issues. However, these issues are very common in clinical settings, as clinical practice is constantly updated due to advances in clinical research. Therefore, the cost involved in maintaining clinical applications becomes prohibitive, and applications quickly run out of date.

An approach which has been receiving much attention recently in order to address this issue is the so-called *two-level modeling* [5, 21], also called *Adaptive Object-Model* [51] in the software engineering area. Instead of trying to capture all required information in one large data model, this approach advocates a separation between information and knowledge [1]. The former, it is claimed, can be represented with a rather simple data model which is stable over time, while the

**Table 1** Framework for EHR systems analysis

| Views | | | Choices | | |
|---|---|---|---|---|---|
| Model type | Single model | Two-level modelling | | | |
| Distribution of data | Consolidated (warehouse) | Federated (virtual) | Materialized | | |
| Objectives (*) | Improve patient safety | Improve efficiency | Deliver effective care | | |
| Temporal (*) | Retrospective | Concurrent | Prospective | | |
| Functionality (*) | Administrative processes | Results management | Order entry | Health information and data | Patient support |
| Organization | Speciality-oriented | Episode-oriented | Problem-oriented | Neutral | |
| Uses (*) | Deliver health care | Personal EHR | Research | Public health and policy | |
| Interoperability | Not interoperable | Functional interoperability | Semantic interoperability | | |

latter is modeled as instances of the former. Information (data model) is the first level in this approach, and knowledge is the second level. The term archetype has become widely used to refer to the knowledge represented in the second level of this approach (e.g. blood pressure). Archetypes are also linked to ontologies of clinical knowledge (▶Section 7). As the nature of the information in an EHR is updated, archetypes are maintained accordingly. However, as these are only instances of the underlying data model, commonly termed r*eference model*, this update will not require changes to the clinical application. This approach, then, is expected to shield applications from a large number of evolutionary changes that would be needed if using the traditional single model approach.

### 3.2.2 Distribution of Data

Several mechanisms have been devised to create this 'unified view' of relevant clinical information that an EHR system provides. The first and technically most feasible approach, referred to here as c*onsolidated* [31], stores all this data in a repository considered part of the EHR system itself. It is the most commonly used in practice, due to its conceptual simplicity and because its development relies on sound database methodologies. It suffers, however, from a significant limitation. It assumes that the EHR system's own data repository will be the only source from which data is delivered to the caregiver. This assumption will hamper the adoption of any EHR system that is based on this approach, as healthcare provider organizations have already invested heavily on existing information technology (e.g., hospital information systems, order entry systems, PACS), and such an approach will require significant changes in this underlying infrastructure. For example, applications may need to adapt in order to use this new repository or, instead, mapping applications need to be developed to periodically transfer data into the new consolidated repository, much like in a data warehouse [35]. The first alternative, if at all possible, requires important initial investment on applications that, in their limited scope, may very well function satisfactorily, so will very likely face opposition from management. The second option (warehousing) will suffer, in addition to the development costs, from a necessary obsolescence in the data which is warehoused.

The consolidated approach also suffers from two additional essential limitations, relating to scalability and to security. Scalability issues arise because, at the time of writing, such an approach could not possibly scale up to a national level, as the hardware requirements (e.g. disc space) would be exceptional, due to the characteristic of clinical information (e.g. high resolution imaging). Security concerns would be a limitation, if all sensitive data is stored on one single system, which must be accessed by many different stakeholders.

In order to address these issues, it is also possible to provide the so-called *federated EHR* [31]. This approach provides a true view of the underlying data, querying the underlying data sources which store all required information [37], without requiring any changes to existing system. Thus, it leverages the investment made in legacy systems [8], in contrast to the consolidated approach. Another advantage of the federated approach is that data is never out-of-date, as it is at all times taken from its original data source. The approach is not without its difficulties, however. It must address syntactic and semantic integration issues, just like any other approach (except for the unlikely case of a green field site). It will also suffer from significant performance limitations, due to repeated queries to remote database servers and data integration (transformation) processes that must be performed 'on the fly'.

There is a middle ground between the consolidated and federated approaches, referred to here as *materialized EHR*, in which all or part of the EHR data may be materialized in a local data repository [26].

### 3.2.3 Objectives

This framework includes a set of objectives which represent the motivations to consider the use of an EHR system. These objectives should guide the development, deployment, and evaluation of any EHR system. The Institute of Medicine reported [30] an initial set of objectives (originally called 'criteria'). This set has been modified here as follows.

An EHR should *improve patient safety*, which means that the potential harm to patients is reduced thanks to the use of an EHR system. How this is done depends on where the system lies along the other dimensions. For example, some specific functionality such as a CPOE module may prevent some types of errors; also, semantic interoperability will facilitate the provision of all relevant data, even from independent care givers, which will reduce the likelihood of adverse drug reactions due to lack of knowledge of other current treatments.

The introduction of an EHR should improve efficiency of the care delivery process. Efficiency is the avoidance of waste, like for example of supplies and time. Managing the change to an EHR-based environment is an organizational challenge, and not all studies agree that current EHR system deployments actually improve efficiency [3, 14]. Other studies claim that this lack of evidence is only due to the special characteristics of the healthcare domain and that the time and intensity of investments needed in order to observe improved efficiency (the so-called 'tipping point') is larger in healthcare than in other sectors [44].

Finally, an EHR should also facilitate the *delivery of effective care* providing evidence-based treatment. Stage 4 of the evolution of health organizations described in ▶Section 1.1 required the realization of the shared healthcare scenario, also supported by evidence-based practice. This would involve the tight integration of EHR systems with decision support systems [39].

The IOM report [30] identifies "management of chronic conditions" as an objective of an EHR system. It should not be considered as such, however. It is precisely the prototypical example of service which can not be provided until the shared healthcare scenario has been realized. It does not appear, therefore, in any axis of this framework, as it is a consequence of this scenario, as opposed to a specific objective.

### 3.2.4 Temporal

An EHR system should provide a longitudinal view of a patient's health care, *from cradle to grave* [20]. This includes *retrospective* [31] or historical health care, that is, the patients' medical history; *concurrent* data, that is, the current status and current treatments of a patient; and, finally, *prospective* clinical actions, that is, planned interventions, etc.



 

### 3.2.5 Functionality

In the framework presented here, in order to clearly differentiate this axis from the rest, the functionality of an EHR system refers to the user-observable functions. There are other non-functional requirements that must be satisfied by an EHR system, but this framework places them along other axes.

The number of possible functionalities of an EHR is clearly very large. This again is due to the complexity and diversity of the healthcare domain. ▶Table 1 does not present an exhaustive list of possible functionalities, as this had been done elsewhere [30]. An annual report on 'EHR attributes and subattributes' has been published for the last 12 years [4]. It provides a taxonomy of potential functionalities of an EHR system. It also reports on a survey to over 160 EHR vendors, where they state which of these functionalities are provided by their products.

Despite the exhaustiveness of this annual report, some of these categories are not disjoint (e.g. simultaneous view of EHR, provides problem lists), which makes system comparison complicated, and others should be better placed on a different axis (e.g. clinical data repository, links with other patient records), as advocated in this paper.

Also, the Institute of Medicine published a report [29] with the key functionalities that should be expected in any EHR system, and these functionalities have been incorporated in the framework presented here, with some modifications.

When discussing available functionality, it is unavoidable to raise the need for *certification criteria*. Previous analyses of EHR products, prominently [4], feature claims from vendors that provide a wide selection of functionalities. Some of these claims, particularly claims of interoperability, should be scoped. This particular functionality, in a general case, is currently beyond technological viability, therefore, unless it is precisely defined, evaluation and comparison of EHR systems is not possible.

Europe's EuroRec[a] and USA's Certification Commission for Healthcare Information Technology[b] (CCHIT) are examples of non-profit organizations with this objective. These certificating agencies will play a major role in advancing the current state of the EHR market. Informed analyses of provided functionalities and meaningful comparison frameworks of EHR systems, like the one presented here, will foster competition and contribute to the realization of the shared healthcare scenario.

[a] http://www.eurorec.org/
[b] http://www.cchit.org/

### 3.2.6 Organization

There are several different ways to organize the data of an EHR. Data can be structured according to the problem-oriented paradigm [48], in which patient information is indexed by the list of clinical 'problems' of the subject. This provides a clinically-oriented view of patient information, commonly preferred by caregivers and commonly available in primary care, but not yet widely used in secondary/tertiary care [11].

An alternative view, very common in existing EHR systems, is the *episode-based EHR*, in which data is indexed along the timeline according to the interactions between a patient and the care provider(s). It emphasizes the administrative side of patient information.

An additional approach is to organize an EHR according to the clinical specialties (e.g. departments) for which patients can receive attention. This approach emphasizes the organizational issues of care providers, as opposed to patient care delivery.

Finally, more flexible approaches acknowledge the complexity of the health care domain and the variety of user types that interact with an EHR system [5, 21]. No a priori EHR structure will be defined by the EHR system, so it is referred to here as *neutral* approach. Thus, the organization of EHR data will be defined by each caregiver, according to his/her specific needs.

### 3.2.7 Uses

The final use to which an EHR is to be put influences many of the decisions of the EHR system that will manage it. The primary use of EHR system is clearly the *delivery of health care* to patients [29, 31]. Therefore, an EHR should emphasize the caregiver's view of the information.

There are, however, other secondary uses of an EHR that also influence their design. Economical, historical, and organizational reasons have lead to many EHR systems with a clear *administrative* purpose. The tension between these two alternative, and often contradictory views, has lead to EHR systems that must face the opposition of clinicians, because they are not perceived as being sufficiently clinically oriented, but rather as another administrative tool.

The current trend towards empowering citizens to take responsibility for their health care [18] has raised the need for so-called *personal EHR* or *PHR* [29, 34] to facilitate health self-management. PHR developers must also face the challenges discussed in this paper. Consider, for example, semantic interoperability, when a PHR needs to be made available to caregivers, as it provides a more detailed patient history. PHRs pose additional challenges, particularly related to data provenance [42], as the information stored in a PHR is not as trustworthy as information originated by a healthcare professional.

The information stored in EHR systems could foster clinical *research* [45] as well as support *health policy* makers. EHRs hold valuable information about population health status [38] that would facilitate the assessment of treatment modalities, evaluate real impact of treatments, etc. *Public health* risks (e.g. pandemics) could also be detected effectively. Finally, *health policy* makers could rely on this information in order to allocate resources, update statistics, etc. Privacy concerns must be met before this information is made generally available. Also, interoperability between independent providers must be addressed in order to faithfully integrate data at the population level.

### 3.2.8 Interoperability

An essential goal of EHR systems development, which has attracted significant attention, is interoperability. This refers to the ability to exchange information between systems [43]. The extent to which this exchange can be realized varies greatly between EHR systems [7].

In order to bring a health organization to Stage 4 as described in ▶Section 1.1, the interoperability between independent health providers is essential.



 

Many EHR systems currently available[c] are not concerned with interoperation with other systems, thus would be classified as *not interoperable*. These systems have been built in order to satisfy immediate requirements of their health care organizations, making decisions regarding the other dimensions of the framework presented here, but overlooking interoperability issues. Commonly, the main requirement of an EHR system is to electronically store the information needed for the daily activities of a given healthcare organization. A proprietary information model suffices to satisfy this requirement. No attention is paid as to how other organizations made the same decisions. If a patient must receive treatment at more than one health provider, it is unclear as to how data generated at one provider would be accessible by the other.

The level of interoperability can be raised if systems agree on the structure of the information to be exchanged. This is often called *functional interoperability*, with which the only objective is to transfer information so that it is humanly readable by the receiver [31]. HL7[d] de-facto standards represent the most significant effort on this direction.

Functional interoperability alone, however, can not realize the shared healthcare scenario outlined in ▶Section 1. It requires that any two systems that need to exchange information agree on exactly the structure of the information to be exchanged, and more importantly, on the meaning of all the information to be exchanged. Unless one single standard becomes universally accepted as the means to exchange information, functional interoperability will not suffice. HL7v2.x represents one such approach. It is available in the most advanced products and certain health regions and even national health authorities have adopted it for various health information communication projects. However, the documents being exchanged in an HL7v2.x-based approach lack an explicit information model. Also, in order to provide the flexibility which characterizes the healthcare environment, HL7v2.x messages contained vague definitions and optional information elements [27]. The result has been that interoperability could not be guaranteed without agreement on meaning and precise document contents.

In any event, given the existing fragmentation of the healthcare commercial market, both in the USA and Europe, and the context of mixed public and private healthcare providers, it is considered quite unlikely that one single standard will become universally accepted [7, 40]. Research has for some time focused on achieving *semantic interoperability*, in which the exchanged information is computer-processable [31]. Semantic interoperability is being addressed in many domains [43], and it is essential in the healthcare domain in order to fulfil the shared healthcare scenario.

Semantic interoperability is not an all-or-nothing concept. The level of semantic interoperability depends on the degree of previous agreement that is needed in order to successfully exchange information. Despite being a very active research area in many domains, there is no universal approach to quantify this degree of agreement. As a result, semantic approaches are generally compared on a qualitative basis.

The current belief is that standardized terminology and domain concepts will raise the level of semantic interoperability [31]. The *two-level approach* described above (▶Section 2.1) is particularly tailored to this goal. Since it was initially proposed [21], this approach has evolved in order to include further constraints [5] so that standardized domain concepts (archetypes) explicitly represent the context in which information has been captured while providing links to terminology. The momentum of this approach is being exemplified by current standardization efforts at CEN (standard EN-13606[e], known as EHRCom) as well as HL7 (RIM version 3).

### 3.3 Framework Dimensions and Outcome of Care

The framework described in ▶Section 3.2 can be used to objectively measure how a given EHR system can contribute to the evolution towards stage 4 of patient care, shared multidisciplinary care, as outlined in ▶Section 1.1. Since this measure can not be absolute, what matters here is the trend of such systems as they evolve over time. In that respect, for any given axis shown in ▶Table 1, as an EHR system evolves from left to right (horizontally), it will improve its ability to support such multidisciplinary shared healthcare.

Therefore, this framework can be used as an objective guide to focus the evolutionary trend of any EHR system. Any EHR system will necessary have to adapt to new requirements. Such changes will modify how a given system is placed along some of the axis shown in ▶Table 1. When planning such evolutions, decision makers could use this table in order to evaluate how it is evolving, and how it compares to other systems, according to the major points of view of EHR systems as shown in the table.

## 4. EHR Projects

This section reviews a set of EHR systems and projects that have had a significant impact on the EHR field. It is not meant to provide an exhaustive list of proposed solutions. The selected systems each focus on a particular view of the EHR solution space, as described in ▶Section 2. Also, as a whole, the list is representative of the most common decisions that EHR projects are likely to make, and illustrates the resulting system's capabilities and limitations in the context of the health care delivered in industrialized countries. The final goal is to view these approaches, decisions, capabilities and limitations in the light shed by the framework presented in this paper.

### 4.1 GEHR

The Good European Health Record (GEHR) was the first major European Union (EU)-funded project specifically focused on the challenges posed by the development of EHR systems [28]. It produced a comprehensive analysis of requirements for such a system, and developed an electronic healthcare record system based on the single model approach, according the framework presented here. It followed also a consolidated approach. This resulted on a very large data model which was, at the same time, neces-

c e.g. http://openmrs.org, http://www.care2x.org/, http://www.gnumed.org, http://www.va.gov/vistA
d http://www.hl7.org
e http://www.centc251.org



 

sarily limited in its scope and applicability, due the complexity of the healthcare domain, which is characterized by many different views and objectives as perceived by all stakeholders involved.

## 4.2 Synapses

Synapses [21] was also an EU-funded project. It proposed to base the EHR system's data model on a very limited number of stable and abstract concepts, which were referred to as the Synapses Object Model (SynOM). The SynOM also included a set of constraints, in the form of aggregation rules, that described how its (eight) classes could be rightfully aggregated in order to build a health record organized in a specific way. Therefore, each caregiver could organize his/her healthcare record as better suited his/her specific needs. These organizations were all valid instances of the SynOM, and collectively were referred to as the Synapses Object Dictionary (SynOD). As a result, Synapses was the first two-level-modeled EHR system that had been proposed, as referred to in ▶Section 3.2.1, and had a neutral organization as of ▶Section 3.2.6.

A Synapses-based EHR was originally designed as a federated EHR system, as described in ▶Section 3.2.2. One of the classes in the SynOM described how to access relevant clinical data from their original sources (e.g. relational database, proprietary API) to be included in a patient's EHR. Some implementations of the Synapses approach [21] exploited this design principle so that the system could be used without changes to the underlying (legacy) databases; therefore an EHR could be introduced in a healthcare organization with minimal disruption to its daily activities.

## 4.3 OpenEHR

The OpenEHR[f] foundation was created by research and industrial partners with experiences in GEHR and Synapses, as well as in the commercial EHR field. It has created a set of specifications of an EHR system, and is currently developing reference implementations (e.g. Java, .NET).

OpenEHR follows a two-level modeling approach (▶Section 3.2.1). The first level is similar to the SynOM, described above, and is referred to as the reference model. The second level has been inspired by the SynOD, also described above, and it is referred to as archetypes. However, archetypes include cardinality constraints and value constraints, in addition to the aggregation constraints used in Synapses, in order to define when an archetype is a valid instance of the reference model. Also, archetypes are meant to describe clinical concepts. They are not meant to describe the organization of a (full) "view" of a patient EHR, as was originally intended by the Synapses project when it defined the SynOD concept.

OpenEHR is advocating a consolidated approach (▶Section 3.2.2), storing all relevant patient information in the OpenEHR system repository. The organization of the EHR is neutral (▶Section 3.2.6).

The works at OpenEHR have had a significant influence at current standardization efforts, both at CEN (EN-13606, *EHRCom*) and HL7, and future systems using any of these approaches are expected to be (to some extent) interoperable.

## 4.4 VistA

The U.S. Department of Veterans Affairs hospital information system, known as VistA[g], is one of the largest implementations of a national-scale medical decision support system in the world, which offers EHR functionality [12]. Its development began in the late 1970s and by 2002 had been installed in 163 hospitals, 800 clinics, and 136 nursing homes.

VistA is also being adopted by several organizations around the world. Despite of the undeniable success of this set of applications, it can not easily be exported to other kinds of organizations [14]. It is a proprietary solution based on a single model approach (▶Section 3.2.1) and each site manages its data following a consolidated approach (▶Section 3.2.2). Interoperability was not a design requirement in the 1970s, and thus it is only possible at a human level (functional). Semantic interoperability is not possible even between sites that run the same VistA installation. Interoperability is hampered by the lack of standardized terminologies [12], data models and precisely defined concepts. Even if semantic interoperability is achieved between VistA installations, its design principles will limit the interoperability capabilities with other systems, thus not being able to fulfil the shared healthcare scenario outlined in ▶Section 1.

## 4.5 Health Infoway

Health Infoway[h] is a very ambitious program by the Canadian federal government created in 2001, with a \$10 billion estimated investment by the end of the program (2014), aimed at accelerating the development and adoption of electronic health record systems.

Its funding strategy is organized in ten different investment programs (e.g. interoperable EHR, infostructure, patient access to quality care) in order to foster innovation. Despite of being a remarkable initiative in terms of facilitating technology transfer into clinical practice, its objectives and outcomes were not to produce significant contributions to the concepts, techniques, paradigms and challenges involved in the EHR field, when compared to the projects described above.

## 4.6 Connecting for Health

Connecting for Health[i] is a United Kingdom's NHS initiative with comparable goals as Health Infoway, and which ultimately aims at facilitating the transition from the current healthcare system to stage 4, shared multidisciplinary care, identified in ▶Section 1.1. It is also organized into several core programs, specifically: secure broadband, linked patient records, digital imaging, and secure mail. Particular attention is given to the GP (general practitioners) needs and IT infra-

f http://www.openehr.org

g VistA is freely available as open source (http://www.va.gov/vistA), written in the M programming language (formerly known as MUMPS).

h http://www.infoway-inforoute.ca

i http://www.connectingforhealth.nhs.uk

structure, as opposed to the whole healthcare system.

As is the case for Health Infoway, the goal of Connecting for Health is not to advance the state of the art in the field of EHR. In contrast, it aims at adapting existing knowledge and technology to clinical practice.

### 4.7 Personal Health Record Projects

Several projects have been launched over the last decade in order to facilitate the involvement of patients into their own health care [24]. A personal health record (PHR) allows patients access to their own health care record. This is still a very active field of research [34], in terms of the most appropriate technological architecture, the role of the patient, security, privacy, ethical concerns, etc.

The business model for this type of systems is still unclear. Some are created and hosted by hospitals, while others are institution-neutral [24]. Remarkable newer players in the field, like Microsoft's HealthVault[j] and Google Health[k], represent additional possibilities in terms of business models and privacy concerns.

To date, these systems do not consider interoperability as a design (business) priority, being based in a single model and consolidated approaches as described in ▶Section 3.

### 4.8 OpenMRS

A number of open source initiatives are addressing EHR challenge. The motivation is usually that of fulfilling the needs of small clinical practices. One such initiative is the OpenMRS[l] (Medical Record System) following the single model approach (▶Section 3.2.1), and it is consolidated (▶Section 3.2.2) on a centralized database. It claims to use a data model that has been proven to be very successful in real clinical practice. The resulting EHR system is clearly organized by episode (▶Section 3.2.6).

This is an example of an EHR system particularly designed for use in a small clinic. It suffers from limitations in terms of interoperability, which is not addressed, and of its organization, which is hard coded to be episode-oriented, so alternative views (e.g. problem-oriented) could not be easily incorporated.

Some other open source projects have followed very similar approaches (e.g. gnuMed[m], Carte2X[n], and OpenEmed[o]), although using different data models and organizational principles. These differences are only justified by the specific requirements of the clinical users involved in the project. Collaboration between all these initiatives would probably fulfil their objectives better than currently do in isolation.

## 5. Standardization Initiatives

One of the most pressing challenges that need to be addressed by existing systems is that of interoperability. As justified in ▶Section 1.1, due to economic constraints and quality requirements there is a clear trend towards shared multidisciplinary care. This scenario requires that caregivers share patient information in a safe, reliable and efficient manner.

Currently, it is believed that semantic interoperability in healthcare can only be achieved through standardization of data models, clinical data structures, and terminologies. Several efforts exist that elaborate the required standards. The most relevant ones are reviewed in this section.

### 5.1 HL7 (v2 and v3)

HL7[p] is an industry consortium which agreed on a set of specifications for clinical and administrative data exchange and systems functionality. Patient data interoperability was originally based on message exchanging. Due to the interoperability limitations outlined in ▶Section 3.2.8, HL7 version 3 represented a major revision in its conception [27], including an explicit underlying data model (reference information model, or RIM) and the two-level modeling approach applied to HL7 Clinical Document Architecture (CDA).

Two-level modeling relies on an agreed and stable reference model. The organizations that subscribe such an approach, namely OpenEHR, CEN and HL7, have not arrived at an agreement. Although they are clearly influencing each other, and similar concepts appear in all of them, there are also significant differences [7, 40]. Therefore, even though such approach will clearly raise the level of semantic interoperability being achieved, as compared to the current state of the art, it is also clear that full semantic interoperability will not be achieved [9].

### 5.2 CEN 13606 (EHRcom)

The two-level modeling paradigm was initiated in Europe by the Synapses project (described above), and has evolved through the OpenEHR initiative. These efforts have led to the CEN 13606 standard for health information communication currently under development.

As it has been discussed, all these initiatives, together with HL7 RIMv3, are influencing each other and some reconciliation efforts exist. While HL7 is being supported by the industry, there is no specific support group for CEN 13606, and preliminary experiences on its usage are still lacking.

### 5.3 IHE XDS

Integrating the Healthcare Enterprise[q] (IHE) Cross-Enterprise Document Sharing (XDS) is an industry-led initiative that addresses the integration of health records which adhere to different standards. It does so by maintaining a registry of documents stored in the interoperating EHR systems, which must have agreed on a set of policies, referred to as profiles [27]. This is a pragmatic approach that addresses the fragmentation of the healthcare vendor market. However, it does not contribute to semantic interoperability beyond what its underlying standards may already support.

j http://www.healthvault.com/
k https://www.google.com/health
l https://www.openmrs.org

m http://www.gnumed.org
n http://www.care2x.org/
o http://www.openemed.org
p http://www.hl7.org

q http://www.ihe.net/

## 6. Related Technologies

Apart from communications facilities there are three principal information services which underpin an EHR system: identity, terminology, and security.

Firstly, an identity or demographics service identifies the subject of care from a set of traits such as name, address and date of birth. This service typically returns a health identifier which provides a link to the appropriate EHR information [25]. It can also cross-reference identities between identity domains so that health information for the subject of care can be accessed from other EHR systems that use different identifiers.

Secondly, terminology services provide a means to insert codes into the record which link to large structured sets of clinical terminology and so allow subtle clinical meaning which has been inserted by the author of a section of an EHR to be conveyed to a reader.

Finally, security and access control facilities [19] are an essential feature of any EHR system and require particular care where information is being shared between health organizations.

While these services are fundamental for successful implementation of an EHR, they exist in a number of different forms and so could be dealt with in a taxonomy of their own. They can also be used independently of the EHR and so are not included in the framework presented here.

## 7. Conclusion and Research Directions

This paper has presented a framework that provides a unified view of various dimensions that current and past approaches to building electronic health record systems have addressed.

Interoperability is the most significant challenge still to be solved by the research community. Semantic interoperability is also addressed in many other domains besides health care [43], and interoperability has indeed been an outstanding challenge in the database community for decades [6]. Semantic interoperability in the medical domain, however, poses additional challenges, not commonly addressed in other domains. For example, the need to represent the context in which clinical information was captured is essential in healthcare [5], and it has only been recently identified in other domains, like bioinformatics [10, 22]. However, the existence of relatively few and somewhat similar standard metamodels (e.g. openEHR, CEN 13606, HL7) for the clinical domain, allows for the development of generic solutions which may not be applicable to the bioinformatics community in the near future.

Research on semantic interoperability must address a means to quantify its level of interoperability, as it is not an all-or-nothing concept (▶Section 3.2.8). Current approaches are compared on a qualitative basis [7, 40], thus progress is difficult to assess.

The framework described in this article has been designed to compare existing approaches. However, the authors believe that the primary goal of an EHR system should be limited to the provision of a unified view of information for clinical purposes. Other uses and functionalities (e.g. administrative, research, education, and health policy) should be implemented by other components. In such a set up, interoperability and integration would be, again, essential. This approach would foster clear definitions of what should be expected from EHR systems, thus comparison and certification could become a common tool used by decision makers.

Research on EHR poses interesting challenges to fields like database systems, artificial intelligence, human-computer interaction, and image processing. Researchers from these fields are commonly attracted by the challenges posed by medical informatics and EHR. There seems to be insufficient cross-fertilization between these fields, however. For example, Agrawal [2] addresses access control in databases in the medical domain. Despite the scientific quality of this contribution, it does not make one single reference to the medical informatics research field. Therefore, it overlooks many research issues in the field without justification, like interoperability of clinical information and patient identification.

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