Can OpenEHR, ISO 13606 and HL7 FHIR work together? An agnostic perspective for the selection and application of EHR standards from Spain

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Abstract

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Keywords: Electronic Health Records, Health Information Standards, OpenEHR, ISO 13606, HL7 FHIR.

Abstract

Due to the heterogeneity of Electronic Health Record (EHR) standards, the decision-making teams, who are not experts in health information, express confusion for selecting and applying these resources in their data platforms. For this reason, a group of experts has analyzed strengths and weaknesses about design, modeling capabilities, flexibility and resources implemented of three relevant standards based on Detailed Clinical Models: OpenEHR, ISO 13606 and HL7 FHIR. Thus, it was concluded that: (1) they are useful for the purposes for which they have been designed and show shortcomings in those for which they have not; (2) they are functionally compatible in health data platforms and methodologies developed in a standards-agnostic perspective; and (3) they are conceptually and technically compatible with each other, so the choice of one or the other does not have a high impact as long as one starts from the one richer in modeling capabilities and flexibility.

1. PROBLEMS IN THE SELECTION AND APPLICATION OF EHR STANDARDS

The Electronic Health Record (EHR) is defined as the repository of health data generated throughout the patient's lifetime, which is used in the provision of healthcare to the subject or the population [1]. In addition, these data may have uses other than healthcare practice, known as secondary uses, including activities such as health research or the evaluation of health outcomes [2]. In recent years, numerous initiatives plan the construction of advanced data infrastructures for primary and secondary use at regional, national and international levels. These proposals have incorporated different health information standards in their design to make data Findable, Accessible, Interoperable and Reusable, in accordance with the FAIR Principles [3]. However, the selection and application of these standards has not been homogeneous across different initiatives, leading to questions about which standard is the most suitable for specific needs, such as persistence and exchange of EHR.

In Spain, at regional level, different initiatives have emerged for the construction of standard EHR ecosystems, such as the project launched in the region of Catalonia [4], based on the OpenEHR specification [5]; and the collaborative project between the regions of Castilla La Mancha and the Canary Islands [6], based on the ISO 13606 standard [7]. At the national level, a project is being carried out for sharing EHR extracts between regions, also based on the ISO 13606 standard [8], as other European countries have done previously, such as Norway and Denmark, which have developed their national health data infrastructures based on the OpenEHR specification [9, 10]. Likewise, at international level, there is the European Patient Summary initiative (EUPS) [11], which uses the HL7 CDA standard [12], and the International Patient Summary (IPS) [13], which uses HL7 FHIR [14], whose objectives are the exchange of summarized EHR extracts at the European and international levels, respectively. Table 1 summarizes the current ecosystem of EHR projects in Spain, indicating purpose, scope and standard used for each proposal.

Project	**Purpose**	**Scope**	**Standard**
CataloniaEHR	FAIR-based EHR	Regional	OpenEHR
ISOHCE	FAIR-based EHR	Inter-regional	ISO 13606
HCDSNS	Interoperability of clinical documents (including PS)	National	ISO 13606
EUPS	Interoperability of PS document	European	HL7 CDA
IPS	Interoperability of PS document	International	HL7 FHIR

Table 1. Summary of FAIR EHR project ecosystems in Spain.

Due to this heterogeneity of standardization proposals for similar purposes, the decision-making teams, who are not experts in health information, have knowledge gaps regarding the selection and application of these resources [15]. Previous studies have analyzed the interaction between different EHR standards [16], but the progress made in recent years in this area, which has led to new standardization specifications and advanced uses of data, merits a new review and framework of recommendations. Therefore, this work aims to analyze the relevant EHR standards such as OpenEHR [5], ISO 13606 [7], and HL7 FHIR [14], describing the characteristics of each one of them, as well as their existing conceptual relationships, in order to establish a common perspective for agnostic use in future health data infrastructures.

2. DESCRIPTION OF RELEVANT EHR STANDARDS: OPENEHR, ISO 13606 AND HL7 FHIR

Most health information systems are designed using *single-model* methodologies, in which the health domain concept model is implicit in the data model. In scenarios characterized by complexity, with a large number of concepts and high tendency to change, systems based on this methodology are inflexible, expensive to maintain and generally have to be replaced after a few years. The Detailed Clinical Models (DCM) paradigm, also known as *dual-model* methodology, provides a solution to the problems of evolution and maintenance of health information systems [17]. On the one hand, it defines a reference model with the necessary components, and their constraints, to build a standard EHR based on FAIR Principles [3]. On the other hand, it establishes an archetype model for the formalization of the clinical-domain concepts according to the reference model. With this approach, it is possible to separate knowledge and information in EHR systems, allowing the concept model to be extended without the need for specific developments, being independent of the software process and even introducing new concepts when the system is already implemented [18]. Thus, with formal information models built from common components, and linked to standard terminologies [19], a receiving system can interpret the meaning of the information without prior agreement, achieving in this way semantic interoperability [20]. However, to this end, it is necessary that the different specifications applied for the persistence and exchange of EHR are used in accordance with the purpose for which they were conceived. The following sections describe the design and implementation aspects of three relevant EHR standards: OpenEHR, ISO 13606 and HL7 FHIR.

2.1. OpenEHR specification

OpenEHR is a specification for the construction of a standard EHR, based on the two-level modelling paradigm [5]. Thus, the reference model of this standard defines the components *EHR*, *Folder*,

Composition, *Section* and *Entry*. It also categorizes *entries* into *observations*, *evaluations*, *instructions* and *actions* [21], according to clinical investigation recording process, as well as establishes the applicable data types. In addition, it offers a platform model that includes services related to data entry, querying, persistence and versioning. Because OpenEHR is used in multiple healthcare organizations in several countries, an active community has been openly created around this specification, which formally implements and reviews a set of more than 880 archetypes, which includes around 10,000 clinical data points, being the largest open clinical model repository in the world [22].

2.2. ISO 13606 standard

ISO 13606 constitutes a standard, based on DCM, for the full-meaning exchange of EHR extracts. It consists of five parts, being part 1 (reference model) [7] and part 2 (archetype model) [23], the foundational core of the standard. Hence, its reference model defines the components: *EHR*, *Folder*, *Composition*, *Section*, *Entry*, *Cluster* and *Element*; as well as the data types for the data elements. This standard was designed based on the one proposed by OpenEHR, being both reference and archetype models highly compatible, which facilitates the exchange of the registered and persisted EHR according to the DCM paradigm [24].

2.3. HL7 FHIR standard

The HL7 FHIR specification provides a standard framework for the agile creation of health data communication infrastructures [14]. This standard focuses on fast and simple implementation using web standards, e.g., RESTful web services, as the technology infrastructure for data exchange. Thus, FHIR was inspired in the dual-model paradigm to implement a predefined catalog of information models designed mostly at the *entry* level, called *Resources*. They can be grouped into *bundles*, referenced from *compositions*, refined through *extensions* and transmitted through *messages*. They can also be translated through clinical archetypes conforming to the ISO 13606 standard and, therefore, to OpenEHR [25, 26].

2.4. Conceptual relationships

Based on the above descriptions, the conceptual relationships between OpenEHR, ISO 13606 and HL7 FHIR were established and schematically described in Figure 1.

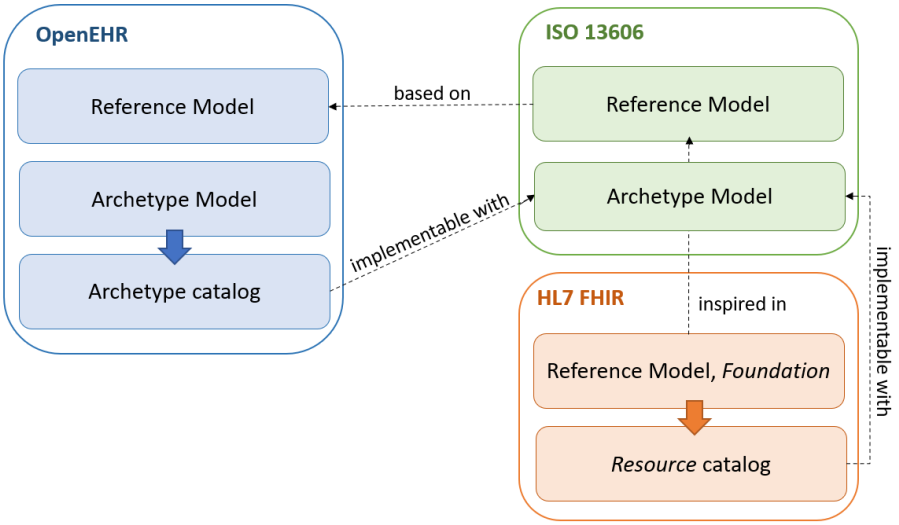

Figure 1. Diagram of conceptual relationships between OpenEHR, ISO 13606 and HL7 FHIR.

3. COMPARISON BETWEEN OPENEHR, ISO 13606 AND HL7 FHIR

Previous descriptions about OpenEHR, ISO 13606 and HL7 FHIR have shown that they differ in certain aspects that make them optimal for some purposes and limited for others. Therefore, EHR platforms currently under implementation [4, 6, 8, 11, 12] were analyzed to identify common error points made by the teams in charge of their design and implementation. Hence, these aspects were grouped into: (1) design approach, (2) modeling capabilities, (3) archetype flexibility, and (4) resources implemented. Thus, different aspects related to these aspects were independently studied and agreed upon by the Spanish expert group on EHR standards. Table 2 confronts these key points, indicating, for each one, "yes" when the standard incorporates it by design; "limited" when it is restricted by design, or it is proposed as a theoretical approach; and "no" when it is not possible to incorporate by design or it is proposed as a future step.

	OpenEHR	**ISO 13606**	**HL7 FHIR**
Design focused on EHR clinical recording	Yes	Limited	Limited
Design focused on EHR persistence	Yes	Limited	Limited
Design focused on EHR exchange	Limited	Yes	Yes
Design focused on EHR query and analysis	Yes	No	No
Modeling and formalization of clinical knowledge	Yes	Yes	Limited
Modeling and formalization of clinical documents	Yes	Yes	Yes
Modeling and formalization of clinical entries	Yes	Yes	Yes

Flexibility to create new concepts	Yes	Yes	No
Flexibility to specialize implemented concepts	Yes	Yes	Yes
Flexibility to incorporate terminological standards	Yes	Yes	Yes
Implementation of clinical model catalog	Yes	Limited	Limited
Implementation of CDSS component	Yes	No	Limited
Implementation of API query component	Yes	Limited	Yes
Implementation of messaging component	Limited	No	Yes

Table 2. Comparison of relevant aspects of OpenEHR, ISO 13606 and HL7 FHIR.

Hence, in terms of design, it can be observed that the only specification that provides a complete response to the needs of data recording, persistence and exploitation is OpenEHR [21, 27, 28], while ISO 13606 and HL7 FHIR allow the construction of solutions that must be supported by additional developments [7, 23, 29]. Likewise, ISO 13606 and HL7 FHIR offer operational mechanisms for data exchange [23, 30], whereas OpenEHR, not being specifically designed for this purpose, offers a limited solution focused on on-demand exchange [31]. In terms of modeling capabilities, both OpenEHR and ISO 13606 allow modeling and formalization of clinical knowledge through their reference models and archetypes [22, 23], while HL7 FHIR offers limited functionality for building profiles from restricted resources [32]. In contrast, all three specifications allow formalizing clinical documents and clinical entries [5, 9, 14, 33]. Regarding flexibility, although the three specifications allow specialization of already created concepts [5, 22, 32], only OpenEHR and ISO 13606 allow building new concepts based on specific requirements. Likewise, the three specifications are flexible to the incorporation of terminological standards to the information models [22, 34, 35]. Finally, in terms of implemented resources, both OpenEHR [22, 29, 36, 37] and HL7 FHIR [14, 30, 38, 39] have solutions complete or in a limited way due to the above explained, for information model catalog, clinical decision support, query API and data messaging. In contrast, ISO 13606 does not offer implemented components beyond theoretical formalizations of information models and communication interfaces [40, 41], although this has been compensated for by externally developed solutions [8, 42-44].

Based on the previous analysis, it can be established that for building a standardized EHR the only specification that offers a complete response to this need is OpenEHR, since it supplies a complete specification of implemented resources for the persistence and exploitation of health data. This is evident in the numerous implementations of EHR architectures that have incorporated this standard around the world [37]. Despite this, there are proposals for clinical repositories and exploitation mechanism based on

ISO 13606 and FHIR that have proven useful [42, 43, 45], but one must be aware that this is a use for which these standards were not designed, assuming the limitations presented for such a purpose, and the additional external developments necessary for their suitability. On the other hand, the exchange of health data can be achieved through different proposals such as ISO 13606 and the HL7 FHIR standard, depending on the complexity, as well as the capacity of agreement between parties. Thus, HL7 FHIR offers a common minimum exchange framework, limiting flexibility by virtue of convergence and simplicity. This is useful in processes where agility and pragmatism are needed, such as integrating a device with the Laboratory Information System. In contrast, ISO 13606 offers a solution for semantic interoperability with the flexibility to adapt to the information models implemented in the EHR. Therefore, it is postulated as a preferred standard in complex projects of exchange of health data between different nodes, for example, in EHR interoperability initiatives at regional, national or international level. In any case, these specifications are functionally and technically compatible with each other, as long as they are applied according to their design purposes, from the most flexible to the most restrictive.

As an extension of this analysis, a set of frequently asked questions (FAQ) about the selection and application of OpenEHR, ISO 13606 and HL7 FHIR is included in Appendix A.

4. STANDARD-AGNOSTIC USE CASES IN SPAIN

As real use cases where this standards-agnostic view has been applied, several relevant data initiatives, in which the Spanish expert group participates, are described below.

4.1. IMPaCT Data: clinical and genomic data combination framework for 5P medicine

IMPaCT is the infrastructure oriented to the generation, development and implementation of knowledge and the scientific-technical bases to support the deployment of Precision Medicine within the R&D+i system of the Spanish National Health System [46]. The Data Science program defines the requirements for acquiring and combining data from different sources and of different types, so that, semantic interoperability is achieved: data are data, but they express concepts that must be interpreted correctly when they are out of their original context. Furthermore, IMPaCT adheres to the FAIR initiative, i.e., EHR must incorporate metadata standards, terminology and classification standards, standards providing common data models and interoperability standards. At the time of writing this work, IMPaCT has started the tasks (deliverable 4.1) of analyzing the requirements and studying the existing standards, which includes OpenEHR, ISO 13606 and HL7 FHIR, for proposing an interoperability standard ecosystem in Spain for

5P medicine [47]. The result of this study concluded that the EHR standards to be used will depend on the purpose and scope of the use case in which they are applied, no existing single EHR standard for solving all existing challenges in the health domain.

4.2. INFOBANCO: advanced health data platform for research and analytics

INFOBANCO project of the Madrid Region in Spain [48], which was designed at Hospital Universitario 12 de Octubre, aims to create a platform for the management, persistence, exchange and reuse of health data, contemplating two types of outputs: interoperability and persistence. As interoperability outputs it includes the previously explained standards HL7 FHIR and ISO 13606 standards, in addition to another one specific to the clinical research domain called CDISC [49]. On the other hand, as persistence outputs, it implements an OpenEHR repository, as well as others relying on standardized models for secondary uses such as i2b2 and OMOP CDM [50, 51]. This architecture relies on an archetype server, a terminology server and an ETL process server. Hence, its standard-agnostic design is based on the principle of applying each standard for the purpose it was intended, thereby building an advanced data architecture that offers multiple interoperability and exploitation services that are provided according to the needs of the use case in which it is applied.

4.3. OntoCR: conversions between reference models through semantic ontologies

OntoCR is an ontology-based clinical repository for the registry and storage of structured data designed and implemented by the Unit of Medical Informatics of Hospital Clínic de Barcelona [42]. Besides the reutilization of previously declared knowledge and inference of new knowledge, the use of ontologies allows the modelling of information using any terminology, classification and health information standard. To this end, an ontology must be created with the classes, metaclasses and properties that define the standard, and they are then mapped to the variables defined in the local data model. Therefore, there is complete independence regarding any specific standard, being able to carry out transformations between ISO 13606, OpenEHR, FHIR and even standards for secondary use of data, such as OMOP. As an example, in the European project ASCAPE [52], data related to daily step count and adverse events coming from a mobile app were standardized under the ISO 13606 standard and then loaded into OntoCR. Thus, these EHR extracts could be translated to other reference models through semantic conversions based on the defined ontologies.

4.4. LinkEHR: a multi-reference model approach based on formal semantics

LinkEHR is a multi-reference model approach for the mapping of archetypes from legacy data and the model transformation between standards [53]. This resource is completely based on the Archetype Object Model, which allows the tool to be able to work with any reference model, including ISO13606, openEHR, HL7 CDA, HL7 FHIR, and CDISC ODM. This method also allows for the translation of archetypes between different reference models. It provides both syntactic and semantic transformations to transform archetypes, e.g., openEHR archetype into ISO13606 or HL7 FHIR standards. Syntactic transformations use a defined set of rules to transform semantically rich models into more generic ones, such as the the openEHR to ISO13606 automatic transformation or the semiautomatic openEHR to FHIR Observation transform (i.e., requires the user to make decisions to guide the transformation). While most of the standards such as ISO13606, openEHR, and HL7 CDA provide generic classes to accommodate foreign models (e.g. Generic Entries), most of the time semantics are implied in the classes themselves. Finally, it also allows exporting archetypes in any reference model into FHIR Logical Models, FHIR mechanism to represent clinical models based in other standards.

5. AGNOSTIC PERSPECTIVE ON THE USE OF EHR STANDARDS

In this paper we have analyzed three EHR standards of great relevance nowadays, such as OpenEHR, ISO 13606 and HL7 FHIR, due to the knowledge gaps perceived in the selection and application processes of these standards in different EHR projects developed in Spain (Table 1). Thus, these specifications have been described and a comparative framework was established between them in terms of design, modeling capabilities, flexibility and implemented resources (Table 2). Firstly, it can be established that the three standards are useful for the purposes (knowledge modeling and formalization, data persistence, data exploitation and data exchange) for which they have been designed and show shortcomings in those for which they have not. Related to this, these specifications are functionally compatible in health data platforms and methodologies developed in a standards-agnostic perspective. On the other hand, these standards overlap in certain purposes of use for which they are useful, e.g., knowledge modeling and formalization (OpenEHR vs. ISO 13606), or data exchange (ISO 13606 vs. HL7 FHIR). In this sense, they are conceptually and technically compatible with each other, so the selection of them, as long as they are applied to the purposes previously established, does not have a high impact as long as one starts from the one richer in modeling capabilities and flexibility. Finally, OpenEHR and HL7 FHIR have more resources

implemented than ISO 13606, due to the active community behind them. This is especially relevant in the case of OpenEHR, which has a rich collection of real clinical models/archetypes that have gone through a review process that guarantees their quality. Figure 2 summarize the agnostic vision of selection of health information standards, as well as the conversion flow between them, according to the purpose for which they are to be applied and the intended use of the data.

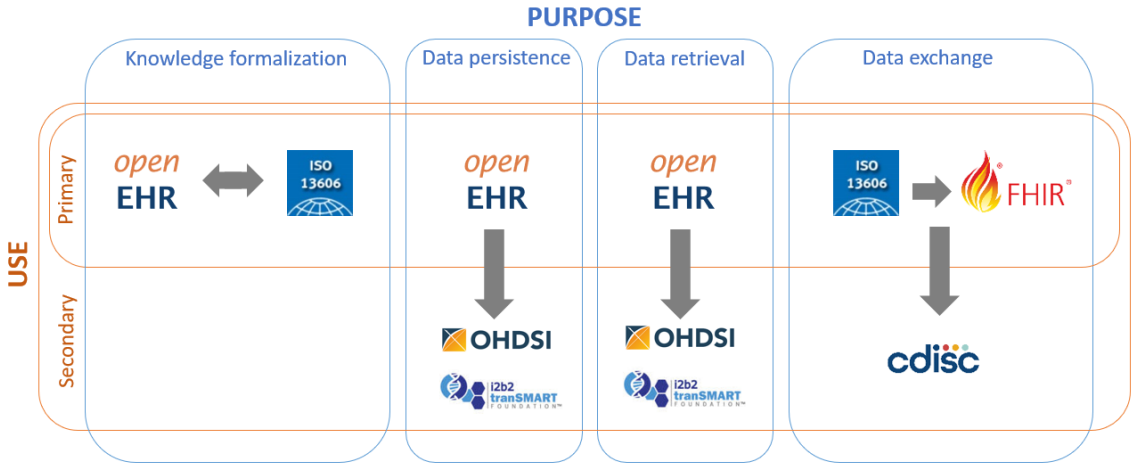

Figure 2. Agnostic perspective on selection and translation of EHR standards.

As future steps in this line of research, we will analyze other standards for which difficulties in their selection have been reported, such as those intended for biomedical research, e.g., i2b2, OMOP CDM and CDISC, previously introduced in this work, as well as standards for clinical terminologies, classifications and vocabularies.

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Appendix A, FAQ about OpenEHR, ISO 13606 and HL7 FHIR specifications

1. **Can OpenEHR, ISO 13606 and HL7 FHIR be used together?** Yes, these standards have designs that make them useful for different needs such as data persistence, and interoperability processes of different degrees of complexity and agreement between parties. Thus, in an advanced health data platform, data can be collected, stored, managed and consulted from the resources offered by OpenEHR, and shared through the ISO 13606 and HL7 FHIR standards.
2. **When is it useful to incorporate the OpenEHR specification?** OpenEHR provides a complete standard specification of resources for the creation, storage, maintenance and exploitation of health data, and is therefore useful to apply to the design of healthcare information systems that make up the EHR.
3. **When is it useful to incorporate the ISO 13606 standard?** ISO 13606 offers a real solution for semantic interoperability with the necessary flexibility to adapt to the information models implemented in the EHR. This is useful in complex projects involving the exchange and combination of data between different nodes, for example, in regional, national or international EHR interoperability implementations.
4. **When is it useful to incorporate the HL7 FHIR standard?** HL7 FHIR provides a common minimum exchange framework, limiting flexibility by virtue of convergence and simplicity. This is useful in processes where agility and pragmatism are needed, for example, in the process of integrating a clinical device with the Laboratory Information System (LIS).
5. **Do these standards allow building information models according to my specific requirements?** OpenEHR and ISO 13606 allow building and refining clinical archetypes, based on its reference models, according to the specific needs of information to be persisted or exchanged. HL7 FHIR, on the other hand, only allows the refinement of the resources through the extension mechanism, which enables new data elements to be added to the predefined ones in the resources.
6. **Are these standards compatible with the same terminology standards?** Yes, OpenEHR and ISO 13606 archetypes can be linked to any standard terminology needed for the use case to which it applies. FHIR predefines the allowed mappings but incorporates the main terminologies such as SNOMED CT and LOINC.
7. **Are the reference and archetype models of these standards compatible?** Yes, the OpenEHR reference model was the basis on which the ISO 13606 reference model was designed. This dual model

paradigm served as inspiration for the HL7 RIM and thus for FHIR. Today, there are numerous research studies, standardization initiatives and data tools available to harmonize them.

8. **There is a sufficiently rich collection of actual clinical models/archetypes, based on these standards, that have been through a quality assurance process?** OpenEHR has an active community that formally implements and reviews a set of more than 880 archetypes, which includes around 10,000 clinical data points, being the largest open clinical model repository in the world. ISO 13606 in its part 3, and HL7 with its *resources*, also offer a catalog of clinical models, although more limited than OpenEHR.
9. **Are these standards applicable for both primary and secondary purposes?** Yes, they were designed for primary use, with the necessary components and metadata necessary for the persistence or exchange of EHR, and therefore they can be extended to secondary use. However, there are specific standards for secondary use, e.g., i2b2, OMOP CDM and CDISC, which are compatible with them. Thus, there are numerous research studies, standardization initiatives and data tools to harmonize them.
10. **Are there examples of agnostic use of these health information standards?** Yes, several health data initiatives such as IMPaCT, INFOBANCO, OntoCR and LinkEHR incorporate OpenEHR, ISO 13606 and HL7 FHIR standards in their designs, in addition to others specific to secondary use such as OMOP, i2b2 or CDISC. Therefore, each data specification is applied to the purpose and use for which it was conceived.