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ABSTRACT The present descriptive–comparative study was conducted to give an overview of the messaging standards that are necessary for interoperable electronic health records (EHRs). We designed a preliminary model after data collection and compared the messaging standards of Health Level Seven (HL7) and the International Organization for Standardization (ISO). The data were assessed with the Delphi technique. A comprehensive model for the messaging standards of EHRs in the Islamic Republic of Iran was presented in three pivots: structural characteristics (standard for all EHRs, XML-based and object-oriented messages, and dual model); model specifications (reference model, archetypes and classes of reference model), and general features (distinct ontology, mapping with other standards, and using reference archetypes for exchanging documents). In conclusion, we gave an overview of messaging standards for the interoperability of EHRs and experts selected ISO13606 as a suitable

standard for the Islamic Republic of Iran.

## Critères des normes de messagerie pour les dossiers de santé électroniques en République islamique d'Iran : une étude selon la méthode de Delphes

RÉSUMÉ La présente étude descriptive comparative a été menée afin de fournir une vue d'ensemble des normes de messagerie nécessaires pour des dossiers de santé électroniques interopérables (DSEi). Nous avons conçu un modèle préliminaire après avoir collecté des données et avons comparé les normes de messagerie de Health Level 7 (HL7) et de l'Organisation internationale de normalisation (ISO). Les données ont été réalisées à l'aide de la technique de Delphes. Un modèle complet pour les normes de messagerie des DSE en République islamique d'Iran a été présenté en trois axes : particularités structurelles (norme pour tous les DSE, messages XML et messages orientés objet, et modèle double) ; spécifications du modèle (modèle de référence, archétypes et classes du modèle de référence) ; et caractéristiques générales (ontologie distincte, correspondance avec d'autres normes, et utilisation d'archétypes de référence pour l'échange de documents). En conclusion, nous avons donné une vue d'ensemble des normes de messagerie pour l'interopérabilité des DSE et les experts ont sélectionné l'ISO13606 comme norme appropriée pour la République islamique d'Iran.

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## Introduction

Electronic health records (EHRs) can be processed by computer and stored and exchanged securely by authorized users. Development and use of messaging standards for EHRs are needed for information exchange (1–4), and the absence of standards and lack of coordination between systems have made healthcare data sharing difficult (5–8). Lack of standards also hinders the widespread use of EHRs and integrated systems in healthcare services in the

Islamic Republic of Iran. So, selecting appropriate standards is a priority for the development of national EHRs (9,10).

Syntactic interoperability guarantees exchange of the data structure but does not ensure that the meaning will be interpreted identically by all parties. HTML and XML are good examples of syntactic standards. Semantic interoperability guarantees that the meaning of a structure is unambiguously exchanged between people (8). Agreement on a standardized set of domain-specific conceptual models and agreement on standardized terminology associated with controlled vocabulary are two basic requisites for semantic interoperability. Currently, there are different health informatics standards that define domain models, such as HL7 version 3 Reference Information Model (RIM) and ISO EN 13606 “Health Informatics – EHR communication” (1,11).

Since the 1980s, many countries have tried to implement e-health and then EHRs. This has had a significant influence on the development of EHR standards by the two main international e-health standard development organizations: HL7 (Health Level 7) and ISO (International Organization for Standardization). HL7 is based in the United States of America and is accredited by the American National Standards Institute (ANSI). HL7 operates in the healthcare field and covers the Americas, some European and Asian countries, and Australia. The purpose of HL7 is to provide standards for data exchange between different types of healthcare computer applications (12–14). HL7 is formed of health care and information professionals who establish standards for exchange, management and integration of healthcare information (1). HL7 version 3 uses an object-oriented development methodology and an RIM to create messages; it also uses XML-based messages, a message development structure with an emphasis on semantic interaction, and interactive models (15–17). In addition to the reference model, HL7 version 3 uses a template to describe specific patterns for description and interpretation by humans rather than machines. Four types of models are used in HL7: case, information, interaction and message design models (15,18). Clinical Document Architecture (CDA) is one of the HL7 standards that has been created for presenting and machine processing of clinical documents (19).

The ISO Technical Committee, ISO/TC 215, is an international standard body that deals with health informatics (20). The EN 13606 (Health Informatics – Electronic Health Record Communication) standard is a European norm from the European Committee for Standardization (CEN) that is also approved as an international ISO standard. It is designed to achieve semantic interoperability for EHR communication and ISO is now responsible for development of the EN 13606 standard. The standard defines architecture for communicating part or all of EHRs. ISO 13606 has two major ontologisms (21,22) and five parts (reference model, archetype interchanges specification, reference archetypes and term lists, security, and interface specification) (6,16,21,23).

The features of the HL7 and ISO13606 messaging standards are shown in Table 1 . The strengths of HL7 version 3 have been investigated in six pivots: interoperability, RIM, simplicity, object orientation, dual model and use of XML. Its weaknesses are also presented in three pivots: structural problems, difficulties in use, and relationship with other standards (1,12,13, 20–24). The strengths of ISO13606 include simplicity, archetype, dual model, reference model, object orientation and linkage or mapping with other terminology. The lack of relationship between Parts 1–5 is one of the weaknesses of this standard. No more weaknesses have been mentioned in other studies because of the lack of long-term use of the standard (1,22,25,28)

The responsibility for implementing EHRs in the Islamic Republic of Iran lies with the Statistic and Information Technology Office in the Ministry of Health and Medical Education that works on EHR infrastructure, standards and requirements. Furthermore, the Corresponding Technical Committee 215 of ISO has been established in the Ministry. Its mission is the implementation of e-health by preparation of national and international standards in health informatics.

Considering the importance of messaging standards for achieving EHRs and the recent decision by the Iran Ministry of Health and Medical Education to develop EHRs for individuals, this study investigated the EHR messaging standards and proposed an appropriate model for the Islamic Republic of Iran.

## Methods

This descriptive–comparative study was conducted in the Islamic Republic of Iran between 2011 and 2012 in the following 3 phases.

### Phase I: literature review

We reviewed books, journals, reports and websites and identified HL7 (http://www.hl7.org) and ISO (http://www.ISO.org) as organizations that have messaging standards for EHRs. Other organizations do not have messaging standards specific for EHRs.

### Phase II: model design

After Phase I, to design a preliminary study pattern, we surveyed messaging standards criteria based on three major pivots (structural features, model specification and general features).

### Phase III: testing questionnaire reliability and validity of proposed model

To design the proposed model, we used the Delphi technique. A questionnaire was designed. For each item in every pivot, three options were considered: I agree, I disagree, and no idea. Pivot priority was considered in model specification. To assess the validity of the questionnaire, it was administered to several academic professionals, medical record specialists and health information administrator. After 10 days, the same individuals were asked to complete the questionnaire for a second time. The data collection method was approved by the specialists.

After testing the reliability, the questionnaires were sent to 37 specialists, including university staff in health information management departments and experts in the EHR domain of the Ministry of Health and Medical Education who were familiar with EHR standards. The questionnaires were either sent by e-mail or delivered in person, and reminders were sent after a few days. Thirty-three participants completed the questionnaires. The questionnaires were received within 7 weeks and the data were collected and analysed.

We applied descriptive statistical methods for data analysis. For the first part of the questionnaire, the items in the model that were approved by < 50% of experts were excluded and those approved by ≥ 75% of the experts were adopted. The items approved by 50–74% of the experts and their recommended items based on other options were identified. These items were assessed in the second stage of the Delphi technique to achieve a consensus. In the second stage, questionnaires were sent to the same 37 experts, and 29 completed the questionnaires. The second part of the questionnaire related to the standard models and the questions were designed based on their priority. The frequency was calculated for each priority and then the means of the priorities were calculated. Calculated priorities ranged from 1 to 3, and in some cases from 1 to 6. The scores were multiplied by the response frequency and divided by the number of respondents. When analysing the results, the smaller the percentage, the greater the priority and vice versa. The final model design was based on the means of the priorities.

## Results

In the Delphi phases, about 56.5% and 43.5% of the specialists were women and men, respectively, and 52.2% were aged 25–34 years and the rest 35–54 years. About 43.5% of the participants had 3–9 years of work experience and 56.5% had > 10 years. For academic achievement, 17.4% had a master’s degree, 4.3% had a bachelor’s degree and 78.3% had a PhD. The field of study was health information management in 82.6% of the participants and health informatics and software engineering in 13%. A total of 65.2% were faculty members while about 34.8% were not.

According to the specialists' views about appropriate messaging standards for EHRs, standards for exchange, management and integration of healthcare data were necessary. In other words, messaging standards were deemed necessary for all areas of health care. Reference models were most important for the essential and main parts of the messaging standards for EHRs. The emphasis was on the reference model and interactive model of EHRs. The use of terminology such as SNOMED (Systematized Nomenclature of Medicine), LOINC (Logical Observation Identifiers), and ICD-10 (International Statistical Classification of Diseases and Related Health Problems, 10th Revision), is considered suitable for the ontology of the EHRs ( Table 2 ).

The experts' emphasis on structural features required for EHRs was based on XML-based and object-oriented messages ( Table 3 ).

To select an appropriate model for messaging standards and designing its classes, essential subclasses of each class were expressed and the priority of each one was determined by the experts ( Table 4 ).

## Discussion

A major healthcare challenge is to create interoperability between EHR systems that can be achieved with the selection of appropriate standards (10). Some comparative studies have shown that some organizations have a messaging standard like HL7 for the exchange, management and integration of healthcare information and ISO13606 defines rigorous and stable information architecture for communicating part or all of the EHRs of a single recipient of care (20, 25). The proposed model of Iranian experts emphasized the use of standards for exchange of data and information in all areas of health care.

Atalag et al. (1) and Jaffe (29) determined the structural features of standards for EHRs that included the use of RIM, messages based on XML, message development framework with an emphasis on interoperability, object orientation, interaction model, and displaying complex relationships. The Iranian experts also had an emphasis on XML-based and object-oriented messages. Although other studies have emphasized the information models, the experts in our study placed this feature as the second priority.

Wollersheim et al. have suggested that, to present the clinical documentation components, each messaging standard uses a number of models and the types of model in the 2 standards are different and based on different objectives (27). Among the existing models, experts emphasize the reference and interaction models. Wollersheim et al. have reported that the reference model

provides a base for data definition and includes several classes that support medicolegal requirements and record management functions (27). The model makes it possible to access further requirements of EHRs, which leads to the exchange of information between discrete systems.

Results of previous studies have revealed that ontology is used to share and reuse specific domains. As ontology is the structural framework for the transfer of information by systems, its use by messaging standards is inevitable (20, 26, 30). The Iranian experts emphasized the use of terminology such as SNOMED, LOINC and ICD10 for ontology. SNOMED and LOINC are not commonly used in the Islamic Republic of Iran; therefore, the experts emphasized the use of ICD10 for death and disease coding.

Several studies have indicated that the HL7 organization uses the necessary terminology when it exists in a specific area; otherwise, the technical committee will create it. With regard to using ontology, the ISO13606 standard tries to maintain coordination with common terminology. In the context of ISO13606 standards, plans have been devised for homogenization with other standards such as HL7 and openEHR (6). A research by Karla has suggested that different standards have to be matched with each other to meet the broad need for healthcare (31), which was confirmed by the current study.

Our results also indicate that the 2 standards have specific methods for the exchange of clinical documents. HL7 uses a CDA standard and ISO13606 uses reference archetypes (1,6,20). Iranian experts put emphasis on reference archetype for the exchange of clinical documents.

The proposed model is presented in three main pivots of EHR messaging standards: structural characteristics (standards for all EHRs, XML-based and object-oriented messages, and dual model), model specifications (reference model, archetypes, and classes of reference model), and general features (separate ontology, mapping with other standards, and using reference archetypes for exchanging documents).

Other countries like Turkey, Egypt, Saudi Arabia, South Africa and Malaysia emphasize XML, reference models and interaction models as requirements for messaging standards. Previous studies – Other countries like Turkey, Egypt, Saudi Arabia, South Africa and Malaysia emphasize XML, reference models and interaction models as requirements for messaging standards. Previous studies have also mentioned the use of special standards for exchanging documents (32–35).

EHRs and their standards are important in the Islamic Republic of Iran; therefore, more research in this field must be conducted. According to the results of the current study and research experience, ISO 13606 is suitable for the situation in the Islamic Republic of Iran. Also, having a committee corresponding to ISO/TC 215 in the Iranian Ministry of Health and Medical Education provides an opportunity for better cooperation with ISO.

Considering the approach of the Ministry of Health and Medical Education towards the creation of an EHR for each Iranian, and the absence of customized messaging standards in the healthcare system, we recommend using the proposed model in an attempt to meet the requirements for messaging standards in the Islamic Republic of Iran ( Figure 1 ).

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## References

1. Atalag, K., Kingsford D, Paton C, Warren J. Putting health record interoperability standards to work. Electronic J Health Inform. 2010;5(1):e1 (http://www.ejhi.net/ojs/index.php/ejhi/article/view/100/59).

2. McDonald CJ, Tang PC, Hripcsak G. Electronic health record systems. In: Shortliffe EH, Cimino JJ, editors. Biomedical informatics. Computer applications in health care and biomedicine. London: Springer; 2014:391–421.

3. Costa CM, Menárguez-Tortosa M, Fernández-Breis JT. Clinical data interoperability based on archetype transformation. J Biomed Inform. 2011 Oct; 44(5):869–80. PMID: 21645637

4. van der Velde ET, Foeken H, Witteman TA, van Erven L, Schalij MJ. Integration of data from remote monitoring systems and programmers into the hospital electronic health record system based on international standards. Neth Heart J. 2012 Feb; 20(2):66–70. PMID: 22231151

5. Blobel B, Pharow P. Analysis and evaluation of EHR approaches. Methods Inf Med. 2009; 48(2):162–9. PMID: 19283314

6. ISO 13606-3:2009(en). Health informatics – electronic health record communication – part 3: reference archetypes and term lists. Geneva: International Organization for Standardization (https://www.iso.org/obp/ui/#iso:std:iso:13606:-3:ed-1:v1:en, accessed 1 November 2016).

7. Asadi F, Moghaddasi H, Rabiei R, Rahimi F, Mirshekarlou SJ. The Evaluation of SEPAS

National Project Based on Electronic Health Record System (EHRS) Coordinates in Iran. Acta Inform Med. 2015 Dec; 23(6):369–73. PMID: 26862248

8. WHO forum on health data standardization and interoperability 3–4 December 2012 Geneva, Switzerland. Geneva: World Health Organization; 2013 (http://www.who.int/ehealth/WHO_Forum_on_HDSI_Report.pdf?ua=1, accessed 12 October 2016).

9. Moghaddasi H, Hosseini A, Asadi F, Ganjali R. Infrastructures of the system for developing electronic health record. J Paramed Sci. 2011 Aug; 2(2) (http://journals.sbmu.ac.ir/jps/article/view/2331, accessed 12 October 2016).

10. Ajami S, Arab-Chadegani R. Barriers to implement electronic health records (EHRs). Mater Sociomed. 2013; 25(3):213–5. PMID: 24167440

11. López DM, Blobel B. Enhanced semantic interoperability by profiling health informatics standards. Methods Inf Med. 2009; 48(2):170–7. PMID: 19283315

12. Health information services: electronic health records system. Online services. Tehran: Ministry of Health and Medical Education; 2009 (http://it.behdasht.gov.ir/uploads/101_105_15.pdf, accessed 1 November 2016) (in Persian).

13. Begoyan. An Overview of Interoperability Standards for Electronic Health Records. Integrated Design and Process Technology. 2007. http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.131.4421&rep=rep1&type=pdf.

14. Health Level Seven International. About HL7. (http://www.hl7.org/about/index.cfm?ref=common, accessed 12 October 2016).

15. Karla D. Electronic health record standards. IMIA Yearbook of Medical Informatics. 2006:136–44 (http://www.schattauer.de/index.php?id=5236&mid=6382&L=1).

16. Sinha PK, Sunder G, Bendale P, Mantri M, Dande A. Electronic health record: standards, coding systems, frameworks, and infrastructures. Wiley; 2013.

17. e-Santé EFES. Report WP10-1. Concept paper on a national EHR. Luxembourg: Centre de Recherche Public Henri Tudor (http://santec.tudor.lu/_media/project/esante/efes/rep_esante-efes_wp_10-1_concept_paper_on_a_national_ehr_v1.1_.pdf, accessed 1 November 2016).

18. Dolin RH, Alschuler L. Approaching semantic interoperability in Health Level Seven. J Am Med Inform Assoc. 2011 Jan–Feb; 18(1):99–103. PMID: 21106995

19. Duftschmid G, Wrba T, Rinner C. Extraction of standardized archetyped data from Electronic Health Record systems based on the Entity-Attribute-Value Model. Int J Med Inform. 2010 Aug: 79(8):27–32. PMID: 20537942

20. Benson T. The HL7 V3 RIM. In: Principles of health interoperability HL7 and SNOMED. London: Springer; 2010:107–28 (http://dns.uls.cl/~ej/web_Elect_2011/Lect_Elect_2010/Principles%20of%20Health%20Interoperability%20HL7%20and%20SNOMED.pdf).

21. Lopez D, Blobel BGME. A development framework for semantically interoperable. Int J Med Inform. 2009 Feb; 78(2):83–103 (http://dx.doi.org/10.1016/j.ijmedinf.2008.05.009).

22. 22. Bointner K, Duftschmid G. HL7 template model and EN/ISO 13606 archetype object model - a comparison. Stud Health Technol Inform. 2009; 150:249. PMID: 19745307

23. Smith B, Ceusters W. HL7 RIM: an incoherent standard. Stud Health Technol Inform. 2006; 124:133–8. PMID: 17108516

24. Sadoughi F, Delgoshaei B, Foozonkhah S, Tofighi S, Khalesi N. Designing an object-oriented model for some key messages to support the electronic health record. J Health Admin. 2006; 9(25):21–30 (http://jha.iums.ac.ir/browse.php?a_id=333&sid=1&slc_lang=en).

25. ISO 13606-1:2008. Health informatics – electronic health record communication – part 1: reference model. Geneva: International Organization for Standardization; 2008 (http://www.iso.org/iso/catalogue_detail.htm?csnumber=40784, accessed12 October 2016).

26. ISO 13606-2:2008. Health informatics – electronic health record communication – part 2: archetype interchange specification. Geneva: International Organization for Standardization; 2008 (http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=50119, accessed 12 October 2016).

27. Wollersheim D, Sari A, Rahayu W. Archetype-based electronic health records: a literature review and evaluation of their applicability to health data interoperability and access. HIM J. 2009; 38(2):7–17. PMID:19546483

28. Menárguez-Tortosa M, Martínez-Costa C, Fernández-Breis JT. A generative tool for building health applications driven by ISO 13606 archetypes. J Med Syst. 2012 Oct;36(5):3063–75. PMID:21968574

29. Jaffe C. HL7 roadmap for 2008. Challenging the future (https://www.hl7.org/documentcenter/public_temp_38599AAD-1C23-BA17-0C031E450E1DDD82/calendarofevents/himss/2008/presentations/HL7%20Roadmap%202008.pdf, accessed 12 October 2016).

30. Ryan A. Towards semantic interoperability in healthcare: ontology mapping from SNOMED-CT to HL7 version 3 ( http://crpit.com/confpapers/CRPITV72Ryan.pdf, accessed 12 October 2016).

31. Kalra D. ISO EN 13606 Electronic Health Communication (EHRCOM): the contribution of archetypes towards ehealth semantic interoperability. Norwegian Seminar on Archetypes and Architecture, Oslo, 26th November 2009 (http://www.kith.no/upload/5414/ehrcom-archetypes-dipakkalra-20091126.pdf, accessed 12 October 2016).

32. Dogac A, Yuksel M, Avci A, Ceyhan B, Hülür U, Eryilmaz Z, et al. Electronic health record interoperability as realized in the Turkish health information system. Methods Inf Med. 2011;50(2):140–9. PMID:21132219

33. Eldin AS, Saad D, Samie GA. Evaluation of electronic health records adoption in Egypt. Int J Eng Res Appl. 2013 Jan–Feb;3(1):1131–4 (http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.444.9289&rep=rep1&type=pdf).

34. National health normative standards framework for interoperability in eHealth in South Africa. Department of Health, Republic of South Africa; 2014 (http://hufee.meraka.org.za/Hufeesite/staff/the-hufee-group/paula-kotze-1/hnsf-complete-version , accessed 12 October 2016).

35. Alkraiji A, Jackson T, Murray I. Barriers to the widespread adoption of health data standards: an exploratory qualitative study in tertiary healthcare organizations in Saudi Arabia. J Med Syst. 2013 Apr;37(2):9895. PMID:23321966

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