Healthcare Terminology Management and Integration in Italy: Where we are and What we need for Semantic Interoperability

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Abstract

Objectives: The purpose of this paper is to present and discuss the adoption and use of medical terminologies and coding systems in Italy, focusing on their management and integration for guaranteeing semantic interoperability among Electronic Health Records (EHRs). Semantic interoperability guarantees meaningful exchange of data between two or more healthcare information systems, ensuring that data content is not only understandable within its original context, but also in the destination one, and is capable of supporting health service management, clinical decision-making care collaboration, as well as public health reporting, and improving clinical research.

Methods: The approach used for the coding systems management and integration in the Italian Fascicolo Sanitario

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1 Introduction and Objectives

The importance of knowledge management in the healthcare domain is well recognized and widely treated in the literature. This is strictly related to the use of vocabularies, terminologies or classification and coding systems to better organize and define clinical concepts and to identify access keys to codified data that can be thus combined, manipulated and shared among healthcare professionals (physicians, data analysists, and all the healthcare operators) during the entire process of care. Those systems, generally referred as Knowledge Organization Systems (KOS), in fact, allow to structure and represent complex information fostering their correct interpretation and sharing.

More specifically, coding and classification systems are essential instrument for the unambiguous coding of clinical concepts during the process of care and during the Elettronico $(FSE)^a$ use case is presented according to the current Italian regulations on federated EHRs.

Results: Results show the need to promote an advanced approach, in conformance to the literature best cases, which takes care about a better integration and maintenance of medical terminologies and coding systems through the use of standardized models of terminology services. **Conclusion:** The paper presents terminology interoperability issues arisen from the described approach and related requirements to propose a solution that could allow, through sophisticated terminology services framework, to achieve also in Italy semantic interoperability.

Keywords

Health Information Management; Clinical Coding; Health Information Exchange; Terminology as Topic; Semantics

^aThis is the italian equivalent for Electronic Health Records.

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delivery of health services (e.g. diagnostic process, statistical analysis for epidemiological studies, etc.) and for improving access to and elaboration of data in healthcare information systems. They are used particularly to overcome problems related to the lexical complexity of the domain, that is characterized by a high level of specificity. Content and structure of classification systems vary according to their granularity, scope and to the cultural and social context they are built for. A detailed overview of the differences and scopes of these types of resources in the healthcare domain is presented in [1].

In the last decade, the problem related to management, integration and correct use of terminologies and coding systems in healthcare has become a non-trivial resolution issue. Standards, at a national and local level, are often adapted to different purposes, other than those for which they were originally built. On one hand, this entails that it is not possible to use them in their completeness,

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and, on the other hand, those standards will inevitably undergo a misuse of their original structure. The use of the International Classification of Diseases (ICD) in the Italian primary care setting is an example of this issue, as the classification system, originally built for classifying morbidity and mortality information for statistical purposes, is used by General Practitioners (GPs) for coding diagnoses and comorbidities and also for a plethora of other applications (e.g. in research, health care policy, and health care finance), generating ambiguities in the registered information, coding errors, concept generalization, dissatisfaction about the coding practice, etc. [2].

Issues related to terminology management and integration have been treated by many researchers in the last 20 years. Initial studies and applications were focused on the use of the Unified Medical Language System (UMLS) Metathesaurus, known as the first medical terminology integration service, a largest repository of biomedical vocabularies (more than 100), developed by the US National Library of Medicine [3]. Researchers used the UMLS Metathesaurus to create knowledge-based representation for controlled terminologies of clinical information and to extract and validate semantic relationships. It is the case for example of the Medical Entities Dictionary (MED) [4] that provides domain coverage, synonymy, consistency of views, explicit relationships, and multiple classification while preventing redundancy, ambiguity (homonymy) and misclassification. More recently researchers and stakeholders, especially in some European (EU) countries and in the United States, are promoting the use of terminology server's services which permit access, query and search for the different semantic resources (terminologies, coding systems, ontologies). These tools are specifically designed to work with controlled vocabularies as they provide, among others, vocabulary management, distribution or update functionalities [5].

As many other European countries, after the publication of the European Directives on Integrated EHRs, Cross-boarding care, Semantic Interoperability of healthcare data [6] also Italy carried out an Institutional Programme for the digital healthcare in order to adapt the EU legislation to the national context. This programme was in particular targeted to the construction of a national federated and interoperable infrastructure for the management and sharing of patient's healthcare data, namely "Fascicolo Sanitario Elettronico" (FSE), which is the Italian equivalent acronym for EHR [7, 8, 9]. This infrastructure aims to promote the decentralization of patient care, facilitate access to healthcare data for both healthcare providers and patients, and improve diagnostic and therapeutic care pathways. In order to allow an efficient healthcare data management in the context of the FSE,

¹Decreto Legislativo N. 179 del 18/10/2012 Ulteriori misure urgenti per la crescita del Paese. Available from: http://www.normattiva.it/uri-res/N2Ls?urn:nir:stato: decreto.legge:2012-10-18;179

²With Semantic interoperability is meant the ability of a healthcare system to share information and have that information properly regulatory actions, finalized to uniform and standardize the use of coding systems for coding consumers' healthcare data and their transmission in an interoperable perspective, have been recently launched. This would allow the exchange of patient's data and documents between different healthcare information systems through a codified and shared language. In particular the Legislative Decree No.179/2012¹ urges Italian Regions and Autonomous Provinces to establish and implement regional FSE systems, highlighting the need to ensure interregional interoperability services.

Giving the context and issues described above, the aim of this paper is to show i) where Italy is positioned with respect to other countries regarding the topic of healthcare terminology/coding systems management and integration, ii) what effort has been made after the legislation on FSE to implement terminology management within the context of FSE itself, and iii) what stakeholders and researchers still need to do in order to guarantee Semantic Interoperability² and adopt standardized and updated medical terminologies to facilitate data access, registration, integration, and sharing within the national context so to be aligned to EU countries for promoting cross-border care.

2 Terminologies and Coding Systems Management in the FSE

Approaching the world of medical terminologies is quite confusing at first glance, despite the aim of those systems is to organize the domain knowledge in a structured and clear way. Due to the standardization effort, a huge number of medical terminologies and classification systems have been developed, but although they are called "standards", they are quite far from being unique for each medical semantic area. Because of this, in the last two decades significant effort has been spent by researchers to create conversion mappings among them, often enriched with a semantic network.

The management of medical terminologies in Italy is even further complex, mainly because the legislator has never addressed the theme from a general and integrated point of view, but often according to the needs of the moment, especially the economic ones. The most significant legislative interventions are the Ministerial Decree 26/07/1993, which makes mandatory diagnoses encoding in the hospital discharge letters by using the 9th revision of the International Classification of Diseases – Clinical Modifications (ICD-9-CM) and the recent Prime Minister Decree No. $178/2015^3$, which is more specifically focused on the FSE, widely addressing medical terminologies use in a specific section. Over the years between 1993

interpreted by the receiving system in the same sense as intended by the transmitting system.

³Decreto del Presidente del Consiglio dei Ministri N. 178 del 29/09/2015, Regolamento in materia di fascicolo sanitario elettronico, Gazzetta Ufficiale n.263 11/11/2015. Available from: http: //www.gazzettaufficiale.it/eli/id/2015/11/11/15G00192/sg and 2015 a lot of recommendations about the use of standard terminologies in different types of clinical documents [10, 11], such as prescriptions and Patient Summary (PS), were issued by technical working groups, but none of them had the power to encourage the effective creation of a national task force for coordinating the numerous efforts related to the use and management of medical standardized terminologies. Beside the national vacatio legis, different regional and local initiatives led to the creation of systems tailored for specific contexts of use, thus losing semantic interoperability, which is the fundamental feature of standardized terminologies.

The following sections will describe, on one hand, the governmental effort, supported by the National Research Council of Italy (CNR), for the regulation of the use of coding systems in FSE and, on the other hand, the work done for the implementation of the Logical Observation Identifiers Names and Codes (LOINC) in Italy.

2.1 Italian Regulations for the Use of Coding Systems in the FSE

Since 2009 CNR is cooperating with governmental bodies, respectively the Department of Digitalization of Public Administration and Technological Innovation of Public Administration and the Agency of Digital Italy (AgID), to define the national technological infrastructure of the FSE^4 , also supporting the regulatory action and participating to national Technical Boards with all the different stakeholders involved into the matter. This activity led to i) the definition of the FSE infrastructure [9], whose aim is to allow the full interoperability among the different regional EHR systems; ii) the publication of national guidelines for the implementation of regional EHRs⁵, which guided Regions in presenting their EHR projects compliant to the national infrastructure; and iii) the definition of Specifications related to different interoperability aspects.

The cited Prime Minister Decree on the FSE states that the content of the clinical documents produced and to be stored in the FSE have to be represented through classification and coding systems able to ensure, eventually recurring to transcoding, semantic interoperability at regional, national and international level (art.25) and refers to its Technical Annex for all the relative details. The Technical Annex specifies the use of the following standard terminologies:

- ICD-9-CM for diagnoses encoding;
- LOINC for laboratory tests encoding;
- ATC (Anatomical Therapeutic Chemical Classification System), developed by the World Health Orga-

nization (WHO), for medications' active ingredient encoding;

• AIC (Autorizzazione all'Immissione in Commercio), developed by the Italian Medicines Agency (AIFA), for medications encoding.

Furthermore, their use in the PS and in the Laboratory Report (the two kinds of document to be firstly implemented, according to the law) is described in detailed tables.

Those standard terminologies are not new into the national context but their systematic use is not always consistent and needs to be adapted in order to be coherent with the new requirements. At the state of the art when the Prime Minister Decree entered into force, standard terminologies were often known by name, but barely used or properly used, thus causing a general underestimation of all the possible benefits deriving from them.

In recent years, different studies [2, 12] try to get an outline of the Italian situation related to the effective use of standardized terminologies among physicians, especially focusing on GPs, or to evaluate how different classification systems would adapt to the use in GPs' daily practice and how to support them in the coding process. They generally agree in depicting either an inappropriate use or a not sufficiently deep knowledge of the recommended classification system, i.e. ICD-9-CM, that brings GPs to use only high level codes (e.g. for ICD the three digit codes) instead of selecting the adequate code respecting granularity and precision. The wrong use of coding systems is often related to the lack of an adequate training of the professionals involved in the process of care.

About laboratory observations, the state of the art is slightly different because existing regional and local coding systems are like service catalogs more oriented to reimbursement purposes than to detail clinical information. Moreover, they differ in each Region and increase the existing idiosyncrasy when they are mapped to internal laboratories catalogs. The following paragraph presents the process of adapting and introducing LOINC into the Italian context.

2.2 LOINC Implementation in Italy

In 2009, when the first CNR project related to the FSE infrastructure started, LOINC was just mentioned as recommended standard by the Tavolo di Sanità Elettronica, a temporary technical board in charge of releasing technical specifications for e-health documents. A detailed analysis of the laboratory records workflow and data description revealed a strong use of idiosyncratic conventions to represent the same clinical concepts in different local electronic

⁴Projects realized between 2009 and 2016 are: InFSE, OpenIn-FSE, Interventi a supporto della realizzazione del Fascicolo Sanitario Elettronico, Realizzazione di servizi della infrastruttura nazionale per l'interoperabilità per il Fascicolo Sanitario Elettronico, Realizzazione di servizi e strumenti a favore delle Pubbliche Amministrazioni per l'attuazione del Fascicolo Sanitario Elettronico.

⁵Linee Guida per la presentazione dei piani di progetto regionali per la realizzazione del Fascicolo Sanitario Elettronico. Available from: http://www.agid.gov.it/sites/default/files/linee_ guida/fse_linee_guida_31032014_dpcm_dt.pdf.

systems. LOINC, internationally renowned standard for clinical and laboratory tests encoding, appeared as the right solution to overcome this issue. The Institute of Informatics and Telematics (IIT) of the CNR in agreement with Regenstrief Institute (RI), which is the LOINC creator and manager, started the translation process of the standard into Italian, refining it from release to release by establishing translation rules, thanks to the continuous collaboration with different domain experts. The first LOINC Italian translation was realized according to the part based translational approach (as described in [13]) and published in 2010, containing 43,152 codes. Further refinements based on the analysis of the automatic process outcomes were conducted at each biannual release, the last of which in December 2015, containing 61,424 codes. Thanks to the creation of the LOINC Italia workgroup, the adaptation and the introduction of the standard in Italy has been continuously managed and supported also cooperating with the LOINC master creators. This is often a weak point of the national version of international standardized terminologies as they lack of planned maintenance and references. LOINC Italia working group has over time produced support materials for the use of the standard, provides educational activities and assists all the processes that require relations with the LOINC mother company, such as new codes submission requests.

Mentioned FSE projects offered also the chance to test the introduction of the LOINC Italian version into some laboratories. It was a time of major confrontation with the actual daily practices of laboratories and an occasion for assessing the usefulness and usability of the translation results. Mapping local terms to a standardized vocabulary is not only a matter of interoperable informative systems, but it requires a deep knowledge of both the destination terminology structure, i.e. LOINC, and the way in which the tests are actually realized. It was possible to find solutions to the multiple issues encountered during this phase thanks to a continuous collaboration with RI experts and the keen interest of the laboratorians involved in the mapping process. The high percentage of correct mappings and the low percentage of not identified matches demonstrate that the first impression of the system is not as difficult as one might expect for people unaccustomed to the use of standard terminology, and secondly, that the training phase is effective making the system well understandable.

All the actions taken for introducing and adapting LOINC in Italy revealed that a central coordination center is essential for having a common reference point to address questions, support users, maintain relationships with governmental bodies and third parties, keep updated the standard and consider international updates and challenges in the domain. An integrated management of a medical terminology cannot be able to leave all those aspects out of consideration, as they all contribute to make effective and efficient the use of a standardized system.

3 Preliminary Results

According to the Prime Minister Decree No 178/2015 and to the agreement between CNR and AgID, the interoperability platform of the FSE was firstly released in the last month of December 2015. It offers a series of services for allowing a "dialog" between two regional EHR systems and the consequent exchange of clinical documents. Regions are progressively starting to test their interoperability services in order to accomplish step by step to their regional EHR projects drawn up according to the cited Decree. The management of standard terminologies to be used in PS and laboratory reports is being centralized and offered through the FSE platform⁶ to serve as a common point of reference for Regions and end users. Services that have been firstly released include, among others, the download of the official versions of the recommended standard terminologies and additional support (e.g. guidelines, manuals); the possibility to have information about the version to be used and how to use it in the specified documents; to perform queries, by keywords or codes, to find data in one or all the medical terminologies available in the platform; helpdesk services to contact national qualified support centers; and finally, the possibility to require, through the platform, specific training activities.

This is only a first step performed to reach the general objective of centralizing the management of medical terminologies through an integrated system based on internationally recognized standards. Toward this aim, there are many international initiatives in the literature that could be considered. Some of them offer mapping and multilingual functionalities (e.g. the HETOP terminology service, that offers cross lingual multi-terminological mappings on a semantic basis [14]), some others integrate semantic resources represented as ontologies and allow users to continuously update their mappings (e.g. the Bioportal repository)⁷. Furthermore, some international initiative promoted the use of common terminology models to accommodate multiple vocabulary and ontology distribution formats and support of multiple data stores for federated vocabulary distribution. It is the case of LexGrid, a community-driven initiative coordinated by the Mayo Clinic Division of Biomedical Statistics and Informatics [15], and of the HL7 CTS2 (Common Terminology Services $2)^8$ specifications for the development of standardized terminology services. Regarding this last standard, its most relevant international implementation is by Mayo Clinic Informatics, but similar experiences are known also in France (by PHAST, a non-profit development stan-

⁶www.fascicolosanitario.gov.it

⁷http://bioportal.bioontology.org/

⁸http://wiki.hl7.org/index.php?title=Common_Terminology_ Services_-_Release_2_%28Normative%29

⁹http://wiki.phast.fr/index.php?title=Common_

Terminology_Services_2_(CTS_2)

¹⁰http://www.wiki.mi.fh-dortmund.de/cts2/index.php?title= Hauptseite

dards and services organization, that used CTS2 to build the Standard Terminology Services - STS⁹), Germany (by the University of Applied Science, Dortmund¹⁰), Austria (by the Ministry of Health, that used a modified version of the cited Dortmund Terminology Server as central eHealth terminology source in Austria, Austrian Terminology Server¹¹, especially for the national federated patient health record "ELGA") and Italy (by the University of Genova [16], and by the Codices company that use it to develop the Distributed Terminology Assets Management system13). In particular in Italy, the raising awareness of the fundamental importance of having an integrated and centralized system for terminologies management is driving the first initiatives related to HL7 CTS2, such as the cited ones, and also the first requirements of some Regions about it.

4 Discussion

This paper shows the Italian status regarding semantic interoperability in health domain, presenting what has been done starting from the national state-of-art and from some issues related to the different local realities. In fact, the autonomy in healthcare management given to Italian Regions and the lack of a centralized management of a terminology service generated, over the years, a proliferation of different regional solutions/implementations, causing thus many issues from different perspectives.

As already mentioned, the activity carried out by the Italian Government, with the continuous support of the CNR, has been first of all aimed at ensuring the cooperation among all the different actors involved into the subject so to realize a service for centralized management of healthcare services according to the current Italian regulations and compliant to the stakeholders' needs. Within this activity the need for an integrated and centralized medical terminology service, ensuring semantic interoperability of information exchanged, is motivated, as stated above, by several critical factors: i) the widespread misuse of medical coding systems in most national health facilities; ii) the large use of local coding systems instead of the recommended standards; iii) the adoption of obsolete coding systems. The semantic interoperability among health information systems is a longstanding aspiration of the healthcare community, but the way to reach it can lead to many non-trivial issues, particularly for the application domain. In Italy the problem is not only related to a technical matter, but there are also other open issues, most of which would be solved through the creation of a national authority for medical terminologies management, such as in some EU and non EU countries (e.g. Belgium, with the Terminology Center belonging to the Federal Public Service of Health, Food Chain Safety and Environment; Sweden, with the National Board of Health and Welfare that provides nationally agreed upon concepts and terms within health and social care services in the terminology database; United kingdom, with the UK Terminology Centre - UKTC; etc.).

The national interoperability is only the first step on a long pathway to have an efficient and effective EHR. The international level, only addressed in some research projects (e.g. EpSOS¹²; SemanticHealthNet¹³; Antilope¹⁴; Trillium Bridge¹⁵), could turn out as a further issue for Italy in the next future. Furthermore, the adoption of unappropriated (or not updated) standards could leave Italy out from "international" semantic interoperability. It might be necessary then an additional step oriented to transcoding the national recommended systems to up-todate versions or other standard classification systems or nomenclatures in use in EU and non EU countries (such as SNOMED CT that is already adopted in many Countries). As discussed in this paper, the activity carried out with LOINC is a valuable example of the importance of a constant work on the codes translation and more generally of the efficient management of the standard itself (e.g. the importance of developing tools for promoting its distribution and supporting its implementation and mapping).

5 Conclusions

The paper presented the initiative undertaken in Italy to provide regulations to the use of medical terminologies and coding systems within the context of FSE, the national federated EHR, and what has been done to reach national semantic interoperability. Preliminary results show that, despite the recent advancements promoted by the law and supported by the AgID and CNR projects, a lot of work still needs to be done to be aligned with international initiatives that promote the use of integrated management services of medical coding systems as well as dedicated Authorities to coordinate the entire process. To accomplish this task, it is strongly required a synergy and cooperation among national Standard Development Organizations (SDOs), which are responsible for each system maintenance and distribution. It is to be considered that the implementation of integrated terminology services is just the beginning of a process. In fact, the most important aspect in managing medical terminologies is the constant maintenance over time to update resources and the coordination of processes such as transcoding, translation, and licensing that need to be accomplished by a dedicated governmental authority. To this end, the creation of a national body strictly focused on these themes appears urgent to not let the national FSE infrastructure be merely a matter of technologies, forgetting its most important aim: the clinical information management and sharing to improve patient quality of care. In this perspective, the

¹¹https://termpub.gesundheit.gv.at/TermBrowser/gui/main/ main.zul

¹²http://www.epsos.eu/

¹³http://www.semantichealthnet.eu/

¹⁴https://www.antilope-project.eu/front/index.html

¹⁵http://www.trilliumbridge.eu/

creation of a central terminology management service is not only a way to reach semantic interoperability, but it is also a way to better support healthcare professionals in improving the quality of their data ensuring maximum benefits along the healthcare process and the cooperation among different healthcare providers.

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