epSOS learnings: semantics a matter of patient safety and the ultimate health care delivery system

epSOS contributors

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Summary

How do we arrive at a usable maintenance process for health terminologies? What size and scope of cooperation, integration and interoperability is appropriate, and for what services? How can the management of terminologies be improved? Who should lead this endeavour? Much has been written on the subject but there is some way to go before it is widely implemented. epSOS has advanced a long way in showing the need for and the possibility of attaining semantic interoperability on a fairly large scale, and it has already proved extendable to new countries. The real proof of success, however, will only come after several years of usage, development and maintenance.

Key words: patient summaries; prescriptions; dispensation

Introduction

The semantic services are an important aspect of the epSOS Large Scale Project, since they address the level of processable information from which medical data is inferred. Functional requirements identified the content for three documents: Prescription, Dispensation and the Patient Summary. Semantic services must take into consideration at times the structure of these documents, ensuring that the information is expressed by the use of interoperable syntax, while also taking into account the code systems that are used to represent the information to be coded and translated. Furthermore, semantic services need to provide initial solutions tending towards semantic interoperability to overcome problems arising from the use of different terminologies and vocabularies. Terminology Access Services are also provided to ensure the on-the-fly interoperability between the different Member States. Many issues were handled, for example:

1. The Medication Summary is part of the Patient Summary but is not necessarily related to the Prescription or Dispensation. The way the information is gathered in the Medication Summary is up to the participating nation. The Medication Summary is not to be described as a special, separate document.

2. The fact that substitution of a medication while dispensing must be documented with a “yes” or “no” value; however, the substitution itself is a human action. The human action is performed by the pharmacist after consulting/talking to the patient.

3. In some countries the Patient Summaries are created on the fly. This document will only be visualised and not imported. The question of the accuracy and the imputability of the data visualised falls within the realm of the national authorities.

4. The cross-reference between the code systems does not exist officially, except between the code systems ICD-9 and SNOMED CT. The cross-mapping between the code systems with regard to the terms employed in the epSOS Master Translation/Transcoding Catalogue is done with the cooperation of the medical and semantic specialist.

5. Since it was not clear what legal responsibility the patient’s contact (guardian) has for the patient in each country, information on the participation type and the personal relationship roles is given (ParticipationTypePatientContact and PersonalRelationshipRoleType). These designations indicate what type of contact this is, such as informant (source of information), a person to call urgently etc. Also the relationship to the patient indicates if the person is a relative, a neighbour etc. This is extra information that might be needed in accordance with the legislative procedures in the Member State where the patient receives care.

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There are some issues that remain:

1. **Face of evolution** – There are two contradictory measurements when it comes to spreading health care knowledge: speed vs. safety. The epSOS services setup can work in the short term but in the long term countries need to make decisions in conjunction with the standardisation organisations and the research community with regard to simplification of the very cumbersome handling of medical terminologies and other standards. It is necessary to build a structure that is strong and stable to maintain and yet flexible enough to bring the latest research results to the industry as rapidly as possible. Two examples of scenarios can be outlined – either Governments and/or the SDOs set the pace or a more community-based approach such as the NCBO setup is used. They may even be complementary but, if so, how would the organisational setup be outlined? What are the criteria for selection/survival in an ecosystem like this?

2. **Testing tools** – The test tools to be developed need to be maintained. Two types of maintenance are needed: a functional process along with physical storage and development.

3. **Central Storage** – Can Member States and other countries agree to a physical storage space for the epSOS Master Translation/Transcoding Catalogue (MTC) and the epSOS Master Value Sets Catalogue (MVC)? The question whether or not a country can be a host for content concerning the whole European community was left open.

Is it possible to advance from keeping each actor – Patient, Health Professional, Researcher, Administrator and Developer – similarly miserable and confused to equally happy?

**Background on epSOS and Semantic Services**

Semantic Services describes the components necessary to achieve semantic interoperability in the exchange of medical information between the epSOS pilot sites. Semantic interoperability needs common elements such as:

- A common data structure of the three documents to be exchanged (Pivot Documents);
- A commonly understood medical terminology based on value sets extracted from officially existing code systems used in these documents, namely the epSOS Master Value Sets Catalogue (epSOS MVC). The content of the epSOS MVC serves as the basis for translating to each Member State’s Language and cross-reference between different code systems, resulting in the epSOS MTC. The content of the epSOS MVC will also be provided in an ontology (coded in OWL) to foster semantic interoperability;
- A way of accessing and maintaining the content present in the epSOS MTC that is transparent to the user: the Terminology Access Services interface.

All these components are needed to enable the health professional to make competent and informed decisions fostering continuity of care.

**Overall description**

The general flow of information within the semantic services is presented for a better comprehension of the processes involved. The flow of information concerns the content defined by functional experts or the data elements. The data elements lead to an overview of the syntax and the build of a collection of terms grouped thematically into value sets. The value sets are at the basis of the epSOS MVC, which, when turned over to the National Linguistic Competence Centres, results in turn in the epSOS MTC. The epSOS MVC is also the basis for the epSOS Ontology. Terminology access service interfaces are defined so that the content of the epSOS MTC can be easily accessed and maintained. The methodology and the approach chosen are presented, as well as the perimeter of the work accomplished. To obtain a better overview of the results, the reader is asked to read the full semantic deliverables of the epSOS project.

**Code systems selection**

To simplify the epSOS Value Sets Catalogue and bring it to a manageable scale will include different code systems which are chosen according to the following criteria:

- **Internationally used** – An international code system such as those released by ISO or WHO, for example, has the advantage that it was formulated by experts having wide experience of terminology implementation and application. The internationally used code systems have implementation guidelines that are used at the national level, as well as maintenance guidelines. The code system used in the epSOS Value Sets Catalogue must be internationally recognised. The suitability should be evaluated by experts in the field, both medical and non-medical.

- **In use** – The second most important criterion in selecting the code system is its use in the Member State. A survey is done among the experts working on the epSOS Value Sets Catalogue with a view to securing an accurate representation of the code systems used in each country.

- **Existence of translation in different languages** – The existence of translation via versions in different languages is another key element to be evaluated, since it will dramatically reduce the activity of translating the epSOS Value Sets Catalogue terms into the local (national) language. If a code system exists in the local (national) version, it is likely that existing translations have already been validated/certified and kept aligned when newer versions are released.

- **Has a maintenance process** – A code system that has an official maintenance process is highly desirable. The release of new versions should be taken into account during the decision-making process. The maintenance process should include specifications for distribution and support.

- **Existence of transcoding systems/services** – The existence of officially defined or at least of consolidated systems/services to perform transcoding from one code system to another is a desirable element in reducing costs and risks. However, this is known to be an important issue that most Standard Organisation Bodies are struggling with, and therefore much bigger than the epSOS perimeter. Nevertheless, whenever official attempts exist to map
one code system to another it is considered very useful since it provides guidance for mapping.

- **Cost of licenses, implementation and maintenance** – Although for research purposes most of the code system licenses are provided free of charge, the cost might prove to be prohibitive. In addition to the cost of the licenses, the cost of implementation and maintenance needs to be considered.

- **The code system must be easily implementable** – The code system must be easily implementable on the basis of sound methodology which takes into account both the syntactic and vocabulary aspects.

**Term selection**
The primary goal of the epSOS terminology is to develop cross-border semantic interoperable services with regard to the three documents to be exchanged within the pan-European space. Since no specific terms were indicated by the need to be spent must be judiciously evaluated.

Criteria for concept selection
Since no particular indications originated from the functional work packages, the Semantic Services Work Package makes inferences based on the most used data in Europe within a particular context, such as the European Emergency Card for the Patient Summary or the most commonly used terms within a particular context, such as the Prescription. Within this context it is important to indicate whether a part of a code system needs to be used, and therefore mapping needs to be done across code systems, or whether an entire code system or a branch thereof needs to be used. The effort needed to be spent must be judiciously evaluated.

The restricted scope of the emergency data set makes it very difficult to reduce the choice to a particular set of terms; nevertheless, this is seen as a first step towards achieving semantic interoperability while positively contributing to European patient safety. The purpose of the Emergency Data Set is to provide the health professional with the necessary amount of data to enable minimal patient treatment to be administered, weighing the risk and the benefits.

Criteria for concept selection
Since no particular indications originated from the functional work packages, the terms to be used within the epSOS project are limited to the most commonly indicated recommendations in the pan-European space. The following criteria were employed:

- **Relevancy to scope documents** – Several terminology sources should be used for the epSOS Value Sets Catalogue on the basis of organisational requirements and definitions as translated by the Semantic experts. Elements were selected from the European Emergency Health Card, the Czech and Slovak proposal for an Emergency Data Set (EDS), the ISO 21549-3 (Patient Health Card Data – Limited Clinical Data), the Hospital Data Project data set, the HL7 Terminology and the IHE Recommendations, etc. These data elements define the basic categories of terms in use. However, they are too general to be used as specifications for data exchange. These data elements should be used as a representation of the data elements, all the concepts must be clearly related to the specific domain they represent and they should be used in its context.

- **Presence in clinical data** – The relevance of the epSOS terms is evaluated with respect to the following criteria:

  - **Information sufficient for clinical decision** – Health terminology is very complex and covers a large area of knowledge requiring major effort to organise a part of this terminology for a specific purpose. It is hard to decide what level of detail should be used, especially when cases of use cannot be precisely specified. But having fundamental cases of HCP use taking care of citizens of foreign countries (possibly in emergency situations) one should always think of what information it is really necessary to obtain concerning given conditions. Sometimes it is necessary to know merely the presence or absence of something (e.g. patient was immunised against tetanus), in other cases more specific attributes are necessary (e.g. type of pacemaker, date of last examination, clinical course). These various levels of information and granularity were addressed in choosing the syntax and the value set that accompany the respective value sets syntax (please see the epSOS Master Value Sets Catalogue [epSOS MVC] as well as the table at the end of this document). Each coded element was studied as a group, within the health professionals in the semantic group, resulting in the epSOS MVC (or the epSOS Reference Terminology).

  - **Information systems behind** – When we are creating an epSOS Value Set Catalogue, its main purpose must be borne in mind: it is the representation usable for communication between information systems (e.g. NCP, national systems). The content and representation should follow constraints given by their implementation – semantic services and communication standards. Moreover, current local systems may introduce more constraints that need to be confronted. The revision of approved technical specifications of semantic services is necessary.

  - **Frequency of use** – Even within one domain delimited by scope documents, the number of possible concepts may exceed the possibilities of implementation.

  - **Severity (consequences)** – Contrary to the previous criterion, or together with it, severity of the information carried by concept needs to be considered. If the absence of particular even very sparse facts can lead to serious harm for the patient’s health, it should be incorporated even if some less important ones must be omitted.

  - **Content evaluation and acceptance** – The process of choosing concepts is quite demanding and time-consuming. But it must be done properly and evaluation must not be omitted. The evaluation should run in parallel with ontology creation, because the task is a major one. Evaluation should cover various levels, from basic level in a working group selecting concepts, to project representatives of health professionals and medical specialists in all the countries involved. Syntactical and orthographic rules of each language must be applied.

  - **Reconcilability** – Special emphasis should be placed on reconcilability of a concept’s meaning through the chosen term. Generally, self-explanatory terms should be preferred. On the international level, higher priority should be given to terms incorporating Latin or Greek elements.

  - **Non-ambiguity** – Ambiguous terms should be avoided. The meaning of the concept should be as clearly understandable from the term as possible and also for professionals from all medical specialities.
– **Clinical acceptability** – Similarly to concept selection, following clinicians’ preferences is crucial. Qualification and acceptance in practice plays a major role.

– **Consistency and systematic order** – Decisions on which terms to choose must be consistent within the framework of the whole terminological system. If it is decided to follow some morphological or syntactical rules for a specific category of concepts, they must be applied to all terms from this category and all exceptions should be properly justified.

The same set of criteria is applicable for translation of the terms into languages of participating countries.

**The epSOS Ontology and its maintenance**

The epSOS Ontology is presented as a file in the Web Ontology Language (OWL)\(^2\,^3\). Once the initial version of the epSOS Ontology is available it will be distributed over the internet using a URL. A standard interface for the epSOS Ontology is defined which satisfies the need for "ad-hoc" accurate translation of the epSOS Ontology contained in the pivot documents in the exchange between NCPs.

Translating from one language to another is never exact; hence translation must minimise distortion or the loss of meaning, and is supported by carefully managed mapping of semantically equivalent medical terms and concepts within the reference corpus. Hence the interface also supports the various activities related to mapping or cross-referencing of the terms present within the epSOS MTC.

Code systems are usually imported into a repository before mapping activities can be performed. The administrative tasks such as loading, activation and inactivation of various code system versions are also taken into account when specifying the interface.

To find and map semantically equivalent concepts of various code systems, versions and in different languages, system administrators and software managers must have the ability to search codes, terms, and nominal phrases, to browse concept hierarchies within a particular code system, and to define relationships between concepts.

Some characteristics are required to support the evolution of the epSOS Master Value Sets Catalogue which is the basis for the epSOS Ontology over time. It must be noted that these considerations are fairly general and they are typical of any international code systems.

– **Context-free identifiers** – Concept identifiers such as codes shall not be tied to a hierarchical position or other contexts; their format shall not carry any meaning (non-semantic identifiers).

– **Persistence of identifiers** – Codes shall not be reused when a concept is obsolete or superseded.

– **Version control** – Updates and modifications to the epSOS value sets shall point to consistent version identifiers (OIDs). Use in patient records should carry this version information as the interpretation of coded patient data is a function of the terminology used at a point in time. This version information should also be recorded in all audit data stored.

– **Editorial information** – New and revised terms, concepts and synonyms shall have information on their date of entry or effect in the terminological system associated with them, along with pointers to their source and/or authority.

– **Obsolete marking** – Superseded terminological entries shall be so marked, together with their preferred successor. Data may still exist in historical patient records using obsolete terms; their future interpretation and aggregation are dependent upon that term being carried and cross-referenced to subsequent terms.

– **Identification and registration** – Terminologies that are intended to be used for the purpose of information interchange in health shall have a unique, permanent terminology identifier (OID) registered with an appropriate organisation. HL7 Version 3 messages and CDA use OIDs (Object Identifiers) to identify terminological systems. prEN 1068-1 (superseded) proposes a Registration Authority to maintain a register of health coding systems in Europe.

– **Interoperability** – Health care terminologies shall conform to international terminological standards and the relationship between the terminology and relevant messaging/information standards shall be explicitly recognised.

If there is a need to extend the content of the epSOS terms, this shall be addressed in the maintenance and implementation process.

**Conclusion**

epSOS has come a long way in showing the need for and the possibility of reaching semantic interoperability on a fairly large scale, and it has already proved extendable to new countries. The real proof of success, however, will only emerge after several years of use, development and maintenance.