EU level eHealth DSI – Semantic coordination proposal

Discussion paper (v.2.0)

Version	Date	Subject	Modified by
0.1	15.04.2015	Basic draft document	Henrique Martins (Portugal) Zoi Kolitsi (expert)
1.0	20.04.2015	1st draft document for circulation	Henrique Martins
1.1	23.04.2015	Sharing with EXPAND Workshop in Luxemburg	Licínio Kustra Mano (Portugal)
2.0	28.04.2015	Broadness of scope following SG4i – SubGroup for Implementation – TCON 24.4.15 discussion Change of title and content detail level	Henrique Martins (Portugal, as chair of SG4i)

i. Purpose of the document

The document discusses alternatives and makes proposals on how to secure the EU level coordination and a respective CEF core service, necessary for creating, adopting, maintaining, distributing and localizing use case specific Value Sets (MVCs and MTCs), that are necessary to operationalize the eHealth DSI under CEF, supporting the Patient Summary and ePrescription/eDispensation cross border eHealth services. The need for such co-ordination and core service was highlighted as necessity in August 2014 by EXPAND when providing details about necessary core services for eHealth under CEF. However now it seems evident that further detail and clarification are needed.

The original scope of the document was limited to eHealth use cases to be implemented under CEF and it was not intended to address aspects regarding general/broad semantic interoperability strategy such as CEN standardization, use of ICD 10 vs ICD 11 or use of SNOMED CT by Member States. It is also confined to CEF period and its considerations; therefore the sustainability for after 2020 would be the subject of VALUEHealth.

Within the perspective of the JA, this document aims to be a contribution to the broader scope document under preparation, on “Organizational Framework of eHealth NCP” and as such it will be further processed and matured within the relevant JA activities.

The preliminary conclusions may be brought to the attention of the eHealth Network meeting in Riga, as this will be a topic for debate within the CEF Subgroup for Implementation. Furthermore, there is an urgent need that this core service is defined and operationalized under preCEF/ CEF conditions as a way to ensure coordination of efforts around existing MVC and MTC assets. The Network will be requested to agree to the establishment of a Semantic Expert Committee to be included under the broader CEF eHealth Governance framework, composed of National Semantic experts and supported by aDG Santé Secretariat and administration.

Following the SG4i meeting on 24.4.15 (TCON with presence of 12 member States) it was made clear by a number of member states that the discussion of Semantic Interoperability co-ordination is very relevant, and it became clear that they agree on the importance and urgency of the establish of a mechanism by which countries come together, define common datasets/value-sets, but also share experiences and work on the approximation of their existing/"to established" national semantic interoperability roadmaps. As such, the scope of the paper was broadened into a discussion on how to operationalize in the short term a **Semantic Interoperability coordination.** In this sense the details of the previous version were considered to narrow in light of the main aim to be discussed at this stage.

ii. Circulation and contribution calendar

20.4.15 – version 1.0 is circulated between – eHealth Network subgroup for implementation and participants of the EXPAND members states workshop

22.4.15 – version 2.0 is discussed and incorporates comments from the EXPAND members states workshop

24.4.15 – version 2.0 is sent to eHN Joint action sub-task members in WP 5, some preliminary recommendations may be presented to the eHealth Network Subgroup for implementation eHN SG4i) at the TCON for endorsement

27.4.15 – the concept of the document and preliminary proposals are shared in the eHealth Network (sent as point for information under the eHN subgroup for implementation)

30.5.15 – version 3 of the document may be incorporated into deliverable D5.1.1 of eHN JAction, or constitute an annex to it.

1. Background - Catalogue Maintenance needs, value-set coordination at the EU level, semantics coordination drivers

Discussions in EXPAND Semantic Maintenance shop on semantic sustainability and strategy, to elicit needed expansions on the Master Value and Translation catalogues created in epSOS, have provided a number of observations. These in turn, informed a position in the document on "Organizational Framework of eHealth NCP", prepared for the eHealth Network under the new Joint Action, which addressed such observations and indicated that further work is needed to ensure value set sustainability.

EXPAND aimed at reviewing epSOS semantic assets and "prepare" them to be CEF assets by updating them and, when possible, including improvements and alignments that can be done within the resources and time schedule of the EXPAND project. The specific goals are: i) in the short-term: to resolve detected issues; ii) in the medium-term: improve and align following different criteria (end user perspective, adherence to guidelines, etc). The mandate of EXPAND is restricted to work on limited improvements and present

evidence and support for changes to be proposed to eHN Joint Action for further analysis and discussion or to a competent decision body, within the CEF eHealth DSI governance.

Drivers for an EU-level coordination of National eHealth Semantics efforts:

1) EXPAND concluded that while there is good usability of epSOS assets, in this case semantic assets, further work is needed to expand their use into other use-cases, as well as for adapting them to ongoing evolution introduced by the adopted eHealth Network guidelines on Patient Summary and ePrescription/eDispensation as well as the inevitable evolution of more sophisticated vocabularies and catalogues.

2) It has become increasingly obvious over the last few months, that a core eHealth DSIs service supporting both the cross-border Patient Summary exchange and the exchange of ePrescriptions, should undertake an - at least annual - update, if it is to be kept as a live, viable, and clinically relevant service.

3) The catalogues derived from epSOS (MVC/MTC) are common minimum denominators that, if nothing else, show the need for commonly agreed value-sets, however, these do not represent the solution for all patient cross-border data exchange needs. As some member states commented in the SubGroup meeting these are not the final solution but constitute a useful first step. A global terminology strategy as well as the necessary mapping was appointed as key.

4) The eHealth Network has discussed on the existence of a Standing Coordination Committee, however as such it has not been identified as possible to fund under CEF nor has it been materialized in any other way. However, the operation of relevant activities to guarantee coherence in core services supporting the eHealth DSIs fall within the scope of possible funded activities under CEF.

5) There is a need for a central governance and coordination of the production, maintenance and localization of the Value Sets, which is neither part SDOs' workflows per se, nor of each individual country; likewise also for the coordination semantic efforts around useful clinical use cases. There is a core function that needs to be part of the organizational framework for the eHealth NCP, and aiming to ensure that national level semantic experts have a single source of information for performing certain adaptations to their national semantic infrastructure and its manifestations on the NCP.

6) Assuming use cases involving medication are significant; starting with ePrescription/eDispensation, the involvement of EMEA in a committee of experts of some sort was transparent in the Subgroup discussion.

7) Likewise it is very difficult to sustain a discussion on a functional framework without clarifying policy on the existence of common strategy/processes for adopting semantic structures and its updates (organizational layer) and even a central reference terminology server (technical layer), even if the technical approach, form and the mechanisms of implementation are still open to analysis and debate.

8) Finally, all of the above indicate a need for a EU level mechanism to ensure proper link between decisions about use-cases to be supported - centred on patient care - and value-sets. Thus, making the appropriate use of the relevant, valid and revised semantic assets/catalogues is critical.

9) The subgroup agreed that many countries to date do not have a global eHealth semantic interoperability strategy, while a few member states claimed to have the possibility of appointing a National Semantic Expert (either an official one, or the person that performed that function under epSOS).

10) The subgroup also highlighted the fact that different member states display significantly different speeds in this regard, deferring investments in terminology servers, as well as different levels of granularity in their semantic approach.

2. Need for Catalogue Maintenance and value-set coordination at the EU level during CEF supported eHealth services deployment

Regarding catalogue maintenance and value-sets during CEF it is critical for both ePrescription/eDispensation, as well as, Patient Summary, - or even extensions of these services – that the adoption of MVC 1.9 and the respective MTC in epSOS needs to be replayed by a swift mechanism to revise and approve (ie, centrally coordinate the valid versions of the value sets exchanged as well as their corresponding translations). While there is significant ongoing work by SDOs and IHE on the updating of their respective vocabularies and profiles, the coordination and central adoption of a version of a value-set, valid at a certain time, with which all NCPs are in sync is a necessity.

This is needed now, during CEF (Jan 2016-Dec 2020) and beyond CEF (Jan 2021-onwards, the latter to be addressed in VALUeHEALTH project. Presently, the relevant EXPAND Maintenance shop can analyze MVC 1.9; as well as MTC, and, as suggested, propose improvements and upgrades but adoption needs to take place in the appropriate governance bodies. During CEF, a periodic annual review of the

catalogues, and respective endorsements and acceptance process by member states need to be supported.

Issues like translation costs and countries official recognition of the translations need to be addressed, sometimes just clarified and use of translations for projects like Trillium, or for patient mediated access to Patient summary are still open. Finally, what value sets to choose from which sematic standards (eg SNOMED CT, ICD, etc.) and the process of choice and adoption and adaptation need to become a core service, clear, secured and staffed so that the sustainability of this service is guaranteed. Localization of terms is different from their translation, as some English terms in one country may not apply with the same clinical meaning in another, albeit the use of the same language.

Lastly the need to find how these efforts link with initiatives such as the Semantic Health Net/Institute, as well as, the priorization mechanisms for use cases and quality validation processes and entities still needs to occur. These are likely to benefit from the existence of a collective mind thinking these topics with national experts and bringing their collective intelligence as well as endorsement together.

3. General Considerations

Any proposal should be based on a clear governance possibility linked to the general CEF eHealth DSI governance scheme. It should take into account, amongst others, the following:

1. This activity
    - is distinct from standardization work related to the development and maintenance of base standards (vocabularies, terminologies, classifications etc.),
    - is however a profiling exercise hence should observe standardization principles,
    - should rely heavily on involvement of health professionals,
    - should reflect good co-ordination with SDOs and the standardization framework.
2. National schemes for semantic interoperability engaged in the production or localization of value sets are expected to observe such principles.
3. National level skills and resources may then be exploited through engagement of NCPeH or its competent national partner under EU level co-ordination.
4. The EU level coordination scheme should be associated to the CEF governance as well as eHealth Network.

It is also noted that:

- Semantic work must follow standard procedures including on how to engage health professional and how to validate with professionals and MS;
- There is a need to share, across countries, best practices in this field;
- By promoting such harmonization, we will improve reusability of national and other assets;
- Eventually the MVC construction may rely considerably on existing assets;
- Semantic on going work regarding MVC maintenance and improvement should keep in near consideration that knowledge representation in clinical documents (e.g. Patient Summary and ePrescription) may be, by it self, a source of needs and new requirements to be taken care in a centrally approach.
- EU level work will involve assessment, filling the gaps and reaching agreements and adoption
- Mutual recognition of translations should also be considered as a centrally responsibility, opening strong possibilities in becoming the Patient mediated scenario (for Patient Summary) as a viable and forward looking alternative to the Professional mediated scenario that highly depends on infrastructural resources.
- Eventually we may envisage that by promoting and harmonizing practice for asset development eventually the EU MVCs will grow out of cooperative MS level contribution, similar to the Open NCP concept.

Additionally, the following considerations may be relevant:

- Need for use-case priority setting - – clearly it is with the eHealth Network and the CEF eHealth governance;
- Central orchestration of value sets should be manifested as a core service to be deployed under CEF and beyond, via the business model to be determined in future
- Management of the process of creating and maintaining the MVC is needed.
- During CEF, the Secretariat will be operated within the EC services and be supported by CEF. It is envisaged that by 2020 the activity will be sufficiently standardized and documented to the level that this function could be devolved to MS i.e any “trusted” national semantic interoperability mechanism could offer to act as the Secretariat for a specific “MVC”.
- The EU level mechanism will become lean and will be focused on the management of such MS allocation process, reporting to the eHealth Network and organization of peer reviews

5*. Suggested next steps for Semantic ehealth Co-ordination at EU level*

- A ***Semantic Experts Committee*** of MS representatives would be formed. This would meet, at a maximum , three times per year, in Brussels, to approve valid value sets in use in eHealth services under CEF, as well as approve and endorse best practices and promote their integration in National Semantic interoperability activity.

- The ***executive Secretariat*** proposed to be established in DG Santé would provide support to the Semantic Experts Committee; definition of roles and expectations to be adopted in its 1st meeting.

- The Committee would work with SDOSs, as well as other entities interested in the development of semantic activity to ensure:
    - Translation, and especially localization, follow approved guidelines for national versions, articulation of they approval and calendar of work.

- The committee would define mechanism of linkage into national strategies, where existent, as well as EU bodies, JAction Workpackages and process to achieve a roadmap of activities in the first few months to be approved at eHN in Nov 2015.