Proposal for initiating a platform consisting of the standards developing and profiling organizations relevant to eHealth in Europe and members of the eHealth Network Joint Action

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For discussion by the eHealth Network

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1. Introduction:

This discussion paper should be seen as the follow-up of topic 5 of the eHN meeting of November 2014 regarding "Standardisation process and eHealth". A discussion was held on how the eHealth Network can effectively be involved in the various processes at EU and international level on eHealth standards and technical specifications. Proposed was a possible role for a Standardisation Platform as defined in the Multi-annual Work Programme 2015 - 2018. Within the Joint Action this task is handled in Work package 5 "Interoperability and Standardisation".

This paper provides the members of the eHN additional insight in:

a) General positioning of such a SDO platform within the field of EU eHealth standardisation.
b) Starting points / principles for initiating the SDO platform.
c) The planned next steps towards a platform for Standardisation Organisations to be initiated by the eHN Joint Action.

With this platform, shortly called "SDO platform" hereafter, is meant an assembly which establishes policy cooperation, consultation, alignment and convergence over time between Standards Developing, Standard Profiling Organisations and the members of the eHealth Network Joint Action (i.e. Member States representation) regarding the common objective of managing standards and profiles for eHealth in Europe, to be used in cross-border settings as well in national settings.

This paper, to be discussed in the eHN meeting of May 2015, is meant to give the necessary information regarding the start of the initiation phase of the SDO platform. The information can be used to reflect and discuss on the topic and should be used for adjustments and approval for further proceedings towards a final decision on the establishment of this platform foreseen for the eHN meeting of November 2015.

In the last eHN meeting on this topic it was summarized in the minutes that:

- The eHealth Network will take a role in planning future EU standardisation activities for eHealth, and welcomed the involvement of CEN, as well as other standardisation organisations, in the new joint action.

- The option of starting a standardisation process of specific elements of the guidelines (ePrescription and Patient Summary) involving CEN will be further explored in the new joint action with the support of the eHealth Network Secretariat.

2. Standardisation and eHealth Network

For the advancement of eHealth in Europe, as stimulated and adopted by the eHealth Network (eHN), standards and profiles are an essential asset for the achievement of these goals. This is true for national and regional projects within the MS, but even more essential for cross border interoperability, in order to bridge the differences between the MS.

The playing field of standards in eHealth, however, is complex due to several reasons, amongst which:

- The building of eHealth solutions requires concerted action on several different abstractions layers, as has been made clear in the eHealth European Interoperability Framework (eEIF), with its refinements from the Antilope project. As a consequence standard activities must be undertaken on different layers as well.
- Achieving interoperability refers to the ability of making systems and organizations work together (inter-operate) and should therefor also capture the value of the eHealth collaboration (exchanging information between ICT systems is not enough).
- There are many different standards development organisations (SDOs), with partially overlapping areas of interest. These SDOs can be seen in three categories:

    - Official, formal SDOs These organisations are characterised by a public development process where standards have to be publicly commented upon before being approved. There are three such SDOs on the European level (CEN, CENELEC and ETSI) and three on the international level (ISO, IEC and ITU). In CEN it is the committee TC251 that develops health informatics standards, and in ISO it is TC215. There are also a number of other CEN and ISO committees that develop standards used in connection with eHealth. Every country has a National Standards Body (NSB) (e.g. DIN for DE, NEN for NL, etc.), that is a member of CEN and ISO, but the active participation in eHealth varies between the countries. Also ETSI, CENELEC, ITU and IEC have some healthcare related activities.

    - eHealth specific SDOs. Many of these exist, in most cases supported by healthcare organisations (professional organisations, user groups, etc) and/or the software industry. These SDOs exist on local, national and international levels. The rules for membership vary, but the NSBs are usually not members. These SDOs create standards for content (structuring and coding of information content), interoperability and/or functionality of health specific applications. The scope of such SDOs may be limited to a specific kind of standardization (e.g. DICOM - for digital imaging), specific use of information (e.g. CDISC - medical research), terminology (e.g. IHTSDO) or to other topics.

    - Other SDOs that develop standards used in connection with eHealth. Some SDOs develop industry standards for a broad range of industries, including healthcare. An example is IEEE which develops the 11073-standards for medical device communication. Another example is GS1, that develops standards for identification. There are also some organisations which aren't SDOs that publish documents that are to be considered as standards. WHO and ILO are examples of such organisations.

    - A special category of organisations is formed by the profiling organisations. These are not SDOs in the strict sense of the word, but their contributions to standardisation are of great value. These profiling organisations define, on a use case level, how existing standards should be deployed in order to achieve (near) plug-and-play interoperability, and usually

they organise testing and certification programs. Examples of this category of organisations are Integrating the Health care Enterprise (IHE) and Continua Health Alliance (CHA).

Seeing this widely varying landscape of SDOs the eHN has indicated, in its multi-annual work plan (MWP), that one of the main priority areas of the MWP 2014-2018 is "Standardization and Interoperability", which will be worked out by the eHN-JA core WP5 with the same name. Task T5.4.1 of the mentioned WP will carry out the activity to bring relevant SDOs and profiling organisations together in an SDO platform. .

The proposal for the tasks of this platform is outlined below, but the overall goal of the platform could be formulated as:

> *Provide a one-stop shop to the eHN, where the eHN can ask questions, establish policy cooperation, consultation, alignment, convergence and stimulate actions, which will be picked up in a concerted manner by all SDOs involved, with as the main outcome solutions which are strongly supported by stakeholders, have the necessary legal and formal embedding, and are free of gaps, and free of ambiguities due to overlaps.*

In order to organise the correct involvement of the different SDOs, it is necessary to define how to manage the overlaps (e.g. different codifications for the same item). To that aim, it should be defined when and how in the management of overlapping standards the eHN JA and/or eHN are to be involved.

3. European Interoperability Framework (EIF) and standardisation

The European Commission has adopted the concept of a European Interoperability Framework, which is meant to give a common 'language', a common perspective, for the many discussions on interoperability in public services. In a thematic network project named Antilope, this was further refined[1]. The Antilope project ended February 1, 2015, and its deliverables were formally accepted.

A next step has been to re-formulate this deliverable somewhat (in order to generalise it from the specific Antilope project context) and offer it to the eHN as a framework for the discussions of eHealth interoperability (see topic 5, 7th eHN agenda).

For this paper we will follow one specific aspect from the ReEIF, namely the description of the different interoperability layers that need concerted action by different actors in order to achieve interoperability. Accordingly, on each layer, discussion on standards can be started.

[1] http://www.antilope-project.eu/wp-content/uploads/2013/05/D1.1 Refinement_of_Antilope_Use_Cases_v1.1.pdf

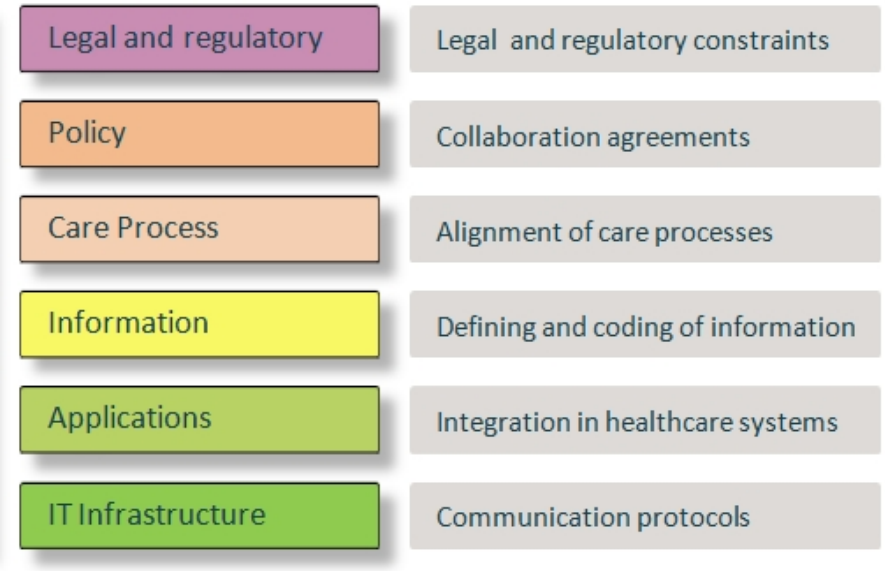

Fig. 1

In fig. 1 the core picture of the Antilope deliverable is shown, The layers are:

1. Legal and regulatory: Here we do not see any action needed from the SDO platform.

2. Policy: This is the main area of interest for the eHN itself, which has an interest and a need for standards. Therefore SDO platform can support the eHN in the definition of guidelines/position papers/technical specifications to be approved by eHN itself.

3. Care Process: This is the place where guidelines are usually developed for health professionals on how to act in a specific care situation. In standards developing, on this abstraction layer use cases are described as the standard care process expected, on which the other standards must provide an answer.

4. Information: This is the abstraction layer for the description of the information (structure, coding, content) needed in the specific care process / use case. This is described independently of implementation.

5. Applications: This is the layer of health specific applications (EHRs, electronic prescription systems, apps, etc), which need standards for the interoperability at the application level in order to exchange the information described in level 4. Especially interoperability requires much effort here: applications of totally different nature and origin (e.g. a hospital based EHR and a community pharmacy based IT environment) must be brought to exchanging information in a meaningful way.

6. IT infrastructure: This is in ReEIF the layer of not-healthcare specific technology: networks, web services, storage, etc. This is by definition not an area for development by the health sector, but the health sector has great interest in these developments as such, and for standards to be available timely and correctly for healthcare to use.

Seeing this the conclusion can be drawn that the SDO platform should have an active role in the standardisation on levels 2, 4 and 5: Information and care specific applications.
The platform must be aware that guidelines on the care process level (3) need to be present in order to match information and information exchange with the care process.
The platform should be closely watching the development of standards in the IT world at large (level 6), and provide demanding input to this sector if the feeling is that healthcare has specific needs that are not, or not with enough urgency, on the agenda.

This approach is generally in line with the "standards and interoperability" objective in the eHN Multi Annual Workplan (2015-2018) :

"An EU eHealth interoperability framework should integrate 4 dimensions: technical, semantic, organizational and legal. On the technical dimension the last years several actions have resulted in increased interoperability assets. Concerning the other dimensions preparatory work has been done within different projects and work packages. However, this work has so far not resulted in sustainable policy assets which were adopted by the eHealth Network. The eHealth Network MWP 2015-2018 should therefore broaden its scope to integrate all dimensions of interoperability. The MWP should reflect this shift".

4. Proposal for initiating an SDO platform

As presented and discussed in the last eHN meeting (Nov 2014) the commission proposed to facilitate an active involvement of the Standards Developing and Profiling Organisations in the activities of the eHN. One of the barriers for the large-scale implementation and adoption of eHealth comes from the lack of clarity around the adequate standards and specifications for interoperability of eHealth systems. There is a need to align the relevant organisations that have a role in eHealth standards and specifications, and promote the use of the standards. Implementing an SDO platform working, initiated and supported by the eHN Joint Action could provide in the coordinated SDO support regarding the objectives noted in the "interoperability and standardisation" chapter of Multi Annual Workplan 2015-2018.

4.1. Tasks of the SDO platform

The suggested eHealth SDO Platform is proposed to take on two very specific tasks:

1. Coordinate the development of eHealth standards and specifications for the European interoperability actions on the agenda of the eHealth Network and European Commission.

   The rationale for this first task is the following:
   a. The (global) eHealth standards and specifications agenda is influenced directly by the European Standards Organizations and their eHealth liaisons through their global counterparts and the Joint Initiative on SDO Global Health Informatics Standardization in which they participate;
   b. Projects and actions around semantic and technical interoperability are undertaken by the EC, the eHealth Network and the Member States in consultation with the eHealth Network;

c. A proper and coordinated embedding of the most appropriate eHealth standards and specifications in these projects and actions is desirable, and to a certain extent lacking in the current situation;

2. Leverage the industry to adopt and implement eHealth interoperability specifications as defined through projects and actions by the eHealth Network, European Commission and Member States
    a. The organisations that develop eHealth standards and specifications represent a network of healthcare provider and ICT vendor organizations on the ground; they are their key members and constituencies;
    b. These health industry organizations, as members of their respective eHealth organizations, are accustomed to engage in the standardization and specification debate and subsequently adopt and implement the standards and specifications that are endorsed by these organizations, i.e. themselves and their peers;
    c. As such, they are the ones to realise the interoperability aspirations of the eHealth Network, European Commission and Member States to the benefit of the European citizens and their health and care.

4.2. Objectives of the SDO platform

Given the description of the main tasks provided above, the objective of the SDO platform is to:

a) contribute current up to date industry knowledge and experience with eHealth specifications to projects and actions in a European context;
b) foster the engagement of the eHealth standards and specifications organizations across such projects and actions, and by doing so:
c) achieve more streamlined eHealth specifications that can count on buy-in and adoption by both health and ICT industry players across Europe.

As such, the SDO platform would function as a single point of contact for the eHealth Network, European Commission, including European Institutions and European projects, seeking guidance on and adoption of eHealth standards and specifications. As a consequence of the envisioned SDO platform operations, increased collaboration and coordination on a national and regional level will be brought about between the existing eHealth standards and specifications organizations and with the Competence Centres on eHealth that have been created by individual governments. This in turn may lead to acceleration in national and regional eHealth programs as well.

The added value of the new SDO platform for the eHealth Network would be:

- To assist the eHN in the coherent decision making process regarding eHealth (related) standards at the EU and International level,
- To advise and support the eHN in initiating standardisation projects and actions that would and could stimulate adoption of standards and (cross border) interoperability in the eHealth domain.
- To stimulate the eHN to act as the demand party regarding the development and implementation of International and European standards and to provide the

possibility of influencing the development of standards (supply side) in the eHealth domain.

4.3. Starting points of the platform

This platform should consist of all the relevant SDOs (including Profiling Organizations and eHN JA member States) that are significantly involved and effective in providing eHealth interoperability across Europe and Internationally. To start building the proposed SDO platform the following starting point should be taken in consideration:

- The platform should enable consistent and coherent SDO support to the eHN based on the ReEIF framework; avoid gaps and overlaps.
- The collective output of the platform members should:
    - Provide the answers and guidance that the eHN is looking for,
    - Be in alignment with the EU standardisation policy,
    - Support the objectives in the eHN MWP 2015-2018
    - Seek maximum transparency in the underlying procedures and methodologies.
- For the platform it is necessary to identify duties and responsibilities of the eHN JA and/or eHN in the management of standards overlapping between the SDOs in order to support the identification of a unitary formal position of the SDOs.
- It should closely cooperate with the European Commission and Multi Stakeholder Platform regarding standardisation actions funded in the Annual Union Workplan and the Rolling Plan for ICT standardisation society-broad.
- The platform should partner with the National Competence Centres of the Member States who function as an important eHealth expert intermediate with their national ministries.
- The output of the platform should reflect the formal positions of the SDOs (i.e. the input of them into the platform should be represent the official opinion of the SDO) and, where applicable, follow the formal processes within the SDO's to achieve at recognized standards.
- The platform should report to the eHN on standardisation activities at EU and international level that are relevant for the eHealth sector
- The platform should provide guidance to the eHN on technical specifications and standardisation activities; notably in the framework of the review of the Guidelines on patient summary (PS) and ePrescription (eP) and patient registries.
- The platform should liaise with standardisation projects (e.g. eStandards, eSENS) that the eHN deems necessary for the widespread adoption of eHealth systems and services in Europe and to achieve interoperability at EU and International level.
- It is necessary that the results of the platform are based on a realistic, pragmatic and financially achievable perspective regarding developing, adopting, promoting and implementing standards and realisation of interoperability.
- The platform must strive for transparent alignment between the National, European and International SDOs and their policy-making bodies.
- In a few countries coordination activities exist with regards to the nationally active SDOs. The Platform should foster the creation of such groups in all countries and liaise with them.

- The formal role of CEN in the SDO platform, as one of the three formal European Standards Organisations, should be brought to value.
- It should support the stakeholders in the eHN JA representing the demand side in formulating their standardisation needs for the advancement of interoperability.
- The platform should first prove its additional value in the eHN (2015-2018) but should be set up in the light of a sustainable eHealth SDO platform after the duration of the eHN JA.
- The management of the new platform will be placed in a team formed at least by a Member State Competence Centre and by CEN.
- A governance structure for the platform should be created, including management of the costs.

5. Proposed next steps in the eHealth Network Joint Action:

In order to decide by the eHN in November 2015 on the implementation of a new SDO platform the following steps are foreseen:

1) Preparation phase for eHN JA Task 5.4 members
   First this activity should result in achieving a common knowledge base between the task 5.4 members regarding standardisation and interoperability in general and the role of the SDO's and EU ICT standardisation policy in particular. The commission has already offered support in organising a workshop for this purpose.

   Secondly this step should result in a common understanding, perspective and expectation of the eHN JA Task 5.4, draft design of the SDO platform and agreement on the task distribution and planning. In order to prepare for the 2nd step valuable output can be used from the first European eHealth Standards Summit in 2013 to prepare for a draft design proposal for the platform.

   Thirdly the way of participation of Member States of the eHN in the SDO platform should be decided upon.

2) Invite the SDO's for the eHN JA platform initiative
   In succession with the first step the relevant identified SDO's are invited for a workshop to discuss and reflect on the concept proposal to initiate a (permanent) SDO platform in the eHN Joint Action. The result of this step is to identify the position of the SDOs on the platform proposal, their terms of agreement and to seek broad support for the initiative.

3) Request the invited and/or indicated SDO's to join the eHN JA SDO platform
   During the summer the SDO's are formally asked for their support for setting up this new platform. The result of this step should be a letter of intent that reflects the common ambition, a solid basis for working out the governance of the platform and securing the expected output of the proposed SDO platform.

4) Set up the governance model for the platform
   Based on sufficient SDO support the SDOs and eNH JA task members work out the governance model of the platform. This governance model should be based on the

assumptions made in the former chapter and seek broad support on MS and EU commission level. A difference should be made between the governance during the JA, which runs from May 2015 to May 2018, and the governance to be designed for a more permanent form of the Platform, sustained after 2018.

5) Construct final deliverable for eHN November 2015
   The governance model should form the basis for the first deliverable for decision on the eHN meeting in November. Together with experience of the followed steps and expected learning curve on this topic the eHN JA should be able to deliver a solid proposal for the new SDO platform.

6) eHN decision on eHN JA SDO platform
   In the eHN meeting in November the WP 5 task 5.4 deliverable will be provided for decision.

7) Act as a platform "under construction" for the eHN JA
   During the installation phase the platform "under construction" should function as a temporary platform for follow up on eHN JA actions related to this topic.