eHealth Standards and Profiles in Action for Europe and Beyond

Deliverable 3.5: Roadmap for collaborative and sustainable standards development

Recommendations for a globally competitive Europe

Companion Document 2:
The *e*Standards Roadmap Components

Final Version 1.0

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Chapter 7 - Patient Summary

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Coordinators:

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Dedicated to

Henk E. Bakker (1959-2015)
Personal Health Record Ambassador

Marcel Heldoorn of the Dutch Patient Federation, who accepted the dedication on behalf of the family of Henk Bakker said: "*Patients become digital citizens faster than hospitals are embracing digital transformation. The patient perspective is a formidable and indispensable driver of change in the digital age, when connected in a safe and meaningful way to the health and wellness professionals. The Patients federation of the Netherlands has taken the initiative for a personal digital health environment for which Henk Bakker was one of the early ambassadors. We still share Henk's experiences and ideas to convince people of the importance of digital health tools for patients almost every day. Making a personal health environment meaningful for patients requires standards for information exchange and a clear regulatory framework to drive trust and adoption. Most standards and regulatory frameworks are the result of co-creation with all parties concerned including patients, health professionals, healthcare providers, their organisations, and the health IT industry. In our shared vision, the connected personal health environment serves as a solid foundation for all kinds of innovative applications ranging from health management for chronic conditions to research into treatment of rare diseases and complex and ill understood conditions. The availability of extensive patient data fuels innovation. Putting patients in charge of what can and cannot be done with their personal health data is key to instilling trust in these innovations. I want to underline and recognize the dedication of your roadmap to Henk Bakker, as one of the ambassadors of the Patient Federation for personal health record adoption.*"

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Companion Document 2
The *e*Standards Roadmap Components

Introduction

The primary objective of the *e*Standards Roadmap is to map a mode of interaction to be adopted jointly by Standards Developing Organisations, policymakers and other parties playing a key role in the full Health Informatics Standards Life Cycle, in order to drive a more effective development, deployment and maintenance of essential eHealth standards, profiles and tools. The ultimate objective for such standards, is to enable a safe and cost-effective large-scale deployment of eHealth solutions in Europe that take into account the needs of its key stakeholder groups from four distinct perspectives:

- Citizens (as patients and consumers of health and wellness services)
- Workforce (healthcare professionals and support staff in the delivery of health services)
- Health System (where care is delivered and cost and access decisions are made)
- Market (where eHealth solutions and services are traded between vendors and their customers)

In developing the first iteration of the Roadmap (presented in Deliverable 3.3), the *e*Standards partners examined fifteen categories of standards, which were developed from the Refined eHealth European Interoperability Framework (ReEIF), as endorsed by the eHealth network in its 8th meeting (November 2015). Based on the interoperability layers of the ReEIF, the following areas of standardisation activity were assessed.

Table 1: Overview of roadmap components and their position in the ReEIF

Issue	Interoperability Layer
1. Legal, Regulatory and Procurement	Legal & Regulatory
2. Health Information Exchange Policy	Policy
3. Care Process and Workflow	Care Process
4. Prescription & Dispensing	Information
5. Patient-generated, Sensor, and Medical Device Data	Information
6. Specialised Reports	Information
7. Patient Summary	Information
8. Clinical Query	Applications/Services, Information
9. Document Directed Transmission	Applications/Services
10. Document Sharing and Access	Applications/Services
11. Terminology and Ontology Content and Services	Applications/Services, Information
12. Patient Consent	Applications/Services, Information
13. Indexing and Directory Services	IT Infrastructure
14. Security	IT Infrastructure
15. User Authentication	IT Infrastructure

The first iteration of the Roadmap developed a detailed analysis of eight of the areas, as indicated in italics in the table above. The analysis in the first iteration was very detailed, covering

- User Needs
- State of the Art
- Competing and Overlapping Standards
- Gaps in the Standards Landscape
- Policy Opportunities
- Legal and Regulatory Opportunities
- Adoption and Deployment Opportunities

Each section concluded with a series of recommendations, which were reported in deliverable 3.3 and have informed this second iteration.

The key elements of each of the fifteen sections are presented now in this companion document, condensed into three core elements which address the following issues:

- **What is needed? -** in order to drive trust and dynamic flow
- **Where are we now? -** what is the state of the art in terms of existing standards
- **What next? -** what is needed to move to the next stage and beyond

Together this analysis forms the *e*Standards Framework of Roadmap Components as identified and used in this deliverable. A graphical representation, linking the framework to the ReEIF is presented below.The results of those analyses were also used to inform the the mapping processes for the four focus areas as set out in the Core Document.

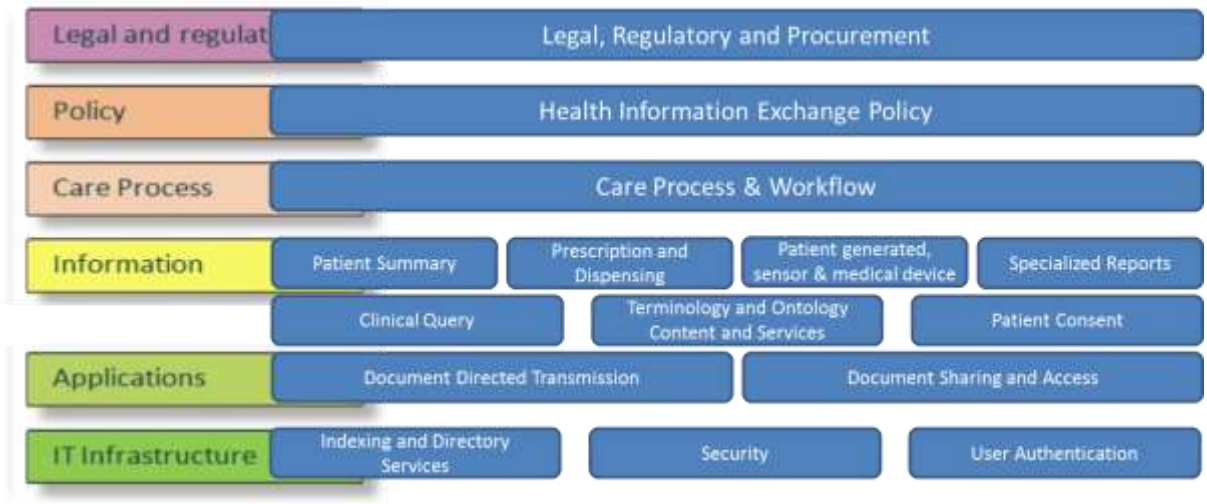

Figure 1: The *e*Standards Framework of Roadmap Components, linked to the layers of the ReEIF

Based on the analysis across the fifteen roadmap components, as well as the current framework of the ReEIF, SDO collaboration, and policy drivers and incentives we derived the Roadmap presented in this document which considers the actions needed by all players (**Citizen, Workforce, Health System, and Market**) to continue to drive forward the adoption of standards through a continuous developmental flow of co-creation, governance and alignment.

As such, the elements identified in the fifteen summaries below form a set of key components for a roadmap, identifying generic requirements, state-of-the-art, and development needs for the areas to be deployed across focus areas for roadmap development.

7 Patient Summary

The concept of 'patient summary' (PS) means different things to different people throughout the world. Any appreciation of it, therefore, must take this fact into consideration, particularly because implementations of a patient summary are intended to be readily accessible across professional, organisational and jurisdictional boundaries, within and across nations.

To be consistent with work done in Europe, the main scope of the PS described in this document is to support unscheduled (i. e., emergency, unexpected and unplanned) care, by providing Health Professionals with a synthesised view of relevant patient data at the point of need.

Furthermore, since summarisation is a clinical skill and not just a collection of recent results, it has been suggested that a distinction shall be also made between the coherent summaries produced as output of a clinical act by a clinician (e. g. a GP that identifies the relevant information to be included in the EHR extract, visualise and validate them before exporting them in a patient summary) and those that are a simple collection of information collected from multiple sources. Even so, it is recognised that a simple eclectic collection of patient data, whilst it might have discrepancies, duplication, and temporal problems, may still be of some value. This value will decrease, however, if the PS is too big and too unreliable, becoming irrelevant and unsafe for emergency use.

7.1 What is needed?

Although the presence of initiatives like epSOS in the past and currently the Digital Service Infrastructure for eHealth (eHDSI), at present the real impact of PS at the EU level is substantially negligible, since each country has in general its own country specific PS service that can differ per type, implementation and potentially service approach. This in turn creates the greatest need, across all user groups, to adopt a PS that can support cross-border and cross-boundary care.

Workforce - in most jurisdiction the needs of doctors in primary and secondary care, will be the group with the most significant set of needs in terms of usability of a PS . In some jurisdictions nurses will also be allowed to access and use a PS, hospital and community pharmacists may also need to access the patient PS. Their primary need is to obtain a synthesised snapshot about the patient relevant to the immediate need of treating that patient.

Citizens/Patients - Citizens and patients also have a significant interest in the PS , whether it is to support their own care, or the care of someone for whom they have a caring responsibility. Their primary needs are to:

- obtain better care during unexpected healthcare problems (this is a social right without discrimination across boundaries)
- access to his/her own clinical data
- (in some cases) integrate the health professional content with patient generated/loaded data

Health Care organisations - Alongside the workforce using the PS the institutional needs of the organisation in which it is being used will also have to be considered. For healthcare provider systems the needs include:

- Provide better informed care
- Saving costs by minimising duplicate and unnecessary tests etc., and by managing the patient effectively
- Social control on the quality of a care setting
- (opportunity) Source for research (by means of reusable standardised fragments).

Vendors - Vendors necessarily also have an interest in the PS, which may be a product they are selling, or may be a component of a system which they are selling or with which their service offering needs to interact.

- improve competitiveness by means of new services
- the availability of standardised fragments may reduce the need for mapping and help the improvement of systems.

7.2 Where are we now?

The large majority of solutions is based on CDA templated documents, e. g.: the epSOS Patient Summary; the US C-CDA CCD; other nationally defined CDA templates (e. g. Italy, Austria, Greece, Luxembourg …). Fewer examples are based on EHR extract EN ISO 13606 and OpenEHR templates. The Netherlands developed standardised logical models (Clinical Building Blocks, based on Detail Clinical Models) to be used potentially also for Implementing Patient Summaries. Local formats are also adopted (e. g. the XML based Belgian standard KMEHR).

There is at present some significant overlap in standards applicable to PSs, largely created by the fact the PSs can be deployed either at the “base standard” level, in which standards such as HL7 CDA R2; EHR extract based on EN 13606; OpenEHR are relevant; or at the “profile level” in which case several HL7 R2 CDA templates listed in the Patient Summary section of the *e*Standards deliverable 3.3.

For future consideration the potential impact of FHIR either as document bundle (a project for defining the representation of the C-CDA templates with FHIR resources is on-going **C-CCD on FHIR**); or as resource based paradigms, should also be taken into consideration.

A significant issue in terms of our current capacity to deploy PSs to their full potential arises in the terminology space. At present several different terminologies are in fact used, a number of domains are covered (problems, medications, procedures,..) and a wide range of solutions adopted (e. g. ICD, ICPC, SNOMED CT) .

7.3 What next?

A key issue to address in PS is availability of supporting resources and tools for mapping, including the development of common ontologies (or meta-terminology) that could help the mapping between data from different origins. In addition, the lack on commonly applicable/applied solutions for specific

domains like the (surgical) procedures, problems and medications[24] also needs to be addressed. In seeking to address these issues it should be noted that several aspects may impact the patient summary service deployment: care / business processes, clinical contents, implementation policies. That implies that for supporting a complete deployment life cycle a set of different standard artefacts have to be in general used, each of them fulfilling specific goals. It is aimed therefore that any effort that can be made for smoothing the cooperative usage of those sets of artifacts is applied.

The needs for further co-creation, governance and alignment in the Patient Summary field, exist also at policy level, here in particular the revision of the EU Patient Summary guidelines provide an opportunity for a closer involvement of Member States (MS) and for improving the alignment of the National solutions with the EU / International patient summaries. Many member states have in fact already their own Patient Summary and this initiative can help the harmonisation of the national Patient Summaries.

There are opportunities for improvement in respect to the governance of the use of PS, in particular in terms of issue such as harmonised consent processed and data protection to allow for more simple international exchange and usage of PS.

7.4 Recommendations on Patient Summaries

A precondition for the PS service is the availability of quality patient data and records, this includes:

- EHR systems capabilities on capturing data for the patient summary and displaying it.
- Education for clinicians/GPs for maintaining “cleaned and updated” patient records and performing the summarisation act.
- For improving the quality of PS, and increase their numbers, incentives for Health Professionals, at least in the initial phase, should be considered.
- The type of PS has an impact on the way it could be summarised and interpreted; in this context the way the PS is visualised is important. Guidance on how data should be collected and shown is suggested. Constraints on, and clarifications about, the provenance of information should be also defined.
- To facilitate the cross-boundary interpretation of coded information it has been suggested to encourage the adoption of multiple coding for coded information.
- In the short term SDOs should provide a clearer and better **classification of the Patient Summaries** considering, for example: scope, provenance of data, intended receivers; aiming however to develop a library of common logical and implementable fragments to be reused for all the types of Patient Summaries.
- JAseHN/eHN should implement a **governance and maintenance process to make the cross boundary Patient Summary safe and trustworthy**.

[24] In the case of medications is reasonable to presume that this might be resolved with the adoption of IDMP (see also the openMedicine project results).

- Jurisdictional entities to be identified (JAseHN/eHN/EC) should **create an outcome framework** that will give evidence of continuous improvement and indicators about: (a) Consent (b) Awareness (c) Quality of data. To be applied at the jurisdictional (National) and European level.
- In the Medium term SDOs should produce an **implementation guidance for the patient summary**, taking in account the revision of the EU Guidelines, the existing activities on International Patient Summary (JIC, INTERPAS); current patient summary specification.
- JAseHN and Member States should better **evaluate the impact of the "granular" patient consent** as possible show stopper for the patient summary services.
- Member States should consider **incentives to promote the quality of the summarisation activity and of the summary itself**.